



PMI RESEARCH & DEVELOPMENT

Study ZRHM-REXA-07-JP 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 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 85 days in an ambulatory setting
Study Number:	ZRHM-REXA-07-JP
Product Name:	Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)
Study Initiated (first subject screened):	01 August 2013
Study Completed (last subject last visit):	03 July 2014
Principal Investigator and Affiliation:	Mamoru Oki, MD, PhD, Seishukai Clinic 3-18-5, Matsugaya, Taitou-ku Tokyo 111-0036, Japan Professor Masahiro Endo, MD, Tokyo Heart Center Osaki Hospital, 5-4-12, Kita-Shinagawa, Shinagawa-ku, Tokyo 141-0001, Japan
Sponsor:	Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland
Sponsor Signatories:	Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist Nicola Lama, PhD, Biostatistician Andrea Donelli, Clinical Scientist Patrick Picavet, MD, Medical Safety Officer
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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=670) n(%)
Screen failures	439 (65.5)
Screening failures, without product test	439 (65.5)
Screening failures, with product test	0
Reason for screen failure	
Entry criteria not met	302 (45.1)
Withdrawal by subject	28 (4.2)
Adverse events	0
Other	109 (16.3)
Enrolled	231 (34.5)
Enrolled not randomized	15 (2.2)
Enrolled not randomized who completed safety follow-up	15 (2.2)
Randomized	216 (32.2)

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 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: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.1 Summary of Subject Disposition - All Screened Subjects**

Status	THSm2.2 (N=107) n(%)	mCC (N=55) n(%)	SA (N=54) n(%)	Overall Randomized (N=216) n(%)
Completed Period 1	106 (99.1)	54 (98.2)	53 (98.1)	213 (98.6)
Completed Period 2	105 (98.1)	54 (98.2)	53 (98.1)	212 (98.1)
Completed Period 3	77 (72.0)	41 (74.5)	38 (70.4)	156 (72.2)
Completed Period 4	76 (71.0)	41 (74.5)	38 (70.4)	155 (71.8)
Completed safety follow-up	107 (100)	55 (100)	54 (100)	216 (100)
Discontinued	31 (29.0)	14 (25.5)	16 (29.6)	61 (28.2)
Discontinued Period 1	1 (0.9)	1 (1.8)	1 (1.9)	3 (1.4)
Discontinued Period 2	1 (0.9)	0	0	1 (0.5)
Discontinued Period 3	28 (26.2)	13 (23.6)	15 (27.8)	56 (25.9)
Discontinued Period 4	1 (0.9)	0	0	1 (0.5)

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 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: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.1 Summary of Subject Disposition - All Screened Subjects**

Status	THSm2.2 (N=78) n(%)	mCC (N=42) n(%)	SA (N=40) n(%)	Randomized in Tokyo Heart Center (N=160) n(%)
Subjects Randomized in Tokyo Heart Center				
Completed Period 1	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
Completed Period 2	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
Completed Period 3	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
Completed Period 4	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
Completed safety follow-up	78 (100)	42 (100)	40 (100)	160 (100)
Discontinued	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
Discontinued Period 1	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
Discontinued Period 2	0	0	0	0
Discontinued Period 3	0	0	1 (2.5)	1 (0.6)
Discontinued Period 4	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: Discontinued refers to randomized subjects who discontinued from the study before the planned discharge at Day 91. ; Completed 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: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.2 Summary of Reasons for Discontinuations - FAS**

Discontinuations	THSm2.2 (N=78) n(%)	mCC (N=42) n(%)	SA (N=40) n(%)	Overall FAS (N=160) n(%)
Total no. of discontinuations	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
Reason for discontinuation				
Adverse events	0	0	0	0
Protocol violation	0	0	0	0
Withdrawal by subject	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
Lost to follow-up	0	0	0	0
Other	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 15.2.1.3.1 Summary of Protocol Deviations - Safety Population**

Classification of Deviation	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
	n (%) Events	n (%) Events	n (%) Events	n (%) Events
Total	77 (98.7) 222	42 (100) 132	40 (100) 109	159 (99.4) 463
Major	12 (15.4) 19	0	3 (7.5) 3	15 (9.4) 22
With evaluability impact	11 (14.1) 15	0	3 (7.5) 3	14 (8.8) 18
Mis-randomization	1 (1.3) 1	0	0	1 (0.6) 1
Mis-use of product in period 1	1 (1.3) 1	0	1 (2.5) 1	2 (1.3) 2
Mis-use of product in period 2	2 (2.6) 2	0	0	2 (1.3) 2
Mis-use of product in period 3	5 (6.4) 5	0	1 (2.5) 1	6 (3.8) 6
Mis-use of product in period 4	6 (7.7) 6	0	1 (2.5) 1	7 (4.4) 7
Without evaluability impact	3 (3.8) 4	0	0	3 (1.9) 4
Assessment missing	3 (3.8) 3	0	0	3 (1.9) 3
Violation	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).

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=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
	n (%) Events	n (%) Events	n (%) Events	n (%) Events
Minor	77 (98.7) 203	42 (100) 132	40 (100) 106	159 (99.4) 441
Assessment missing	23 (29.5) 83	10 (23.8) 21	9 (22.5) 21	42 (26.3) 125
Concomitant medication	4 (5.1) 4	1 (2.4) 1	2 (5.0) 2	7 (4.4) 7
Procedure violation	24 (30.8) 28	22 (52.4) 66	19 (47.5) 55	65 (40.6) 149
Time missing	2 (2.6) 2	1 (2.4) 1	0	3 (1.9) 3
Time schedule deviation	64 (82.1) 86	33 (78.6) 43	28 (70.0) 28	125 (78.1) 157

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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	107	55	54	15	439	670
Subjects included in Full Safety Population	107	55	54	15	0	231
Subjects excluded from Full Safety Population	0	0	0	0	439	439
Not exposed to THS m2.2	0	0	0	0	439	439
Subjects included in Safety Population	78	42	40	15	0	175
Subjects excluded from Safety Population	29	13	14	0	439	495
Exposed at site terminated due to ICH/GCP non-compliance	29	13	14	0	0	56
Not exposed to THS m2.2	0	0	0	0	439	439
Total Subjects Randomized¹	107	55	54	NA	NA	216
Randomized Subjects included in Full Safety Population	107 (100)	55 (100)	54 (100)			216 (100)
Subjects excluded from Full Safety Population	0	0	0			0
Subjects did not have valid safety assessment post-randomization	0	0	0			0

Note: NA = Not applicable; Note: 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.

[1]: "Total Subjects Randomized" refers to randomized subjects and not excluded because of due to ICH/GCP non-compliance.

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]).

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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(%)
Randomized Subjects included in Safety Population	78 (72.9)	42 (76.4)	40 (74.1)			160 (74.1)
Subjects excluded from Safety Population	29 (27.1)	13 (23.6)	14 (25.9)			56 (25.9)
Exposed at site terminated due to ICH/GCP non-compliance	29 (27.1)	13 (23.6)	14 (25.9)			56 (25.9)
Subjects included in FAS	78 (72.9)	42 (76.4)	40 (74.1)			160 (74.1)
Subjects excluded from FAS	29 (27.1)	13 (23.6)	14 (25.9)			56 (25.9)
ICH/GCP non-compliance	29 (27.1)	13 (23.6)	14 (25.9)			56 (25.9)
Subjects included in PP Set						
Period 1	76 (71.0)	42 (76.4)	39 (72.2)			157 (72.7)
Period 2	74 (69.2)	41 (74.5)	39 (72.2)			154 (71.3)
Period 3	71 (66.4)	41 (74.5)	38 (70.4)			150 (69.4)
Period 4	70 (65.4)	41 (74.5)	37 (68.5)			148 (68.5)

Note: NA = Not applicable; Note: 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.

[1]: "Total Subjects Randomized" refers to randomized subjects and not excluded because of due to ICH/GCP non-compliance.

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]).

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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(%)
Subjects excluded from PP Set for Period 1	31 (29.0)	13 (23.6)	15 (27.8)			59 (27.3)
Not in FAS	29 (27.1)	13 (23.6)	14 (25.9)			56 (25.9)
Has major protocol deviations not compliant	1 (0.9)	0	1 (1.9)			2 (0.9)
Has other major protocol deviations impacting evaluability	1 (0.9)	0	0			1 (0.5)
Subjects excluded from PP Set for Period 2	33 (30.8)	14 (25.5)	15 (27.8)			62 (28.7)
Discontinued in previous period	1 (0.9)	1 (1.8)	1 (1.9)			3 (1.4)
Not in FAS	29 (27.1)	13 (23.6)	14 (25.9)			56 (25.9)
Has major protocol deviations not compliant	2 (1.9)	0	0			2 (0.9)
Has other major protocol deviations impacting evaluability	1 (0.9)	0	0			1 (0.5)

Note: NA = Not applicable; Note: 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.

[1]: "Total Subjects Randomized" refers to randomized subjects and not excluded because of due to ICH/GCP non-compliance.

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]).

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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(%)
Subjects excluded from PP Set for Period 3	36 (33.6)	14 (25.5)	16 (29.6)			66 (30.6)
Discontinued in previous period	1 (0.9)	1 (1.8)	1 (1.9)			3 (1.4)
Not in FAS	29 (27.1)	13 (23.6)	14 (25.9)			56 (25.9)
Has major protocol deviations not compliant	5 (4.7)	0	1 (1.9)			6 (2.8)
Has other major protocol deviations impacting evaluability	1 (0.9)	0	0			1 (0.5)
Subjects excluded from PP Set for Period 4	37 (34.6)	14 (25.5)	17 (31.5)			68 (31.5)
Discontinued in previous period	1 (0.9)	1 (1.8)	2 (3.7)			4 (1.9)
Not in FAS	29 (27.1)	13 (23.6)	14 (25.9)			56 (25.9)
Has major protocol deviations not compliant	6 (5.6)	0	1 (1.9)			7 (3.2)
Has other major protocol deviations impacting evaluability	1 (0.9)	0	0			1 (0.5)
Subjects included in Compliant Population						
Period 1	76 (71.0)	42 (76.4)	39 (72.2)			157 (72.7)
Period 2	63 (58.9)	41 (74.5)	38 (70.4)			142 (65.7)
Period 3	65 (60.7)	41 (74.5)	38 (70.4)			144 (66.7)
Period 4	65 (60.7)	41 (74.5)	37 (68.5)			143 (66.2)

Note: NA = Not applicable; Note: 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.

[1]: "Total Subjects Randomized" refers to randomized subjects and not excluded because of due to ICH/GCP non-compliance.

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]).

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**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Sex						
Male	n (%)	45 (57.7)	25 (59.5)	22 (55.0)	10 (66.7)	102 (58.3)
Female	n (%)	33 (42.3)	17 (40.5)	18 (45.0)	5 (33.3)	73 (41.7)
Age (years)						
	n	78	42	40	15	175
	Mean (SD)	37.1 (10.58)	37.4 (11.23)	37.0 (9.96)	43.6 (12.75)	37.7 (10.86)
	Median	37.0	37.0	38.0	45.0	38.0
	Min, Max	23, 65	23, 64	23, 55	26, 59	23, 65
Ethnicity						
Japanese	n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
Non-Japanese	n (%)	0	0	0	0	0
Weight (kg)						
	n	78	42	40	15	175
	Mean (SD)	62.87 (10.976)	61.99 (10.228)	61.36 (11.090)	63.78 (12.053)	62.39 (10.852)
	Median	61.55	63.80	59.95	60.00	61.30
	Min, Max	45.1, 97.8	43.4, 84.4	43.7, 91.8	50.7, 90.5	43.4, 97.8

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.



Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Height (m)	n	78	42	40	15	175
	Mean (SD)	1.655 (0.0748)	1.660 (0.1012)	1.650 (0.0781)	1.689 (0.0925)	1.658 (0.0840)
	Median	1.655	1.660	1.650	1.690	1.660
	Min, Max	1.52, 1.84	1.47, 1.88	1.50, 1.80	1.53, 1.85	1.47, 1.88
BMI (kg/m ²)	n	78	42	40	15	175
	Mean (SD)	22.85 (2.963)	22.44 (2.876)	22.48 (3.386)	22.28 (3.182)	22.62 (3.044)
	Median	22.40	21.90	21.30	21.60	21.90
	Min, Max	18.7, 32.7	18.9, 28.4	18.5, 31.8	18.6, 31.3	18.5, 32.7
Underweight	n (%)	0	0	0	0	0
Normal Weight	n (%)	60 (76.9)	32 (76.2)	32 (80.0)	13 (86.7)	137 (78.3)
Overweight	n (%)	17 (21.8)	10 (23.8)	7 (17.5)	1 (6.7)	35 (20.0)
Obese	n (%)	1 (1.3)	0	1 (2.5)	1 (6.7)	3 (1.7)

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Waist circumference (cm)	n	78	42	40	15	175
	Mean (SD)	86.8 (23.81)	90.6 (30.17)	85.1 (24.33)	87.7 (24.15)	87.4 (25.48)
	Median	81.5	79.5	77.5	81.0	80.0
	Min, Max	65, 174	64, 172	66, 167	72, 169	64, 174
Cigarette consumption						
	10-19 Cig/Day	n (%)	40 (51.3)	23 (54.8)	21 (52.5)	93 (53.1)
	>19 Cig/Day	n (%)	38 (48.7)	19 (45.2)	19 (47.5)	82 (46.9)

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

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**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
ISO tar yields	n	78	42	40	15	175
	Mean (SD)	4.9 (3.53)	4.9 (3.79)	4.7 (3.83)	4.1 (3.80)	4.8 (3.66)
	Median	5.0	5.0	5.0	1.0	5.0
	Min, Max	1, 12	1, 12	1, 12	1, 12	1, 12
1-5 mg	n (%)	46 (59.0)	22 (52.4)	23 (57.5)	10 (66.7)	101 (57.7)
6-8 mg	n (%)	21 (26.9)	14 (33.3)	12 (30.0)	4 (26.7)	51 (29.1)
9-10 mg	n (%)	7 (9.0)	4 (9.5)	2 (5.0)	0	13 (7.4)
>10 mg	n (%)	4 (5.1)	2 (4.8)	3 (7.5)	1 (6.7)	10 (5.7)
ISO nicotine yields	n	78	42	40	15	175
	Mean (SD)	0.40 (0.272)	0.40 (0.277)	0.39 (0.290)	0.32 (0.260)	0.39 (0.275)
	Median	0.40	0.45	0.40	0.10	0.40
	Min, Max	0.1, 1.0	0.1, 0.9	0.1, 0.9	0.1, 0.8	0.1, 1.0
<= 0.6 mg	n (%)	63 (80.8)	32 (76.2)	30 (75.0)	14 (93.3)	139 (79.4)
> 0.6 mg	n (%)	15 (19.2)	10 (23.8)	10 (25.0)	1 (6.7)	36 (20.6)

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
FTND score	n	78	42	39	15	174
	Mean (SD)	4.3 (1.78)	4.3 (1.81)	4.7 (2.08)	3.7 (1.80)	4.4 (1.86)
	Median	4.0	4.0	5.0	4.0	4.0
	Min, Max	1, 9	1, 8	0, 9	1, 6	0, 9
Mild	n (%)	27 (34.6)	17 (40.5)	8 (20.0)	7 (46.7)	59 (33.7)
Moderate	n (%)	44 (56.4)	18 (42.9)	23 (57.5)	8 (53.3)	93 (53.1)
Severe	n (%)	7 (9.0)	7 (16.7)	8 (20.0)	0	22 (12.6)
Individual product preference						
THSm2.2	n (%)	18 (23.1)	10 (23.8)	6 (15.0)	2 (13.3)	36 (20.6)
mCC	n (%)	40 (51.3)	20 (47.6)	25 (62.5)	8 (53.3)	93 (53.1)
SA	n (%)	9 (11.5)	4 (9.5)	5 (12.5)	1 (6.7)	19 (10.9)
No Preference	n (%)	11 (14.1)	8 (19.0)	4 (10.0)	4 (26.7)	27 (15.4)

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Day 4 SES Questionnaire						
Q1: Total number living in household (including yourself)?						
0	n (%)	1 (1.3)	0	0	0	1 (0.6)
1	n (%)	35 (44.9)	12 (28.6)	12 (30.0)	0	59 (33.7)
2	n (%)	13 (16.7)	7 (16.7)	13 (32.5)	0	33 (18.9)
3	n (%)	9 (11.5)	8 (19.0)	8 (20.0)	0	25 (14.3)
4	n (%)	9 (11.5)	7 (16.7)	4 (10.0)	0	20 (11.4)
5	n (%)	3 (3.8)	2 (4.8)	1 (2.5)	0	6 (3.4)
6	n (%)	1 (1.3)	1 (2.4)	0	0	2 (1.1)
Prefer Not to Say	n (%)	6 (7.7)	4 (9.5)	1 (2.5)	0	11 (6.3)
Missing	n (%)	1 (1.3)	1 (2.4)	1 (2.5)	15 (100)	18 (10.3)

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Q2: Highest level education attained / currently attaining?						
Elementary School / Junior High School	n (%)	0	1 (2.4)	2 (5.0)	0	3 (1.7)
Senior High School	n (%)	19 (24.4)	10 (23.8)	14 (35.0)	0	43 (24.6)
College	n (%)	23 (29.5)	7 (16.7)	7 (17.5)	0	37 (21.1)
University / Postgraduate	n (%)	30 (38.5)	18 (42.9)	15 (37.5)	0	63 (36.0)
Prefer Not to Say	n (%)	5 (6.4)	5 (11.9)	1 (2.5)	0	11 (6.3)
Missing	n (%)	1 (1.3)	1 (2.4)	1 (2.5)	15 (100)	18 (10.3)
Q3: How many income earners in household?						
None - All Are Unemployed	n (%)	4 (5.1)	1 (2.4)	4 (10.0)	0	9 (5.1)
Just One Income Earner	n (%)	46 (59.0)	20 (47.6)	18 (45.0)	0	84 (48.0)
Two or More Income Earners	n (%)	27 (34.6)	20 (47.6)	17 (42.5)	0	64 (36.6)
Missing	n (%)	1 (1.3)	1 (2.4)	1 (2.5)	15 (100)	18 (10.3)

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.



Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Q4: What is your occupation?						
General White Collar	n (%)	8 (10.3)	6 (14.3)	2 (5.0)	0	16 (9.1)
Professional/Technical Worker	n (%)	5 (6.4)	5 (11.9)	2 (5.0)	0	12 (6.9)
General Blue Collar	n (%)	1 (1.3)	0	2 (5.0)	0	3 (1.7)
Working In Service Industry	n (%)	7 (9.0)	3 (7.1)	1 (2.5)	0	11 (6.3)
Manager (Kacho or Above)	n (%)	1 (1.3)	1 (2.4)	0	0	2 (1.1)
Director/President (30 Employees or More)	n (%)	0	1 (2.4)	1 (2.5)	0	2 (1.1)
Proprietor (29 Employees or Less)	n (%)	9 (11.5)	4 (9.5)	5 (12.5)	0	18 (10.3)
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	1 (1.3)	0	0	0	1 (0.6)
Farming/Forestry/Fishing	n (%)	1 (1.3)	0	0	0	1 (0.6)
Part-Time Worker (More Than One Day Per Week)	n (%)	20 (25.6)	7 (16.7)	10 (25.0)	0	37 (21.1)
Student	n (%)	7 (9.0)	2 (4.8)	2 (5.0)	0	11 (6.3)

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.



Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Housewife (Including Part-Time Less Than n (%))		1 (1.3)	4 (9.5)	0	0	5 (2.9)
One Day Per Week)						
Unemployed	n (%)	1 (1.3)	1 (2.4)	7 (17.5)	0	9 (5.1)
Others	n (%)	13 (16.7)	6 (14.3)	5 (12.5)	0	24 (13.7)
Missing	n (%)	3 (3.8)	2 (4.8)	3 (7.5)	15 (100)	23 (13.1)
Q5a: What is approximate MONTHLY household income from all sources before tax?						
Don't Know	n (%)	8 (10.3)	6 (14.3)	5 (12.5)	0	19 (10.9)
Prefer Not to Say	n (%)	14 (17.9)	11 (26.2)	3 (7.5)	0	28 (16.0)
Missing	n (%)	4 (5.1)	2 (4.8)	5 (12.5)	15 (100)	26 (14.9)
Any Amount Reported	n (%)	52 (66.7)	23 (54.8)	27 (67.5)	0	102 (58.3)
Below 100,000 Yen	n (%)	2 (2.6)	0	0	0	2 (1.1)
100,000 Yen - 199,999 Yen	n (%)	12 (15.4)	4 (9.5)	5 (12.5)	0	21 (12.0)
200,000 Yen - 299,999 Yen	n (%)	15 (19.2)	4 (9.5)	7 (17.5)	0	26 (14.9)
300,000 Yen - 399,999 Yen	n (%)	8 (10.3)	4 (9.5)	3 (7.5)	0	15 (8.6)

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
400,000 Yen - 499,999 Yen	n (%)	3 (3.8)	3 (7.1)	3 (7.5)	0	9 (5.1)
500,000 Yen - 599,999 Yen	n (%)	6 (7.7)	1 (2.4)	5 (12.5)	0	12 (6.9)
600,000 Yen - 699,999 Yen	n (%)	0	2 (4.8)	1 (2.5)	0	3 (1.7)
700,000 Yen - 799,999 Yen	n (%)	0	1 (2.4)	0	0	1 (0.6)
800,000 Yen - 899,999 Yen	n (%)	1 (1.3)	1 (2.4)	1 (2.5)	0	3 (1.7)
900,000 Yen - 999,999 Yen	n (%)	1 (1.3)	0	0	0	1 (0.6)
1,000,000 Yen - or Above	n (%)	4 (5.1)	3 (7.1)	2 (5.0)	0	9 (5.1)

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**
Safety Time Period: Pre-Randomization

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Replied "Don't Know" or "Prefer not to Say" to n (%) 5a		22	17	8	0	47
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?						
Don't Know	n (%)	4 (5.1)	3 (7.1)	3 (7.5)	0	10 (5.7)
Prefer Not to Say	n (%)	10 (12.8)	8 (19.0)	2 (5.0)	0	20 (11.4)
Any Amount Reported	n (%)	8 (10.3)	6 (14.3)	3 (7.5)	0	17 (9.7)
Under 800,000yen	n (%)	6 (7.7)	5 (11.9)	2 (5.0)	0	13 (7.4)
800,000yen or More	n (%)	2 (2.6)	1 (2.4)	1 (2.5)	0	4 (2.3)

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

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
Sex					
Male	n (%)	45 (57.7)	25 (59.5)	22 (55.0)	92 (57.5)
Female	n (%)	33 (42.3)	17 (40.5)	18 (45.0)	68 (42.5)
Age (years)					
	n	78	42	40	160
	Mean (SD)	37.1 (10.58)	37.4 (11.23)	37.0 (9.96)	37.2 (10.54)
	Median	37.0	37.0	38.0	37.5
	Min, Max	23, 65	23, 64	23, 55	23, 65
Ethnicity					
Japanese	n (%)	78 (100)	42 (100)	40 (100)	160 (100)
Non-Japanese	n (%)	0	0	0	0
Weight (kg)					
	n	78	42	40	160
	Mean (SD)	62.87 (10.976)	61.99 (10.228)	61.36 (11.090)	62.26 (10.765)
	Median	61.55	63.80	59.95	61.40
	Min, Max	45.1, 97.8	43.4, 84.4	43.7, 91.8	43.4, 97.8

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
Height (m)	n	78	42	40	160
	Mean (SD)	1.655 (0.0748)	1.660 (0.1012)	1.650 (0.0781)	1.655 (0.0829)
	Median	1.655	1.660	1.650	1.655
	Min, Max	1.52, 1.84	1.47, 1.88	1.50, 1.80	1.47, 1.88
BMI (kg/m ²)	n	78	42	40	160
	Mean (SD)	22.85 (2.963)	22.44 (2.876)	22.48 (3.386)	22.65 (3.039)
	Median	22.40	21.90	21.30	21.90
	Min, Max	18.7, 32.7	18.9, 28.4	18.5, 31.8	18.5, 32.7
Underweight	n (%)	0	0	0	0
Normal Weight	n (%)	60 (76.9)	32 (76.2)	32 (80.0)	124 (77.5)
Overweight	n (%)	17 (21.8)	10 (23.8)	7 (17.5)	34 (21.3)
Obese	n (%)	1 (1.3)	0	1 (2.5)	2 (1.3)

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
Waist circumference (cm)	n	78	42	40	160
	Mean (SD)	86.8 (23.81)	90.6 (30.17)	85.1 (24.33)	87.4 (25.67)
	Median	81.5	79.5	77.5	79.5
	Min, Max	65, 174	64, 172	66, 167	64, 174
Cigarette consumption					
10-19 Cig/Day	n (%)	40 (51.3)	23 (54.8)	21 (52.5)	84 (52.5)
>19 Cig/Day	n (%)	38 (48.7)	19 (45.2)	19 (47.5)	76 (47.5)

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
ISO tar yields	n	78	42	40	160
	Mean (SD)	4.9 (3.53)	4.9 (3.79)	4.7 (3.83)	4.9 (3.65)
	Median	5.0	5.0	5.0	5.0
	Min, Max	1, 12	1, 12	1, 12	1, 12
	n (%)	46 (59.0)	22 (52.4)	23 (57.5)	91 (56.9)
1-5 mg	n (%)	21 (26.9)	14 (33.3)	12 (30.0)	47 (29.4)
6-8 mg	n (%)	7 (9.0)	4 (9.5)	2 (5.0)	13 (8.1)
9-10 mg	n (%)	4 (5.1)	2 (4.8)	3 (7.5)	9 (5.6)
>10 mg					
ISO nicotine yields	n	78	42	40	160
	Mean (SD)	0.40 (0.272)	0.40 (0.277)	0.39 (0.290)	0.40 (0.276)
	Median	0.40	0.45	0.40	0.40
	Min, Max	0.1, 1.0	0.1, 0.9	0.1, 0.9	0.1, 1.0
	n (%)	63 (80.8)	32 (76.2)	30 (75.0)	125 (78.1)
<= 0.6 mg	n (%)	15 (19.2)	10 (23.8)	10 (25.0)	35 (21.9)
> 0.6 mg					

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
FTND score	n	78	42	39	159
	Mean (SD)	4.3 (1.78)	4.3 (1.81)	4.7 (2.08)	4.4 (1.86)
	Median	4.0	4.0	5.0	4.0
	Min, Max	1, 9	1, 8	0, 9	0, 9
Mild	n (%)	27 (34.6)	17 (40.5)	8 (20.0)	52 (32.5)
Moderate	n (%)	44 (56.4)	18 (42.9)	23 (57.5)	85 (53.1)
Severe	n (%)	7 (9.0)	7 (16.7)	8 (20.0)	22 (13.8)
Individual product preference					
THSm2.2	n (%)	18 (23.1)	10 (23.8)	6 (15.0)	34 (21.3)
mCC	n (%)	40 (51.3)	20 (47.6)	25 (62.5)	85 (53.1)
SA	n (%)	9 (11.5)	4 (9.5)	5 (12.5)	18 (11.3)
No Preference	n (%)	11 (14.1)	8 (19.0)	4 (10.0)	23 (14.4)

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
Day 4 SES Questionnaire					
Q1: Total number living in household (including yourself)?					
0	n (%)	1 (1.3)	0	0	1 (0.6)
1	n (%)	35 (44.9)	12 (28.6)	12 (30.0)	59 (36.9)
2	n (%)	13 (16.7)	7 (16.7)	13 (32.5)	33 (20.6)
3	n (%)	9 (11.5)	8 (19.0)	8 (20.0)	25 (15.6)
4	n (%)	9 (11.5)	7 (16.7)	4 (10.0)	20 (12.5)
5	n (%)	3 (3.8)	2 (4.8)	1 (2.5)	6 (3.8)
6	n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
Prefer Not to Say	n (%)	6 (7.7)	4 (9.5)	1 (2.5)	11 (6.9)
Missing	n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
Q2: Highest level education attained / currently attaining?					
Elementary School / Junior High School	n (%)	0	1 (2.4)	2 (5.0)	3 (1.9)
Senior High School	n (%)	19 (24.4)	10 (23.8)	14 (35.0)	43 (26.9)
College	n (%)	23 (29.5)	7 (16.7)	7 (17.5)	37 (23.1)
University / Postgraduate	n (%)	30 (38.5)	18 (42.9)	15 (37.5)	63 (39.4)
Prefer Not to Say	n (%)	5 (6.4)	5 (11.9)	1 (2.5)	11 (6.9)
Missing	n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
Q3: How many income earners in household?					
None - All Are Unemployed	n (%)	4 (5.1)	1 (2.4)	4 (10.0)	9 (5.6)
Just One Income Earner	n (%)	46 (59.0)	20 (47.6)	18 (45.0)	84 (52.5)
Two or More Income Earners	n (%)	27 (34.6)	20 (47.6)	17 (42.5)	64 (40.0)
Missing	n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
Q4: What is your occupation?					
General White Collar	n (%)	8 (10.3)	6 (14.3)	2 (5.0)	16 (10.0)
Professional/Technical Worker	n (%)	5 (6.4)	5 (11.9)	2 (5.0)	12 (7.5)
General Blue Collar	n (%)	1 (1.3)	0	2 (5.0)	3 (1.9)
Working In Service Industry	n (%)	7 (9.0)	3 (7.1)	1 (2.5)	11 (6.9)
Manager (Kacho or Above)	n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
Director/President (30 Employees or More)	n (%)	0	1 (2.4)	1 (2.5)	2 (1.3)
Proprietor (29 Employees or Less)	n (%)	9 (11.5)	4 (9.5)	5 (12.5)	18 (11.3)
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	1 (1.3)	0	0	1 (0.6)
Farming/Forestry/Fishing	n (%)	1 (1.3)	0	0	1 (0.6)
Part-Time Worker (More Than One Day Per Week)	n (%)	20 (25.6)	7 (16.7)	10 (25.0)	37 (23.1)
Student	n (%)	7 (9.0)	2 (4.8)	2 (5.0)	11 (6.9)

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	1 (1.3)	4 (9.5)	0	5 (3.1)
Unemployed	n (%)	1 (1.3)	1 (2.4)	7 (17.5)	9 (5.6)
Others	n (%)	13 (16.7)	6 (14.3)	5 (12.5)	24 (15.0)
Missing	n (%)	3 (3.8)	2 (4.8)	3 (7.5)	8 (5.0)
Q5a: What is approximate MONTHLY household income from all sources before tax?					
Don't Know	n (%)	8 (10.3)	6 (14.3)	5 (12.5)	19 (11.9)
Prefer Not to Say	n (%)	14 (17.9)	11 (26.2)	3 (7.5)	28 (17.5)
Missing	n (%)	4 (5.1)	2 (4.8)	5 (12.5)	11 (6.9)
Any Amount Reported	n (%)	52 (66.7)	23 (54.8)	27 (67.5)	102 (63.8)
Below 100,000 Yen	n (%)	2 (2.6)	0	0	2 (1.3)
100,000 Yen - 199,999 Yen	n (%)	12 (15.4)	4 (9.5)	5 (12.5)	21 (13.1)
200,000 Yen - 299,999 Yen	n (%)	15 (19.2)	4 (9.5)	7 (17.5)	26 (16.3)
300,000 Yen - 399,999 Yen	n (%)	8 (10.3)	4 (9.5)	3 (7.5)	15 (9.4)

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
400,000 Yen - 499,999 Yen	n (%)	3 (3.8)	3 (7.1)	3 (7.5)	9 (5.6)
500,000 Yen - 599,999 Yen	n (%)	6 (7.7)	1 (2.4)	5 (12.5)	12 (7.5)
600,000 Yen - 699,999 Yen	n (%)	0	2 (4.8)	1 (2.5)	3 (1.9)
700,000 Yen - 799,999 Yen	n (%)	0	1 (2.4)	0	1 (0.6)
800,000 Yen - 899,999 Yen	n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
900,000 Yen - 999,999 Yen	n (%)	1 (1.3)	0	0	1 (0.6)
1,000,000 Yen - or Above	n (%)	4 (5.1)	3 (7.1)	2 (5.0)	9 (5.6)

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	22	17	8	47
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?					
Don't Know	n (%)	4 (5.1)	3 (7.1)	3 (7.5)	10 (6.3)
Prefer Not to Say	n (%)	10 (12.8)	8 (19.0)	2 (5.0)	20 (12.5)
Any Amount Reported	n (%)	8 (10.3)	6 (14.3)	3 (7.5)	17 (10.6)
Under 800,000yen	n (%)	6 (7.7)	5 (11.9)	2 (5.0)	13 (8.1)
800,000yen or More	n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)

Note: The Overall FAS refers to all subjects in the FAS 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Sex					
Male	n (%)	43 (56.6)	25 (59.5)	22 (56.4)	90 (57.3)
Female	n (%)	33 (43.4)	17 (40.5)	17 (43.6)	67 (42.7)
Age (years)					
	n	76	42	39	157
	Mean (SD)	37.2 (10.69)	37.4 (11.23)	37.4 (9.83)	37.3 (10.57)
	Median	37.0	37.0	38.0	38.0
	Min, Max	23, 65	23, 64	23, 55	23, 65
Ethnicity					
Japanese	n (%)	76 (100)	42 (100)	39 (100)	157 (100)
Non-Japanese	n (%)	0	0	0	0
Weight (kg)					
	n	76	42	39	157
	Mean (SD)	62.61 (10.835)	61.99 (10.228)	61.68 (11.044)	62.21 (10.668)
	Median	61.55	63.80	61.00	61.40
	Min, Max	45.1, 97.8	43.4, 84.4	43.7, 91.8	43.4, 97.8

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Height (m)	n	76	42	39	157
	Mean (SD)	1.653 (0.0750)	1.660 (0.1012)	1.653 (0.0774)	1.655 (0.0829)
	Median	1.650	1.660	1.650	1.650
	Min, Max	1.52, 1.84	1.47, 1.88	1.50, 1.80	1.47, 1.88
BMI (kg/m ²)	n	76	42	39	157
	Mean (SD)	22.80 (2.905)	22.44 (2.876)	22.53 (3.411)	22.64 (3.015)
	Median	22.40	21.90	21.30	21.90
	Min, Max	18.7, 32.7	18.9, 28.4	18.5, 31.8	18.5, 32.7
Underweight	n (%)	0	0	0	0
Normal Weight	n (%)	59 (77.6)	32 (76.2)	31 (79.5)	122 (77.7)
Overweight	n (%)	16 (21.1)	10 (23.8)	7 (17.9)	33 (21.0)
Obese	n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Waist circumference (cm)	n	76	42	39	157
	Mean (SD)	86.8 (24.07)	90.6 (30.17)	85.3 (24.58)	87.5 (25.87)
	Median	81.5	79.5	78.0	80.0
	Min, Max	65, 174	64, 172	66, 167	64, 174
Cigarette consumption					
	10-19 Cig/Day	n (%)	39 (51.3)	23 (54.8)	82 (52.2)
	>19 Cig/Day	n (%)	37 (48.7)	19 (48.7)	75 (47.8)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
ISO tar yields	n	76	42	39	157
	Mean (SD)	4.9 (3.52)	4.9 (3.79)	4.7 (3.88)	4.9 (3.66)
	Median	5.0	5.0	5.0	5.0
	Min, Max	1, 12	1, 12	1, 12	1, 12
1-5 mg	n (%)	45 (59.2)	22 (52.4)	22 (56.4)	89 (56.7)
6-8 mg	n (%)	21 (27.6)	14 (33.3)	12 (30.8)	47 (29.9)
9-10 mg	n (%)	6 (7.9)	4 (9.5)	2 (5.1)	12 (7.6)
>10 mg	n (%)	4 (5.3)	2 (4.8)	3 (7.7)	9 (5.7)
ISO nicotine yields	n	76	42	39	157
	Mean (SD)	0.40 (0.265)	0.40 (0.277)	0.39 (0.294)	0.39 (0.274)
	Median	0.40	0.45	0.40	0.40
	Min, Max	0.1, 1.0	0.1, 0.9	0.1, 0.9	0.1, 1.0
<= 0.6 mg	n (%)	62 (81.6)	32 (76.2)	29 (74.4)	123 (78.3)
> 0.6 mg	n (%)	14 (18.4)	10 (23.8)	10 (25.6)	34 (21.7)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
FTND score	n	76	42	38	156
	Mean (SD)	4.3 (1.81)	4.3 (1.81)	4.7 (2.11)	4.4 (1.88)
	Median	4.0	4.0	5.0	4.0
	Min, Max	1, 9	1, 8	0, 9	0, 9
Mild	n (%)	27 (35.5)	17 (40.5)	8 (20.5)	52 (33.1)
Moderate	n (%)	42 (55.3)	18 (42.9)	22 (56.4)	82 (52.2)
Severe	n (%)	7 (9.2)	7 (16.7)	8 (20.5)	22 (14.0)
Individual product preference					
THSm2.2	n (%)	17 (22.4)	10 (23.8)	6 (15.4)	33 (21.0)
mCC	n (%)	39 (51.3)	20 (47.6)	24 (61.5)	83 (52.9)
SA	n (%)	9 (11.8)	4 (9.5)	5 (12.8)	18 (11.5)
No Preference	n (%)	11 (14.5)	8 (19.0)	4 (10.3)	23 (14.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Day 4 SES Questionnaire					
Q1: Total number living in household (including yourself)?					
0	n (%)	1 (1.3)	0	0	1 (0.6)
1	n (%)	35 (46.1)	12 (28.6)	12 (30.8)	59 (37.6)
2	n (%)	13 (17.1)	7 (16.7)	13 (33.3)	33 (21.0)
3	n (%)	8 (10.5)	8 (19.0)	8 (20.5)	24 (15.3)
4	n (%)	9 (11.8)	7 (16.7)	4 (10.3)	20 (12.7)
5	n (%)	3 (3.9)	2 (4.8)	1 (2.6)	6 (3.8)
6	n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
Prefer Not to Say	n (%)	6 (7.9)	4 (9.5)	1 (2.6)	11 (7.0)
Missing	n (%)	0	1 (2.4)	0	1 (0.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Q2: Highest level education attained / currently attaining?					
Elementary School / Junior High School	n (%)	0	1 (2.4)	2 (5.1)	3 (1.9)
Senior High School	n (%)	19 (25.0)	10 (23.8)	14 (35.9)	43 (27.4)
College	n (%)	22 (28.9)	7 (16.7)	7 (17.9)	36 (22.9)
University / Postgraduate	n (%)	30 (39.5)	18 (42.9)	15 (38.5)	63 (40.1)
Prefer Not to Say	n (%)	5 (6.6)	5 (11.9)	1 (2.6)	11 (7.0)
Missing	n (%)	0	1 (2.4)	0	1 (0.6)
Q3: How many income earners in household?					
None - All Are Unemployed	n (%)	4 (5.3)	1 (2.4)	4 (10.3)	9 (5.7)
Just One Income Earner	n (%)	45 (59.2)	20 (47.6)	18 (46.2)	83 (52.9)
Two or More Income Earners	n (%)	27 (35.5)	20 (47.6)	17 (43.6)	64 (40.8)
Missing	n (%)	0	1 (2.4)	0	1 (0.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Q4: What is your occupation?					
General White Collar	n (%)	8 (10.5)	6 (14.3)	2 (5.1)	16 (10.2)
Professional/Technical Worker	n (%)	5 (6.6)	5 (11.9)	2 (5.1)	12 (7.6)
General Blue Collar	n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)
Working In Service Industry	n (%)	7 (9.2)	3 (7.1)	1 (2.6)	11 (7.0)
Manager (Kacho or Above)	n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
Director/President (30 Employees or More)	n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
Proprietor (29 Employees or Less)	n (%)	8 (10.5)	4 (9.5)	5 (12.8)	17 (10.8)
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	1 (1.3)	0	0	1 (0.6)
Farming/Forestry/Fishing	n (%)	1 (1.3)	0	0	1 (0.6)
Part-Time Worker (More Than One Day Per Week)	n (%)	20 (26.3)	7 (16.7)	10 (25.6)	37 (23.6)
Student	n (%)	7 (9.2)	2 (4.8)	2 (5.1)	11 (7.0)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	1 (1.3)	4 (9.5)	0	5 (3.2)
Unemployed	n (%)	1 (1.3)	1 (2.4)	7 (17.9)	9 (5.7)
Others	n (%)	13 (17.1)	6 (14.3)	5 (12.8)	24 (15.3)
Missing	n (%)	2 (2.6)	2 (4.8)	2 (5.1)	6 (3.8)
Q5a: What is the approximate MONTHLY household income from all sources before tax?					
Don't Know	n (%)	8 (10.5)	6 (14.3)	5 (12.8)	19 (12.1)
Prefer Not to Say	n (%)	13 (17.1)	11 (26.2)	3 (7.7)	27 (17.2)
Missing	n (%)	3 (3.9)	2 (4.8)	4 (10.3)	9 (5.7)
Any Amount Reported	n (%)	52 (68.4)	23 (54.8)	27 (69.2)	102 (65.0)
Below 100,000 Yen	n (%)	2 (2.6)	0	0	2 (1.3)
100,000 Yen - 199,999 Yen	n (%)	12 (15.8)	4 (9.5)	5 (12.8)	21 (13.4)
200,000 Yen - 299,999 Yen	n (%)	15 (19.7)	4 (9.5)	7 (17.9)	26 (16.6)
300,000 Yen - 399,999 Yen	n (%)	8 (10.5)	4 (9.5)	3 (7.7)	15 (9.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
400,000 Yen - 499,999 Yen	n (%)	3 (3.9)	3 (7.1)	3 (7.7)	9 (5.7)
500,000 Yen - 599,999 Yen	n (%)	6 (7.9)	1 (2.4)	5 (12.8)	12 (7.6)
600,000 Yen - 699,999 Yen	n (%)	0	2 (4.8)	1 (2.6)	3 (1.9)
700,000 Yen - 799,999 Yen	n (%)	0	1 (2.4)	0	1 (0.6)
800,000 Yen - 899,999 Yen	n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
900,000 Yen - 999,999 Yen	n (%)	1 (1.3)	0	0	1 (0.6)
1,000,000 Yen - or Above	n (%)	4 (5.3)	3 (7.1)	2 (5.1)	9 (5.7)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 1**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	21	17	8	46
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?					
Don't Know	n (%)	4 (5.3)	3 (7.1)	3 (7.7)	10 (6.4)
Prefer Not to Say	n (%)	10 (13.2)	8 (19.0)	2 (5.1)	20 (12.7)
Any Amount Reported	n (%)	7 (9.2)	6 (14.3)	3 (7.7)	16 (10.2)
Under 800,000yen	n (%)	5 (6.6)	5 (11.9)	2 (5.1)	12 (7.6)
800,000yen or More	n (%)	2 (2.6)	1 (2.4)	1 (2.6)	4 (2.5)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
Sex					
Male	n (%)	42 (56.8)	24 (58.5)	22 (56.4)	88 (57.1)
Female	n (%)	32 (43.2)	17 (41.5)	17 (43.6)	66 (42.9)
Age (years)	n	74	41	39	154
	Mean (SD)	37.4 (10.75)	37.7 (11.14)	37.4 (9.83)	37.5 (10.56)
	Median	37.5	39.0	38.0	38.0
	Min, Max	23, 65	23, 64	23, 55	23, 65
Ethnicity					
Japanese	n (%)	74 (100)	41 (100)	39 (100)	154 (100)
Non-Japanese	n (%)	0	0	0	0
Weight (kg)	n	74	41	39	154
	Mean (SD)	62.62 (10.981)	62.01 (10.354)	61.68 (11.044)	62.22 (10.771)
	Median	61.55	63.90	61.00	61.45
	Min, Max	45.1, 97.8	43.4, 84.4	43.7, 91.8	43.4, 97.8

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
Height (m)	n	74	41	39	154
	Mean (SD)	1.652 (0.0758)	1.658 (0.1007)	1.653 (0.0774)	1.654 (0.0830)
	Median	1.650	1.660	1.650	1.650
	Min, Max	1.52, 1.84	1.47, 1.88	1.50, 1.80	1.47, 1.88
BMI (kg/m ²)	n	74	41	39	154
	Mean (SD)	22.83 (2.939)	22.51 (2.868)	22.53 (3.411)	22.67 (3.031)
	Median	22.40	21.90	21.30	21.90
	Min, Max	18.7, 32.7	18.9, 28.4	18.5, 31.8	18.5, 32.7
Underweight	n (%)	0	0	0	0
Normal Weight	n (%)	57 (77.0)	31 (75.6)	31 (79.5)	119 (77.3)
Overweight	n (%)	16 (21.6)	10 (24.4)	7 (17.9)	33 (21.4)
Obese	n (%)	1 (1.4)	0	1 (2.6)	2 (1.3)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
Waist circumference (cm)	n	74	41	39	154
	Mean (SD)	87.0 (24.36)	91.0 (30.45)	85.3 (24.58)	87.6 (26.08)
	Median	82.5	80.0	78.0	80.0
	Min, Max	65, 174	64, 172	66, 167	64, 174
Cigarette consumption					
10-19 Cig/Day	n (%)	38 (51.4)	23 (56.1)	20 (51.3)	81 (52.6)
>19 Cig/Day	n (%)	36 (48.6)	18 (43.9)	19 (48.7)	73 (47.4)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
ISO tar yields	n	74	41	39	154
	Mean (SD)	4.9 (3.52)	4.9 (3.83)	4.7 (3.88)	4.9 (3.67)
	Median	5.0	5.0	5.0	5.0
	Min, Max	1, 12	1, 12	1, 12	1, 12
	1-5 mg n (%)	44 (59.5)	22 (53.7)	22 (56.4)	88 (57.1)
	6-8 mg n (%)	20 (27.0)	13 (31.7)	12 (30.8)	45 (29.2)
	9-10 mg n (%)	6 (8.1)	4 (9.8)	2 (5.1)	12 (7.8)
	>10 mg n (%)	4 (5.4)	2 (4.9)	3 (7.7)	9 (5.8)
ISO nicotine yields	n	74	41	39	154
	Mean (SD)	0.40 (0.264)	0.39 (0.280)	0.39 (0.294)	0.39 (0.274)
	Median	0.40	0.40	0.40	0.40
	Min, Max	0.1, 1.0	0.1, 0.9	0.1, 0.9	0.1, 1.0
	<= 0.6 mg n (%)	61 (82.4)	31 (75.6)	29 (74.4)	121 (78.6)
	> 0.6 mg n (%)	13 (17.6)	10 (24.4)	10 (25.6)	33 (21.4)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
FTND score	n	74	41	38	153
	Mean (SD)	4.3 (1.83)	4.3 (1.82)	4.7 (2.11)	4.4 (1.90)
	Median	4.0	4.0	5.0	4.0
	Min, Max	1, 9	1, 8	0, 9	0, 9
Mild	n (%)	27 (36.5)	17 (41.5)	8 (20.5)	52 (33.8)
Moderate	n (%)	40 (54.1)	17 (41.5)	22 (56.4)	79 (51.3)
Severe	n (%)	7 (9.5)	7 (17.1)	8 (20.5)	22 (14.3)
Individual product preference					
THSm2.2	n (%)	17 (23.0)	10 (24.4)	6 (15.4)	33 (21.4)
mCC	n (%)	39 (52.7)	19 (46.3)	24 (61.5)	82 (53.2)
SA	n (%)	7 (9.5)	4 (9.8)	5 (12.8)	16 (10.4)
No Preference	n (%)	11 (14.9)	8 (19.5)	4 (10.3)	23 (14.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
Day 4 SES Questionnaire					
Q1: Total number living in household (including yourself)?					
0	n (%)	1 (1.4)	0	0	1 (0.6)
1	n (%)	35 (47.3)	12 (29.3)	12 (30.8)	59 (38.3)
2	n (%)	12 (16.2)	7 (17.1)	13 (33.3)	32 (20.8)
3	n (%)	8 (10.8)	8 (19.5)	8 (20.5)	24 (15.6)
4	n (%)	9 (12.2)	7 (17.1)	4 (10.3)	20 (13.0)
5	n (%)	3 (4.1)	2 (4.9)	1 (2.6)	6 (3.9)
6	n (%)	1 (1.4)	1 (2.4)	0	2 (1.3)
Prefer Not to Say	n (%)	5 (6.8)	4 (9.8)	1 (2.6)	10 (6.5)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
Q2: Highest level education attained / currently attaining?					
Elementary School / Junior High School	n (%)	0	1 (2.4)	2 (5.1)	3 (1.9)
Senior High School	n (%)	19 (25.7)	10 (24.4)	14 (35.9)	43 (27.9)
College	n (%)	20 (27.0)	7 (17.1)	7 (17.9)	34 (22.1)
University / Postgraduate	n (%)	30 (40.5)	18 (43.9)	15 (38.5)	63 (40.9)
Prefer Not to Say	n (%)	5 (6.8)	5 (12.2)	1 (2.6)	11 (7.1)
Q3: How many income earners in household?					
None - All Are Unemployed	n (%)	4 (5.4)	1 (2.4)	4 (10.3)	9 (5.8)
Just One Income Earner	n (%)	43 (58.1)	20 (48.8)	18 (46.2)	81 (52.6)
Two or More Income Earners	n (%)	27 (36.5)	20 (48.8)	17 (43.6)	64 (41.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
Q4: What is your occupation?					
General White Collar	n (%)	8 (10.8)	6 (14.6)	2 (5.1)	16 (10.4)
Professional/Technical Worker	n (%)	5 (6.8)	5 (12.2)	2 (5.1)	12 (7.8)
General Blue Collar	n (%)	1 (1.4)	0	2 (5.1)	3 (1.9)
Working In Service Industry	n (%)	7 (9.5)	3 (7.3)	1 (2.6)	11 (7.1)
Manager (Kacho or Above)	n (%)	1 (1.4)	1 (2.4)	0	2 (1.3)
Director/President (30 Employees or More)	n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
Proprietor (29 Employees or Less)	n (%)	8 (10.8)	4 (9.8)	5 (12.8)	17 (11.0)
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	1 (1.4)	0	0	1 (0.6)
Farming/Forestry/Fishing	n (%)	1 (1.4)	0	0	1 (0.6)
Part-Time Worker (More Than One Day Per Week)	n (%)	19 (25.7)	7 (17.1)	10 (25.6)	36 (23.4)
Student	n (%)	7 (9.5)	2 (4.9)	2 (5.1)	11 (7.1)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	1 (1.4)	4 (9.8)	0	5 (3.2)
Unemployed	n (%)	1 (1.4)	1 (2.4)	7 (17.9)	9 (5.8)
Others	n (%)	12 (16.2)	6 (14.6)	5 (12.8)	23 (14.9)
Missing	n (%)	2 (2.7)	1 (2.4)	2 (5.1)	5 (3.2)
Q5a: What is the approximate MONTHLY household income from all sources before tax?					
Don't Know	n (%)	8 (10.8)	6 (14.6)	5 (12.8)	19 (12.3)
Prefer Not to Say	n (%)	13 (17.6)	11 (26.8)	3 (7.7)	27 (17.5)
Missing	n (%)	3 (4.1)	1 (2.4)	4 (10.3)	8 (5.2)
Any Amount Reported	n (%)	50 (67.6)	23 (56.1)	27 (69.2)	100 (64.9)
Below 100,000 Yen	n (%)	2 (2.7)	0	0	2 (1.3)
100,000 Yen - 199,999 Yen	n (%)	11 (14.9)	4 (9.8)	5 (12.8)	20 (13.0)
200,000 Yen - 299,999 Yen	n (%)	14 (18.9)	4 (9.8)	7 (17.9)	25 (16.2)
300,000 Yen - 399,999 Yen	n (%)	8 (10.8)	4 (9.8)	3 (7.7)	15 (9.7)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
400,000 Yen - 499,999 Yen	n (%)	3 (4.1)	3 (7.3)	3 (7.7)	9 (5.8)
500,000 Yen - 599,999 Yen	n (%)	6 (8.1)	1 (2.4)	5 (12.8)	12 (7.8)
600,000 Yen - 699,999 Yen	n (%)	0	2 (4.9)	1 (2.6)	3 (1.9)
700,000 Yen - 799,999 Yen	n (%)	0	1 (2.4)	0	1 (0.6)
800,000 Yen - 899,999 Yen	n (%)	1 (1.4)	1 (2.4)	1 (2.6)	3 (1.9)
900,000 Yen - 999,999 Yen	n (%)	1 (1.4)	0	0	1 (0.6)
1,000,000 Yen - or Above	n (%)	4 (5.4)	3 (7.3)	2 (5.1)	9 (5.8)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 2**

Variable	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)	Overall PP Set (N=154)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	21	17	8	46
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?					
Don't Know	n (%)	4 (5.4)	3 (7.3)	3 (7.7)	10 (6.5)
Prefer Not to Say	n (%)	10 (13.5)	8 (19.5)	2 (5.1)	20 (13.0)
Any Amount Reported	n (%)	7 (9.5)	6 (14.6)	3 (7.7)	16 (10.4)
Under 800,000yen	n (%)	5 (6.8)	5 (12.2)	2 (5.1)	12 (7.8)
800,000yen or More	n (%)	2 (2.7)	1 (2.4)	1 (2.6)	4 (2.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
Sex					
Male	n (%)	41 (57.7)	24 (58.5)	21 (55.3)	86 (57.3)
Female	n (%)	30 (42.3)	17 (41.5)	17 (44.7)	64 (42.7)
Age (years)	n	71	41	38	150
	Mean (SD)	37.7 (10.80)	37.7 (11.14)	37.6 (9.83)	37.7 (10.59)
	Median	39.0	39.0	38.5	39.0
	Min, Max	23, 65	23, 64	23, 55	23, 65
Ethnicity					
Japanese	n (%)	71 (100)	41 (100)	38 (100)	150 (100)
Non-Japanese	n (%)	0	0	0	0
Weight (kg)	n	71	41	38	150
	Mean (SD)	62.67 (10.863)	62.01 (10.354)	61.83 (11.152)	62.28 (10.735)
	Median	62.10	63.90	61.20	61.90
	Min, Max	45.1, 97.8	43.4, 84.4	43.7, 91.8	43.4, 97.8

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
Height (m)	n	71	41	38	150
	Mean (SD)	1.650 (0.0732)	1.658 (0.1007)	1.653 (0.0784)	1.653 (0.0823)
	Median	1.650	1.660	1.660	1.650
	Min, Max	1.52, 1.84	1.47, 1.88	1.50, 1.80	1.47, 1.88
BMI (kg/m ²)	n	71	41	38	150
	Mean (SD)	22.90 (2.956)	22.51 (2.868)	22.58 (3.445)	22.71 (3.048)
	Median	22.50	21.90	21.35	21.95
	Min, Max	18.7, 32.7	18.9, 28.4	18.5, 31.8	18.5, 32.7
Underweight	n (%)	0	0	0	0
Normal Weight	n (%)	54 (76.1)	31 (75.6)	30 (78.9)	115 (76.7)
Overweight	n (%)	16 (22.5)	10 (24.4)	7 (18.4)	33 (22.0)
Obese	n (%)	1 (1.4)	0	1 (2.6)	2 (1.3)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
Waist circumference (cm)	n	71	41	38	150
	Mean (SD)	87.4 (24.74)	91.0 (30.45)	85.6 (24.86)	87.9 (26.34)
	Median	82.0	80.0	78.5	80.0
	Min, Max	65, 174	64, 172	66, 167	64, 174
Cigarette consumption					
10-19 Cig/Day	n (%)	36 (50.7)	23 (56.1)	20 (52.6)	79 (52.7)
>19 Cig/Day	n (%)	35 (49.3)	18 (43.9)	18 (47.4)	71 (47.3)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
ISO tar yields	n	71	41	38	150
	Mean (SD)	5.1 (3.53)	4.9 (3.83)	4.6 (3.89)	4.9 (3.68)
	Median	5.0	5.0	4.5	5.0
	Min, Max	1, 12	1, 12	1, 12	1, 12
	1-5 mg n (%)	41 (57.7)	22 (53.7)	22 (57.9)	85 (56.7)
	6-8 mg n (%)	20 (28.2)	13 (31.7)	11 (28.9)	44 (29.3)
	9-10 mg n (%)	6 (8.5)	4 (9.8)	2 (5.3)	12 (8.0)
	>10 mg n (%)	4 (5.6)	2 (4.9)	3 (7.9)	9 (6.0)
ISO nicotine yields	n	71	41	38	150
	Mean (SD)	0.41 (0.266)	0.39 (0.280)	0.38 (0.294)	0.40 (0.275)
	Median	0.40	0.40	0.35	0.40
	Min, Max	0.1, 1.0	0.1, 0.9	0.1, 0.9	0.1, 1.0
	<= 0.6 mg n (%)	57 (80.3)	31 (75.6)	29 (76.3)	117 (78.0)
	> 0.6 mg n (%)	14 (19.7)	10 (24.4)	9 (23.7)	33 (22.0)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
FTND score	n	71	41	37	149
	Mean (SD)	4.3 (1.83)	4.3 (1.82)	4.7 (2.13)	4.4 (1.91)
	Median	4.0	4.0	5.0	4.0
	Min, Max	1, 9	1, 8	0, 9	0, 9
Mild	n (%)	26 (36.6)	17 (41.5)	8 (21.1)	51 (34.0)
Moderate	n (%)	39 (54.9)	17 (41.5)	21 (55.3)	77 (51.3)
Severe	n (%)	6 (8.5)	7 (17.1)	8 (21.1)	21 (14.0)
Individual product preference					
THSm2.2	n (%)	16 (22.5)	10 (24.4)	6 (15.8)	32 (21.3)
mCC	n (%)	38 (53.5)	19 (46.3)	23 (60.5)	80 (53.3)
SA	n (%)	7 (9.9)	4 (9.8)	5 (13.2)	16 (10.7)
No Preference	n (%)	10 (14.1)	8 (19.5)	4 (10.5)	22 (14.7)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
Day 4 SES Questionnaire					
Q1: Total number living in household (including yourself)?					
0	n (%)	1 (1.4)	0	0	1 (0.7)
1	n (%)	34 (47.9)	12 (29.3)	12 (31.6)	58 (38.7)
2	n (%)	11 (15.5)	7 (17.1)	13 (34.2)	31 (20.7)
3	n (%)	8 (11.3)	8 (19.5)	7 (18.4)	23 (15.3)
4	n (%)	8 (11.3)	7 (17.1)	4 (10.5)	19 (12.7)
5	n (%)	3 (4.2)	2 (4.9)	1 (2.6)	6 (4.0)
6	n (%)	0	1 (2.4)	0	1 (0.7)
Prefer Not to Say	n (%)	6 (8.5)	4 (9.8)	1 (2.6)	11 (7.3)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
Q2: Highest level education attained / currently attaining?					
Elementary School / Junior High School	n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
Senior High School	n (%)	19 (26.8)	10 (24.4)	14 (36.8)	43 (28.7)
College	n (%)	20 (28.2)	7 (17.1)	7 (18.4)	34 (22.7)
University / Postgraduate	n (%)	27 (38.0)	18 (43.9)	15 (39.5)	60 (40.0)
Prefer Not to Say	n (%)	5 (7.0)	5 (12.2)	1 (2.6)	11 (7.3)
Q3: How many income earners in household?					
None - All Are Unemployed	n (%)	4 (5.6)	1 (2.4)	4 (10.5)	9 (6.0)
Just One Income Earner	n (%)	42 (59.2)	20 (48.8)	18 (47.4)	80 (53.3)
Two or More Income Earners	n (%)	25 (35.2)	20 (48.8)	16 (42.1)	61 (40.7)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
Q4: What is your occupation?					
General White Collar	n (%)	8 (11.3)	6 (14.6)	2 (5.3)	16 (10.7)
Professional/Technical Worker	n (%)	5 (7.0)	5 (12.2)	2 (5.3)	12 (8.0)
General Blue Collar	n (%)	1 (1.4)	0	2 (5.3)	3 (2.0)
Working In Service Industry	n (%)	7 (9.9)	3 (7.3)	1 (2.6)	11 (7.3)
Manager (Kacho or Above)	n (%)	1 (1.4)	1 (2.4)	0	2 (1.3)
Director/President (30 Employees or More)	n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
Proprietor (29 Employees or Less)	n (%)	8 (11.3)	4 (9.8)	5 (13.2)	17 (11.3)
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	1 (1.4)	0	0	1 (0.7)
Farming/Forestry/Fishing	n (%)	1 (1.4)	0	0	1 (0.7)
Part-Time Worker (More Than One Day Per Week)	n (%)	19 (26.8)	7 (17.1)	10 (26.3)	36 (24.0)
Student	n (%)	6 (8.5)	2 (4.9)	2 (5.3)	10 (6.7)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	1 (1.4)	4 (9.8)	0	5 (3.3)
Unemployed	n (%)	1 (1.4)	1 (2.4)	6 (15.8)	8 (5.3)
Others	n (%)	10 (14.1)	6 (14.6)	5 (13.2)	21 (14.0)
Missing	n (%)	2 (2.8)	1 (2.4)	2 (5.3)	5 (3.3)
Q5a: What is the approximate MONTHLY household income from all sources before tax?					
Don't Know	n (%)	7 (9.9)	6 (14.6)	4 (10.5)	17 (11.3)
Prefer Not to Say	n (%)	11 (15.5)	11 (26.8)	3 (7.9)	25 (16.7)
Missing	n (%)	3 (4.2)	1 (2.4)	4 (10.5)	8 (5.3)
Any Amount Reported	n (%)	50 (70.4)	23 (56.1)	27 (71.1)	100 (66.7)
Below 100,000 Yen	n (%)	2 (2.8)	0	0	2 (1.3)
100,000 Yen - 199,999 Yen	n (%)	12 (16.9)	4 (9.8)	5 (13.2)	21 (14.0)
200,000 Yen - 299,999 Yen	n (%)	13 (18.3)	4 (9.8)	7 (18.4)	24 (16.0)
300,000 Yen - 399,999 Yen	n (%)	8 (11.3)	4 (9.8)	3 (7.9)	15 (10.0)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
400,000 Yen - 499,999 Yen	n (%)	3 (4.2)	3 (7.3)	3 (7.9)	9 (6.0)
500,000 Yen - 599,999 Yen	n (%)	6 (8.5)	1 (2.4)	5 (13.2)	12 (8.0)
600,000 Yen - 699,999 Yen	n (%)	0	2 (4.9)	1 (2.6)	3 (2.0)
700,000 Yen - 799,999 Yen	n (%)	0	1 (2.4)	0	1 (0.7)
800,000 Yen - 899,999 Yen	n (%)	1 (1.4)	1 (2.4)	1 (2.6)	3 (2.0)
900,000 Yen - 999,999 Yen	n (%)	1 (1.4)	0	0	1 (0.7)
1,000,000 Yen - or Above	n (%)	4 (5.6)	3 (7.3)	2 (5.3)	9 (6.0)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 3**

Variable	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)	Overall PP Set (N=150)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	18	17	7	42
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?					
Don't Know	n (%)	3 (4.2)	3 (7.3)	2 (5.3)	8 (5.3)
Prefer Not to Say	n (%)	8 (11.3)	8 (19.5)	2 (5.3)	18 (12.0)
Any Amount Reported	n (%)	7 (9.9)	6 (14.6)	3 (7.9)	16 (10.7)
Under 800,000yen	n (%)	5 (7.0)	5 (12.2)	2 (5.3)	12 (8.0)
800,000yen or More	n (%)	2 (2.8)	1 (2.4)	1 (2.6)	4 (2.7)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
Sex					
Male	n (%)	39 (55.7)	24 (58.5)	21 (56.8)	84 (56.8)
Female	n (%)	31 (44.3)	17 (41.5)	16 (43.2)	64 (43.2)
Age (years)					
	n	70	41	37	148
	Mean (SD)	37.7 (10.68)	37.7 (11.14)	37.8 (9.91)	37.8 (10.55)
	Median	38.5	39.0	39.0	39.0
	Min, Max	23, 65	23, 64	23, 55	23, 65
Ethnicity					
Japanese	n (%)	70 (100)	41 (100)	37 (100)	148 (100)
Non-Japanese	n (%)	0	0	0	0
Weight (kg)					
	n	70	41	37	148
	Mean (SD)	62.35 (11.097)	62.01 (10.354)	62.24 (11.013)	62.23 (10.803)
	Median	61.55	63.90	61.40	61.60
	Min, Max	45.1, 97.8	43.4, 84.4	43.7, 91.8	43.4, 97.8

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
Height (m)	n	70	41	37	148
	Mean (SD)	1.651 (0.0773)	1.658 (0.1007)	1.655 (0.0788)	1.654 (0.0842)
	Median	1.650	1.660	1.670	1.650
	Min, Max	1.52, 1.84	1.47, 1.88	1.50, 1.80	1.47, 1.88
BMI (kg/m ²)	n	70	41	37	148
	Mean (SD)	22.76 (2.958)	22.51 (2.868)	22.69 (3.424)	22.67 (3.038)
	Median	22.20	21.90	21.40	21.90
	Min, Max	18.7, 32.7	18.9, 28.4	18.7, 31.8	18.7, 32.7
Underweight	n (%)	0	0	0	0
Normal Weight	n (%)	55 (78.6)	31 (75.6)	29 (78.4)	115 (77.7)
Overweight	n (%)	14 (20.0)	10 (24.4)	7 (18.9)	31 (20.9)
Obese	n (%)	1 (1.4)	0	1 (2.7)	2 (1.4)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
Waist circumference (cm)	n	70	41	37	148
	Mean (SD)	87.1 (25.03)	91.0 (30.45)	86.0 (25.09)	87.9 (26.54)
	Median	80.0	80.0	79.0	79.5
	Min, Max	65, 174	64, 172	66, 167	64, 174
Cigarette consumption					
10-19 Cig/Day	n (%)	36 (51.4)	23 (56.1)	20 (54.1)	79 (53.4)
>19 Cig/Day	n (%)	34 (48.6)	18 (43.9)	17 (45.9)	69 (46.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
ISO tar yields	n	70	41	37	148
	Mean (SD)	4.9 (3.53)	4.9 (3.83)	4.5 (3.90)	4.8 (3.69)
	Median	5.0	5.0	4.0	5.0
	Min, Max	1, 12	1, 12	1, 12	1, 12
	1-5 mg n (%)	42 (60.0)	22 (53.7)	22 (59.5)	86 (58.1)
	6-8 mg n (%)	19 (27.1)	13 (31.7)	10 (27.0)	42 (28.4)
	9-10 mg n (%)	5 (7.1)	4 (9.8)	2 (5.4)	11 (7.4)
	>10 mg n (%)	4 (5.7)	2 (4.9)	3 (8.1)	9 (6.1)
ISO nicotine yields	n	70	41	37	148
	Mean (SD)	0.39 (0.256)	0.39 (0.280)	0.37 (0.293)	0.39 (0.270)
	Median	0.40	0.40	0.30	0.40
	Min, Max	0.1, 1.0	0.1, 0.9	0.1, 0.9	0.1, 1.0
	<= 0.6 mg n (%)	59 (84.3)	31 (75.6)	29 (78.4)	119 (80.4)
	> 0.6 mg n (%)	11 (15.7)	10 (24.4)	8 (21.6)	29 (19.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
FTND score	n	70	41	36	147
	Mean (SD)	4.3 (1.78)	4.3 (1.82)	4.7 (2.13)	4.4 (1.88)
	Median	4.0	4.0	5.0	4.0
	Min, Max	1, 8	1, 8	0, 9	0, 9
Mild	n (%)	26 (37.1)	17 (41.5)	8 (21.6)	51 (34.5)
Moderate	n (%)	38 (54.3)	17 (41.5)	21 (56.8)	76 (51.4)
Severe	n (%)	6 (8.6)	7 (17.1)	7 (18.9)	20 (13.5)
Individual product preference					
THSm2.2	n (%)	16 (22.9)	10 (24.4)	5 (13.5)	31 (20.9)
mCC	n (%)	36 (51.4)	19 (46.3)	23 (62.2)	78 (52.7)
SA	n (%)	7 (10.0)	4 (9.8)	5 (13.5)	16 (10.8)
No Preference	n (%)	11 (15.7)	8 (19.5)	4 (10.8)	23 (15.5)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
Day 4 SES Questionnaire					
Q1: Total number living in household (including yourself)?					
0	n (%)	1 (1.4)	0	0	1 (0.7)
1	n (%)	34 (48.6)	12 (29.3)	12 (32.4)	58 (39.2)
2	n (%)	10 (14.3)	7 (17.1)	13 (35.1)	30 (20.3)
3	n (%)	8 (11.4)	8 (19.5)	6 (16.2)	22 (14.9)
4	n (%)	9 (12.9)	7 (17.1)	4 (10.8)	20 (13.5)
5	n (%)	3 (4.3)	2 (4.9)	1 (2.7)	6 (4.1)
6	n (%)	0	1 (2.4)	0	1 (0.7)
Prefer Not to Say	n (%)	5 (7.1)	4 (9.8)	1 (2.7)	10 (6.8)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
Q2: Highest level education attained / currently attaining?					
Elementary School / Junior High School	n (%)	0	1 (2.4)	1 (2.7)	2 (1.4)
Senior High School	n (%)	19 (27.1)	10 (24.4)	14 (37.8)	43 (29.1)
College	n (%)	18 (25.7)	7 (17.1)	7 (18.9)	32 (21.6)
University / Postgraduate	n (%)	28 (40.0)	18 (43.9)	14 (37.8)	60 (40.5)
Prefer Not to Say	n (%)	5 (7.1)	5 (12.2)	1 (2.7)	11 (7.4)
Q3: How many income earners in household?					
None - All Are Unemployed	n (%)	4 (5.7)	1 (2.4)	4 (10.8)	9 (6.1)
Just One Income Earner	n (%)	41 (58.6)	20 (48.8)	18 (48.6)	79 (53.4)
Two or More Income Earners	n (%)	25 (35.7)	20 (48.8)	15 (40.5)	60 (40.5)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
Q4: What is your occupation?					
General White Collar	n (%)	8 (11.4)	6 (14.6)	2 (5.4)	16 (10.8)
Professional/Technical Worker	n (%)	4 (5.7)	5 (12.2)	1 (2.7)	10 (6.8)
General Blue Collar	n (%)	1 (1.4)	0	2 (5.4)	3 (2.0)
Working In Service Industry	n (%)	7 (10.0)	3 (7.3)	1 (2.7)	11 (7.4)
Manager (Kacho or Above)	n (%)	1 (1.4)	1 (2.4)	0	2 (1.4)
Director/President (30 Employees or More)	n (%)	0	1 (2.4)	1 (2.7)	2 (1.4)
Proprietor (29 Employees or Less)	n (%)	7 (10.0)	4 (9.8)	5 (13.5)	16 (10.8)
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	1 (1.4)	0	0	1 (0.7)
Farming/Forestry/Fishing	n (%)	1 (1.4)	0	0	1 (0.7)
Part-Time Worker (More Than One Day Per Week)	n (%)	17 (24.3)	7 (17.1)	10 (27.0)	34 (23.0)
Student	n (%)	7 (10.0)	2 (4.9)	2 (5.4)	11 (7.4)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	1 (1.4)	4 (9.8)	0	5 (3.4)
Unemployed	n (%)	1 (1.4)	1 (2.4)	6 (16.2)	8 (5.4)
Others	n (%)	12 (17.1)	6 (14.6)	5 (13.5)	23 (15.5)
Missing	n (%)	2 (2.9)	1 (2.4)	2 (5.4)	5 (3.4)
Q5a: What is the approximate MONTHLY household income from all sources before tax?					
Don't Know	n (%)	6 (8.6)	6 (14.6)	3 (8.1)	15 (10.1)
Prefer Not to Say	n (%)	13 (18.6)	11 (26.8)	3 (8.1)	27 (18.2)
Missing	n (%)	3 (4.3)	1 (2.4)	4 (10.8)	8 (5.4)
Any Amount Reported	n (%)	48 (68.6)	23 (56.1)	27 (73.0)	98 (66.2)
Below 100,000 Yen	n (%)	2 (2.9)	0	0	2 (1.4)
100,000 Yen - 199,999 Yen	n (%)	10 (14.3)	4 (9.8)	5 (13.5)	19 (12.8)
200,000 Yen - 299,999 Yen	n (%)	13 (18.6)	4 (9.8)	7 (18.9)	24 (16.2)
300,000 Yen - 399,999 Yen	n (%)	8 (11.4)	4 (9.8)	3 (8.1)	15 (10.1)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set
Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
400,000 Yen - 499,999 Yen	n (%)	3 (4.3)	3 (7.3)	3 (8.1)	9 (6.1)
500,000 Yen - 599,999 Yen	n (%)	6 (8.6)	1 (2.4)	5 (13.5)	12 (8.1)
600,000 Yen - 699,999 Yen	n (%)	0	2 (4.9)	1 (2.7)	3 (2.0)
700,000 Yen - 799,999 Yen	n (%)	0	1 (2.4)	0	1 (0.7)
800,000 Yen - 899,999 Yen	n (%)	1 (1.4)	1 (2.4)	1 (2.7)	3 (2.0)
900,000 Yen - 999,999 Yen	n (%)	1 (1.4)	0	0	1 (0.7)
1,000,000 Yen - or Above	n (%)	4 (5.7)	3 (7.3)	2 (5.4)	9 (6.1)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set Per-Protocol Population - Period 4**

Variable	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)	Overall PP Set (N=148)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	19	17	6	42
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?					
Don't Know	n (%)	2 (2.9)	3 (7.3)	1 (2.7)	6 (4.1)
Prefer Not to Say	n (%)	10 (14.3)	8 (19.5)	2 (5.4)	20 (13.5)
Any Amount Reported	n (%)	7 (10.0)	6 (14.6)	3 (8.1)	16 (10.8)
Under 800,000yen	n (%)	5 (7.1)	5 (12.2)	2 (5.4)	12 (8.1)
800,000yen or More	n (%)	2 (2.9)	1 (2.4)	1 (2.7)	4 (2.7)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Age (years)	n	43	33	25	17	22	17
	Mean (SD)	35.4 (10.65)	39.4 (10.48)	35.5 (11.19)	40.2 (11.02)	38.0 (9.27)	36.6 (10.73)
	Median	34.0	42.0	31.0	39.0	39.0	34.0
	Min, Max	23, 65	23, 56	23, 56	23, 64	24, 55	23, 54
Ethnicity							
Japanese	n (%)	43 (100)	33 (100)	25 (100)	17 (100)	22 (100)	17 (100)
Non-Japanese	n (%)	0	0	0	0	0	0
Weight (kg)	n	43	33	25	17	22	17
	Mean (SD)	68.10 (10.043)	55.46 (7.045)	67.25 (8.356)	54.26 (7.530)	66.58 (9.825)	55.34 (9.339)
	Median	65.70	55.20	67.00	51.50	64.45	53.00
	Min, Max	52.1, 97.8	45.1, 75.0	51.8, 84.4	43.4, 67.4	53.9, 91.8	43.7, 74.8

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 1**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Height (m)	n	43	33	25	17	22	17
	Mean (SD)	1.702 (0.0527)	1.590 (0.0473)	1.721 (0.0724)	1.571 (0.0646)	1.704 (0.0465)	1.586 (0.0563)
	Median	1.700	1.580	1.720	1.560	1.700	1.590
	Min, Max	1.58, 1.84	1.52, 1.72	1.58, 1.88	1.47, 1.72	1.64, 1.80	1.50, 1.73
BMI (kg/m ²)	n	43	33	25	17	22	17
	Mean (SD)	23.49 (3.135)	21.92 (2.334)	22.75 (3.009)	21.97 (2.688)	22.96 (3.412)	21.98 (3.430)
	Median	22.80	21.30	22.10	21.30	22.00	20.40
	Min, Max	18.9, 32.7	18.7, 27.9	19.0, 28.3	18.9, 28.4	18.7, 31.8	18.5, 29.6
Underweight	n (%)	0	0	0	0	0	0
Normal Weight	n (%)	30 (69.8)	29 (87.9)	17 (68.0)	15 (88.2)	17 (77.3)	14 (82.4)
Overweight	n (%)	12 (27.9)	4 (12.1)	8 (32.0)	2 (11.8)	4 (18.2)	3 (17.6)
Obese	n (%)	1 (2.3)	0	0	0	1 (4.5)	0

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 1**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Waist circumference (cm)	n	43	33	25	17	22	17
	Mean (SD)	94.0 (29.31)	77.3 (8.19)	99.1 (36.57)	78.2 (7.13)	92.4 (30.41)	76.2 (7.97)
	Median	85.0	76.0	83.0	77.0	79.5	76.0
	Min, Max	69, 174	65, 95	72, 172	64, 90	68, 167	66, 94
Cigarette consumption							
10-19 Cig/Day	n (%)	21 (48.8)	18 (54.5)	13 (52.0)	10 (58.8)	11 (50.0)	9 (52.9)
>19 Cig/Day	n (%)	22 (51.2)	15 (45.5)	12 (48.0)	7 (41.2)	11 (50.0)	8 (47.1)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
ISO tar yields	n	43	33	25	17	22	17
	Mean (SD)	6.2 (3.28)	3.3 (3.13)	6.5 (3.65)	2.6 (2.74)	5.8 (4.01)	3.3 (3.28)
	Median	6.0	1.0	8.0	1.0	6.0	1.0
	Min, Max	1, 12	1, 12	1, 12	1, 8	1, 12	1, 8
1-5 mg	n (%)	20 (46.5)	25 (75.8)	8 (32.0)	14 (82.4)	10 (45.5)	12 (70.6)
6-8 mg	n (%)	14 (32.6)	7 (21.2)	11 (44.0)	3 (17.6)	7 (31.8)	5 (29.4)
9-10 mg	n (%)	6 (14.0)	0	4 (16.0)	0	2 (9.1)	0
>10 mg	n (%)	3 (7.0)	1 (3.0)	2 (8.0)	0	3 (13.6)	0
ISO nicotine yields	n	43	33	25	17	22	17
	Mean (SD)	0.49 (0.247)	0.28 (0.239)	0.50 (0.259)	0.24 (0.224)	0.47 (0.292)	0.29 (0.272)
	Median	0.50	0.10	0.60	0.10	0.55	0.10
	Min, Max	0.1, 1.0	0.1, 0.8	0.1, 0.9	0.1, 0.7	0.1, 0.9	0.1, 0.7
<= 0.6 mg	n (%)	32 (74.4)	30 (90.9)	16 (64.0)	16 (94.1)	16 (72.7)	13 (76.5)
> 0.6 mg	n (%)	11 (25.6)	3 (9.1)	9 (36.0)	1 (5.9)	6 (27.3)	4 (23.5)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 1**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
FTND score	n	43	33	25	17	21	17
	Mean (SD)	4.2 (1.83)	4.5 (1.79)	4.3 (1.73)	4.4 (1.97)	4.5 (1.75)	5.0 (2.50)
	Median	4.0	4.0	4.0	4.0	5.0	5.0
	Min, Max	1, 9	1, 8	1, 7	2, 8	0, 7	0, 9
Mild	n (%)	17 (39.5)	10 (30.3)	10 (40.0)	7 (41.2)	4 (18.2)	4 (23.5)
Moderate	n (%)	23 (53.5)	19 (57.6)	11 (44.0)	7 (41.2)	15 (68.2)	7 (41.2)
Severe	n (%)	3 (7.0)	4 (12.1)	4 (16.0)	3 (17.6)	2 (9.1)	6 (35.3)
Individual product preference							
THSm2.2	n (%)	11 (25.6)	6 (18.2)	5 (20.0)	5 (29.4)	2 (9.1)	4 (23.5)
mCC	n (%)	25 (58.1)	14 (42.4)	14 (56.0)	6 (35.3)	14 (63.6)	10 (58.8)
SA	n (%)	2 (4.7)	7 (21.2)	1 (4.0)	3 (17.6)	3 (13.6)	2 (11.8)
No Preference	n (%)	5 (11.6)	6 (18.2)	5 (20.0)	3 (17.6)	3 (13.6)	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 1**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 4 SES Questionnaire							
Q1: Total number living in household (including yourself)?							
0	n (%)	1 (2.3)	0	0	0	0	0
1	n (%)	21 (48.8)	14 (42.4)	9 (36.0)	3 (17.6)	9 (40.9)	3 (17.6)
2	n (%)	5 (11.6)	8 (24.2)	2 (8.0)	5 (29.4)	7 (31.8)	6 (35.3)
3	n (%)	4 (9.3)	4 (12.1)	3 (12.0)	5 (29.4)	4 (18.2)	4 (23.5)
4	n (%)	5 (11.6)	4 (12.1)	5 (20.0)	2 (11.8)	1 (4.5)	3 (17.6)
5	n (%)	1 (2.3)	2 (6.1)	2 (8.0)	0	1 (4.5)	0
6	n (%)	1 (2.3)	0	0	1 (5.9)	0	0
Prefer Not to Say	n (%)	5 (11.6)	1 (3.0)	3 (12.0)	1 (5.9)	0	1 (5.9)
Missing	n (%)	0	0	1 (4.0)	0	0	0

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 1**

		THSm2.2		mCC		SA	
Variable	Statistic	Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Q2: Highest level education attained / currently attaining?							
Elementary School / Junior High School	n (%)	0	0	0	1 (5.9)	1 (4.5)	1 (5.9)
Senior High School	n (%)	10 (23.3)	9 (27.3)	7 (28.0)	3 (17.6)	7 (31.8)	7 (41.2)
College	n (%)	10 (23.3)	12 (36.4)	3 (12.0)	4 (23.5)	1 (4.5)	6 (35.3)
University / Postgraduate	n (%)	21 (48.8)	9 (27.3)	12 (48.0)	6 (35.3)	12 (54.5)	3 (17.6)
Prefer Not to Say	n (%)	2 (4.7)	3 (9.1)	2 (8.0)	3 (17.6)	1 (4.5)	0
Missing	n (%)	0	0	1 (4.0)	0	0	0
Q3: How many income earners in household?							
None - All Are Unemployed	n (%)	2 (4.7)	2 (6.1)	1 (4.0)	0	2 (9.1)	2 (11.8)
Just One Income Earner	n (%)	28 (65.1)	17 (51.5)	13 (52.0)	7 (41.2)	10 (45.5)	8 (47.1)
Two or More Income Earners	n (%)	13 (30.2)	14 (42.4)	10 (40.0)	10 (58.8)	10 (45.5)	7 (41.2)
Missing	n (%)	0	0	1 (4.0)	0	0	0

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 1**

		THSm2.2		mCC		SA	
Variable	Statistic	Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Q4: What is your occupation?							
General White Collar	n (%)	2 (4.7)	6 (18.2)	2 (8.0)	4 (23.5)	1 (4.5)	1 (5.9)
Professional/Technical Worker	n (%)	2 (4.7)	3 (9.1)	4 (16.0)	1 (5.9)	1 (4.5)	1 (5.9)
General Blue Collar	n (%)	1 (2.3)	0	0	0	2 (9.1)	0
Working In Service Industry	n (%)	3 (7.0)	4 (12.1)	1 (4.0)	2 (11.8)	0	1 (5.9)
Manager (Kacho or Above)	n (%)	1 (2.3)	0	1 (4.0)	0	0	0
Director/President (30 Employees or More)	n (%)	0	0	1 (4.0)	0	1 (4.5)	0
Proprietor (29 Employees or Less)	n (%)	8 (18.6)	0	4 (16.0)	0	5 (22.7)	0
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	1 (2.3)	0	0	0	0	0
Farming/Forestry/Fishing	n (%)	1 (2.3)	0	0	0	0	0
Part-Time Worker (More Than One Day Per Week)	n (%)	11 (25.6)	9 (27.3)	5 (20.0)	2 (11.8)	2 (9.1)	8 (47.1)
Student	n (%)	5 (11.6)	2 (6.1)	1 (4.0)	1 (5.9)	1 (4.5)	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 1**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	0	1 (3.0)	0	4 (23.5)	0	0
Unemployed	n (%)	0	1 (3.0)	1 (4.0)	0	3 (13.6)	4 (23.5)
Others	n (%)	7 (16.3)	6 (18.2)	3 (12.0)	3 (17.6)	5 (22.7)	0
Missing	n (%)	1 (2.3)	1 (3.0)	2 (8.0)	0	1 (4.5)	1 (5.9)
Q5a: What is approximate MONTHLY household income from all sources before tax?							
Don't Know	n (%)	1 (2.3)	7 (21.2)	3 (12.0)	3 (17.6)	2 (9.1)	3 (17.6)
Prefer Not to Say	n (%)	5 (11.6)	8 (24.2)	6 (24.0)	5 (29.4)	1 (4.5)	2 (11.8)
Missing	n (%)	1 (2.3)	2 (6.1)	2 (8.0)	0	2 (9.1)	2 (11.8)
Any Amount Reported	n (%)	36 (83.7)	16 (48.5)	14 (56.0)	9 (52.9)	17 (77.3)	10 (58.8)
Below 100,000 Yen	n (%)	2 (4.7)	0	0	0	0	0
100,000 Yen - 199,999 Yen	n (%)	8 (18.6)	4 (12.1)	3 (12.0)	1 (5.9)	2 (9.1)	3 (17.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 1**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
200,000 Yen - 299,999 Yen	n (%)	10 (23.3)	5 (15.2)	3 (12.0)	1 (5.9)	5 (22.7)	2 (11.8)
300,000 Yen - 399,999 Yen	n (%)	5 (11.6)	3 (9.1)	3 (12.0)	1 (5.9)	2 (9.1)	1 (5.9)
400,000 Yen - 499,999 Yen	n (%)	1 (2.3)	2 (6.1)	1 (4.0)	2 (11.8)	2 (9.1)	1 (5.9)
500,000 Yen - 599,999 Yen	n (%)	5 (11.6)	1 (3.0)	0	1 (5.9)	3 (13.6)	2 (11.8)
600,000 Yen - 699,999 Yen	n (%)	0	0	2 (8.0)	0	1 (4.5)	0
700,000 Yen - 799,999 Yen	n (%)	0	0	0	1 (5.9)	0	0
800,000 Yen - 899,999 Yen	n (%)	1 (2.3)	0	1 (4.0)	0	1 (4.5)	0
900,000 Yen - 999,999 Yen	n (%)	1 (2.3)	0	0	0	0	0
1,000,000 Yen - or Above	n (%)	3 (7.0)	1 (3.0)	1 (4.0)	2 (11.8)	1 (4.5)	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	6	15	9	8	3	5
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?							
Don't Know	n (%)	1 (2.3)	3 (9.1)	1 (4.0)	2 (11.8)	1 (4.5)	2 (11.8)
Prefer Not to Say	n (%)	2 (4.7)	8 (24.2)	4 (16.0)	4 (23.5)	1 (4.5)	1 (5.9)
Any Amount Reported	n (%)	3 (7.0)	4 (12.1)	4 (16.0)	2 (11.8)	1 (4.5)	2 (11.8)
Under 800,000yen	n (%)	2 (4.7)	3 (9.1)	3 (12.0)	2 (11.8)	1 (4.5)	1 (5.9)
800,000yen or More	n (%)	1 (2.3)	1 (3.0)	1 (4.0)	0	0	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Age (years)	n	42	32	24	17	22	17
	Mean (SD)	35.7 (10.67)	39.6 (10.62)	36.0 (11.12)	40.2 (11.02)	38.0 (9.27)	36.6 (10.73)
	Median	34.5	42.0	31.5	39.0	39.0	34.0
	Min, Max	23, 65	23, 56	23, 56	23, 64	24, 55	23, 54
Ethnicity							
	Japanese	42 (100)	32 (100)	24 (100)	17 (100)	22 (100)	17 (100)
Non-Japanese	n (%)	0	0	0	0	0	0
Weight (kg)	n	42	32	24	17	22	17
	Mean (SD)	68.21 (10.134)	55.28 (7.078)	67.50 (8.435)	54.26 (7.530)	66.58 (9.825)	55.34 (9.339)
	Median	66.40	55.20	67.05	51.50	64.45	53.00
	Min, Max	52.1, 97.8	45.1, 75.0	51.8, 84.4	43.4, 67.4	53.9, 91.8	43.7, 74.8

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 2**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Height (m)	n	42	32	24	17	22	17
	Mean (SD)	1.702 (0.0531)	1.586 (0.0437)	1.719 (0.0728)	1.571 (0.0646)	1.704 (0.0465)	1.586 (0.0563)
	Median	1.700	1.580	1.715	1.560	1.700	1.590
	Min, Max	1.58, 1.84	1.52, 1.72	1.58, 1.88	1.47, 1.72	1.64, 1.80	1.50, 1.73
BMI (kg/m ²)	n	42	32	24	17	22	17
	Mean (SD)	23.51 (3.169)	21.94 (2.368)	22.90 (2.984)	21.97 (2.688)	22.96 (3.412)	21.98 (3.430)
	Median	22.90	21.45	22.15	21.30	22.00	20.40
	Min, Max	18.9, 32.7	18.7, 27.9	19.0, 28.3	18.9, 28.4	18.7, 31.8	18.5, 29.6
Underweight	n (%)	0	0	0	0	0	0
Normal Weight	n (%)	29 (69.0)	28 (87.5)	16 (66.7)	15 (88.2)	17 (77.3)	14 (82.4)
Overweight	n (%)	12 (28.6)	4 (12.5)	8 (33.3)	2 (11.8)	4 (18.2)	3 (17.6)
Obese	n (%)	1 (2.4)	0	0	0	1 (4.5)	0

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 2**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Waist circumference (cm)	n	42	32	24	17	22	17
	Mean (SD)	94.5 (29.54)	77.2 (8.29)	100.1 (37.00)	78.2 (7.13)	92.4 (30.41)	76.2 (7.97)
	Median	85.0	76.0	85.5	77.0	79.5	76.0
	Min, Max	69, 174	65, 95	72, 172	64, 90	68, 167	66, 94
Cigarette consumption							
10-19 Cig/Day	n (%)	21 (50.0)	17 (53.1)	13 (54.2)	10 (58.8)	11 (50.0)	9 (52.9)
>19 Cig/Day	n (%)	21 (50.0)	15 (46.9)	11 (45.8)	7 (41.2)	11 (50.0)	8 (47.1)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
ISO tar yields	n	42	32	24	17	22	17
	Mean (SD)	6.2 (3.31)	3.3 (3.15)	6.5 (3.72)	2.6 (2.74)	5.8 (4.01)	3.3 (3.28)
	Median	6.0	1.0	8.0	1.0	6.0	1.0
	Min, Max	1, 12	1, 12	1, 12	1, 8	1, 12	1, 8
	1-5 mg n (%)	20 (47.6)	24 (75.0)	8 (33.3)	14 (82.4)	10 (45.5)	12 (70.6)
6-8 mg	n (%)	13 (31.0)	7 (21.9)	10 (41.7)	3 (17.6)	7 (31.8)	5 (29.4)
9-10 mg	n (%)	6 (14.3)	0	4 (16.7)	0	2 (9.1)	0
>10 mg	n (%)	3 (7.1)	1 (3.1)	2 (8.3)	0	3 (13.6)	0
ISO nicotine yields	n	42	32	24	17	22	17
	Mean (SD)	0.49 (0.248)	0.28 (0.241)	0.50 (0.265)	0.24 (0.224)	0.47 (0.292)	0.29 (0.272)
	Median	0.50	0.10	0.60	0.10	0.55	0.10
	Min, Max	0.1, 1.0	0.1, 0.8	0.1, 0.9	0.1, 0.7	0.1, 0.9	0.1, 0.7
	<= 0.6 mg n (%)	32 (76.2)	29 (90.6)	15 (62.5)	16 (94.1)	16 (72.7)	13 (76.5)
> 0.6 mg	n (%)	10 (23.8)	3 (9.4)	9 (37.5)	1 (5.9)	6 (27.3)	4 (23.5)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 2**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
FTND score	n	42	32	24	17	21	17
	Mean (SD)	4.2 (1.85)	4.5 (1.82)	4.3 (1.76)	4.4 (1.97)	4.5 (1.75)	5.0 (2.50)
	Median	4.0	4.0	4.0	4.0	5.0	5.0
	Min, Max	1, 9	1, 8	1, 7	2, 8	0, 7	0, 9
Mild	n (%)	17 (40.5)	10 (31.3)	10 (41.7)	7 (41.2)	4 (18.2)	4 (23.5)
Moderate	n (%)	22 (52.4)	18 (56.3)	10 (41.7)	7 (41.2)	15 (68.2)	7 (41.2)
Severe	n (%)	3 (7.1)	4 (12.5)	4 (16.7)	3 (17.6)	2 (9.1)	6 (35.3)
Individual product preference							
THSm2.2	n (%)	11 (26.2)	6 (18.8)	5 (20.8)	5 (29.4)	2 (9.1)	4 (23.5)
mCC	n (%)	25 (59.5)	14 (43.8)	13 (54.2)	6 (35.3)	14 (63.6)	10 (58.8)
SA	n (%)	1 (2.4)	6 (18.8)	1 (4.2)	3 (17.6)	3 (13.6)	2 (11.8)
No Preference	n (%)	5 (11.9)	6 (18.8)	5 (20.8)	3 (17.6)	3 (13.6)	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 2**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Day 4 SES Questionnaire							
Q1: Total number living in household (including yourself)?							
0	n (%)	1 (2.4)	0	0	0	0	0
1	n (%)	21 (50.0)	14 (43.8)	9 (37.5)	3 (17.6)	9 (40.9)	3 (17.6)
2	n (%)	5 (11.9)	7 (21.9)	2 (8.3)	5 (29.4)	7 (31.8)	6 (35.3)
3	n (%)	4 (9.5)	4 (12.5)	3 (12.5)	5 (29.4)	4 (18.2)	4 (23.5)
4	n (%)	5 (11.9)	4 (12.5)	5 (20.8)	2 (11.8)	1 (4.5)	3 (17.6)
5	n (%)	1 (2.4)	2 (6.3)	2 (8.3)	0	1 (4.5)	0
6	n (%)	1 (2.4)	0	0	1 (5.9)	0	0
Prefer Not to Say	n (%)	4 (9.5)	1 (3.1)	3 (12.5)	1 (5.9)	0	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

		THSm2.2		mCC		SA	
Variable	Statistic	Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Q2: Highest level education attained / currently attaining?							
Elementary School / Junior High School	n (%)	0	0	0	1 (5.9)	1 (4.5)	1 (5.9)
Senior High School	n (%)	10 (23.8)	9 (28.1)	7 (29.2)	3 (17.6)	7 (31.8)	7 (41.2)
College	n (%)	9 (21.4)	11 (34.4)	3 (12.5)	4 (23.5)	1 (4.5)	6 (35.3)
University / Postgraduate	n (%)	21 (50.0)	9 (28.1)	12 (50.0)	6 (35.3)	12 (54.5)	3 (17.6)
Prefer Not to Say	n (%)	2 (4.8)	3 (9.4)	2 (8.3)	3 (17.6)	1 (4.5)	0
Q3: How many income earners in household?							
None - All Are Unemployed	n (%)	2 (4.8)	2 (6.3)	1 (4.2)	0	2 (9.1)	2 (11.8)
Just One Income Earner	n (%)	27 (64.3)	16 (50.0)	13 (54.2)	7 (41.2)	10 (45.5)	8 (47.1)
Two or More Income Earners	n (%)	13 (31.0)	14 (43.8)	10 (41.7)	10 (58.8)	10 (45.5)	7 (41.2)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 2**

		THSm2.2		mCC		SA	
Variable	Statistic	Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Q4: What is your occupation?							
General White Collar	n (%)	2 (4.8)	6 (18.8)	2 (8.3)	4 (23.5)	1 (4.5)	1 (5.9)
Professional/Technical Worker	n (%)	2 (4.8)	3 (9.4)	4 (16.7)	1 (5.9)	1 (4.5)	1 (5.9)
General Blue Collar	n (%)	1 (2.4)	0	0	0	2 (9.1)	0
Working In Service Industry	n (%)	3 (7.1)	4 (12.5)	1 (4.2)	2 (11.8)	0	1 (5.9)
Manager (Kacho or Above)	n (%)	1 (2.4)	0	1 (4.2)	0	0	0
Director/President (30 Employees or More)	n (%)	0	0	1 (4.2)	0	1 (4.5)	0
Proprietor (29 Employees or Less)	n (%)	8 (19.0)	0	4 (16.7)	0	5 (22.7)	0
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	1 (2.4)	0	0	0	0	0
Farming/Forestry/Fishing	n (%)	1 (2.4)	0	0	0	0	0
Part-Time Worker (More Than One Day Per Week)	n (%)	10 (23.8)	9 (28.1)	5 (20.8)	2 (11.8)	2 (9.1)	8 (47.1)
Student	n (%)	5 (11.9)	2 (6.3)	1 (4.2)	1 (5.9)	1 (4.5)	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 2**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	0	1 (3.1)	0	4 (23.5)	0	0
Unemployed	n (%)	0	1 (3.1)	1 (4.2)	0	3 (13.6)	4 (23.5)
Others	n (%)	7 (16.7)	5 (15.6)	3 (12.5)	3 (17.6)	5 (22.7)	0
Missing	n (%)	1 (2.4)	1 (3.1)	1 (4.2)	0	1 (4.5)	1 (5.9)
Q5a: What is approximate MONTHLY household income from all sources before tax?							
Don't Know	n (%)	1 (2.4)	7 (21.9)	3 (12.5)	3 (17.6)	2 (9.1)	3 (17.6)
Prefer Not to Say	n (%)	5 (11.9)	8 (25.0)	6 (25.0)	5 (29.4)	1 (4.5)	2 (11.8)
Missing	n (%)	1 (2.4)	2 (6.3)	1 (4.2)	0	2 (9.1)	2 (11.8)
Any Amount Reported	n (%)	35 (83.3)	15 (46.9)	14 (58.3)	9 (52.9)	17 (77.3)	10 (58.8)
Below 100,000 Yen	n (%)	2 (4.8)	0	0	0	0	0
100,000 Yen - 199,999 Yen	n (%)	7 (16.7)	4 (12.5)	3 (12.5)	1 (5.9)	2 (9.1)	3 (17.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 2**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
200,000 Yen - 299,999 Yen	n (%)	10 (23.8)	4 (12.5)	3 (12.5)	1 (5.9)	5 (22.7)	2 (11.8)
300,000 Yen - 399,999 Yen	n (%)	5 (11.9)	3 (9.4)	3 (12.5)	1 (5.9)	2 (9.1)	1 (5.9)
400,000 Yen - 499,999 Yen	n (%)	1 (2.4)	2 (6.3)	1 (4.2)	2 (11.8)	2 (9.1)	1 (5.9)
500,000 Yen - 599,999 Yen	n (%)	5 (11.9)	1 (3.1)	0	1 (5.9)	3 (13.6)	2 (11.8)
600,000 Yen - 699,999 Yen	n (%)	0	0	2 (8.3)	0	1 (4.5)	0
700,000 Yen - 799,999 Yen	n (%)	0	0	0	1 (5.9)	0	0
800,000 Yen - 899,999 Yen	n (%)	1 (2.4)	0	1 (4.2)	0	1 (4.5)	0
900,000 Yen - 999,999 Yen	n (%)	1 (2.4)	0	0	0	0	0
1,000,000 Yen - or Above	n (%)	3 (7.1)	1 (3.1)	1 (4.2)	2 (11.8)	1 (4.5)	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	6	15	9	8	3	5
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?							
Don't Know	n (%)	1 (2.4)	3 (9.4)	1 (4.2)	2 (11.8)	1 (4.5)	2 (11.8)
Prefer Not to Say	n (%)	2 (4.8)	8 (25.0)	4 (16.7)	4 (23.5)	1 (4.5)	1 (5.9)
Any Amount Reported	n (%)	3 (7.1)	4 (12.5)	4 (16.7)	2 (11.8)	1 (4.5)	2 (11.8)
Under 800,000yen	n (%)	2 (4.8)	3 (9.4)	3 (12.5)	2 (11.8)	1 (4.5)	1 (5.9)
800,000yen or More	n (%)	1 (2.4)	1 (3.1)	1 (4.2)	0	0	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Age (years)	n	41	30	24	17	21	17
	Mean (SD)	35.8 (10.76)	40.3 (10.50)	36.0 (11.12)	40.2 (11.02)	38.5 (9.22)	36.6 (10.73)
	Median	35.0	42.0	31.5	39.0	40.0	34.0
	Min, Max	23, 65	23, 56	23, 56	23, 64	24, 55	23, 54
Ethnicity							
	Japanese	41 (100)	30 (100)	24 (100)	17 (100)	21 (100)	17 (100)
Non-Japanese	n (%)	0	0	0	0	0	0
Weight (kg)	n	41	30	24	17	21	17
	Mean (SD)	68.01 (10.036)	55.37 (7.109)	67.50 (8.435)	54.26 (7.530)	67.08 (9.772)	55.34 (9.339)
	Median	65.70	55.20	67.05	51.50	65.90	53.00
	Min, Max	52.1, 97.8	45.1, 75.0	51.8, 84.4	43.4, 67.4	53.9, 91.8	43.7, 74.8

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 3**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Height (m)	n	41	30	24	17	21	17
	Mean (SD)	1.698 (0.0492)	1.585 (0.0439)	1.719 (0.0728)	1.571 (0.0646)	1.707 (0.0454)	1.586 (0.0563)
	Median	1.700	1.580	1.715	1.560	1.700	1.590
	Min, Max	1.58, 1.84	1.52, 1.72	1.58, 1.88	1.47, 1.72	1.64, 1.80	1.50, 1.73
BMI (kg/m ²)	n	41	30	24	17	21	17
	Mean (SD)	23.55 (3.181)	22.01 (2.392)	22.90 (2.984)	21.97 (2.688)	23.07 (3.461)	21.98 (3.430)
	Median	22.80	21.45	22.15	21.30	22.10	20.40
	Min, Max	18.9, 32.7	18.7, 27.9	19.0, 28.3	18.9, 28.4	18.7, 31.8	18.5, 29.6
Underweight	n (%)	0	0	0	0	0	0
Normal Weight	n (%)	28 (68.3)	26 (86.7)	16 (66.7)	15 (88.2)	16 (76.2)	14 (82.4)
Overweight	n (%)	12 (29.3)	4 (13.3)	8 (33.3)	2 (11.8)	4 (19.0)	3 (17.6)
Obese	n (%)	1 (2.4)	0	0	0	1 (4.8)	0

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 3**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Waist circumference (cm)	n	41	30	24	17	21	17
	Mean (SD)	94.5 (29.97)	77.7 (8.35)	100.1 (37.00)	78.2 (7.13)	93.2 (30.91)	76.2 (7.97)
	Median	85.0	76.5	85.5	77.0	80.0	76.0
	Min, Max	69, 174	65, 95	72, 172	64, 90	68, 167	66, 94
Cigarette consumption							
10-19 Cig/Day	n (%)	20 (48.8)	16 (53.3)	13 (54.2)	10 (58.8)	11 (52.4)	9 (52.9)
>19 Cig/Day	n (%)	21 (51.2)	14 (46.7)	11 (45.8)	7 (41.2)	10 (47.6)	8 (47.1)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
ISO tar yields	n	41	30	24	17	21	17
	Mean (SD)	6.2 (3.35)	3.5 (3.20)	6.5 (3.72)	2.6 (2.74)	5.7 (4.08)	3.3 (3.28)
	Median	6.0	1.0	8.0	1.0	6.0	1.0
	Min, Max	1, 12	1, 12	1, 12	1, 8	1, 12	1, 8
	1-5 mg n (%)	19 (46.3)	22 (73.3)	8 (33.3)	14 (82.4)	10 (47.6)	12 (70.6)
6-8 mg	n (%)	13 (31.7)	7 (23.3)	10 (41.7)	3 (17.6)	6 (28.6)	5 (29.4)
9-10 mg	n (%)	6 (14.6)	0	4 (16.7)	0	2 (9.5)	0
>10 mg	n (%)	3 (7.3)	1 (3.3)	2 (8.3)	0	3 (14.3)	0
ISO nicotine yields	n	41	30	24	17	21	17
	Mean (SD)	0.49 (0.253)	0.29 (0.244)	0.50 (0.265)	0.24 (0.224)	0.46 (0.295)	0.29 (0.272)
	Median	0.50	0.10	0.60	0.10	0.50	0.10
	Min, Max	0.1, 1.0	0.1, 0.8	0.1, 0.9	0.1, 0.7	0.1, 0.9	0.1, 0.7
	<= 0.6 mg n (%)	30 (73.2)	27 (90.0)	15 (62.5)	16 (94.1)	16 (76.2)	13 (76.5)
> 0.6 mg	n (%)	11 (26.8)	3 (10.0)	9 (37.5)	1 (5.9)	5 (23.8)	4 (23.5)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 3**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
FTND score	n	41	30	24	17	20	17
	Mean (SD)	4.2 (1.87)	4.5 (1.80)	4.3 (1.76)	4.4 (1.97)	4.5 (1.80)	5.0 (2.50)
	Median	4.0	4.0	4.0	4.0	5.0	5.0
	Min, Max	1, 9	1, 8	1, 7	2, 8	0, 7	0, 9
Mild	n (%)	17 (41.5)	9 (30.0)	10 (41.7)	7 (41.2)	4 (19.0)	4 (23.5)
Moderate	n (%)	21 (51.2)	18 (60.0)	10 (41.7)	7 (41.2)	14 (66.7)	7 (41.2)
Severe	n (%)	3 (7.3)	3 (10.0)	4 (16.7)	3 (17.6)	2 (9.5)	6 (35.3)
Individual product preference							
THSm2.2	n (%)	10 (24.4)	6 (20.0)	5 (20.8)	5 (29.4)	2 (9.5)	4 (23.5)
mCC	n (%)	24 (58.5)	14 (46.7)	13 (54.2)	6 (35.3)	13 (61.9)	10 (58.8)
SA	n (%)	2 (4.9)	5 (16.7)	1 (4.2)	3 (17.6)	3 (14.3)	2 (11.8)
No Preference	n (%)	5 (12.2)	5 (16.7)	5 (20.8)	3 (17.6)	3 (14.3)	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 3**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Day 4 SES Questionnaire							
Q1: Total number living in household (including yourself)?							
0	n (%)	1 (2.4)	0	0	0	0	0
1	n (%)	20 (48.8)	14 (46.7)	9 (37.5)	3 (17.6)	9 (42.9)	3 (17.6)
2	n (%)	5 (12.2)	6 (20.0)	2 (8.3)	5 (29.4)	7 (33.3)	6 (35.3)
3	n (%)	4 (9.8)	4 (13.3)	3 (12.5)	5 (29.4)	3 (14.3)	4 (23.5)
4	n (%)	5 (12.2)	3 (10.0)	5 (20.8)	2 (11.8)	1 (4.8)	3 (17.6)
5	n (%)	1 (2.4)	2 (6.7)	2 (8.3)	0	1 (4.8)	0
6	n (%)	0	0	0	1 (5.9)	0	0
Prefer Not to Say	n (%)	5 (12.2)	1 (3.3)	3 (12.5)	1 (5.9)	0	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

		THSm2.2		mCC		SA	
Variable	Statistic	Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Q2: Highest level education attained / currently attaining?							
Elementary School / Junior High School	n (%)	0	0	0	1 (5.9)	0	1 (5.9)
Senior High School	n (%)	10 (24.4)	9 (30.0)	7 (29.2)	3 (17.6)	7 (33.3)	7 (41.2)
College	n (%)	9 (22.0)	11 (36.7)	3 (12.5)	4 (23.5)	1 (4.8)	6 (35.3)
University / Postgraduate	n (%)	20 (48.8)	7 (23.3)	12 (50.0)	6 (35.3)	12 (57.1)	3 (17.6)
Prefer Not to Say	n (%)	2 (4.9)	3 (10.0)	2 (8.3)	3 (17.6)	1 (4.8)	0
Q3: How many income earners in household?							
None - All Are Unemployed	n (%)	2 (4.9)	2 (6.7)	1 (4.2)	0	2 (9.5)	2 (11.8)
Just One Income Earner	n (%)	27 (65.9)	15 (50.0)	13 (54.2)	7 (41.2)	10 (47.6)	8 (47.1)
Two or More Income Earners	n (%)	12 (29.3)	13 (43.3)	10 (41.7)	10 (58.8)	9 (42.9)	7 (41.2)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

		THSm2.2		mCC		SA	
Variable	Statistic	Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Q4: What is your occupation?							
General White Collar	n (%)	2 (4.9)	6 (20.0)	2 (8.3)	4 (23.5)	1 (4.8)	1 (5.9)
Professional/Technical Worker	n (%)	2 (4.9)	3 (10.0)	4 (16.7)	1 (5.9)	1 (4.8)	1 (5.9)
General Blue Collar	n (%)	1 (2.4)	0	0	0	2 (9.5)	0
Working In Service Industry	n (%)	3 (7.3)	4 (13.3)	1 (4.2)	2 (11.8)	0	1 (5.9)
Manager (Kacho or Above)	n (%)	1 (2.4)	0	1 (4.2)	0	0	0
Director/President (30 Employees or More)	n (%)	0	0	1 (4.2)	0	1 (4.8)	0
Proprietor (29 Employees or Less)	n (%)	8 (19.5)	0	4 (16.7)	0	5 (23.8)	0
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	1 (2.4)	0	0	0	0	0
Farming/Forestry/Fishing	n (%)	1 (2.4)	0	0	0	0	0
Part-Time Worker (More Than One Day Per Week)	n (%)	10 (24.4)	9 (30.0)	5 (20.8)	2 (11.8)	2 (9.5)	8 (47.1)
Student	n (%)	5 (12.2)	1 (3.3)	1 (4.2)	1 (5.9)	1 (4.8)	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 3**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	0	1 (3.3)	0	4 (23.5)	0	0
Unemployed	n (%)	0	1 (3.3)	1 (4.2)	0	2 (9.5)	4 (23.5)
Others	n (%)	6 (14.6)	4 (13.3)	3 (12.5)	3 (17.6)	5 (23.8)	0
Missing	n (%)	1 (2.4)	1 (3.3)	1 (4.2)	0	1 (4.8)	1 (5.9)
Q5a: What is approximate MONTHLY household income from all sources before tax?							
Don't Know	n (%)	0	7 (23.3)	3 (12.5)	3 (17.6)	1 (4.8)	3 (17.6)
Prefer Not to Say	n (%)	5 (12.2)	6 (20.0)	6 (25.0)	5 (29.4)	1 (4.8)	2 (11.8)
Missing	n (%)	1 (2.4)	2 (6.7)	1 (4.2)	0	2 (9.5)	2 (11.8)
Any Amount Reported	n (%)	35 (85.4)	15 (50.0)	14 (58.3)	9 (52.9)	17 (81.0)	10 (58.8)
Below 100,000 Yen	n (%)	2 (4.9)	0	0	0	0	0
100,000 Yen - 199,999 Yen	n (%)	8 (19.5)	4 (13.3)	3 (12.5)	1 (5.9)	2 (9.5)	3 (17.6)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 3**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
200,000 Yen - 299,999 Yen	n (%)	9 (22.0)	4 (13.3)	3 (12.5)	1 (5.9)	5 (23.8)	2 (11.8)
300,000 Yen - 399,999 Yen	n (%)	5 (12.2)	3 (10.0)	3 (12.5)	1 (5.9)	2 (9.5)	1 (5.9)
400,000 Yen - 499,999 Yen	n (%)	1 (2.4)	2 (6.7)	1 (4.2)	2 (11.8)	2 (9.5)	1 (5.9)
500,000 Yen - 599,999 Yen	n (%)	5 (12.2)	1 (3.3)	0	1 (5.9)	3 (14.3)	2 (11.8)
600,000 Yen - 699,999 Yen	n (%)	0	0	2 (8.3)	0	1 (4.8)	0
700,000 Yen - 799,999 Yen	n (%)	0	0	0	1 (5.9)	0	0
800,000 Yen - 899,999 Yen	n (%)	1 (2.4)	0	1 (4.2)	0	1 (4.8)	0
900,000 Yen - 999,999 Yen	n (%)	1 (2.4)	0	0	0	0	0
1,000,000 Yen - or Above	n (%)	3 (7.3)	1 (3.3)	1 (4.2)	2 (11.8)	1 (4.8)	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	5	13	9	8	2	5
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?							
Don't Know	n (%)	0	3 (10.0)	1 (4.2)	2 (11.8)	0	2 (11.8)
Prefer Not to Say	n (%)	2 (4.9)	6 (20.0)	4 (16.7)	4 (23.5)	1 (4.8)	1 (5.9)
Any Amount Reported	n (%)	3 (7.3)	4 (13.3)	4 (16.7)	2 (11.8)	1 (4.8)	2 (11.8)
Under 800,000yen	n (%)	2 (4.9)	3 (10.0)	3 (12.5)	2 (11.8)	1 (4.8)	1 (5.9)
800,000yen or More	n (%)	1 (2.4)	1 (3.3)	1 (4.2)	0	0	1 (5.9)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Age (years)	n	39	31	24	17	21	16
	Mean (SD)	35.9 (10.67)	40.1 (10.40)	36.0 (11.12)	40.2 (11.02)	38.5 (9.22)	36.9 (10.99)
	Median	35.0	42.0	31.5	39.0	40.0	36.5
	Min, Max	23, 65	23, 56	23, 56	23, 64	24, 55	23, 54
Ethnicity							
	Japanese	39 (100)	31 (100)	24 (100)	17 (100)	21 (100)	16 (100)
Non-Japanese	n (%)	0	0	0	0	0	0
Weight (kg)	n	39	31	24	17	21	16
	Mean (SD)	68.10 (10.335)	55.13 (7.142)	67.50 (8.435)	54.26 (7.530)	67.08 (9.772)	55.88 (9.367)
	Median	65.70	55.20	67.05	51.50	65.90	53.15
	Min, Max	52.1, 97.8	45.1, 75.0	51.8, 84.4	43.4, 67.4	53.9, 91.8	43.7, 74.8

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 4**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Height (m)	n	39	31	24	17	21	16
	Mean (SD)	1.703 (0.0550)	1.585 (0.0442)	1.719 (0.0728)	1.571 (0.0646)	1.707 (0.0454)	1.586 (0.0581)
	Median	1.700	1.580	1.715	1.560	1.700	1.590
	Min, Max	1.58, 1.84	1.52, 1.72	1.58, 1.88	1.47, 1.72	1.64, 1.80	1.50, 1.73
BMI (kg/m ²)	n	39	31	24	17	21	16
	Mean (SD)	23.45 (3.204)	21.90 (2.397)	22.90 (2.984)	21.97 (2.688)	23.07 (3.461)	22.19 (3.420)
	Median	22.80	21.30	22.15	21.30	22.10	20.60
	Min, Max	18.9, 32.7	18.7, 27.9	19.0, 28.3	18.9, 28.4	18.7, 31.8	18.9, 29.6
Underweight	n (%)	0	0	0	0	0	0
Normal Weight	n (%)	28 (71.8)	27 (87.1)	16 (66.7)	15 (88.2)	16 (76.2)	13 (81.3)
Overweight	n (%)	10 (25.6)	4 (12.9)	8 (33.3)	2 (11.8)	4 (19.0)	3 (18.8)
Obese	n (%)	1 (2.6)	0	0	0	1 (4.8)	0

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 4**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Waist circumference (cm)	n	39	31	24	17	21	16
	Mean (SD)	95.0 (30.59)	77.0 (8.36)	100.1 (37.00)	78.2 (7.13)	93.2 (30.91)	76.4 (8.15)
	Median	85.0	76.0	85.5	77.0	80.0	76.0
	Min, Max	69, 174	65, 95	72, 172	64, 90	68, 167	66, 94
Cigarette consumption							
10-19 Cig/Day	n (%)	19 (48.7)	17 (54.8)	13 (54.2)	10 (58.8)	11 (52.4)	9 (56.3)
>19 Cig/Day	n (%)	20 (51.3)	14 (45.2)	11 (45.8)	7 (41.2)	10 (47.6)	7 (43.8)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
ISO tar yields	n	39	31	24	17	21	16
	Mean (SD)	6.3 (3.30)	3.2 (3.09)	6.5 (3.72)	2.6 (2.74)	5.7 (4.08)	3.0 (3.15)
	Median	6.0	1.0	8.0	1.0	6.0	1.0
	Min, Max	1, 12	1, 12	1, 12	1, 8	1, 12	1, 8
	n (%)	18 (46.2)	24 (77.4)	8 (33.3)	14 (82.4)	10 (47.6)	12 (75.0)
1-5 mg	n (%)	18 (46.2)	24 (77.4)	8 (33.3)	14 (82.4)	10 (47.6)	12 (75.0)
6-8 mg	n (%)	13 (33.3)	6 (19.4)	10 (41.7)	3 (17.6)	6 (28.6)	4 (25.0)
9-10 mg	n (%)	5 (12.8)	0	4 (16.7)	0	2 (9.5)	0
>10 mg	n (%)	3 (7.7)	1 (3.2)	2 (8.3)	0	3 (14.3)	0
ISO nicotine yields	n	39	31	24	17	21	16
	Mean (SD)	0.48 (0.235)	0.27 (0.232)	0.50 (0.265)	0.24 (0.224)	0.46 (0.295)	0.26 (0.258)
	Median	0.50	0.10	0.60	0.10	0.50	0.10
	Min, Max	0.1, 1.0	0.1, 0.8	0.1, 0.9	0.1, 0.7	0.1, 0.9	0.1, 0.7
	n (%)	30 (76.9)	29 (93.5)	15 (62.5)	16 (94.1)	16 (76.2)	13 (81.3)
<= 0.6 mg	n (%)	30 (76.9)	29 (93.5)	15 (62.5)	16 (94.1)	16 (76.2)	13 (81.3)
> 0.6 mg	n (%)	9 (23.1)	2 (6.5)	9 (37.5)	1 (5.9)	5 (23.8)	3 (18.8)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 4**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
FTND score	n	39	31	24	17	20	16
	Mean (SD)	4.1 (1.74)	4.5 (1.85)	4.3 (1.76)	4.4 (1.97)	4.5 (1.80)	4.9 (2.53)
	Median	4.0	4.0	4.0	4.0	5.0	5.0
	Min, Max	1, 8	1, 8	1, 7	2, 8	0, 7	0, 9
Mild	n (%)	16 (41.0)	10 (32.3)	10 (41.7)	7 (41.2)	4 (19.0)	4 (25.0)
Moderate	n (%)	21 (53.8)	17 (54.8)	10 (41.7)	7 (41.2)	14 (66.7)	7 (43.8)
Severe	n (%)	2 (5.1)	4 (12.9)	4 (16.7)	3 (17.6)	2 (9.5)	5 (31.3)
Individual product preference							
THSm2.2	n (%)	10 (25.6)	6 (19.4)	5 (20.8)	5 (29.4)	2 (9.5)	3 (18.8)
mCC	n (%)	23 (59.0)	13 (41.9)	13 (54.2)	6 (35.3)	13 (61.9)	10 (62.5)
SA	n (%)	1 (2.6)	6 (19.4)	1 (4.2)	3 (17.6)	3 (14.3)	2 (12.5)
No Preference	n (%)	5 (12.8)	6 (19.4)	5 (20.8)	3 (17.6)	3 (14.3)	1 (6.3)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 4**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Day 4 SES Questionnaire							
Q1: Total number living in household (including yourself)?							
0	n (%)	1 (2.6)	0	0	0	0	0
1	n (%)	20 (51.3)	14 (45.2)	9 (37.5)	3 (17.6)	9 (42.9)	3 (18.8)
2	n (%)	4 (10.3)	6 (19.4)	2 (8.3)	5 (29.4)	7 (33.3)	6 (37.5)
3	n (%)	4 (10.3)	4 (12.9)	3 (12.5)	5 (29.4)	3 (14.3)	3 (18.8)
4	n (%)	5 (12.8)	4 (12.9)	5 (20.8)	2 (11.8)	1 (4.8)	3 (18.8)
5	n (%)	1 (2.6)	2 (6.5)	2 (8.3)	0	1 (4.8)	0
6	n (%)	0	0	0	1 (5.9)	0	0
Prefer Not to Say	n (%)	4 (10.3)	1 (3.2)	3 (12.5)	1 (5.9)	0	1 (6.3)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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

		THSm2.2		mCC		SA	
Variable	Statistic	Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Q2: Highest level education attained / currently attaining?							
Elementary School / Junior High School	n (%)	0	0	0	1 (5.9)	0	1 (6.3)
Senior High School	n (%)	10 (25.6)	9 (29.0)	7 (29.2)	3 (17.6)	7 (33.3)	7 (43.8)
College	n (%)	8 (20.5)	10 (32.3)	3 (12.5)	4 (23.5)	1 (4.8)	6 (37.5)
University / Postgraduate	n (%)	19 (48.7)	9 (29.0)	12 (50.0)	6 (35.3)	12 (57.1)	2 (12.5)
Prefer Not to Say	n (%)	2 (5.1)	3 (9.7)	2 (8.3)	3 (17.6)	1 (4.8)	0
Q3: How many income earners in household?							
None - All Are Unemployed	n (%)	2 (5.1)	2 (6.5)	1 (4.2)	0	2 (9.5)	2 (12.5)
Just One Income Earner	n (%)	25 (64.1)	16 (51.6)	13 (54.2)	7 (41.2)	10 (47.6)	8 (50.0)
Two or More Income Earners	n (%)	12 (30.8)	13 (41.9)	10 (41.7)	10 (58.8)	9 (42.9)	6 (37.5)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 4**

		THSm2.2		mCC		SA	
Variable	Statistic	Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Q4: What is your occupation?							
General White Collar	n (%)	2 (5.1)	6 (19.4)	2 (8.3)	4 (23.5)	1 (4.8)	1 (6.3)
Professional/Technical Worker	n (%)	2 (5.1)	2 (6.5)	4 (16.7)	1 (5.9)	1 (4.8)	0
General Blue Collar	n (%)	1 (2.6)	0	0	0	2 (9.5)	0
Working In Service Industry	n (%)	3 (7.7)	4 (12.9)	1 (4.2)	2 (11.8)	0	1 (6.3)
Manager (Kacho or Above)	n (%)	1 (2.6)	0	1 (4.2)	0	0	0
Director/President (30 Employees or More)	n (%)	0	0	1 (4.2)	0	1 (4.8)	0
Proprietor (29 Employees or Less)	n (%)	7 (17.9)	0	4 (16.7)	0	5 (23.8)	0
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	1 (2.6)	0	0	0	0	0
Farming/Forestry/Fishing	n (%)	1 (2.6)	0	0	0	0	0
Part-Time Worker (More Than One Day Per Week)	n (%)	8 (20.5)	9 (29.0)	5 (20.8)	2 (11.8)	2 (9.5)	8 (50.0)
Student	n (%)	5 (12.8)	2 (6.5)	1 (4.2)	1 (5.9)	1 (4.8)	1 (6.3)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 4**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	0	1 (3.2)	0	4 (23.5)	0	0
Unemployed	n (%)	0	1 (3.2)	1 (4.2)	0	2 (9.5)	4 (25.0)
Others	n (%)	7 (17.9)	5 (16.1)	3 (12.5)	3 (17.6)	5 (23.8)	0
Missing	n (%)	1 (2.6)	1 (3.2)	1 (4.2)	0	1 (4.8)	1 (6.3)
Q5a: What is approximate MONTHLY household income from all sources before tax?							
Don't Know	n (%)	0	6 (19.4)	3 (12.5)	3 (17.6)	1 (4.8)	2 (12.5)
Prefer Not to Say	n (%)	5 (12.8)	8 (25.8)	6 (25.0)	5 (29.4)	1 (4.8)	2 (12.5)
Missing	n (%)	1 (2.6)	2 (6.5)	1 (4.2)	0	2 (9.5)	2 (12.5)
Any Amount Reported	n (%)	33 (84.6)	15 (48.4)	14 (58.3)	9 (52.9)	17 (81.0)	10 (62.5)
Below 100,000 Yen	n (%)	2 (5.1)	0	0	0	0	0
100,000 Yen - 199,999 Yen	n (%)	6 (15.4)	4 (12.9)	3 (12.5)	1 (5.9)	2 (9.5)	3 (18.8)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 4**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
200,000 Yen - 299,999 Yen	n (%)	9 (23.1)	4 (12.9)	3 (12.5)	1 (5.9)	5 (23.8)	2 (12.5)
300,000 Yen - 399,999 Yen	n (%)	5 (12.8)	3 (9.7)	3 (12.5)	1 (5.9)	2 (9.5)	1 (6.3)
400,000 Yen - 499,999 Yen	n (%)	1 (2.6)	2 (6.5)	1 (4.2)	2 (11.8)	2 (9.5)	1 (6.3)
500,000 Yen - 599,999 Yen	n (%)	5 (12.8)	1 (3.2)	0	1 (5.9)	3 (14.3)	2 (12.5)
600,000 Yen - 699,999 Yen	n (%)	0	0	2 (8.3)	0	1 (4.8)	0
700,000 Yen - 799,999 Yen	n (%)	0	0	0	1 (5.9)	0	0
800,000 Yen - 899,999 Yen	n (%)	1 (2.6)	0	1 (4.2)	0	1 (4.8)	0
900,000 Yen - 999,999 Yen	n (%)	1 (2.6)	0	0	0	0	0
1,000,000 Yen - or Above	n (%)	3 (7.7)	1 (3.2)	1 (4.2)	2 (11.8)	1 (4.8)	1 (6.3)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set Period 4**

Variable	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	5	14	9	8	2	4
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?							
Don't Know	n (%)	0	2 (6.5)	1 (4.2)	2 (11.8)	0	1 (6.3)
Prefer Not to Say	n (%)	2 (5.1)	8 (25.8)	4 (16.7)	4 (23.5)	1 (4.8)	1 (6.3)
Any Amount Reported	n (%)	3 (7.7)	4 (12.9)	4 (16.7)	2 (11.8)	1 (4.8)	2 (12.5)
Under 800,000yen	n (%)	2 (5.1)	3 (9.7)	3 (12.5)	2 (11.8)	1 (4.8)	1 (6.3)
800,000yen or More	n (%)	1 (2.6)	1 (3.2)	1 (4.2)	0	0	1 (6.3)

Note: The Overall PP Set refers to all subjects in the Per Protocol 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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

Study ID: ZRHM-REXA-07-JP

Program: t150201040301-ZRHM-REXA-07-JP-v3.0.sas

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Sex							
Male	n (%)	21 (53.8)	22 (59.5)	13 (56.5)	12 (63.2)	11 (55.0)	11 (57.9)
Female	n (%)	18 (46.2)	15 (40.5)	10 (43.5)	7 (36.8)	9 (45.0)	8 (42.1)
Age (years)							
	n	39	37	23	19	20	19
	Mean (SD)	35.6 (10.03)	38.8 (11.25)	38.6 (11.92)	35.9 (10.46)	37.6 (8.86)	37.2 (11.00)
	Median	36.0	39.0	39.0	32.0	38.5	32.0
	Min, Max	23, 56	23, 65	23, 64	23, 55	23, 54	24, 55
Ethnicity							
Japanese	n (%)	39 (100)	37 (100)	23 (100)	19 (100)	20 (100)	19 (100)
Non-Japanese	n (%)	0	0	0	0	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Weight (kg)	n	39	37	23	19	20	19
	Mean (SD)	61.91 (9.860)	63.34 (11.869)	62.37 (11.565)	61.53 (8.626)	61.14 (9.331)	62.25 (12.841)
	Median	61.30	62.10	64.30	61.10	61.25	58.90
	Min, Max	46.5, 88.3	45.1, 97.8	43.4, 84.4	48.9, 79.7	43.7, 79.4	46.7, 91.8
Height (m)	n	39	37	23	19	20	19
	Mean (SD)	1.655 (0.0726)	1.651 (0.0785)	1.658 (0.1078)	1.664 (0.0956)	1.655 (0.0863)	1.650 (0.0692)
	Median	1.660	1.650	1.660	1.680	1.660	1.650
	Min, Max	1.52, 1.78	1.52, 1.84	1.47, 1.88	1.50, 1.84	1.50, 1.80	1.53, 1.79

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
BMI (kg/m ²)	n	39	37	23	19	20	19
	Mean (SD)	22.52 (2.711)	23.11 (3.105)	22.57 (2.764)	22.27 (3.073)	22.34 (3.217)	22.74 (3.682)
	Median	22.00	22.60	22.00	21.10	21.60	21.30
	Min, Max	18.9, 29.8	18.7, 32.7	19.0, 28.0	18.9, 28.4	18.7, 29.5	18.5, 31.8
	n (%)	0	0	0	0	0	0
Underweight	n (%)	0	0	0	0	0	0
Normal Weight	n (%)	32 (82.1)	27 (73.0)	17 (73.9)	15 (78.9)	17 (85.0)	14 (73.7)
Overweight	n (%)	7 (17.9)	9 (24.3)	6 (26.1)	4 (21.1)	3 (15.0)	4 (21.1)
Obese	n (%)	0	1 (2.7)	0	0	0	1 (5.3)
Waist circumference (cm)	n	39	37	23	19	20	19
	Mean (SD)	88.9 (29.33)	84.6 (17.01)	92.4 (31.14)	88.5 (29.66)	90.1 (32.87)	80.3 (9.13)
	Median	80.0	83.0	81.0	78.0	76.5	79.0
	Min, Max	65, 174	67, 166	64, 171	70, 172	66, 167	67, 95

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
ISO tar yields	n	39	37	23	19	20	19
	Mean (SD)	4.8 (3.51)	5.0 (3.57)	4.2 (3.85)	5.8 (3.62)	3.9 (3.56)	5.6 (4.11)
	Median	5.0	5.0	1.0	7.0	1.0	6.0
	Min, Max	1, 12	1, 12	1, 12	1, 10	1, 10	1, 12
	1-5 mg n (%)	25 (64.1)	20 (54.1)	15 (65.2)	7 (36.8)	13 (65.0)	9 (47.4)
	6-8 mg n (%)	9 (23.1)	12 (32.4)	6 (26.1)	8 (42.1)	5 (25.0)	7 (36.8)
9-10 mg n (%)		2 (5.1)	4 (10.8)	0	4 (21.1)	2 (10.0)	0
	>10 mg n (%)	3 (7.7)	1 (2.7)	2 (8.7)	0	0	3 (15.8)
ISO nicotine yields	n	39	37	23	19	20	19
	Mean (SD)	0.39 (0.258)	0.41 (0.275)	0.34 (0.285)	0.46 (0.262)	0.32 (0.270)	0.46 (0.310)
	Median	0.40	0.40	0.10	0.60	0.10	0.50
	Min, Max	0.1, 1.0	0.1, 1.0	0.1, 0.9	0.1, 0.7	0.1, 0.7	0.1, 0.9
	<= 0.6 mg n (%)	34 (87.2)	28 (75.7)	19 (82.6)	13 (68.4)	16 (80.0)	13 (68.4)
	> 0.6 mg n (%)	5 (12.8)	9 (24.3)	4 (17.4)	6 (31.6)	4 (20.0)	6 (31.6)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
FTND score	n	39	37	23	19	20	18
	Mean (SD)	3.6 (1.70)	5.1 (1.57)	3.7 (1.53)	5.1 (1.83)	3.8 (2.22)	5.8 (1.40)
	Median	3.0	5.0	3.0	5.0	4.0	6.0
	Min, Max	1, 8	2, 9	1, 7	2, 8	0, 8	4, 9
Mild	n (%)	22 (56.4)	5 (13.5)	13 (56.5)	4 (21.1)	8 (40.0)	0
Moderate	n (%)	16 (41.0)	26 (70.3)	9 (39.1)	9 (47.4)	10 (50.0)	12 (63.2)
Severe	n (%)	1 (2.6)	6 (16.2)	1 (4.3)	6 (31.6)	2 (10.0)	6 (31.6)
Individual product preference							
THSm2.2	n (%)	9 (23.1)	8 (21.6)	5 (21.7)	5 (26.3)	3 (15.0)	3 (15.8)
mCC	n (%)	19 (48.7)	20 (54.1)	11 (47.8)	9 (47.4)	11 (55.0)	13 (68.4)
SA	n (%)	5 (12.8)	4 (10.8)	2 (8.7)	2 (10.5)	4 (20.0)	1 (5.3)
No Preference	n (%)	6 (15.4)	5 (13.5)	5 (21.7)	3 (15.8)	2 (10.0)	2 (10.5)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 4 SES Questionnaire							
Q1: Total number living in household (including yourself)?							
0	n (%)	0	1 (2.7)	0	0	0	0
1	n (%)	20 (51.3)	15 (40.5)	5 (21.7)	7 (36.8)	7 (35.0)	5 (26.3)
2	n (%)	6 (15.4)	7 (18.9)	3 (13.0)	4 (21.1)	7 (35.0)	6 (31.6)
3	n (%)	2 (5.1)	6 (16.2)	8 (34.8)	0	4 (20.0)	4 (21.1)
4	n (%)	5 (12.8)	4 (10.8)	5 (21.7)	2 (10.5)	2 (10.0)	2 (10.5)
5	n (%)	3 (7.7)	0	1 (4.3)	1 (5.3)	0	1 (5.3)
6	n (%)	1 (2.6)	0	0	1 (5.3)	0	0
Prefer Not to Say	n (%)	2 (5.1)	4 (10.8)	1 (4.3)	3 (15.8)	0	1 (5.3)
Missing	n (%)	0	0	0	1 (5.3)	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Q2: Highest level education attained / currently attaining?							
Elementary School / Junior High School	n (%)	0	0	0	1 (5.3)	0	2 (10.5)
Senior High School	n (%)	12 (30.8)	7 (18.9)	4 (17.4)	6 (31.6)	6 (30.0)	8 (42.1)
College	n (%)	10 (25.6)	12 (32.4)	5 (21.7)	2 (10.5)	4 (20.0)	3 (15.8)
University / Postgraduate	n (%)	15 (38.5)	15 (40.5)	11 (47.8)	7 (36.8)	9 (45.0)	6 (31.6)
Prefer Not to Say	n (%)	2 (5.1)	3 (8.1)	3 (13.0)	2 (10.5)	1 (5.0)	0
Missing	n (%)	0	0	0	1 (5.3)	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Q3: How many income earners in household?							
None - All Are Unemployed	n (%)	3 (7.7)	1 (2.7)	1 (4.3)	0	2 (10.0)	2 (10.5)
Just One Income Earner	n (%)	22 (56.4)	23 (62.2)	9 (39.1)	11 (57.9)	10 (50.0)	8 (42.1)
Two or More Income Earners	n (%)	14 (35.9)	13 (35.1)	13 (56.5)	7 (36.8)	8 (40.0)	9 (47.4)
Missing	n (%)	0	0	0	1 (5.3)	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

		THSm2.2		mCC		SA	
Variable	Statistic	10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Q4: What is your occupation?							
General White Collar	n (%)	5 (12.8)	3 (8.1)	3 (13.0)	3 (15.8)	1 (5.0)	1 (5.3)
Professional/Technical Worker	n (%)	0	5 (13.5)	2 (8.7)	3 (15.8)	0	2 (10.5)
General Blue Collar	n (%)	0	1 (2.7)	0	0	2 (10.0)	0
Working In Service Industry	n (%)	3 (7.7)	4 (10.8)	0	3 (15.8)	0	1 (5.3)
Manager (Kacho or Above)	n (%)	0	1 (2.7)	1 (4.3)	0	0	0
Director/President (30 Employees or More)	n (%)	0	0	0	1 (5.3)	0	1 (5.3)
Proprietor (29 Employees or Less)	n (%)	4 (10.3)	4 (10.8)	2 (8.7)	2 (10.5)	2 (10.0)	3 (15.8)
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	0	1 (2.7)	0	0	0	0
Farming/Forestry/Fishing	n (%)	1 (2.6)	0	0	0	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Part-Time Worker (More Than One Day Per Week)	n (%)	13 (33.3)	7 (18.9)	4 (17.4)	3 (15.8)	7 (35.0)	3 (15.8)
Student	n (%)	4 (10.3)	3 (8.1)	2 (8.7)	0	2 (10.0)	0
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	1 (2.6)	0	4 (17.4)	0	0	0
Unemployed	n (%)	0	1 (2.7)	1 (4.3)	0	2 (10.0)	5 (26.3)
Others	n (%)	6 (15.4)	7 (18.9)	3 (13.0)	3 (15.8)	3 (15.0)	2 (10.5)
Missing	n (%)	2 (5.1)	0	1 (4.3)	1 (5.3)	1 (5.0)	1 (5.3)
Q5a: What is approximate MONTHLY household income from all sources before tax?							
Don't Know	n (%)	5 (12.8)	3 (8.1)	6 (26.1)	0	1 (5.0)	4 (21.1)
Prefer Not to Say	n (%)	5 (12.8)	8 (21.6)	2 (8.7)	9 (47.4)	2 (10.0)	1 (5.3)
Missing	n (%)	3 (7.7)	0	1 (4.3)	1 (5.3)	2 (10.0)	2 (10.5)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Any Amount Reported	n (%)	26 (66.7)	26 (70.3)	14 (60.9)	9 (47.4)	15 (75.0)	12 (63.2)
Below 100,000 Yen	n (%)	1 (2.6)	1 (2.7)	0	0	0	0
100,000 Yen - 199,999 Yen	n (%)	5 (12.8)	7 (18.9)	2 (8.7)	2 (10.5)	3 (15.0)	2 (10.5)
200,000 Yen - 299,999 Yen	n (%)	7 (17.9)	8 (21.6)	1 (4.3)	3 (15.8)	6 (30.0)	1 (5.3)
300,000 Yen - 399,999 Yen	n (%)	4 (10.3)	4 (10.8)	3 (13.0)	1 (5.3)	2 (10.0)	1 (5.3)
400,000 Yen - 499,999 Yen	n (%)	2 (5.1)	1 (2.7)	1 (4.3)	2 (10.5)	0	3 (15.8)
500,000 Yen - 599,999 Yen	n (%)	3 (7.7)	3 (8.1)	1 (4.3)	0	1 (5.0)	4 (21.1)
600,000 Yen - 699,999 Yen	n (%)	0	0	2 (8.7)	0	1 (5.0)	0
700,000 Yen - 799,999 Yen	n (%)	0	0	1 (4.3)	0	0	0
800,000 Yen - 899,999 Yen	n (%)	1 (2.6)	0	1 (4.3)	0	1 (5.0)	0
900,000 Yen - 999,999 Yen	n (%)	1 (2.6)	0	0	0	0	0
1,000,000 Yen - or Above	n (%)	2 (5.1)	2 (5.4)	2 (8.7)	1 (5.3)	1 (5.0)	1 (5.3)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 1

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	10	11	8	9	3	5
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?							
Don't Know	n (%)	2 (5.1)	2 (5.4)	3 (13.0)	0	0	3 (15.8)
Prefer Not to Say	n (%)	4 (10.3)	6 (16.2)	1 (4.3)	7 (36.8)	1 (5.0)	1 (5.3)
Any Amount Reported	n (%)	4 (10.3)	3 (8.1)	4 (17.4)	2 (10.5)	2 (10.0)	1 (5.3)
Under 800,000yen	n (%)	3 (7.7)	2 (5.4)	4 (17.4)	1 (5.3)	1 (5.0)	1 (5.3)
800,000yen or More	n (%)	1 (2.6)	1 (2.7)	0	1 (5.3)	1 (5.0)	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Sex							
Male	n (%)	21 (55.3)	21 (58.3)	13 (56.5)	11 (61.1)	11 (55.0)	11 (57.9)
Female	n (%)	17 (44.7)	15 (41.7)	10 (43.5)	7 (38.9)	9 (45.0)	8 (42.1)
Age (years)							
	n	38	36	23	18	20	19
	Mean (SD)	35.6 (10.16)	39.2 (11.20)	38.6 (11.92)	36.6 (10.27)	37.6 (8.86)	37.2 (11.00)
	Median	36.5	39.0	39.0	35.5	38.5	32.0
	Min, Max	23, 56	23, 65	23, 64	23, 55	23, 54	24, 55
Ethnicity							
Japanese	n (%)	38 (100)	36 (100)	23 (100)	18 (100)	20 (100)	19 (100)
Non-Japanese	n (%)	0	0	0	0	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Weight (kg)	n	38	36	23	18	20	19
	Mean (SD)	61.93 (9.992)	63.35 (12.037)	62.37 (11.565)	61.56 (8.875)	61.14 (9.331)	62.25 (12.841)
	Median	61.35	61.75	64.30	61.70	61.25	58.90
	Min, Max	46.5, 88.3	45.1, 97.8	43.4, 84.4	48.9, 79.7	43.7, 79.4	46.7, 91.8
Height (m)	n	38	36	23	18	20	19
	Mean (SD)	1.654 (0.0732)	1.650 (0.0795)	1.658 (0.1078)	1.657 (0.0940)	1.655 (0.0863)	1.650 (0.0692)
	Median	1.660	1.645	1.660	1.660	1.660	1.650
	Min, Max	1.52, 1.78	1.52, 1.84	1.47, 1.88	1.50, 1.84	1.50, 1.80	1.53, 1.79

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
BMI (kg/m ²)	n	38	36	23	18	20	19
	Mean (SD)	22.55 (2.739)	23.12 (3.148)	22.57 (2.764)	22.44 (3.075)	22.34 (3.217)	22.74 (3.682)
	Median	22.00	22.55	22.00	21.25	21.60	21.30
	Min, Max	18.9, 29.8	18.7, 32.7	19.0, 28.0	18.9, 28.4	18.7, 29.5	18.5, 31.8
Underweight	n (%)	0	0	0	0	0	0
Normal Weight	n (%)	31 (81.6)	26 (72.2)	17 (73.9)	14 (77.8)	17 (85.0)	14 (73.7)
Overweight	n (%)	7 (18.4)	9 (25.0)	6 (26.1)	4 (22.2)	3 (15.0)	4 (21.1)
Obese	n (%)	0	1 (2.8)	0	0	0	1 (5.3)
Waist circumference (cm)	n	38	36	23	18	20	19
	Mean (SD)	89.1 (29.69)	84.8 (17.20)	92.4 (31.14)	89.2 (30.34)	90.1 (32.87)	80.3 (9.13)
	Median	80.0	83.0	81.0	78.0	76.5	79.0
	Min, Max	65, 174	67, 166	64, 171	70, 172	66, 167	67, 95

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
ISO tar yields	n	38	36	23	18	20	19
	Mean (SD)	4.9 (3.50)	4.9 (3.58)	4.2 (3.85)	5.8 (3.72)	3.9 (3.56)	5.6 (4.11)
	Median	5.0	5.0	1.0	7.5	1.0	6.0
	Min, Max	1, 12	1, 12	1, 12	1, 10	1, 10	1, 12
	1-5 mg n (%)	24 (63.2)	20 (55.6)	15 (65.2)	7 (38.9)	13 (65.0)	9 (47.4)
6-8 mg n (%)		9 (23.7)	11 (30.6)	6 (26.1)	7 (38.9)	5 (25.0)	7 (36.8)
9-10 mg n (%)		2 (5.3)	4 (11.1)	0	4 (22.2)	2 (10.0)	0
>10 mg n (%)		3 (7.9)	1 (2.8)	2 (8.7)	0	0	3 (15.8)
ISO nicotine yields	n	38	36	23	18	20	19
	Mean (SD)	0.39 (0.257)	0.40 (0.274)	0.34 (0.285)	0.46 (0.269)	0.32 (0.270)	0.46 (0.310)
	Median	0.40	0.40	0.10	0.60	0.10	0.50
	Min, Max	0.1, 1.0	0.1, 1.0	0.1, 0.9	0.1, 0.7	0.1, 0.7	0.1, 0.9
	<= 0.6 mg n (%)	33 (86.8)	28 (77.8)	19 (82.6)	12 (66.7)	16 (80.0)	13 (68.4)
> 0.6 mg n (%)		5 (13.2)	8 (22.2)	4 (17.4)	6 (33.3)	4 (20.0)	6 (31.6)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
FTND score	n	38	36	23	18	20	18
	Mean (SD)	3.6 (1.72)	5.1 (1.59)	3.7 (1.53)	5.1 (1.88)	3.8 (2.22)	5.8 (1.40)
	Median	3.0	5.0	3.0	5.0	4.0	6.0
	Min, Max	1, 8	2, 9	1, 7	2, 8	0, 8	4, 9
Mild	n (%)	22 (57.9)	5 (13.9)	13 (56.5)	4 (22.2)	8 (40.0)	0
Moderate	n (%)	15 (39.5)	25 (69.4)	9 (39.1)	8 (44.4)	10 (50.0)	12 (63.2)
Severe	n (%)	1 (2.6)	6 (16.7)	1 (4.3)	6 (33.3)	2 (10.0)	6 (31.6)
Individual product preference							
THSm2.2	n (%)	9 (23.7)	8 (22.2)	5 (21.7)	5 (27.8)	3 (15.0)	3 (15.8)
mCC	n (%)	19 (50.0)	20 (55.6)	11 (47.8)	8 (44.4)	11 (55.0)	13 (68.4)
SA	n (%)	4 (10.5)	3 (8.3)	2 (8.7)	2 (11.1)	4 (20.0)	1 (5.3)
No Preference	n (%)	6 (15.8)	5 (13.9)	5 (21.7)	3 (16.7)	2 (10.0)	2 (10.5)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 4 SES Questionnaire							
Q1: Total number living in household (including yourself)?							
0	n (%)	0	1 (2.8)	0	0	0	0
1	n (%)	20 (52.6)	15 (41.7)	5 (21.7)	7 (38.9)	7 (35.0)	5 (26.3)
2	n (%)	5 (13.2)	7 (19.4)	3 (13.0)	4 (22.2)	7 (35.0)	6 (31.6)
3	n (%)	2 (5.3)	6 (16.7)	8 (34.8)	0	4 (20.0)	4 (21.1)
4	n (%)	5 (13.2)	4 (11.1)	5 (21.7)	2 (11.1)	2 (10.0)	2 (10.5)
5	n (%)	3 (7.9)	0	1 (4.3)	1 (5.6)	0	1 (5.3)
6	n (%)	1 (2.6)	0	0	1 (5.6)	0	0
Prefer Not to Say	n (%)	2 (5.3)	3 (8.3)	1 (4.3)	3 (16.7)	0	1 (5.3)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Q2: Highest level education attained / currently attaining?							
Elementary School / Junior High School	n (%)	0	0	0	1 (5.6)	0	2 (10.5)
Senior High School	n (%)	12 (31.6)	7 (19.4)	4 (17.4)	6 (33.3)	6 (30.0)	8 (42.1)
College	n (%)	9 (23.7)	11 (30.6)	5 (21.7)	2 (11.1)	4 (20.0)	3 (15.8)
University / Postgraduate	n (%)	15 (39.5)	15 (41.7)	11 (47.8)	7 (38.9)	9 (45.0)	6 (31.6)
Prefer Not to Say	n (%)	2 (5.3)	3 (8.3)	3 (13.0)	2 (11.1)	1 (5.0)	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
		(N=38)	(N=36)	(N=23)	(N=18)	(N=20)	(N=19)
Q3: How many income earners in household?							
None - All Are Unemployed	n (%)	3 (7.9)	1 (2.8)	1 (4.3)	0	2 (10.0)	2 (10.5)
Just One Income Earner	n (%)	21 (55.3)	22 (61.1)	9 (39.1)	11 (61.1)	10 (50.0)	8 (42.1)
Two or More Income Earners	n (%)	14 (36.8)	13 (36.1)	13 (56.5)	7 (38.9)	8 (40.0)	9 (47.4)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

		THSm2.2		mCC		SA	
Variable	Statistic	10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Q4: What is your occupation?							
General White Collar	n (%)	5 (13.2)	3 (8.3)	3 (13.0)	3 (16.7)	1 (5.0)	1 (5.3)
Professional/Technical Worker	n (%)	0	5 (13.9)	2 (8.7)	3 (16.7)	0	2 (10.5)
General Blue Collar	n (%)	0	1 (2.8)	0	0	2 (10.0)	0
Working In Service Industry	n (%)	3 (7.9)	4 (11.1)	0	3 (16.7)	0	1 (5.3)
Manager (Kacho or Above)	n (%)	0	1 (2.8)	1 (4.3)	0	0	0
Director/President (30 Employees or More)	n (%)	0	0	0	1 (5.6)	0	1 (5.3)
Proprietor (29 Employees or Less)	n (%)	4 (10.5)	4 (11.1)	2 (8.7)	2 (11.1)	2 (10.0)	3 (15.8)
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	0	1 (2.8)	0	0	0	0
Farming/Forestry/Fishing	n (%)	1 (2.6)	0	0	0	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Part-Time Worker (More Than One Day Per Week)	n (%)	13 (34.2)	6 (16.7)	4 (17.4)	3 (16.7)	7 (35.0)	3 (15.8)
Student	n (%)	4 (10.5)	3 (8.3)	2 (8.7)	0	2 (10.0)	0
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	1 (2.6)	0	4 (17.4)	0	0	0
Unemployed	n (%)	0	1 (2.8)	1 (4.3)	0	2 (10.0)	5 (26.3)
Others	n (%)	5 (13.2)	7 (19.4)	3 (13.0)	3 (16.7)	3 (15.0)	2 (10.5)
Missing	n (%)	2 (5.3)	0	1 (4.3)	0	1 (5.0)	1 (5.3)
Q5a: What is approximate MONTHLY household income from all sources before tax?							
Don't Know	n (%)	5 (13.2)	3 (8.3)	6 (26.1)	0	1 (5.0)	4 (21.1)
Prefer Not to Say	n (%)	5 (13.2)	8 (22.2)	2 (8.7)	9 (50.0)	2 (10.0)	1 (5.3)
Missing	n (%)	3 (7.9)	0	1 (4.3)	0	2 (10.0)	2 (10.5)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Any Amount Reported	n (%)	25 (65.8)	25 (69.4)	14 (60.9)	9 (50.0)	15 (75.0)	12 (63.2)
Below 100,000 Yen	n (%)	1 (2.6)	1 (2.8)	0	0	0	0
100,000 Yen - 199,999 Yen	n (%)	5 (13.2)	6 (16.7)	2 (8.7)	2 (11.1)	3 (15.0)	2 (10.5)
200,000 Yen - 299,999 Yen	n (%)	6 (15.8)	8 (22.2)	1 (4.3)	3 (16.7)	6 (30.0)	1 (5.3)
300,000 Yen - 399,999 Yen	n (%)	4 (10.5)	4 (11.1)	3 (13.0)	1 (5.6)	2 (10.0)	1 (5.3)
400,000 Yen - 499,999 Yen	n (%)	2 (5.3)	1 (2.8)	1 (4.3)	2 (11.1)	0	3 (15.8)
500,000 Yen - 599,999 Yen	n (%)	3 (7.9)	3 (8.3)	1 (4.3)	0	1 (5.0)	4 (21.1)
600,000 Yen - 699,999 Yen	n (%)	0	0	2 (8.7)	0	1 (5.0)	0
700,000 Yen - 799,999 Yen	n (%)	0	0	1 (4.3)	0	0	0
800,000 Yen - 899,999 Yen	n (%)	1 (2.6)	0	1 (4.3)	0	1 (5.0)	0
900,000 Yen - 999,999 Yen	n (%)	1 (2.6)	0	0	0	0	0
1,000,000 Yen - or Above	n (%)	2 (5.3)	2 (5.6)	2 (8.7)	1 (5.6)	1 (5.0)	1 (5.3)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 2

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	10	11	8	9	3	5
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?							
Don't Know	n (%)	2 (5.3)	2 (5.6)	3 (13.0)	0	0	3 (15.8)
Prefer Not to Say	n (%)	4 (10.5)	6 (16.7)	1 (4.3)	7 (38.9)	1 (5.0)	1 (5.3)
Any Amount Reported	n (%)	4 (10.5)	3 (8.3)	4 (17.4)	2 (11.1)	2 (10.0)	1 (5.3)
Under 800,000yen	n (%)	3 (7.9)	2 (5.6)	4 (17.4)	1 (5.6)	1 (5.0)	1 (5.3)
800,000yen or More	n (%)	1 (2.6)	1 (2.8)	0	1 (5.6)	1 (5.0)	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Sex							
Male	n (%)	20 (55.6)	21 (60.0)	13 (56.5)	11 (61.1)	11 (55.0)	10 (55.6)
Female	n (%)	16 (44.4)	14 (40.0)	10 (43.5)	7 (38.9)	9 (45.0)	8 (44.4)
Age (years)							
	n	36	35	23	18	20	18
	Mean (SD)	36.2 (10.14)	39.3 (11.38)	38.6 (11.92)	36.6 (10.27)	37.6 (8.86)	37.7 (11.08)
	Median	37.0	39.0	39.0	35.5	38.5	36.5
	Min, Max	23, 56	23, 65	23, 64	23, 55	23, 54	24, 55
Ethnicity							
Japanese	n (%)	36 (100)	35 (100)	23 (100)	18 (100)	20 (100)	18 (100)
Non-Japanese	n (%)	0	0	0	0	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Weight (kg)	n	36	35	23	18	20	18
	Mean (SD)	62.39 (9.959)	62.96 (11.861)	62.37 (11.565)	61.56 (8.875)	61.14 (9.331)	62.59 (13.121)
	Median	62.00	62.10	64.30	61.70	61.25	60.15
	Min, Max	46.5, 88.3	45.1, 97.8	43.4, 84.4	48.9, 79.7	43.7, 79.4	46.7, 91.8
Height (m)	n	36	35	23	18	20	18
	Mean (SD)	1.655 (0.0734)	1.645 (0.0737)	1.658 (0.1078)	1.657 (0.0940)	1.655 (0.0863)	1.651 (0.0711)
	Median	1.660	1.650	1.660	1.660	1.660	1.660
	Min, Max	1.52, 1.78	1.52, 1.84	1.47, 1.88	1.50, 1.84	1.50, 1.80	1.53, 1.79

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
BMI (kg/m ²)	n	36	35	23	18	20	18
	Mean (SD)	22.69 (2.737)	23.11 (3.192)	22.57 (2.764)	22.44 (3.075)	22.34 (3.217)	22.84 (3.757)
	Median	22.20	22.60	22.00	21.25	21.60	21.35
	Min, Max	18.9, 29.8	18.7, 32.7	19.0, 28.0	18.9, 28.4	18.7, 29.5	18.5, 31.8
	n (%)	0	0	0	0	0	0
Underweight	n (%)	0	0	0	0	0	0
Normal Weight	n (%)	29 (80.6)	25 (71.4)	17 (73.9)	14 (77.8)	17 (85.0)	13 (72.2)
Overweight	n (%)	7 (19.4)	9 (25.7)	6 (26.1)	4 (22.2)	3 (15.0)	4 (22.2)
Obese	n (%)	0	1 (2.9)	0	0	0	1 (5.6)
Waist circumference (cm)	n	36	35	23	18	20	18
	Mean (SD)	89.8 (30.30)	84.8 (17.38)	92.4 (31.14)	89.2 (30.34)	90.1 (32.87)	80.6 (9.30)
	Median	80.0	83.0	81.0	78.0	76.5	79.0
	Min, Max	65, 174	67, 166	64, 171	70, 172	66, 167	67, 95

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
ISO tar yields	n	36	35	23	18	20	18
	Mean (SD)	5.1 (3.53)	5.1 (3.57)	4.2 (3.85)	5.8 (3.72)	3.9 (3.56)	5.4 (4.18)
	Median	5.0	5.0	1.0	7.5	1.0	5.5
	Min, Max	1, 12	1, 12	1, 12	1, 10	1, 10	1, 12
	1-5 mg n (%)	22 (61.1)	19 (54.3)	15 (65.2)	7 (38.9)	13 (65.0)	9 (50.0)
	6-8 mg n (%)	9 (25.0)	11 (31.4)	6 (26.1)	7 (38.9)	5 (25.0)	6 (33.3)
9-10 mg n (%)		2 (5.6)	4 (11.4)	0	4 (22.2)	2 (10.0)	0
	>10 mg n (%)	3 (8.3)	1 (2.9)	2 (8.7)	0	0	3 (16.7)
ISO nicotine yields	n	36	35	23	18	20	18
	Mean (SD)	0.40 (0.259)	0.41 (0.276)	0.34 (0.285)	0.46 (0.269)	0.32 (0.270)	0.44 (0.313)
	Median	0.40	0.40	0.10	0.60	0.10	0.50
	Min, Max	0.1, 1.0	0.1, 1.0	0.1, 0.9	0.1, 0.7	0.1, 0.7	0.1, 0.9
	<= 0.6 mg n (%)	31 (86.1)	26 (74.3)	19 (82.6)	12 (66.7)	16 (80.0)	13 (72.2)
	> 0.6 mg n (%)	5 (13.9)	9 (25.7)	4 (17.4)	6 (33.3)	4 (20.0)	5 (27.8)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
FTND score	n	36	35	23	18	20	17
	Mean (SD)	3.6 (1.77)	5.1 (1.57)	3.7 (1.53)	5.1 (1.88)	3.8 (2.22)	5.8 (1.43)
	Median	3.0	5.0	3.0	5.0	4.0	6.0
	Min, Max	1, 8	2, 9	1, 7	2, 8	0, 8	4, 9
Mild	n (%)	21 (58.3)	5 (14.3)	13 (56.5)	4 (22.2)	8 (40.0)	0
Moderate	n (%)	14 (38.9)	25 (71.4)	9 (39.1)	8 (44.4)	10 (50.0)	11 (61.1)
Severe	n (%)	1 (2.8)	5 (14.3)	1 (4.3)	6 (33.3)	2 (10.0)	6 (33.3)
Individual product preference							
THSm2.2	n (%)	8 (22.2)	8 (22.9)	5 (21.7)	5 (27.8)	3 (15.0)	3 (16.7)
mCC	n (%)	19 (52.8)	19 (54.3)	11 (47.8)	8 (44.4)	11 (55.0)	12 (66.7)
SA	n (%)	4 (11.1)	3 (8.6)	2 (8.7)	2 (11.1)	4 (20.0)	1 (5.6)
No Preference	n (%)	5 (13.9)	5 (14.3)	5 (21.7)	3 (16.7)	2 (10.0)	2 (11.1)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Day 4 SES Questionnaire							
Q1: Total number living in household (including yourself)?							
0	n (%)	0	1 (2.9)	0	0	0	0
1	n (%)	20 (55.6)	14 (40.0)	5 (21.7)	7 (38.9)	7 (35.0)	5 (27.8)
2	n (%)	5 (13.9)	6 (17.1)	3 (13.0)	4 (22.2)	7 (35.0)	6 (33.3)
3	n (%)	2 (5.6)	6 (17.1)	8 (34.8)	0	4 (20.0)	3 (16.7)
4	n (%)	4 (11.1)	4 (11.4)	5 (21.7)	2 (11.1)	2 (10.0)	2 (11.1)
5	n (%)	3 (8.3)	0	1 (4.3)	1 (5.6)	0	1 (5.6)
6	n (%)	0	0	0	1 (5.6)	0	0
Prefer Not to Say	n (%)	2 (5.6)	4 (11.4)	1 (4.3)	3 (16.7)	0	1 (5.6)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Q2: Highest level education attained / currently attaining?							
Elementary School / Junior High School	n (%)	0	0	0	1 (5.6)	0	1 (5.6)
Senior High School	n (%)	12 (33.3)	7 (20.0)	4 (17.4)	6 (33.3)	6 (30.0)	8 (44.4)
College	n (%)	8 (22.2)	12 (34.3)	5 (21.7)	2 (11.1)	4 (20.0)	3 (16.7)
University / Postgraduate	n (%)	14 (38.9)	13 (37.1)	11 (47.8)	7 (38.9)	9 (45.0)	6 (33.3)
Prefer Not to Say	n (%)	2 (5.6)	3 (8.6)	3 (13.0)	2 (11.1)	1 (5.0)	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Q3: How many income earners in household?							
None - All Are Unemployed	n (%)	3 (8.3)	1 (2.9)	1 (4.3)	0	2 (10.0)	2 (11.1)
Just One Income Earner	n (%)	20 (55.6)	22 (62.9)	9 (39.1)	11 (61.1)	10 (50.0)	8 (44.4)
Two or More Income Earners	n (%)	13 (36.1)	12 (34.3)	13 (56.5)	7 (38.9)	8 (40.0)	8 (44.4)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

		THSm2.2		mCC		SA	
Variable	Statistic	10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Q4: What is your occupation?							
General White Collar	n (%)	5 (13.9)	3 (8.6)	3 (13.0)	3 (16.7)	1 (5.0)	1 (5.6)
Professional/Technical Worker	n (%)	0	5 (14.3)	2 (8.7)	3 (16.7)	0	2 (11.1)
General Blue Collar	n (%)	0	1 (2.9)	0	0	2 (10.0)	0
Working In Service Industry	n (%)	3 (8.3)	4 (11.4)	0	3 (16.7)	0	1 (5.6)
Manager (Kacho or Above)	n (%)	0	1 (2.9)	1 (4.3)	0	0	0
Director/President (30 Employees or More)	n (%)	0	0	0	1 (5.6)	0	1 (5.6)
Proprietor (29 Employees or Less)	n (%)	4 (11.1)	4 (11.4)	2 (8.7)	2 (11.1)	2 (10.0)	3 (16.7)
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	0	1 (2.9)	0	0	0	0
Farming/Forestry/Fishing	n (%)	1 (2.8)	0	0	0	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Part-Time Worker (More Than One Day Per Week)	n (%)	12 (33.3)	7 (20.0)	4 (17.4)	3 (16.7)	7 (35.0)	3 (16.7)
Student	n (%)	3 (8.3)	3 (8.6)	2 (8.7)	0	2 (10.0)	0
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	1 (2.8)	0	4 (17.4)	0	0	0
Unemployed	n (%)	0	1 (2.9)	1 (4.3)	0	2 (10.0)	4 (22.2)
Others	n (%)	5 (13.9)	5 (14.3)	3 (13.0)	3 (16.7)	3 (15.0)	2 (11.1)
Missing	n (%)	2 (5.6)	0	1 (4.3)	0	1 (5.0)	1 (5.6)
Q5a: What is approximate MONTHLY household income from all sources before tax?							
Don't Know	n (%)	4 (11.1)	3 (8.6)	6 (26.1)	0	1 (5.0)	3 (16.7)
Prefer Not to Say	n (%)	4 (11.1)	7 (20.0)	2 (8.7)	9 (50.0)	2 (10.0)	1 (5.6)
Missing	n (%)	3 (8.3)	0	1 (4.3)	0	2 (10.0)	2 (11.1)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Any Amount Reported	n (%)	25 (69.4)	25 (71.4)	14 (60.9)	9 (50.0)	15 (75.0)	12 (66.7)
Below 100,000 Yen	n (%)	1 (2.8)	1 (2.9)	0	0	0	0
100,000 Yen - 199,999 Yen	n (%)	5 (13.9)	7 (20.0)	2 (8.7)	2 (11.1)	3 (15.0)	2 (11.1)
200,000 Yen - 299,999 Yen	n (%)	6 (16.7)	7 (20.0)	1 (4.3)	3 (16.7)	6 (30.0)	1 (5.6)
300,000 Yen - 399,999 Yen	n (%)	4 (11.1)	4 (11.4)	3 (13.0)	1 (5.6)	2 (10.0)	1 (5.6)
400,000 Yen - 499,999 Yen	n (%)	2 (5.6)	1 (2.9)	1 (4.3)	2 (11.1)	0	3 (16.7)
500,000 Yen - 599,999 Yen	n (%)	3 (8.3)	3 (8.6)	1 (4.3)	0	1 (5.0)	4 (22.2)
600,000 Yen - 699,999 Yen	n (%)	0	0	2 (8.7)	0	1 (5.0)	0
700,000 Yen - 799,999 Yen	n (%)	0	0	1 (4.3)	0	0	0
800,000 Yen - 899,999 Yen	n (%)	1 (2.8)	0	1 (4.3)	0	1 (5.0)	0
900,000 Yen - 999,999 Yen	n (%)	1 (2.8)	0	0	0	0	0
1,000,000 Yen - or Above	n (%)	2 (5.6)	2 (5.7)	2 (8.7)	1 (5.6)	1 (5.0)	1 (5.6)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 3

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	8	10	8	9	3	4
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?							
Don't Know	n (%)	1 (2.8)	2 (5.7)	3 (13.0)	0	0	2 (11.1)
Prefer Not to Say	n (%)	3 (8.3)	5 (14.3)	1 (4.3)	7 (38.9)	1 (5.0)	1 (5.6)
Any Amount Reported	n (%)	4 (11.1)	3 (8.6)	4 (17.4)	2 (11.1)	2 (10.0)	1 (5.6)
Under 800,000yen	n (%)	3 (8.3)	2 (5.7)	4 (17.4)	1 (5.6)	1 (5.0)	1 (5.6)
800,000yen or More	n (%)	1 (2.8)	1 (2.9)	0	1 (5.6)	1 (5.0)	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Sex							
Male	n (%)	19 (52.8)	20 (58.8)	13 (56.5)	11 (61.1)	11 (55.0)	10 (58.8)
Female	n (%)	17 (47.2)	14 (41.2)	10 (43.5)	7 (38.9)	9 (45.0)	7 (41.2)
Age (years)							
	n	36	34	23	18	20	17
	Mean (SD)	36.2 (10.14)	39.4 (11.14)	38.6 (11.92)	36.6 (10.27)	37.6 (8.86)	38.1 (11.29)
	Median	37.0	39.0	39.0	35.5	38.5	41.0
	Min, Max	23, 56	23, 65	23, 64	23, 55	23, 54	24, 55
Ethnicity							
Japanese	n (%)	36 (100)	34 (100)	23 (100)	18 (100)	20 (100)	17 (100)
Non-Japanese	n (%)	0	0	0	0	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Weight (kg)	n	36	34	23	18	20	17
	Mean (SD)	61.63 (10.034)	63.12 (12.228)	62.37 (11.565)	61.56 (8.875)	61.14 (9.331)	63.53 (12.892)
	Median	61.35	61.75	64.30	61.70	61.25	61.40
	Min, Max	46.5, 88.3	45.1, 97.8	43.4, 84.4	48.9, 79.7	43.7, 79.4	48.5, 91.8
Height (m)	n	36	34	23	18	20	17
	Mean (SD)	1.652 (0.0744)	1.650 (0.0815)	1.658 (0.1078)	1.657 (0.0940)	1.655 (0.0863)	1.654 (0.0716)
	Median	1.655	1.645	1.660	1.660	1.660	1.670
	Min, Max	1.52, 1.78	1.52, 1.84	1.47, 1.88	1.50, 1.84	1.50, 1.80	1.53, 1.79

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
BMI (kg/m ²)	n	36	34	23	18	20	17
	Mean (SD)	22.51 (2.744)	23.03 (3.190)	22.57 (2.764)	22.44 (3.075)	22.34 (3.217)	23.10 (3.708)
	Median	22.00	22.45	22.00	21.25	21.60	21.40
	Min, Max	18.9, 29.8	18.7, 32.7	19.0, 28.0	18.9, 28.4	18.7, 29.5	19.0, 31.8
	n (%)	0	0	0	0	0	0
Underweight	n (%)	0	0	0	0	0	0
Normal Weight	n (%)	30 (83.3)	25 (73.5)	17 (73.9)	14 (77.8)	17 (85.0)	12 (70.6)
Overweight	n (%)	6 (16.7)	8 (23.5)	6 (26.1)	4 (22.2)	3 (15.0)	4 (23.5)
Obese	n (%)	0	1 (2.9)	0	0	0	1 (5.9)
Waist circumference (cm)	n	36	34	23	18	20	17
	Mean (SD)	89.4 (30.50)	84.6 (17.65)	92.4 (31.14)	89.2 (30.34)	90.1 (32.87)	81.1 (9.33)
	Median	78.5	82.5	81.0	78.0	76.5	79.0
	Min, Max	65, 174	67, 166	64, 171	70, 172	66, 167	67, 95

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
ISO tar yields	n	36	34	23	18	20	17
	Mean (SD)	4.8 (3.53)	5.0 (3.59)	4.2 (3.85)	5.8 (3.72)	3.9 (3.56)	5.3 (4.26)
	Median	5.0	5.0	1.0	7.5	1.0	5.0
	Min, Max	1, 12	1, 12	1, 12	1, 10	1, 10	1, 12
	1-5 mg n (%)	23 (63.9)	19 (55.9)	15 (65.2)	7 (38.9)	13 (65.0)	9 (52.9)
	6-8 mg n (%)	9 (25.0)	10 (29.4)	6 (26.1)	7 (38.9)	5 (25.0)	5 (29.4)
9-10 mg n (%)		1 (2.8)	4 (11.8)	0	4 (22.2)	2 (10.0)	0
	>10 mg n (%)	3 (8.3)	1 (2.9)	2 (8.7)	0	0	3 (17.6)
ISO nicotine yields	n	36	34	23	18	20	17
	Mean (SD)	0.38 (0.242)	0.40 (0.272)	0.34 (0.285)	0.46 (0.269)	0.32 (0.270)	0.43 (0.316)
	Median	0.40	0.40	0.10	0.60	0.10	0.50
	Min, Max	0.1, 0.8	0.1, 1.0	0.1, 0.9	0.1, 0.7	0.1, 0.7	0.1, 0.9
	<= 0.6 mg n (%)	32 (88.9)	27 (79.4)	19 (82.6)	12 (66.7)	16 (80.0)	13 (76.5)
	> 0.6 mg n (%)	4 (11.1)	7 (20.6)	4 (17.4)	6 (33.3)	4 (20.0)	4 (23.5)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
FTND score	n	36	34	23	18	20	16
	Mean (SD)	3.6 (1.77)	5.0 (1.49)	3.7 (1.53)	5.1 (1.88)	3.8 (2.22)	5.8 (1.44)
	Median	3.0	5.0	3.0	5.0	4.0	6.0
	Min, Max	1, 8	2, 8	1, 7	2, 8	0, 8	4, 9
Mild	n (%)	21 (58.3)	5 (14.7)	13 (56.5)	4 (22.2)	8 (40.0)	0
Moderate	n (%)	14 (38.9)	24 (70.6)	9 (39.1)	8 (44.4)	10 (50.0)	11 (64.7)
Severe	n (%)	1 (2.8)	5 (14.7)	1 (4.3)	6 (33.3)	2 (10.0)	5 (29.4)
Individual product preference							
THSm2.2	n (%)	8 (22.2)	8 (23.5)	5 (21.7)	5 (27.8)	3 (15.0)	2 (11.8)
mCC	n (%)	18 (50.0)	18 (52.9)	11 (47.8)	8 (44.4)	11 (55.0)	12 (70.6)
SA	n (%)	4 (11.1)	3 (8.8)	2 (8.7)	2 (11.1)	4 (20.0)	1 (5.9)
No Preference	n (%)	6 (16.7)	5 (14.7)	5 (21.7)	3 (16.7)	2 (10.0)	2 (11.8)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Day 4 SES Questionnaire							
Q1: Total number living in household (including yourself)?							
0	n (%)	0	1 (2.9)	0	0	0	0
1	n (%)	19 (52.8)	15 (44.1)	5 (21.7)	7 (38.9)	7 (35.0)	5 (29.4)
2	n (%)	5 (13.9)	5 (14.7)	3 (13.0)	4 (22.2)	7 (35.0)	6 (35.3)
3	n (%)	2 (5.6)	6 (17.6)	8 (34.8)	0	4 (20.0)	2 (11.8)
4	n (%)	5 (13.9)	4 (11.8)	5 (21.7)	2 (11.1)	2 (10.0)	2 (11.8)
5	n (%)	3 (8.3)	0	1 (4.3)	1 (5.6)	0	1 (5.9)
6	n (%)	0	0	0	1 (5.6)	0	0
Prefer Not to Say	n (%)	2 (5.6)	3 (8.8)	1 (4.3)	3 (16.7)	0	1 (5.9)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Q2: Highest level education attained / currently attaining?							
Elementary School / Junior High School	n (%)	0	0	0	1 (5.6)	0	1 (5.9)
Senior High School	n (%)	12 (33.3)	7 (20.6)	4 (17.4)	6 (33.3)	6 (30.0)	8 (47.1)
College	n (%)	8 (22.2)	10 (29.4)	5 (21.7)	2 (11.1)	4 (20.0)	3 (17.6)
University / Postgraduate	n (%)	14 (38.9)	14 (41.2)	11 (47.8)	7 (38.9)	9 (45.0)	5 (29.4)
Prefer Not to Say	n (%)	2 (5.6)	3 (8.8)	3 (13.0)	2 (11.1)	1 (5.0)	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Q3: How many income earners in household?							
None - All Are Unemployed	n (%)	3 (8.3)	1 (2.9)	1 (4.3)	0	2 (10.0)	2 (11.8)
Just One Income Earner	n (%)	20 (55.6)	21 (61.8)	9 (39.1)	11 (61.1)	10 (50.0)	8 (47.1)
Two or More Income Earners	n (%)	13 (36.1)	12 (35.3)	13 (56.5)	7 (38.9)	8 (40.0)	7 (41.2)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

		THSm2.2		mCC		SA	
Variable	Statistic	10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Q4: What is your occupation?							
General White Collar	n (%)	5 (13.9)	3 (8.8)	3 (13.0)	3 (16.7)	1 (5.0)	1 (5.9)
Professional/Technical Worker	n (%)	0	4 (11.8)	2 (8.7)	3 (16.7)	0	1 (5.9)
General Blue Collar	n (%)	0	1 (2.9)	0	0	2 (10.0)	0
Working In Service Industry	n (%)	3 (8.3)	4 (11.8)	0	3 (16.7)	0	1 (5.9)
Manager (Kacho or Above)	n (%)	0	1 (2.9)	1 (4.3)	0	0	0
Director/President (30 Employees or More)	n (%)	0	0	0	1 (5.6)	0	1 (5.9)
Proprietor (29 Employees or Less)	n (%)	4 (11.1)	3 (8.8)	2 (8.7)	2 (11.1)	2 (10.0)	3 (17.6)
Professional/Technical Worker (Lawyer, Accountant, Professor Etc)	n (%)	0	1 (2.9)	0	0	0	0
Farming/Forestry/Fishing	n (%)	1 (2.8)	0	0	0	0	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Part-Time Worker (More Than One Day Per Week)	n (%)	11 (30.6)	6 (17.6)	4 (17.4)	3 (16.7)	7 (35.0)	3 (17.6)
Student	n (%)	4 (11.1)	3 (8.8)	2 (8.7)	0	2 (10.0)	0
Housewife (Including Part-Time Less Than One Day Per Week)	n (%)	1 (2.8)	0	4 (17.4)	0	0	0
Unemployed	n (%)	0	1 (2.9)	1 (4.3)	0	2 (10.0)	4 (23.5)
Others	n (%)	5 (13.9)	7 (20.6)	3 (13.0)	3 (16.7)	3 (15.0)	2 (11.8)
Missing	n (%)	2 (5.6)	0	1 (4.3)	0	1 (5.0)	1 (5.9)
Q5a: What is approximate MONTHLY household income from all sources before tax?							
Don't Know	n (%)	4 (11.1)	2 (5.9)	6 (26.1)	0	1 (5.0)	2 (11.8)
Prefer Not to Say	n (%)	5 (13.9)	8 (23.5)	2 (8.7)	9 (50.0)	2 (10.0)	1 (5.9)
Missing	n (%)	3 (8.3)	0	1 (4.3)	0	2 (10.0)	2 (11.8)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Any Amount Reported	n (%)	24 (66.7)	24 (70.6)	14 (60.9)	9 (50.0)	15 (75.0)	12 (70.6)
Below 100,000 Yen	n (%)	1 (2.8)	1 (2.9)	0	0	0	0
100,000 Yen - 199,999 Yen	n (%)	5 (13.9)	5 (14.7)	2 (8.7)	2 (11.1)	3 (15.0)	2 (11.8)
200,000 Yen - 299,999 Yen	n (%)	5 (13.9)	8 (23.5)	1 (4.3)	3 (16.7)	6 (30.0)	1 (5.9)
300,000 Yen - 399,999 Yen	n (%)	4 (11.1)	4 (11.8)	3 (13.0)	1 (5.6)	2 (10.0)	1 (5.9)
400,000 Yen - 499,999 Yen	n (%)	2 (5.6)	1 (2.9)	1 (4.3)	2 (11.1)	0	3 (17.6)
500,000 Yen - 599,999 Yen	n (%)	3 (8.3)	3 (8.8)	1 (4.3)	0	1 (5.0)	4 (23.5)
600,000 Yen - 699,999 Yen	n (%)	0	0	2 (8.7)	0	1 (5.0)	0
700,000 Yen - 799,999 Yen	n (%)	0	0	1 (4.3)	0	0	0
800,000 Yen - 899,999 Yen	n (%)	1 (2.8)	0	1 (4.3)	0	1 (5.0)	0
900,000 Yen - 999,999 Yen	n (%)	1 (2.8)	0	0	0	0	0
1,000,000 Yen - or Above	n (%)	2 (5.6)	2 (5.9)	2 (8.7)	1 (5.6)	1 (5.0)	1 (5.9)

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, 15.3.6.11

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Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set Period 4

Variable	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Replied "Don't Know" or "Prefer not to Say" to 5a	n (%)	9	10	8	9	3	3
Q5b: (For those who answered "Don't know" or "Prefer not to say" to 5a) Would MONTHLY household income be over or under 800,000 yen?							
Don't Know	n (%)	1 (2.8)	1 (2.9)	3 (13.0)	0	0	1 (5.9)
Prefer Not to Say	n (%)	4 (11.1)	6 (17.6)	1 (4.3)	7 (38.9)	1 (5.0)	1 (5.9)
Any Amount Reported	n (%)	4 (11.1)	3 (8.8)	4 (17.4)	2 (11.1)	2 (10.0)	1 (5.9)
Under 800,000yen	n (%)	3 (8.3)	2 (5.9)	4 (17.4)	1 (5.6)	1 (5.0)	1 (5.9)
800,000yen or More	n (%)	1 (2.8)	1 (2.9)	0	1 (5.6)	1 (5.0)	0

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 = Fagerström Test for Nicotine Dependence, SES = Socio-Economic Status.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.1.5 Summary of Current Cigarette Brands At Screening - Safety Population**

Brand	ISO nicotine yield (mg)	ISO tar yield (mg)	THSm2.2 (N=78) n(%)	mCC (N=42) n(%)	SA (N=40) n(%)	Product Test (N=15) n(%)	Overall Safety (N=175) n(%)
Hi-Lite Menthol	0.7	10	3 (3.8)	3 (7.1)	1 (2.5)	0	7 (4.0)
Marlboro Lights Menthol	0.6	8	4 (5.1)	1 (2.4)	1 (2.5)	0	6 (3.4)
Marlboro Menthol	0.8	12	3 (3.8)	1 (2.4)	0	1 (6.7)	5 (2.9)
Pianissimo Aria Menthol	0.1	1	3 (3.8)	1 (2.4)	0	1 (6.7)	5 (2.9)
Marlboro Black Menthol	0.6	8	1 (1.3)	2 (4.8)	0	1 (6.7)	4 (2.3)
Marlboro Black Menthol Box	0.6	8	1 (1.3)	2 (4.8)	0	1 (6.7)	4 (2.3)
Marlboro Ice Blast 5 Mg	0.4	5	2 (2.6)	1 (2.4)	0	1 (6.7)	4 (2.3)
Mevius Premium Menthol 1	0.1	1	1 (1.3)	1 (2.4)	2 (5.0)	0	4 (2.3)
Mevius Premium Menthol 1 100's	0.1	1	3 (3.8)	0	0	1 (6.7)	4 (2.3)
Mevius Premium Menthol Option 1 100's	0.1	1	2 (2.6)	2 (4.8)	0	0	4 (2.3)
Mevius Premium Menthol Option 8	0.7	8	1 (1.3)	0	3 (7.5)	0	4 (2.3)
Other	0.1	1	20 (25.6)	14 (33.3)	16 (40.0)	6 (40.0)	56 (32.0)
Other	0.4	5	10 (12.8)	1 (2.4)	2 (5.0)	1 (6.7)	14 (8.0)
Other	0.6	8	5 (6.4)	1 (2.4)	3 (7.5)	2 (13.3)	11 (6.3)
Other	0.7	8	3 (3.8)	4 (9.5)	2 (5.0)	0	9 (5.1)
Other	0.5	5	2 (2.6)	1 (2.4)	2 (5.0)	0	5 (2.9)

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 15.2.1.5 Summary of Current Cigarette Brands At Screening - Safety Population**

Brand	ISO nicotine yield (mg)	ISO tar yield (mg)	THSm2.2 (N=78) n(%)	mCC (N=42) n(%)	SA (N=40) n(%)	Product Test (N=15) n(%)	Overall Safety (N=175) n(%)
Other	0.3	4	2 (2.6)	1 (2.4)	1 (2.5)	0	4 (2.3)
Other	0.5	6	3 (3.8)	1 (2.4)	0	0	4 (2.3)
Other	0.6	6	1 (1.3)	1 (2.4)	2 (5.0)	0	4 (2.3)
Other	0.6	7	2 (2.6)	2 (4.8)	0	0	4 (2.3)
Other	0.9	12	0	1 (2.4)	3 (7.5)	0	4 (2.3)
Other	0.7	10	1 (1.3)	1 (2.4)	1 (2.5)	0	3 (1.7)
Other	1	9	3 (3.8)	0	0	0	3 (1.7)
Other	0.3	5	1 (1.3)	0	0	0	1 (0.6)
Other	0.5	7	0	0	1 (2.5)	0	1 (0.6)
Other	0.8	12	1 (1.3)	0	0	0	1 (0.6)

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=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any medical history	6 (7.7)	7	0	0	5 (12.5)	6	2 (13.3)	2	13 (7.4)	15
Injury, poisoning and procedural complications	2 (2.6)	2			3 (7.5)	4	1 (6.7)	1	6 (3.4)	7
Clavicle fracture	0	0			2 (5.0)	2	0	0	2 (1.1)	2
Foot fracture	0	0			1 (2.5)	1	0	0	1 (0.6)	1
Jaw fracture	0	0			0	0	1 (6.7)	1	1 (0.6)	1
Rib fracture	1 (1.3)	1			0	0	0	0	1 (0.6)	1
Scapula fracture	1 (1.3)	1			0	0	0	0	1 (0.6)	1
Sternal fracture	0	0			1 (2.5)	1	0	0	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Infections and infestations	2 (2.6)	2			1 (2.5)	1	0	0	3 (1.7)	3
Appendicitis	2 (2.6)	2			0	0			2 (1.1)	2
Parotitis	0	0			1 (2.5)	1			1 (0.6)	1
Surgical and medical procedures	2 (2.6)	2			0	0	1 (6.7)	1	3 (1.7)	3
Tonsillectomy	2 (2.6)	2					0	0	2 (1.1)	2
Meniscus removal	0	0					1 (6.7)	1	1 (0.6)	1
Reproductive system and breast disorders	1 (1.3)	1			1 (2.5)	1	0	0	2 (1.1)	2
Ovarian cyst	1 (1.3)	1			1 (2.5)	1			2 (1.1)	2

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test Only (N=15)		Overall Safety (N=175)	
	n(%) Events		n(%) Events		n(%) Events		n(%) Events		n(%) Events	
Any Concomitant Diseases	13 (16.7)	14	4 (9.5)	4	4 (10.0)	5	2 (13.3)	2	23 (13.1)	25
Vascular Disorders	3 (3.8)	3	1 (2.4)	1	1 (2.5)	1	0		5 (2.9)	5
Hypotension	3 (3.8)	3	1 (2.4)	1	1 (2.5)	1			5 (2.9)	5
Gastrointestinal Disorders	1 (1.3)	1	1 (2.4)	1	2 (5.0)	2	0		4 (2.3)	4
Constipation	1 (1.3)	1	1 (2.4)	1	2 (5.0)	2			4 (2.3)	4
Metabolism And Nutrition Disorders	3 (3.8)	3	0		0		0		3 (1.7)	3
Hypercholesterolaemia	1 (1.3)	1							1 (0.6)	1
Hypertriglyceridaemia	1 (1.3)	1							1 (0.6)	1
Hypo Hdl Cholesterolaemia	1 (1.3)	1							1 (0.6)	1
Skin And Subcutaneous Tissue Disorders	2 (2.6)	3	0		1 (2.5)	1	0		3 (1.7)	4
Eczema	2 (2.6)	2			0				2 (1.1)	2
Acne	1 (1.3)	1			0				1 (0.6)	1
Dry Skin	0				1 (2.5)	1			1 (0.6)	1

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

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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=78)	mCC (N=42)	SA (N=40)	Product Test Only (N=15)		Overall Safety (N=175)	
	n(%) Events	n(%) Events	n(%) Events	n(%) Events		n(%) Events	
Cardiac Disorders	0	0	1 (2.5) 1	1 (6.7) 1		2 (1.1) 2	
Sinus Bradycardia			1 (2.5) 1	1 (6.7) 1		2 (1.1) 2	
Immune System Disorders	1 (1.3) 1	1 (2.4) 1	0	0		2 (1.1) 2	
Seasonal Allergy	1 (1.3) 1	1 (2.4) 1				2 (1.1) 2	
Nervous System Disorders	1 (1.3) 1	1 (2.4) 1	0	0		2 (1.1) 2	
Dizziness	1 (1.3) 1	0				1 (0.6) 1	
Headache	0	1 (2.4) 1				1 (0.6) 1	
Blood And Lymphatic System Disorders	1 (1.3) 1	0	0	0		1 (0.6) 1	
Anaemia	1 (1.3) 1					1 (0.6) 1	
Musculoskeletal And Connective Tissue Disorders	0	0	0	1 (6.7) 1		1 (0.6) 1	
Intervertebral Disc Protrusion				1 (6.7) 1		1 (0.6) 1	
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	1 (1.3) 1	0	0	0		1 (0.6) 1	
Uterine Leiomyoma	1 (1.3) 1					1 (0.6) 1	

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

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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	Product Use	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
THSm2.2 Test	Day -2	THSm2.2	n	78	42	40	160
		1	n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		2	n (%)	1 (1.3)	0	0	1 (0.6)
		3	n (%)	0	0	0	0
			Mean (SD)	1.0 (0.12)	1.0 (0.00)	1.0 (0.00)	1.0 (0.08)
			95% CI	1, 1	1, 1	1, 1	1, 1
			Median	1.0	1.0	1.0	1.0
			Min, Max	1, 2	1, 1	1, 1	1, 2
Pre-Randomization Period	Day -1	THSm2.2	n	0	0	0	0
			Mean (SD)				
			95% CI				
			Median				
			Min, Max				
		mCC	n	78	42	40	160
			Mean (SD)	11.5 (3.33)	11.3 (4.69)	11.8 (3.48)	11.5 (3.75)
			95% CI	11, 12	10, 13	11, 13	11, 12
			Median	12.0	11.0	11.5	11.0
			Min, Max	4, 19	4, 25	4, 18	4, 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: Confinement period is defined as period from Day -2 to Day 6.

Note: n indicates the number of reporting subjects.

Appendix: 15.3.2.1.1, 15.3.2.1.2

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**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period - FAS**

Occasion	Visit	Product Use	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
Randomization Period	Day 0	THSm2.2	n	0	0	0	0
			Mean (SD)				
			95% CI				
			Median				
			Min, Max				
		mCC	n	78	42	40	160
			Mean (SD)	13.0 (3.83)	12.5 (3.87)	12.9 (3.93)	12.8 (3.84)
			95% CI	12, 14	11, 14	12, 14	12, 13
			Median	13.0	12.0	12.0	12.0
			Min, Max	4, 22	5, 24	7, 24	4, 24
	Day 1	THSm2.2	n	78	0	0	78
			Mean (SD)	11.4 (3.90)			11.4 (3.90)
			95% CI	11, 12			11, 12
			Median	11.0			11.0
			Min, Max	4, 24			4, 24
		mCC	n	0	42	0	42
			Mean (SD)		11.0 (4.01)		11.0 (4.01)
			95% CI		10, 12		10, 12
			Median		10.0		10.0
			Min, Max		5, 25		5, 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: Confinement period is defined as period from Day -2 to Day 6.

Note: n indicates the number of reporting subjects.

Appendix: 15.3.2.1.1, 15.3.2.1.2

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**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period - FAS**

Occasion	Visit	Product Use	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
Day 2	THSm2.2		n	77	0	0	77
			Mean (SD)	12.0 (4.12)			12.0 (4.12)
			95% CI	11, 13			11, 13
			Median	11.0			11.0
			Min, Max	3, 28			3, 28
	mCC		n	0	41	0	41
			Mean (SD)		12.5 (4.16)		12.5 (4.16)
			95% CI		11, 14		11, 14
			Median		11.0		11.0
			Min, Max		7, 25		7, 25
	THSm2.2		n	77	0	0	77
			Mean (SD)	12.2 (3.74)			12.2 (3.74)
			95% CI	11, 13			11, 13
			Median	11.0			11.0
			Min, Max	5, 21			5, 21
	mCC		n	0	41	0	41
			Mean (SD)		12.1 (4.17)		12.1 (4.17)
			95% CI		11, 13		11, 13
			Median		11.0		11.0
			Min, Max		7, 23		7, 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: Confinement period is defined as period from Day -2 to Day 6.

Note: n indicates the number of reporting subjects.

Appendix: 15.3.2.1.1, 15.3.2.1.2

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**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period - FAS**

Occasion	Visit	Product Use	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
	Day 4	THSm2.2	n	77	0	0	77
			Mean (SD)	12.4 (3.82)			12.4 (3.82)
			95% CI	12, 13			12, 13
			Median	12.0			12.0
			Min, Max	5, 21			5, 21
		mCC	n	0	41	0	41
			Mean (SD)		11.3 (3.96)		11.3 (3.96)
			95% CI		10, 13		10, 13
			Median		10.0		10.0
			Min, Max		6, 25		6, 25
	Day 5	THSm2.2	n	77	0	0	77
			Mean (SD)	14.0 (4.31)			14.0 (4.31)
			95% CI	13, 15			13, 15
			Median	13.0			13.0
			Min, Max	6, 22			6, 22
		mCC	n	0	41	0	41
			Mean (SD)		13.6 (4.68)		13.6 (4.68)
			95% CI		12, 15		12, 15
			Median		12.0		12.0
			Min, Max		6, 24		6, 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: Confinement period is defined as period from Day -2 to Day 6.

Note: n indicates the number of reporting subjects.

Appendix: 15.3.2.1.1, 15.3.2.1.2

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**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period - FAS**

Occasion	Visit	Product Use	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall FAS (N=160)
	Day 6/Discharge Confinement	THSm2.2	n	77	0	0	77
			Mean (SD)	4.9 (1.59)			4.9 (1.59)
			95% CI	5, 5			5, 5
			Median	5.0			5.0
			Min, Max	2, 10			2, 10
		mCC	n	0	41	0	41
			Mean (SD)		4.5 (1.74)		4.5 (1.74)
			95% CI		4, 5		4, 5
			Median		4.0		4.0
			Min, Max		1, 9		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).

Note: Confinement period is defined as period from Day -2 to Day 6.

Note: n indicates the number of reporting subjects.

Appendix: 15.3.2.1.1, 15.3.2.1.2

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**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period - PP Set**

Occasion	Visit (Study Day)	Product Use	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
THSm2.2 Test	Day -2	THSm2.2	n	76	42	39	157
		1	n (%)	75 (98.7)	42 (100)	39 (100)	156 (99.4)
		2	n (%)	1 (1.3)	0	0	1 (0.6)
		3	n (%)	0	0	0	0
			Mean (SD)	1.0 (0.12)	1.0 (0.00)	1.0 (0.00)	1.0 (0.08)
			95% CI	1, 1	1, 1	1, 1	1, 1
			Median	1.0	1.0	1.0	1.0
			Min, Max	1, 2	1, 1	1, 1	1, 2
Pre-Randomization Period	Day -1	THSm2.2	n	0	0	0	0
			Mean (SD)				
			95% CI				
			Median				
			Min, Max				
		mCC	n	76	42	39	157
			Mean (SD)	11.6 (3.31)	11.3 (4.69)	11.7 (3.51)	11.5 (3.75)
			95% CI	11, 12	10, 13	11, 13	11, 12
			Median	12.0	11.0	11.0	11.0
			Min, Max	4, 19	4, 25	4, 18	4, 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: Confinement period is defined as period from Day -2 to Day 6.

Note: n indicates the number of reporting subjects.

Appendix: 15.3.2.1.1, 15.3.2.1.2

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**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period - PP Set**

Occasion	Visit (Study Day)	Product Use	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Randomization Period	Day 0	THSm2.2	n	0	0	0	0
			Mean (SD)				
			95% CI				
			Median				
			Min, Max				
		mCC	n	76	42	39	157
			Mean (SD)	13.1 (3.83)	12.5 (3.87)	12.8 (3.95)	12.8 (3.85)
			95% CI	12, 14	11, 14	11, 14	12, 13
			Median	13.0	12.0	12.0	12.0
			Min, Max	4, 22	5, 24	7, 24	4, 24
	Day 1	THSm2.2	n	76	0	0	76
			Mean (SD)	11.4 (3.91)			11.4 (3.91)
			95% CI	11, 12			11, 12
			Median	11.0			11.0
			Min, Max	4, 24			4, 24
		mCC	n	0	42	0	42
			Mean (SD)		11.0 (4.01)		11.0 (4.01)
			95% CI		10, 12		10, 12
			Median		10.0		10.0
			Min, Max		5, 25		5, 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: Confinement period is defined as period from Day -2 to Day 6.

Note: n indicates the number of reporting subjects.

Appendix: 15.3.2.1.1, 15.3.2.1.2

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**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period - PP Set**

Occasion	Visit (Study Day)	Product Use	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Day 2	THSm2.2		n	76	0	0	76
			Mean (SD)	12.0 (4.14)			12.0 (4.14)
			95% CI	11, 13			11, 13
			Median	11.0			11.0
			Min, Max	3, 28			3, 28
	mCC		n	0	41	0	41
			Mean (SD)		12.5 (4.16)		12.5 (4.16)
			95% CI		11, 14		11, 14
			Median		11.0		11.0
			Min, Max		7, 25		7, 25
Day 3	THSm2.2		n	76	0	0	76
			Mean (SD)	12.1 (3.76)			12.1 (3.76)
			95% CI	11, 13			11, 13
			Median	11.0			11.0
			Min, Max	5, 21			5, 21
	mCC		n	0	41	0	41
			Mean (SD)		12.1 (4.17)		12.1 (4.17)
			95% CI		11, 13		11, 13
			Median		11.0		11.0
			Min, Max		7, 23		7, 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: Confinement period is defined as period from Day -2 to Day 6.

Note: n indicates the number of reporting subjects.

Appendix: 15.3.2.1.1, 15.3.2.1.2

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**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period - PP Set**

Occasion	Visit (Study Day)	Product Use	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
Day 4	THSm2.2		n	76	0	0	76
			Mean (SD)	12.4 (3.84)			12.4 (3.84)
			95% CI	12, 13			12, 13
			Median	11.5			11.5
			Min, Max	5, 21			5, 21
	mCC		n	0	41	0	41
			Mean (SD)		11.3 (3.96)		11.3 (3.96)
			95% CI		10, 13		10, 13
			Median		10.0		10.0
			Min, Max		6, 25		6, 25
Day 5	THSm2.2		n	76	0	0	76
			Mean (SD)	13.9 (4.33)			13.9 (4.33)
			95% CI	13, 15			13, 15
			Median	13.0			13.0
			Min, Max	6, 22			6, 22
	mCC		n	0	41	0	41
			Mean (SD)		13.6 (4.68)		13.6 (4.68)
			95% CI		12, 15		12, 15
			Median		12.0		12.0
			Min, Max		6, 24		6, 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: Confinement period is defined as period from Day -2 to Day 6.

Note: n indicates the number of reporting subjects.

Appendix: 15.3.2.1.1, 15.3.2.1.2

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**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period - PP Set**

Occasion	Visit (Study Day)	Product Use	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)	Overall PP Set (N=157)
	Day 6/Discharge Confinement	THSm2.2	n	76	0	0	76
			Mean (SD)	4.9 (1.60)			4.9 (1.60)
			95% CI	5, 5			5, 5
			Median	5.0			5.0
			Min, Max	2, 10			2, 10
		mCC	n	0	41	0	41
			Mean (SD)		4.5 (1.74)		4.5 (1.74)
			95% CI		4, 5		4, 5
			Median		4.0		4.0
			Min, Max		1, 9		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).

Note: Confinement period is defined as period from Day -2 to Day 6.

Note: n indicates the number of reporting subjects.

Appendix: 15.3.2.1.1, 15.3.2.1.2

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
THSm2.2 sticks	Period 2	n (%)	76 (98.7)	NA	NA
		Mean (SD)	18.1 (8.19)		
		95% CI	16.2, 20.1		
		Median	18.0		
		Min, Max	0, 44		
	Period 3	n (%)	76 (98.7)	NA	NA
		Mean (SD)	18.3 (8.11)		
		95% CI	16.4, 20.2		
		Median	19.0		
		Min, Max	0, 36		
	Period 4	n (%)	76 (98.7)	NA	NA
		Mean (SD)	19.0 (10.84)		
		95% CI	16.5, 21.6		
		Median	17.0		
		Min, Max	0, 63		
	Overall ambulatory period	n (%)	76 (98.7)	NA	NA
		Mean (SD)	21.5 (10.53)		
		95% CI	19.0, 23.9		
		Median	20.5		
		Min, Max	0, 63		

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]).

NA=Not applicable

Appendix: 15.3.2.1.3

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
CC/mCC	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.12)	19.6 (6.76)	0.1 (0.33)
		95% CI	-0.1, 0.1	17.4, 21.8	-0.1, 0.2
		Median	0.0	17.0	0.0
		Min, Max	0, 1	11, 40	0, 2
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.35)	21.7 (7.82)	0.0 (0.00)
		95% CI	-0.1, 0.2	19.2, 24.2	0.0, 0.0
		Median	0.0	19.0	0.0
		Min, Max	0, 3	12, 52	0, 0
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	21.1 (7.28)	0.0 (0.00)
		95% CI	0.0, 0.0	18.8, 23.4	0.0, 0.0
		Median	0.0	21.0	0.0
		Min, Max	0, 0	10, 52	0, 0
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.1 (0.37)	23.0 (8.02)	0.1 (0.33)
		95% CI	-0.1, 0.2	20.4, 25.6	-0.1, 0.2
		Median	0.0	22.0	0.0
		Min, Max	0, 3	12, 52	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]).

NA=Not applicable

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Inhaler	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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]).

NA=Not applicable

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Nasal Spray	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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]).

NA=Not applicable

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Gums	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.5 (1.32)
		95% CI	0.0, 0.0	0.0, 0.0	0.1, 1.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 6
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.9 (1.88)
		95% CI	0.0, 0.0	0.0, 0.0	0.3, 1.6
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 7
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	1.1 (2.01)
		95% CI	0.0, 0.0	0.0, 0.0	0.4, 1.8
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 7
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	1.2 (2.12)
		95% CI	0.0, 0.0	0.0, 0.0	0.4, 1.9
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 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]).

NA=Not applicable

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Lozenges	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.23)
		95% CI	0.0, 0.0	0.0, 0.0	-0.1, 0.2
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 1
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.23)
		95% CI	0.0, 0.0	0.0, 0.0	-0.1, 0.2
		Median	0.0	0.0	0.0
		Min, Max	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]).

NA=Not applicable

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Patches	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.6 (2.26)
		95% CI	0.0, 0.0	0.0, 0.0	-0.2, 1.3
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 14
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.49)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.4
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 2
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.3 (0.51)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.5
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 2
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.6 (2.26)
		95% CI	0.0, 0.0	0.0, 0.0	-0.2, 1.4
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 14

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]).

NA=Not applicable

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Other NRT Products	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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]).

NA=Not applicable

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Chewable/Smokeless Tobacco	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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]).

NA=Not applicable

Appendix: 15.3.2.1.3

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Cigars/Cigarillos	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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]).

NA=Not applicable

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Pipes	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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]).

NA=Not applicable

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Tobacco Not Listed Previously	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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]).

NA=Not applicable

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**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period - FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=77)	mCC (N=41)	SA (N=39)
Electronic Cigarette	Period 2	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	2.6 (7.48)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.9, 4.4	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 40	0, 0	0, 0
	Period 3	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	1.8 (5.88)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.4, 3.2	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 28	0, 0	0, 0
	Period 4	n (%)	76 (98.7)	41 (100)	38 (97.4)
		Mean (SD)	1.5 (5.74)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.1, 2.8	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 31	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (98.7)	41 (100)	39 (100)
		Mean (SD)	2.9 (7.87)	0.0 (0.00)	0.0 (0.00)
		95% CI	1.1, 4.8	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 40	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]).

NA=Not applicable

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**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=78)	mCC (N=42)	SA (N=40)
THSm2.2 Sticks	Period 2	n (%)	76 (97.4)	NA	NA
		Mean (SD)	11.6 (6.11)		
		95% CI	10.2, 13.1		
		Median	11.0		
		Min, Max	0, 26		
	Period 3	n (%)	76 (97.4)	NA	NA
		Mean (SD)	12.2 (6.42)		
		95% CI	10.7, 13.8		
		Median	11.8		
		Min, Max	0, 27		
	Period 4	n (%)	76 (97.4)	NA	NA
		Mean (SD)	12.3 (6.65)		
		95% CI	10.8, 13.9		
		Median	11.8		
		Min, Max	0, 29		
	Overall ambulatory period	n (%)	76 (97.4)	NA	NA
		Mean (SD)	12.1 (6.16)		
		95% CI	10.6, 13.6		
		Median	11.8		
		Min, Max	0, 27		

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).

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**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=78)	mCC (N=42)	SA (N=40)
CC/mCC	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.01)	13.8 (4.16)	0.0 (0.02)
		95% CI	-0.1, 0.1	12.5, 15.2	-0.1, 0.1
		Median	0.0	12.9	0.0
		Min, Max	0, 0	8, 24	0, 0
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.02)	14.9 (5.70)	0.0 (0.00)
		95% CI	-0.1, 0.1	13.0, 16.7	0.0, 0.0
		Median	0.0	14.2	0.0
		Min, Max	0, 0	7, 39	0, 0
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	15.2 (5.04)	0.0 (0.00)
		95% CI	0.0, 0.0	13.5, 16.8	0.0, 0.0
		Median	0.0	14.1	0.0
		Min, Max	0, 0	9, 35	0, 0
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.01)	14.7 (4.80)	0.0 (0.02)
		95% CI	-0.1, 0.1	13.1, 16.2	-0.1, 0.1
		Median	0.0	13.9	0.0
		Min, Max	0, 0	10, 32	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).

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**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=78)	mCC (N=42)	SA (N=40)
Inhaler	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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).

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**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=78)	mCC (N=42)	SA (N=40)
Nasal Spray	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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).

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**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=78)	mCC (N=42)	SA (N=40)
Gums	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.3 (0.83)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.6
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.5 (1.02)
		95% CI	0.0, 0.0	0.0, 0.0	0.1, 0.8
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.5 (1.18)
		95% CI	0.0, 0.0	0.0, 0.0	0.1, 0.9
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 5
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.4 (0.93)
		95% CI	0.0, 0.0	0.0, 0.0	0.1, 0.8
		Median	0.0	0.0	0.0
		Min, Max	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).

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**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=78)	mCC (N=42)	SA (N=40)
Lozenges	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.01)
		95% CI	0.0, 0.0	0.0, 0.0	-0.1, 0.1
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.01)
		95% CI	0.0, 0.0	0.0, 0.0	-0.1, 0.1
		Median	0.0	0.0	0.0
		Min, Max	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).

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**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=78)	mCC (N=42)	SA (N=40)
Patches	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.36)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.3
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 2
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.34)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.3
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 1
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.34)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.3
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 1
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.32)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.3
		Median	0.0	0.0	0.0
		Min, Max	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).

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**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=78)	mCC (N=42)	SA (N=40)
Other NRT	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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).

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**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=78)	mCC (N=42)	SA (N=40)
Chew/Smokeless Tob.	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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).

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**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=78)	mCC (N=42)	SA (N=40)
Cigar/Cigarillo	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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).

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**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=78)	mCC (N=42)	SA (N=40)
Pipes	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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).

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**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=78)	mCC (N=42)	SA (N=40)
Tob. Not Listed	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	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).

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**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=78)	mCC (N=42)	SA (N=40)
E-Cigarette	Period 2	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	1.4 (3.98)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.4, 2.4	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 17	0, 0	0, 0
	Period 3	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	0.9 (3.38)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.1, 1.7	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 16	0, 0	0, 0
	Period 4	n (%)	76 (97.4)	41 (97.6)	38 (95.0)
		Mean (SD)	0.9 (3.33)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 1.7	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 18	0, 0	0, 0
	Overall ambulatory period	n (%)	76 (97.4)	41 (97.6)	39 (97.5)
		Mean (SD)	1.0 (3.41)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.2, 1.9	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 16	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).

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**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
THSm2.2 Sticks	Period 2	N	74	NA	NA
		n (%)	74 (100)		
		Mean (SD)	11.7 (5.95)		
		95% CI	10.2, 13.1		
		Median	11.0		
		Min, Max	0, 26		
	Period 3	N	71	NA	NA
		n (%)	71 (100)		
		Mean (SD)	12.7 (6.25)		
		95% CI	11.1, 14.2		
		Median	11.9		
		Min, Max	0, 27		
	Period 4	N	70	NA	NA
		n (%)	70 (100)		
		Mean (SD)	12.7 (6.48)		
		95% CI	11.2, 14.3		
		Median	12.0		
		Min, Max	0, 29		
	Overall ambulatory period	N	67	NA	NA
		n (%)	67 (100)		
		Mean (SD)	12.8 (5.79)		
		95% CI	11.3, 14.2		
		Median	12.1		
		Min, Max	0, 27		

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

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).

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**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
CC/mCC	Period 2	N	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.01)	13.8 (4.16)	0.0 (0.02)
		95% CI	-0.1, 0.1	12.5, 15.2	-0.1, 0.1
		Median	0.0	12.9	0.0
		Min, Max	0, 0	8, 24	0, 0
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	14.9 (5.70)	0.0 (0.00)
		95% CI	0.0, 0.0	13.0, 16.7	0.0, 0.0
		Median	0.0	14.2	0.0
		Min, Max	0, 0	7, 39	0, 0
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	15.2 (5.04)	0.0 (0.00)
		95% CI	0.0, 0.0	13.5, 16.8	0.0, 0.0
		Median	0.0	14.1	0.0
		Min, Max	0, 0	9, 35	0, 0
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.01)	14.7 (4.80)	0.0 (0.00)
		95% CI	-0.1, 0.1	13.1, 16.2	0.0, 0.0
		Median	0.0	13.9	0.0
		Min, Max	0, 0	10, 32	0, 0

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

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).

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**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	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0

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

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).

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**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	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0

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

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).

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**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 2	N	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.3 (0.83)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.6
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.5 (1.03)
		95% CI	0.0, 0.0	0.0, 0.0	0.1, 0.9
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.5 (1.19)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.9
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 5
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.4 (0.94)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.8
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4

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

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).

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**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 2	N	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.01)
		95% CI	0.0, 0.0	0.0, 0.0	-0.1, 0.1
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.01)
		95% CI	0.0, 0.0	0.0, 0.0	-0.1, 0.1
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0

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

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).

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**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	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.36)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.3
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 2
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.34)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.3
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 1
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.35)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.3
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 1
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.33)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.3
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 1

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

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).

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**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 2	N	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0

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

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).

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**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	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0

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

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).

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**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 2	N	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0

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

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).

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**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 2	N	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0

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

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).

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**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	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0

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

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).

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**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	74	41	39
		n (%)	74 (100)	41 (100)	39 (100)
		Mean (SD)	1.3 (3.76)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.3, 2.2	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 17	0, 0	0, 0
	Period 3	N	71	41	38
		n (%)	71 (100)	41 (100)	38 (100)
		Mean (SD)	0.8 (3.13)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 1.6	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 16	0, 0	0, 0
	Period 4	N	70	41	37
		n (%)	70 (100)	41 (100)	37 (100)
		Mean (SD)	0.7 (3.09)	0.0 (0.00)	0.0 (0.00)
		95% CI	-0.1, 1.5	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 18	0, 0	0, 0
	Overall ambulatory period	N	67	41	37
		n (%)	67 (100)	41 (100)	37 (100)
		Mean (SD)	0.7 (2.58)	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 1.3	0.0, 0.0	0.0, 0.0
		Median	0.0	0.0	0.0
		Min, Max	0, 15	0, 0	0, 0

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

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).

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**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	78	78	78	78	78
THS 2.2 ([70-100]%)	71 (91.0)	69 (88.5)	68 (87.2)	69 (88.5)	71 (91.0)
Exclusively THS 2.2 (100%)	64 (82.1)	66 (84.6)	66 (84.6)	59 (75.6)	62 (79.5)
Primarily THS 2.2 ([95-100]%)	71 (91.0)	69 (88.5)	67 (85.9)	67 (85.9)	71 (91.0)
Predominantly THS 2.2 ([70-95]%)	0	0	1 (1.3)	2 (2.6)	0
Dual ([30-70]%)	0	2 (2.6)	2 (2.6)	2 (2.6)	0
Dual mostly THS 2.2 ([60-70]%)	0	0	0	1 (1.3)	0
Dual balanced ([40-60]%)	0	2 (2.6)	2 (2.6)	1 (1.3)	0
Dual mostly CC ([30-40]%)	0	0	0	0	0
CC ([0-30]%)	2 (2.6)	2 (2.6)	3 (3.8)	1 (1.3)	0
Predominantly CC ([5-30]%)	0	0	1 (1.3)	0	0
Primarily CC ([0-5]%)	2 (2.6)	2 (2.6)	2 (2.6)	1 (1.3)	0
Exclusively CC (0%)	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)	0
Abstinent	0	0	0	0	0
Predominantly Abstinent	0	0	0	0	0
Not Abstinent	4 (5.1)	4 (5.1)	4 (5.1)	5 (6.4)	5 (6.4)
Missing	0	0	0	0	1 (1.3)
Discontinued in previous period	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)

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 refer to the total number of subjects per arm.

Note: Discontinued in previous period for Ambulatory refers to subjects discontinued before period 4.

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**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	42	42	42	42	42
CC	41 (97.6)	41 (97.6)	41 (97.6)	41 (97.6)	41 (97.6)
CC Only (Exclusively CC)	41 (97.6)	41 (97.6)	41 (97.6)	41 (97.6)	41 (97.6)
CC Dual (Use of other products)	0	0	0	0	0
Missing	0	0	0	0	0
Discontinued in previous period	1 (2.4)	1 (2.4)	1 (2.4)	1 (2.4)	1 (2.4)
SA Arm	40	40	40	40	40
Abstinent	38 (95.0)	38 (95.0)	37 (92.5)	37 (92.5)	38 (95.0)
Predominantly Abstinent	1 (2.5)	0	0	0	1 (2.5)
Not Abstinent	0	1 (2.5)	1 (2.5)	1 (2.5)	0
Missing	0	0	0	0	0
Discontinued in previous period	1 (2.5)	1 (2.5)	2 (5.0)	2 (5.0)	1 (2.5)

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 refer to the total number of subjects per arm.

Note: Discontinued in previous period for Ambulatory refers to subjects discontinued before period 4.

Appendix: 15.3.2.1.3

Study ID: ZRHM-REXA-07-JP

Program: t15020204-ZRHM-REXA-07-JP-v3.0.sas

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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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
THSm2.2	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	12.5 (5.45)	NC	NC	0.0 (0.00)	11.6 (6.11)
		95% CI	11.1, 13.8	NC	NC	0.0, 0.0	10.2, 13.1
		Median	11.3	NC	NC	0.0	11.0
		Min, Max	0, 26	NC	NC	0, 0	0, 26
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	13.4 (5.61)	NC	NC	0.0 (0.00)	12.2 (6.42)
		95% CI	12.0, 14.7	NC	NC	0.0, 0.0	10.7, 13.8
		Median	12.0	NC	NC	0.0	11.8
		Min, Max	3, 27	NC	NC	0, 0	0, 27
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	13.5 (5.83)	NC	NC	0.0 (0.00)	12.3 (6.65)
		95% CI	12.1, 15.0	NC	NC	0.0, 0.0	10.8, 13.9
		Median	12.1	NC	NC	0.0	11.8
		Min, Max	3, 29	NC	NC	0, 0	0, 29
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	13.2 (5.31)	NC	NC	0.0 (0.00)	12.1 (6.16)
		95% CI	11.9, 14.5	NC	NC	0.0, 0.0	10.6, 13.6
		Median	12.2	NC	NC	0.0	11.8
		Min, Max	4, 27	NC	NC	0, 0	0, 27

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

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]).

Appendix: 15.3.2.1.3

Study ID:ZRHM-REXA-07-JP

Program: t1502020501-ZRHM-REXA-07-JP-v3.0.sas

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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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
CC/mCC	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.01)	NC	NC	0.0 (0.00)	0.0 (0.01)
		95% CI	-0.1, 0.1	NC	NC	0.0, 0.0	-0.1, 0.1
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.02)	NC	NC	0.0 (0.00)	0.0 (0.02)
		95% CI	-0.1, 0.1	NC	NC	0.0, 0.0	-0.1, 0.1
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.01)	NC	NC	0.0 (0.00)	0.0 (0.01)
		95% CI	-0.1, 0.1	NC	NC	0.0, 0.0	-0.1, 0.1
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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]).

Appendix: 15.3.2.1.3

Study ID:ZRHM-REXA-07-JP

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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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Inhaler	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Nasal Spray	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Gums	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Lozenges	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Patches	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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]).

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				Overall THSm2.2 (N=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Other NRT	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Chew/Smokeless Tob.	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Cigar/Cigarillo	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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=78)
			THS 2.2 [70-100%]	Dual Use]30-70%[CC [0-30%]	Not Abstinent	
Pipes	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Tob. Not Listed	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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=78)
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
E-Cigarette	Period 2	n	71	0	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.6 (2.23)	NC	NC	13.3 (4.92)	1.4 (3.98)
		95% CI	0.0, 1.1	NC	NC	5.4, 21.1	0.4, 2.4
		Median	0.0	NC	NC	14.8	0.0
		Min, Max	0, 11	NC	NC	6, 17	0, 17
	Period 3	n	69	2	1	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.24)	NC	NC	13.0 (3.88)	0.9 (3.38)
		95% CI	-0.1, 0.1	NC	NC	6.8, 19.2	0.1, 1.7
		Median	0.0	NC	NC	14.4	0.0
		Min, Max	0, 2	NC	NC	7, 16	0, 16
	Period 4	n	68	2	2	4	76
		Missing	0	0	1	0	1
		Mean (SD)	0.0 (0.19)	NC	NC	12.4 (5.20)	0.9 (3.33)
		95% CI	-0.1, 0.1	NC	NC	4.1, 20.7	0.0, 1.7
		Median	0.0	NC	NC	13.1	0.0
		Min, Max	0, 2	NC	NC	5, 18	0, 18
	Overall Ambulatory	n	69	2	0	5	76
		Missing	0	0	1	0	1
		Mean (SD)	0.2 (0.69)	NC	NC	13.1 (3.91)	1.0 (3.41)
		95% CI	0.0, 0.4	NC	NC	8.2, 18.0	0.2, 1.9
		Median	0.0	NC	NC	14.6	0.0
		Min, Max	0, 3	NC	NC	6, 16	0, 16

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
CC/mCC	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	13.8 (4.16)	NC	13.8 (4.16)
		95% CI	12.5, 15.2	NC	12.5, 15.2
		Median	12.9	NC	12.9
		Min, Max	8, 24	NC	8, 24
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	14.9 (5.70)	NC	14.9 (5.70)
		95% CI	13.0, 16.7	NC	13.0, 16.7
		Median	14.2	NC	14.2
		Min, Max	7, 39	NC	7, 39
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	15.2 (5.04)	NC	15.2 (5.04)
		95% CI	13.5, 16.8	NC	13.5, 16.8
		Median	14.1	NC	14.1
		Min, Max	9, 35	NC	9, 35
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	14.7 (4.80)	NC	14.7 (4.80)
		95% CI	13.1, 16.2	NC	13.1, 16.2
		Median	13.9	NC	13.9
		Min, Max	10, 32	NC	10, 32

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
Inhaler	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
Nasal Spray	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
Gums	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
Lozenges	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
Patches	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
Other NRT	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
Chew/Smokeless Tob.	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
Cigar/Cigarillo	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
Pipes	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
Tob. Not Listed	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	mCC Product Use Category		Total mCC arm (N=42)
			Exclusively CC	Use of other products	
E-Cigarette	Period 2	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Overall Ambulatory	n	41	0	41
		Missing	0	0	0
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
CC/mCC	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.02)
		95% CI	0.0, 0.0	NC	NC	-0.1, 0.1
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Inhaler	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Nasal Spray	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Gums	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.3 (0.84)	NC	NC	0.3 (0.83)
		95% CI	0.0, 0.6	NC	NC	0.0, 0.6
		Median	0.0	NC	NC	0.0
		Min, Max	0, 4	NC	NC	0, 4
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.5 (1.03)	NC	NC	0.5 (1.02)
		95% CI	0.1, 0.9	NC	NC	0.1, 0.8
		Median	0.0	NC	NC	0.0
		Min, Max	0, 4	NC	NC	0, 4
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.5 (1.19)	NC	NC	0.5 (1.18)
		95% CI	0.0, 0.9	NC	NC	0.1, 0.9
		Median	0.0	NC	NC	0.0
		Min, Max	0, 5	NC	NC	0, 5
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.4 (0.94)	NC	NC	0.4 (0.94)
		95% CI	0.0, 0.8	NC	NC	0.1, 0.8
		Median	0.0	NC	NC	0.0
		Min, Max	0, 4	NC	NC	0, 4

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

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Lozenges	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.01)	NC	NC	0.0 (0.01)
		95% CI	-0.1, 0.1	NC	NC	-0.1, 0.1
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.01)	NC	NC	0.0 (0.01)
		95% CI	-0.1, 0.1	NC	NC	-0.1, 0.1
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Patches	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.1 (0.37)	NC	NC	0.1 (0.36)
		95% CI	0.0, 0.3	NC	NC	0.0, 0.3
		Median	0.0	NC	NC	0.0
		Min, Max	0, 2	NC	NC	0, 2
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.2 (0.34)	NC	NC	0.2 (0.34)
		95% CI	0.0, 0.3	NC	NC	0.0, 0.3
		Median	0.0	NC	NC	0.0
		Min, Max	0, 1	NC	NC	0, 1
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.2 (0.35)	NC	NC	0.2 (0.34)
		95% CI	0.0, 0.3	NC	NC	0.0, 0.3
		Median	0.0	NC	NC	0.0
		Min, Max	0, 1	NC	NC	0, 1
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.2 (0.33)	NC	NC	0.1 (0.32)
		95% CI	0.0, 0.3	NC	NC	0.0, 0.3
		Median	0.0	NC	NC	0.0
		Min, Max	0, 1	NC	NC	0, 1

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

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Other NRT	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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]).

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Chew/Smokeless Tob.	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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]).

Appendix: 15.3.2.1.3

Study ID:ZRHM-REXA-07-JP

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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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Cigar/Cigarillo	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Pipes	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Tob. Not Listed	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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	SA Product Use Category			Total SA arm (N=40)
			Abstinent	Predominantly Abstinent	Not Abstinent	
E-Cigarette	Period 2	n	38	1	0	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	1	39
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Overall Ambulatory	n	37	0	1	38
		Missing	0	0	0	0
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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 15.2.2.5.2 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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
THSm2.2	Period 2	n	70	0	0	4	74
		Mean (SD)	12.3 (5.39)	NC	NC	0.0 (0.00)	11.7 (5.95)
		95% CI	11.0, 13.7	NC	NC	0.0, 0.0	10.2, 13.1
		Median	11.2	NC	NC	0.0	11.0
		Min, Max	0, 26	NC	NC	0, 0	0, 26
	Period 3	n	67	0	0	4	71
		Mean (SD)	13.4 (5.57)	NC	NC	0.0 (0.00)	12.7 (6.25)
		95% CI	12.0, 14.8	NC	NC	0.0, 0.0	11.1, 14.2
		Median	12.0	NC	NC	0.0	11.9
		Min, Max	3, 27	NC	NC	0, 0	0, 27
	Period 4	n	66	0	0	4	70
		Mean (SD)	13.5 (5.83)	NC	NC	0.0 (0.00)	12.7 (6.48)
		95% CI	12.0, 15.0	NC	NC	0.0, 0.0	11.2, 14.3
		Median	12.1	NC	NC	0.0	12.0
		Min, Max	3, 29	NC	NC	0, 0	0, 29

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

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**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
CC/mCC	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.01)	NC	NC	0.0 (0.00)	0.0 (0.01)
		95% CI	-0.1, 0.1	NC	NC	0.0, 0.0	-0.1, 0.1
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Inhaler	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Nasal Spray	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Gums	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Lozenges	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Patches	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

Study ID:ZRHM-REXA-07-JP

Program: t1502020502-ZRHM-REXA-07-JP-v3.0.sas

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**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Other NRT	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Chew/Smokeless Tob.	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Cigar/Cigarillo	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Pipes	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
Tob. Not Listed	Period 2	n	70	0	0	4	74
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0	0.0, 0.0
		Median	0.0	NC	NC	0.0	0.0
		Min, Max	0, 0	NC	NC	0, 0	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

**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
			THS 2.2 [70-100%]	Dual Use [30-70%]	CC [0-30%]	Not Abstinent	
E-Cigarette	Period 2	n	70	0	0	4	74
		Mean (SD)	0.6 (2.24)	NC	NC	13.3 (4.92)	1.3 (3.76)
		95% CI	0.0, 1.1	NC	NC	5.4, 21.1	0.3, 2.2
		Median	0.0	NC	NC	14.8	0.0
		Min, Max	0, 11	NC	NC	6, 17	0, 17
	Period 3	n	67	0	0	4	71
		Mean (SD)	0.0 (0.24)	NC	NC	13.0 (3.88)	0.8 (3.13)
		95% CI	-0.1, 0.1	NC	NC	6.8, 19.2	0.0, 1.6
		Median	0.0	NC	NC	14.4	0.0
		Min, Max	0, 2	NC	NC	7, 16	0, 16
	Period 4	n	66	0	0	4	70
		Mean (SD)	0.0 (0.20)	NC	NC	12.4 (5.20)	0.7 (3.09)
		95% CI	-0.1, 0.1	NC	NC	4.1, 20.7	-0.1, 1.5
		Median	0.0	NC	NC	13.1	0.0
		Min, Max	0, 2	NC	NC	5, 18	0, 18

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

**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		Total mCC arm
			Exclusively CC	Use of other products	
CC/mCC	Period 2	n	41	0	41
		Mean (SD)	13.8 (4.16)	NC	13.8 (4.16)
		95% CI	12.5, 15.2	NC	12.5, 15.2
		Median	12.9	NC	12.9
		Min, Max	8, 24	NC	8, 24
	Period 3	n	41	0	41
		Mean (SD)	14.9 (5.70)	NC	14.9 (5.70)
		95% CI	13.0, 16.7	NC	13.0, 16.7
		Median	14.2	NC	14.2
		Min, Max	7, 39	NC	7, 39
	Period 4	n	41	0	41
		Mean (SD)	15.2 (5.04)	NC	15.2 (5.04)
		95% CI	13.5, 16.8	NC	13.5, 16.8
		Median	14.1	NC	14.1
		Min, Max	9, 35	NC	9, 35

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

Study ID:ZRHM-REXA-07-JP

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**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		Total mCC arm
			Exclusively CC	Use of other products	
Inhaler	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

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**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		Total mCC arm
			Exclusively CC	Use of other products	
Nasal Spray	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

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**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		Total mCC arm
			Exclusively CC	Use of other products	
Gums	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

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**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		Total mCC arm
			Exclusively CC	Use of other products	
Lozenges	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

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**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		Total mCC arm
			Exclusively CC	Use of other products	
Patches	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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		Total mCC arm
			Exclusively CC	Use of other products	
Other NRT	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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		Total mCC arm
			Exclusively CC	Use of other products	
Chew/Smokeless Tob.	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

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**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		Total mCC arm
			Exclusively CC	Use of other products	
Cigar/Cigarillo	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

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**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		Total mCC arm
			Exclusively CC	Use of other products	
Pipes	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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		Total mCC arm
			Exclusively CC	Use of other products	
Tob. Not Listed	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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		Total mCC arm
			Exclusively CC	Use of other products	
E-Cigarette	Period 2	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 3	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0
	Period 4	n	41	0	41
		Mean (SD)	0.0 (0.00)	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	0.0, 0.0
		Median	0.0	NC	0.0
		Min, Max	0, 0	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
CC/mCC	Period 2	n	38	1	0	39
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.02)
		95% CI	0.0, 0.0	NC	NC	-0.1, 0.1
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	0	38
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	0	37
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
Inhaler	Period 2	n	38	1	0	39
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	0	38
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	0	37
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
Nasal Spray	Period 2	n	38	1	0	39
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	0	38
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	0	37
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
Gums	Period 2	n	38	1	0	39
		Mean (SD)	0.3 (0.84)	NC	NC	0.3 (0.83)
		95% CI	0.0, 0.6	NC	NC	0.0, 0.6
		Median	0.0	NC	NC	0.0
		Min, Max	0, 4	NC	NC	0, 4
	Period 3	n	38	0	0	38
		Mean (SD)	0.5 (1.03)	NC	NC	0.5 (1.03)
		95% CI	0.1, 0.9	NC	NC	0.1, 0.9
		Median	0.0	NC	NC	0.0
		Min, Max	0, 4	NC	NC	0, 4
	Period 4	n	37	0	0	37
		Mean (SD)	0.5 (1.19)	NC	NC	0.5 (1.19)
		95% CI	0.0, 0.9	NC	NC	0.0, 0.9
		Median	0.0	NC	NC	0.0
		Min, Max	0, 5	NC	NC	0, 5

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

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: summaries not provided for subject who discontinued in previous periods.

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
Lozenges	Period 2	n	38	1	0	39
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	0	38
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	0	37
		Mean (SD)	0.0 (0.01)	NC	NC	0.0 (0.01)
		95% CI	-0.1, 0.1	NC	NC	-0.1, 0.1
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
Patches	Period 2	n	38	1	0	39
		Mean (SD)	0.1 (0.37)	NC	NC	0.1 (0.36)
		95% CI	0.0, 0.3	NC	NC	0.0, 0.3
		Median	0.0	NC	NC	0.0
		Min, Max	0, 2	NC	NC	0, 2
	Period 3	n	38	0	0	38
		Mean (SD)	0.2 (0.34)	NC	NC	0.2 (0.34)
		95% CI	0.0, 0.3	NC	NC	0.0, 0.3
		Median	0.0	NC	NC	0.0
		Min, Max	0, 1	NC	NC	0, 1
	Period 4	n	37	0	0	37
		Mean (SD)	0.2 (0.35)	NC	NC	0.2 (0.35)
		95% CI	0.0, 0.3	NC	NC	0.0, 0.3
		Median	0.0	NC	NC	0.0
		Min, Max	0, 1	NC	NC	0, 1

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

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: summaries not provided for subject who discontinued in previous periods.

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
Other NRT	Period 2	n	38	1	0	39
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	0	38
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	0	37
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
Chew/Smokeless Tob.	Period 2	n	38	1	0	39
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	0	38
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	0	37
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
Cigar/Cigarillo	Period 2	n	38	1	0	39
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	0	38
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	0	37
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
Pipes	Period 2	n	38	1	0	39
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	0	38
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	0	37
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

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Program: t1502020502-ZRHM-REXA-07-JP-v3.0.sas

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
Tob. Not Listed	Period 2	n	38	1	0	39
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	0	38
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	0	37
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

Study ID:ZRHM-REXA-07-JP

Program: t1502020502-ZRHM-REXA-07-JP-v3.0.sas

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**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			Total SA arm
			Abstinent	Predominantly Abstinent	Not Abstinent	
E-Cigarette	Period 2	n	38	1	0	39
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 3	n	38	0	0	38
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0
	Period 4	n	37	0	0	37
		Mean (SD)	0.0 (0.00)	NC	NC	0.0 (0.00)
		95% CI	0.0, 0.0	NC	NC	0.0, 0.0
		Median	0.0	NC	NC	0.0
		Min, Max	0, 0	NC	NC	0, 0

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

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: summaries not provided for subject who discontinued in previous periods.

Appendix: 15.3.2.1.3

Study ID:ZRHM-REXA-07-JP

Program: t1502020502-ZRHM-REXA-07-JP-v3.0.sas

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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 and Day 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	76	42	
	Geometric LS Mean (CV%)	83.21	617.04	13.49 (58.68)
	95% CI	73.51, 94.19	521.87, 729.55	10.96, 16.60
	p-value (one-sided)			<.001
3-HPMA (ng/mg creat)				
Day 5	n	76	42	
	Geometric LS Mean (CV%)	304.56	601.11	50.67 (32.72)
	95% CI	283.22, 327.50	545.07, 662.91	44.88, 57.20
	p-value (one-sided)			<.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 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.

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 and Day 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	76	42	
	Geometric LS Mean (CV%)	119.18	1086.89	10.97 (46.63)
	95% CI	107.73, 131.85	948.47, 1245.51	9.26, 12.99
	p-value (one-sided)			<.001
COHb (%) Day 5	n	76	42	
	Geometric LS Mean (CV%)	2.47	5.49	44.94 (17.24)
	95% CI	2.37, 2.57	5.21, 5.79	42.11, 47.97
	p-value (one-sided)			<.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 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.

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 and Day 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 90	n	70	41	
	Geometric LS Mean (CV%)	22.48	96.65	23.25 (86.42)
	95% CI	18.82, 26.84	76.63, 121.90	17.38, 31.11
	p-value (one-sided)			<.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 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.

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 and Day 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	76	41	
	Geometric LS Mean (CV%)	83.31	624.33	13.34 (58.78)
	95% CI	73.59, 94.32	526.76, 739.97	10.82, 16.46
	p-value (one-sided)			<.001
3-HPMA (ng/mg creat)				
Day 5	n	76	41	
	Geometric LS Mean (CV%)	304.05	592.47	51.32 (32.54)
	95% CI	282.86, 326.84	536.87, 653.82	45.44, 57.96
	p-value (one-sided)			<.001

Note: Adjusted geometric 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; 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 15.2.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5 and Day 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	76	41	
	Geometric LS Mean (CV%)	119.55	1102.86	10.84 (46.61)
	95% CI	108.07, 132.25	960.79, 1265.93	9.14, 12.85
	p-value (one-sided)			<.001
COHb (%) Day 5	n	76	41	
	Geometric LS Mean (CV%)	2.47	5.49	44.93 (17.30)
	95% CI	2.37, 2.57	5.20, 5.80	42.06, 47.99
	p-value (one-sided)			<.001

Note: Adjusted geometric 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; 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 15.2.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5 and Day 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 90	n	69	41	
	Geometric LS Mean (CV%)	22.46	96.79	23.20 (86.81)
	95% CI	18.77, 26.87	76.68, 122.18	17.31, 31.10
	p-value (one-sided)			<.001

Note: Adjusted geometric 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; 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 15.2.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5 and Day 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	76	42	
	Geometric LS Mean (CV%)	83.21	617.04	13.49 (58.68)
	95% CI	73.51, 94.19	521.87, 729.55	10.96, 16.60
	p-value (one-sided)			<.001
3-HPMA (ng/mg creat)				
Day 5	n	76	42	
	Geometric LS Mean (CV%)	304.56	601.11	50.67 (32.72)
	95% CI	283.22, 327.50	545.07, 662.91	44.88, 57.20
	p-value (one-sided)			<.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 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.

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 and Day 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	76	42	
	Geometric LS Mean (CV%)	119.18	1086.89	10.97 (46.63)
	95% CI	107.73, 131.85	948.47, 1245.51	9.26, 12.99
	p-value (one-sided)			<.001
COHb (%) Day 5	n	76	42	
	Geometric LS Mean (CV%)	2.47	5.49	44.94 (17.24)
	95% CI	2.37, 2.57	5.21, 5.79	42.11, 47.97
	p-value (one-sided)			<.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 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.

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 and Day 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 90	n	65	41	
	Geometric LS Mean (CV%)	21.89	96.86	22.60 (85.85)
	95% CI	18.23, 26.29	76.88, 122.03	16.85, 30.32
	p-value (one-sided)			<.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 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.

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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	83.21	617.04	83.57	13.49 (58.68)	99.57 (58.68)
	95% CI	73.51, 94.19	521.87, 729.55	70.32, 99.32	10.96, 16.60	80.56, 123.06
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	143.17	753.25	141.28	19.01 (74.05)	101.34 (74.05)
	95% CI	122.39, 167.48	612.73, 926.00	113.86, 175.29	14.68, 24.61	77.68, 132.20
	p-value (one-sided)				<.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 = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	304.56	601.11	183.61	50.67 (32.72)	165.87 (32.72)
	95% CI	283.22, 327.50	545.07, 662.91	165.93, 203.18	44.88, 57.20	146.50, 187.81
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	385.25	712.32	278.13	54.08 (37.55)	138.52 (37.55)
	95% CI	353.42, 419.96	636.26, 797.48	247.06, 313.10	46.94, 62.32	119.70, 160.30
	p-value (one-sided)				<.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 = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	119.18	1086.89	104.83	10.97 (46.63)	113.70 (46.63)
	95% CI	107.73, 131.85	948.47, 1245.51	91.07, 120.66	9.26, 12.99	95.67, 135.12
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	148.85	1162.70	150.69	12.80 (74.27)	98.78 (74.27)
	95% CI	127.20, 174.18	945.94, 1429.12	121.40, 187.04	9.88, 16.58	75.68, 128.94
	p-value (one-sided)				<.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 = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	2.47	5.49	2.49	44.94 (17.24)	99.31 (17.24)
	95% CI	2.37, 2.57	5.21, 5.79	2.35, 2.63	42.11, 47.97	92.91, 106.15
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	2.96	5.73	3.05	51.72 (18.97)	97.10 (18.97)
	95% CI	2.83, 3.10	5.40, 6.08	2.87, 3.25	48.07, 55.65	90.03, 104.72
	p-value (one-sided)				<.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 = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	36.95	84.57	30.89	43.69 (26.09)	119.61 (26.09)
	95% CI	34.85, 39.17	78.17, 91.51	28.47, 33.51	39.62, 48.17	108.23, 132.19
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	22.48	96.65	14.90	23.25 (86.42)	150.85 (86.42)
	95% CI	18.82, 26.84	76.63, 121.90	11.67, 19.02	17.38, 31.11	111.62, 203.87
	p-value (one-sided)				<.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 = 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 and Day 90 Visit for THS 2.2 Menthol versus mCC and SA - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	85.65	616.72	85.93	13.89 (61.04)	99.68 (61.04)
	95% CI	75.46, 97.22	518.68, 733.30	72.05, 102.48	11.22, 17.19	80.29, 123.75
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	145.34	743.55	142.54	19.55 (73.56)	101.97 (73.56)
	95% CI	125.34, 168.53	607.34, 910.30	116.02, 175.11	15.23, 25.08	79.19, 131.30
	p-value (one-sided)				<.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 = 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 and Day 90 Visit for THS 2.2 Menthol versus mCC and SA - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ng/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	307.42	600.63	184.81	51.18 (32.79)	166.35 (32.79)
	95% CI	286.08, 330.34	544.54, 662.49	167.19, 204.28	45.35, 57.76	147.10, 188.11
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	383.27	720.83	272.29	53.17 (37.10)	140.76 (37.10)
	95% CI	353.51, 415.53	645.64, 804.77	243.30, 304.74	46.41, 60.91	122.59, 161.61
	p-value (one-sided)				<.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 = 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 and Day 90 Visit for THS 2.2 Menthol versus mCC and SA - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	122.35	1091.25	109.18	11.21 (50.66)	112.07 (50.66)
	95% CI	109.87, 136.25	942.34, 1263.69	94.01, 126.79	9.35, 13.44	93.26, 134.66
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	157.88	1146.25	151.39	13.77 (77.43)	104.28 (77.43)
	95% CI	135.31, 184.22	928.77, 1414.65	122.17, 187.60	10.62, 17.86	80.13, 135.71
	p-value (one-sided)				<.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 = 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 and Day 90 Visit for THS 2.2 Menthol versus mCC and SA - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
COHb (%) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	2.47	5.49	2.48	45.07 (17.15)	99.92 (17.15)
	95% CI	2.38, 2.58	5.20, 5.79	2.34, 2.62	42.26, 48.08	93.59, 106.69
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	2.98	5.72	2.97	52.13 (19.20)	100.36 (19.20)
	95% CI	2.85, 3.12	5.39, 6.07	2.80, 3.16	48.51, 56.03	93.28, 107.98
	p-value (one-sided)				<.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 = 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 and Day 90 Visit for THS 2.2 Menthol versus mCC and SA - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	37.40	84.49	31.18	44.27 (26.84)	119.96 (26.84)
	95% CI	35.24, 39.69	77.92, 91.61	28.70, 33.87	40.06, 48.92	108.39, 132.76
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	23.15	93.48	15.34	24.76 (87.86)	150.92 (87.86)
	95% CI	19.52, 27.45	74.12, 117.91	12.10, 19.44	18.59, 32.97	112.84, 201.85
	p-value (one-sided)				<.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 = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	83.21	617.04	83.57	13.49 (58.68)	99.57 (58.68)
	95% CI	73.51, 94.19	521.87, 729.55	70.32, 99.32	10.96, 16.60	80.56, 123.06
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	143.17	753.25	141.28	19.01 (74.05)	101.34 (74.05)
	95% CI	122.39, 167.48	612.73, 926.00	113.86, 175.29	14.68, 24.61	77.68, 132.20
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	304.56	601.11	183.61	50.67 (32.72)	165.87 (32.72)
	95% CI	283.22, 327.50	545.07, 662.91	165.93, 203.18	44.88, 57.20	146.50, 187.81
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	385.25	712.32	278.13	54.08 (37.55)	138.52 (37.55)
	95% CI	353.42, 419.96	636.26, 797.48	247.06, 313.10	46.94, 62.32	119.70, 160.30
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	119.18	1086.89	104.83	10.97 (46.63)	113.70 (46.63)
	95% CI	107.73, 131.85	948.47, 1245.51	91.07, 120.66	9.26, 12.99	95.67, 135.12
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	148.85	1162.70	150.69	12.80 (74.27)	98.78 (74.27)
	95% CI	127.20, 174.18	945.94, 1429.12	121.40, 187.04	9.88, 16.58	75.68, 128.94
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
COHb (%) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	2.47	5.49	2.49	44.94 (17.24)	99.31 (17.24)
	95% CI	2.37, 2.57	5.21, 5.79	2.35, 2.63	42.11, 47.97	92.91, 106.15
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	2.96	5.73	3.05	51.72 (18.97)	97.10 (18.97)
	95% CI	2.83, 3.10	5.40, 6.08	2.87, 3.25	48.07, 55.65	90.03, 104.72
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	36.95	84.57	30.89	43.69 (26.09)	119.61 (26.09)
	95% CI	34.85, 39.17	78.17, 91.51	28.47, 33.51	39.62, 48.17	108.23, 132.19
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	22.48	96.65	14.90	23.25 (86.42)	150.85 (86.42)
	95% CI	18.82, 26.84	76.63, 121.90	11.67, 19.02	17.38, 31.11	111.62, 203.87
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Exhaled CO (ppm)						
Day 5	n	76	42	39		
	LS Mean	2.29	15.39	3.14	-13.10	-0.85
	95% CI	1.33, 3.25	14.10, 16.68	1.81, 4.47	-14.70, -11.50	-2.49, 0.79
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	LS Mean	2.36	11.65	2.59	-9.28	-0.23
	95% CI	1.47, 3.26	10.47, 12.82	1.36, 3.83	-10.75, -7.81	-1.75, 1.29
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	47.34	120.83	43.17	39.18 (31.60)	109.65 (31.60)
	95% CI	44.12, 50.79	109.84, 132.91	39.14, 47.61	34.82, 44.07	97.23, 123.66
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	86.81	166.86	91.59	52.02 (39.54)	94.78 (39.54)
	95% CI	79.30, 95.02	148.10, 187.99	80.88, 103.72	44.83, 60.38	81.31, 110.48
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	1.18	4.38	0.15	27.02 (61.84)	786.46 (61.84)
	95% CI	1.03, 1.35	3.67, 5.22	0.12, 0.19	21.75, 33.55	630.18, 981.50
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	1.36	4.62	0.28	29.31 (94.14)	488.54 (94.14)
	95% CI	1.12, 1.64	3.60, 5.93	0.21, 0.36	21.48, 39.98	354.58, 673.12
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	1.96	9.76	2.28	20.10 (44.68)	86.22 (44.68)
	95% CI	1.78, 2.17	8.56, 11.14	1.98, 2.61	17.08, 23.64	72.93, 101.94
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	2.08	9.90	2.42	21.00 (57.87)	85.76 (57.87)
	95% CI	1.82, 2.37	8.37, 11.70	2.03, 2.89	17.02, 25.89	69.00, 106.60
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	3.12	54.64	2.98	5.70 (39.23)	104.70 (39.23)
	95% CI	2.85, 3.40	48.65, 61.38	2.63, 3.36	4.93, 6.59	90.26, 121.44
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	3.55	57.11	4.37	6.22 (81.42)	81.26 (81.42)
	95% CI	2.99, 4.21	45.75, 71.28	3.46, 5.52	4.70, 8.22	60.87, 108.47
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	1.97	14.43	2.15	13.66 (33.99)	91.67 (33.99)
	95% CI	1.82, 2.13	13.03, 15.97	1.93, 2.39	12.04, 15.49	80.53, 104.33
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	2.35	15.22	2.75	15.45 (47.02)	85.50 (47.02)
	95% CI	2.11, 2.62	13.24, 17.49	2.37, 3.19	12.98, 18.39	71.35, 102.45
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	40	39		
	Geometric LS Mean (CV%)	52.17	119.11	50.75	43.80 (50.51)	102.80 (50.51)
	95% CI	46.80, 58.15	102.11, 138.93	43.61, 59.04	36.31, 52.83	85.37, 123.79
	p-value (one-sided)				<.001	
Day 90	n	70	40	37		
	Geometric LS Mean (CV%)	69.75	117.90	79.95	59.16 (102.96)	87.24 (102.96)
	95% CI	57.01, 85.34	89.29, 155.68	60.58, 105.50	42.02, 83.29	61.98, 122.80
	p-value (one-sided)				0.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	12.43	68.18	11.61	18.23 (32.43)	107.03 (32.43)
	95% CI	11.56, 13.36	61.87, 75.13	10.50, 12.84	16.16, 20.56	94.63, 121.05
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	7.84	85.45	8.53	9.17 (78.11)	91.93 (78.11)
	95% CI	6.65, 9.24	68.95, 105.89	6.80, 10.68	7.01, 12.00	69.65, 121.33
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	1145.94	2285.36	1121.87	50.14 (34.79)	102.15 (34.79)
	95% CI	1060.99, 1237.70	2060.10, 2535.25	1007.81, 1248.84	44.09, 57.02	89.55, 116.51
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	1719.75	3825.31	1685.89	44.96 (51.89)	102.01 (51.89)
	95% CI	1531.39, 1931.28	3286.61, 4452.29	1437.75, 1976.85	37.17, 54.37	83.82, 124.15
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	20.79	76.46	18.80	27.19 (43.93)	110.59 (43.93)
	95% CI	18.89, 22.89	67.20, 86.99	16.45, 21.49	23.17, 31.91	93.84, 130.33
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	29.83	90.33	31.10	33.02 (68.71)	95.92 (68.71)
	95% CI	25.72, 34.59	74.45, 109.59	25.37, 38.12	25.92, 42.08	74.58, 123.38
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	126.41	293.61	115.40	43.06 (35.59)	109.54 (35.59)
	95% CI	116.85, 136.76	264.09, 326.43	103.43, 128.76	37.75, 49.10	95.76, 125.30
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	158.99	316.01	165.78	50.31 (42.22)	95.90 (42.22)
	95% CI	144.42, 175.02	278.62, 358.40	145.25, 189.21	42.96, 58.91	81.47, 112.89
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	2547.36	2967.89	2693.82	85.83 (30.78)	94.56 (30.78)
	95% CI	2378.56, 2728.13	2702.17, 3259.75	2447.67, 2964.72	76.49, 96.31	84.06, 106.38
	p-value (one-sided)				0.005	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	3335.21	2997.27	3635.94	111.27 (63.33)	91.73 (63.33)
	95% CI	2905.84, 3828.02	2496.25, 3598.86	3005.72, 4398.31	88.65, 139.67	72.53, 116.01
	p-value (one-sided)				0.823	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	6.06	5.23	0.16	116.00 (43.83)	3797.93 (43.83)
	95% CI	5.51, 6.68	4.59, 5.95	0.13, 0.19	98.91, 136.04	3225.82, 4471.49
	p-value (one-sided)				0.966	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	6.75	6.47	0.40	104.30 (165.93)	1695.18 (165.93)
	95% CI	5.13, 8.87	4.52, 9.25	0.27, 0.58	66.65, 163.20	1066.60, 2694.19

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (ng)						
Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	95.28	747.09	99.88	12.75 (62.25)	95.39 (62.25)
	95% CI	83.63, 108.54	626.63, 890.72	83.29, 119.78	10.25, 15.86	76.33, 119.20
	p-value (one-sided)				<.001	
Day 90						
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	158.79	796.02	155.67	19.95 (72.76)	102.01 (72.76)
	95% CI	136.04, 185.35	649.73, 975.23	125.84, 192.56	15.46, 25.73	78.49, 132.56
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ug) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	350.10	730.08	221.15	47.95 (36.50)	158.31 (36.50)
	95% CI	323.01, 379.46	654.82, 813.99	197.68, 247.40	41.91, 54.87	137.94, 181.68
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	425.55	757.13	305.62	56.21 (41.64)	139.24 (41.64)
	95% CI	387.05, 467.87	668.40, 857.65	268.26, 348.19	48.08, 65.70	118.57, 163.52
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	137.25	1329.96	126.09	10.32 (52.48)	108.85 (52.48)
	95% CI	122.66, 153.56	1143.16, 1547.27	107.83, 147.44	8.55, 12.45	89.83, 131.89
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	165.62	1236.20	166.08	13.40 (71.82)	99.73 (71.82)
	95% CI	142.13, 192.99	1011.58, 1510.69	134.58, 204.95	10.42, 17.23	76.95, 129.24
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (ng)						
Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	42.93	105.32	37.40	40.76 (31.11)	114.76 (31.11)
	95% CI	40.05, 46.01	95.94, 115.62	33.96, 41.20	36.31, 45.76	101.94, 129.19
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	25.09	103.75	16.45	24.18 (87.89)	152.53 (87.89)
	95% CI	20.97, 30.03	82.00, 131.26	12.84, 21.07	18.01, 32.48	112.44, 206.91
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	54.63	150.23	51.71	36.36 (40.91)	105.65 (40.91)
	95% CI	49.95, 59.76	133.13, 169.54	45.63, 58.60	31.30, 42.24	90.64, 123.15
	p-value (one-sided)				<.001	
Day 90						
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	96.19	178.23	100.49	53.97 (46.16)	95.72 (46.16)
	95% CI	86.66, 106.76	155.44, 204.37	87.06, 115.99	45.46, 64.06	80.22, 114.22
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	1.36	5.37	0.18	25.42 (65.12)	752.55 (65.12)
	95% CI	1.19, 1.57	4.46, 6.45	0.15, 0.22	20.27, 31.89	597.03, 948.57
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	1.51	4.96	0.31	30.43 (89.91)	494.06 (89.91)
	95% CI	1.25, 1.82	3.90, 6.30	0.23, 0.40	22.53, 41.09	362.51, 673.35
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	2.26	11.84	2.72	19.05 (48.26)	82.92 (48.26)
	95% CI	2.03, 2.51	10.28, 13.63	2.34, 3.15	16.00, 22.69	69.28, 99.24
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	2.28	10.42	2.68	21.91 (61.96)	85.16 (61.96)
	95% CI	1.99, 2.62	8.72, 12.45	2.22, 3.24	17.54, 27.36	67.64, 107.22
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (ng)						
Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	3.58	66.17	3.55	5.42 (43.82)	100.88 (43.82)
	95% CI	3.25, 3.95	58.17, 75.26	3.10, 4.07	4.61, 6.36	85.59, 118.91
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	3.89	60.52	4.87	6.43 (82.29)	79.91 (82.29)
	95% CI	3.27, 4.62	48.38, 75.69	3.84, 6.17	4.85, 8.52	59.75, 106.87
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	2.26	17.53	2.57	12.92 (38.35)	88.03 (38.35)
	95% CI	2.08, 2.47	15.64, 19.65	2.28, 2.90	11.21, 14.87	76.14, 101.77
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	2.59	16.05	3.05	16.13 (49.66)	84.76 (49.66)
	95% CI	2.31, 2.90	13.87, 18.58	2.61, 3.57	13.43, 19.37	70.11, 102.47
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (ng)						
Day 5	n	76	40	39		
	Geometric LS Mean (CV%)	59.98	144.15	60.86	41.61 (51.21)	98.55 (51.21)
	95% CI	53.73, 66.95	123.38, 168.42	52.21, 70.95	34.42, 50.30	81.66, 118.93
	p-value (one-sided)				<.001	
Day 90	n	70	40	37		
	Geometric LS Mean (CV%)	77.95	125.80	88.22	61.96 (100.63)	88.35 (100.63)
	95% CI	63.92, 95.07	95.72, 165.32	67.16, 115.90	44.26, 86.74	63.12, 123.67
	p-value (one-sided)				0.003	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ug) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	14.35	83.94	14.05	17.10 (36.94)	102.15 (36.94)
	95% CI	13.22, 15.57	75.20, 93.69	12.54, 15.74	14.92, 19.59	88.87, 117.42
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	8.72	91.35	9.40	9.55 (75.36)	92.79 (75.36)
	95% CI	7.43, 10.23	74.15, 112.54	7.55, 11.70	7.35, 12.40	70.86, 121.50
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	1326.41	2815.66	1357.47	47.11 (39.96)	97.71 (39.96)
	95% CI	1215.11, 1447.91	2502.07, 3168.56	1201.51, 1533.67	40.69, 54.54	84.12, 113.50
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	1917.63	4099.99	1859.03	46.77 (51.39)	103.15 (51.39)
	95% CI	1709.56, 2151.01	3527.46, 4765.45	1587.61, 2176.86	38.73, 56.48	84.91, 125.32
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	23.88	92.65	22.43	25.77 (46.59)	106.45 (46.59)
	95% CI	21.58, 26.42	80.87, 106.15	19.48, 25.84	21.77, 30.51	89.51, 126.58
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	33.09	95.73	34.17	34.56 (71.49)	96.83 (71.49)
	95% CI	28.40, 38.55	78.40, 116.89	27.69, 42.17	26.90, 44.40	74.69, 125.54
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ug)						
Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	144.79	354.72	138.15	40.82 (38.93)	104.80 (38.93)
	95% CI	132.91, 157.73	316.03, 398.15	122.63, 155.64	35.38, 47.09	90.54, 121.31
	p-value (one-sided)				<.001	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	175.12	334.68	183.32	52.32 (49.42)	95.53 (49.42)
	95% CI	156.74, 195.64	289.32, 387.16	157.37, 213.54	43.60, 62.79	79.15, 115.29
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (ng)						
Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	2942.90	3679.22	3227.72	79.99 (38.51)	91.18 (38.51)
	95% CI	2704.04, 3202.86	3279.99, 4127.05	2866.52, 3634.43	69.40, 92.19	78.83, 105.45
	p-value (one-sided)				0.001	
Day 90						
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	3742.58	3227.88	4035.26	115.95 (64.43)	92.75 (64.43)
	95% CI	3254.64, 4303.68	2684.82, 3880.80	3326.15, 4895.55	92.10, 145.96	73.11, 117.65
	p-value (one-sided)				0.897	

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.

Note: mCC = 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg)						
Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	7.00	6.41	0.19	109.18 (46.28)	3638.56 (46.28)
	95% CI	6.32, 7.74	5.59, 7.34	0.16, 0.23	92.33, 129.10	3064.82, 4319.70
	p-value (one-sided)				0.849	
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	7.54	6.96	0.44	108.39 (157.78)	1717.52 (157.78)
	95% CI	5.78, 9.84	4.91, 9.86	0.30, 0.64	70.13, 167.51	1095.20, 2693.46

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	85.65	616.72	85.93	13.89 (61.04)	99.68 (61.04)
	95% CI	75.46, 97.22	518.68, 733.30	72.05, 102.48	11.22, 17.19	80.29, 123.75
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	145.34	743.55	142.54	19.55 (73.56)	101.97 (73.56)
	95% CI	125.34, 168.53	607.34, 910.30	116.02, 175.11	15.23, 25.08	79.19, 131.30
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ng/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	307.42	600.63	184.81	51.18 (32.79)	166.35 (32.79)
	95% CI	286.08, 330.34	544.54, 662.49	167.19, 204.28	45.35, 57.76	147.10, 188.11
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	383.27	720.83	272.29	53.17 (37.10)	140.76 (37.10)
	95% CI	353.51, 415.53	645.64, 804.77	243.30, 304.74	46.41, 60.91	122.59, 161.61
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	122.35	1091.25	109.18	11.21 (50.66)	112.07 (50.66)
	95% CI	109.87, 136.25	942.34, 1263.69	94.01, 126.79	9.35, 13.44	93.26, 134.66
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	157.88	1146.25	151.39	13.77 (77.43)	104.28 (77.43)
	95% CI	135.31, 184.22	928.77, 1414.65	122.17, 187.60	10.62, 17.86	80.13, 135.71
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
COHb (%) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	2.47	5.49	2.48	45.07 (17.15)	99.92 (17.15)
	95% CI	2.38, 2.58	5.20, 5.79	2.34, 2.62	42.26, 48.08	93.59, 106.69
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	2.98	5.72	2.97	52.13 (19.20)	100.36 (19.20)
	95% CI	2.85, 3.12	5.39, 6.07	2.80, 3.16	48.51, 56.03	93.28, 107.98
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	37.40	84.49	31.18	44.27 (26.84)	119.96 (26.84)
	95% CI	35.24, 39.69	77.92, 91.61	28.70, 33.87	40.06, 48.92	108.39, 132.76
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	23.15	93.48	15.34	24.76 (87.86)	150.92 (87.86)
	95% CI	19.52, 27.45	74.12, 117.91	12.10, 19.44	18.59, 32.97	112.84, 201.85
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Exhaled CO (ppm)						
Day 5	n	78	42	40		
	LS Mean	2.33	15.36	3.12	-13.03	-0.78
	95% CI	1.39, 3.27	14.08, 16.65	1.80, 4.43	-14.62, -11.45	-2.40, 0.83
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	LS Mean	2.42	11.85	2.50	-9.43	-0.08
	95% CI	1.57, 3.27	10.70, 13.00	1.33, 3.67	-10.85, -8.01	-1.52, 1.36
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	47.84	121.03	44.01	39.52 (33.16)	108.69 (33.16)
	95% CI	44.48, 51.45	109.54, 133.72	39.78, 48.70	34.96, 44.68	96.00, 123.06
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	88.35	168.69	89.72	52.37 (41.09)	98.47 (41.09)
	95% CI	80.83, 96.56	149.33, 190.56	79.28, 101.53	45.08, 60.84	84.59, 114.62
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	1.20	4.37	0.15	27.57 (62.27)	810.53 (62.27)
	95% CI	1.05, 1.37	3.66, 5.21	0.12, 0.18	22.20, 34.24	650.48, 1009.95
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	1.37	4.57	0.30	30.04 (110.38)	457.83 (110.38)
	95% CI	1.12, 1.69	3.47, 6.02	0.22, 0.40	21.43, 42.12	324.88, 645.19
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (pg/mg creat) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	2.00	9.76	2.29	20.53 (46.05)	87.47 (46.05)
	95% CI	1.81, 2.22	8.52, 11.17	1.99, 2.63	17.38, 24.24	73.82, 103.63
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	2.16	9.87	2.38	21.90 (60.48)	90.72 (60.48)
	95% CI	1.90, 2.46	8.31, 11.72	1.99, 2.84	17.72, 27.07	73.10, 112.58
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	3.24	54.56	3.07	5.94 (47.34)	105.59 (47.34)
	95% CI	2.92, 3.59	47.53, 62.63	2.66, 3.54	5.01, 7.05	88.75, 125.61
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	3.78	57.40	4.47	6.59 (86.72)	84.66 (86.72)
	95% CI	3.19, 4.48	45.61, 72.23	3.53, 5.66	4.96, 8.76	63.40, 113.06
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	2.03	14.42	2.15	14.05 (37.29)	94.29 (37.29)
	95% CI	1.86, 2.20	12.91, 16.12	1.91, 2.41	12.25, 16.11	82.03, 108.38
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	2.44	15.32	2.66	15.93 (49.24)	91.78 (49.24)
	95% CI	2.19, 2.72	13.28, 17.69	2.29, 3.08	13.35, 19.00	76.67, 109.86
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (pg/mg creat)						
Day 5	n	78	40	40		
	Geometric LS Mean (CV%)	52.92	119.35	51.86	44.34 (50.97)	102.04 (50.97)
	95% CI	47.48, 58.97	102.20, 139.37	44.61, 60.28	36.73, 53.51	84.82, 122.76
	p-value (one-sided)				<.001	
Day 90	n	78	41	40		
	Geometric LS Mean (CV%)	76.93	120.83	79.76	63.66 (107.77)	96.46 (107.77)
	95% CI	63.13, 93.75	91.02, 160.41	60.58, 105.00	45.15, 89.76	68.81, 135.20
	p-value (one-sided)				0.005	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ng/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	12.68	68.01	11.59	18.64 (34.71)	109.36 (34.71)
	95% CI	11.74, 13.68	61.32, 75.43	10.42, 12.89	16.40, 21.18	96.06, 124.51
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	8.17	84.97	8.55	9.61 (80.51)	95.56 (80.51)
	95% CI	6.96, 9.58	68.40, 105.55	6.85, 10.67	7.35, 12.56	72.81, 125.41
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	1151.48	2284.86	1125.63	50.40 (34.99)	102.30 (34.99)
	95% CI	1066.62, 1243.08	2058.52, 2536.08	1011.99, 1252.04	44.31, 57.31	89.77, 116.57
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	1716.73	3803.40	1633.66	45.14 (52.25)	105.08 (52.25)
	95% CI	1536.89, 1917.62	3270.94, 4422.52	1400.67, 1905.41	37.48, 54.36	87.00, 126.93
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (fg/mg creat) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	20.77	76.43	18.86	27.17 (43.80)	110.09 (43.80)
	95% CI	18.89, 22.83	67.20, 86.92	16.54, 21.51	23.18, 31.84	93.67, 129.38
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	29.71	89.53	29.67	33.18 (67.36)	100.15 (67.36)
	95% CI	25.88, 34.11	74.20, 108.04	24.49, 35.94	26.32, 41.83	79.11, 126.77
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ng/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	127.69	293.39	116.89	43.52 (35.87)	109.24 (35.87)
	95% CI	118.07, 138.10	263.68, 326.43	104.83, 130.33	38.15, 49.65	95.57, 124.87
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	158.10	323.78	159.73	48.83 (44.06)	98.98 (44.06)
	95% CI	143.80, 173.83	284.54, 368.45	140.00, 182.23	41.63, 57.27	84.19, 116.38
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (pg/mg creat)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	2527.31	2960.93	2707.29	85.36 (30.72)	93.35 (30.72)
	95% CI	2362.01, 2704.16	2696.24, 3251.59	2463.46, 2975.25	76.12, 95.71	83.12, 104.84
	p-value (one-sided)				0.003	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	3406.26	3026.44	3614.69	112.55 (65.14)	94.23 (65.14)
	95% CI	2979.12, 3894.63	2514.03, 3643.28	2998.31, 4357.78	89.72, 141.19	74.88, 118.59
	p-value (one-sided)				0.848	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg/g creat) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	6.07	5.25	0.17	115.58 (50.26)	3522.42 (50.26)
	95% CI	5.45, 6.76	4.54, 6.08	0.14, 0.20	96.58, 138.32	2934.86, 4227.60
	p-value (one-sided)				0.943	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	6.72	6.55	0.41	102.52 (161.22)	1619.19 (161.22)
	95% CI	5.20, 8.67	4.63, 9.28	0.29, 0.60	66.81, 157.32	1047.86, 2502.03

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (ng) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	97.77	746.62	102.23	13.10 (63.91)	95.64 (63.91)
	95% CI	85.70, 111.54	623.79, 893.63	85.11, 122.79	10.49, 16.35	76.37, 119.77
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	160.63	792.30	158.09	20.27 (71.90)	101.61 (71.90)
	95% CI	138.91, 185.76	649.81, 966.03	129.15, 193.50	15.87, 25.89	79.28, 130.23
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ug) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	352.29	728.21	221.76	48.38 (36.40)	158.86 (36.40)
	95% CI	325.39, 381.41	653.38, 811.61	198.57, 247.66	42.33, 55.29	138.70, 181.96
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	422.97	769.12	300.13	54.99 (41.40)	140.93 (41.40)
	95% CI	386.74, 462.61	680.60, 869.15	264.98, 339.94	47.30, 63.94	120.93, 164.24
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (ng) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	140.58	1332.96	130.80	10.55 (55.63)	107.48 (55.63)
	95% CI	125.08, 158.01	1136.69, 1563.13	111.19, 153.88	8.66, 12.84	88.03, 131.21
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	175.06	1228.82	168.27	14.25 (74.03)	104.03 (74.03)
	95% CI	150.85, 203.14	1003.27, 1505.08	136.83, 206.93	11.09, 18.30	80.69, 134.13
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (ng)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	43.39	104.81	37.59	41.40 (31.76)	115.42 (31.76)
	95% CI	40.46, 46.53	95.29, 115.27	34.11, 41.43	36.81, 46.56	102.45, 130.03
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	25.73	100.75	17.08	25.54 (89.36)	150.62 (89.36)
	95% CI	21.65, 30.57	79.64, 127.45	13.43, 21.72	19.11, 34.12	112.19, 202.20
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (ng)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	55.05	150.03	52.56	36.69 (41.56)	104.75 (41.56)
	95% CI	50.32, 60.23	132.71, 169.61	46.38, 59.56	31.54, 42.69	89.84, 122.12
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	97.53	180.92	99.11	53.91 (47.36)	98.41 (47.36)
	95% CI	88.13, 107.92	157.57, 207.74	86.08, 114.10	45.45, 63.93	82.78, 116.98
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (ng) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	1.39	5.34	0.18	25.96 (65.45)	777.50 (65.45)
	95% CI	1.21, 1.59	4.44, 6.41	0.14, 0.22	20.70, 32.55	618.09, 978.03
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	1.53	4.93	0.33	30.96 (108.01)	457.89 (108.01)
	95% CI	1.25, 1.86	3.75, 6.46	0.25, 0.44	22.19, 43.20	326.59, 641.98
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (ng) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	2.29	11.80	2.72	19.45 (49.11)	84.34 (49.11)
	95% CI	2.06, 2.55	10.23, 13.62	2.35, 3.15	16.30, 23.20	70.46, 100.94
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	2.37	10.47	2.65	22.64 (63.57)	89.53 (63.57)
	95% CI	2.07, 2.71	8.75, 12.53	2.20, 3.19	18.15, 28.24	71.47, 112.15
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (ng) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	3.72	65.95	3.64	5.64 (50.49)	102.13 (50.49)
	95% CI	3.34, 4.15	56.96, 76.35	3.13, 4.24	4.71, 6.77	84.96, 122.77
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	4.14	61.19	4.99	6.77 (87.15)	83.01 (87.15)
	95% CI	3.49, 4.91	48.56, 77.08	3.94, 6.32	5.09, 9.01	62.10, 110.98
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (ng) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	2.32	17.49	2.56	13.28 (40.81)	90.82 (40.81)
	95% CI	2.12, 2.54	15.50, 19.73	2.25, 2.90	11.44, 15.41	78.05, 105.67
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	2.68	16.22	2.96	16.51 (51.27)	90.41 (51.27)
	95% CI	2.40, 2.99	13.98, 18.82	2.54, 3.45	13.75, 19.83	75.03, 108.94
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (ng) Day 5	n	78	40	40		
	Geometric LS Mean (CV%)	60.68	144.20	61.91	42.08 (51.40)	98.02 (51.40)
	95% CI	54.41, 67.68	123.36, 168.56	53.19, 72.06	34.82, 50.86	81.37, 118.09
	p-value (one-sided)				<.001	
Day 90	n	78	41	40		
	Geometric LS Mean (CV%)	85.75	130.10	89.29	65.91 (104.78)	96.04 (104.78)
	95% CI	70.64, 104.10	98.57, 171.70	68.17, 116.94	47.07, 92.30	68.97, 133.73
	p-value (one-sided)				0.008	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ug) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	14.59	83.42	13.97	17.49 (38.54)	104.40 (38.54)
	95% CI	13.41, 15.87	74.41, 93.52	12.43, 15.70	15.19, 20.14	90.47, 120.46
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	9.05	91.09	9.48	9.94 (77.27)	95.51 (77.27)
	95% CI	7.76, 10.57	73.83, 112.39	7.65, 11.75	7.67, 12.88	73.41, 124.26
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (ng) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	1329.45	2807.36	1356.83	47.36 (39.81)	97.98 (39.81)
	95% CI	1219.50, 1449.30	2495.79, 3157.81	1203.36, 1529.88	40.96, 54.75	84.55, 113.55
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	1907.13	4097.25	1817.46	46.55 (52.22)	104.93 (52.22)
	95% CI	1707.57, 2130.00	3524.32, 4763.31	1558.52, 2119.41	38.65, 56.05	86.88, 126.73
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (pg) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	23.76	92.49	22.43	25.69 (46.26)	105.94 (46.26)
	95% CI	21.51, 26.24	80.80, 105.87	19.53, 25.75	21.74, 30.35	89.40, 125.53
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	32.83	95.51	32.83	34.37 (69.56)	99.99 (69.56)
	95% CI	28.49, 37.82	78.77, 115.82	26.96, 39.99	27.10, 43.60	78.49, 127.37
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ug) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	145.77	354.06	139.24	41.17 (38.94)	104.69 (38.94)
	95% CI	133.94, 158.66	315.46, 397.37	123.79, 156.62	35.71, 47.47	90.61, 120.95
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	174.30	343.72	176.51	50.71 (50.66)	98.75 (50.66)
	95% CI	156.50, 194.12	296.78, 398.08	151.98, 205.00	42.32, 60.77	82.17, 118.66
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (ng) Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	2913.56	3657.78	3230.66	79.65 (38.23)	90.18 (38.23)
	95% CI	2681.19, 3166.07	3263.04, 4100.28	2875.85, 3629.25	69.21, 91.67	78.19, 104.01
	p-value (one-sided)				<.001	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	3806.12	3265.10	4077.23	116.57 (65.94)	93.35 (65.94)
	95% CI	3324.73, 4357.21	2711.49, 3931.75	3374.15, 4926.81	92.76, 146.49	74.02, 117.73
	p-value (one-sided)				0.907	

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.

Note: mCC = 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 and Day 90 Visit - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg)						
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	7.00	6.43	0.21	108.77 (52.25)	3384.70 (52.25)
	95% CI	6.26, 7.82	5.53, 7.48	0.17, 0.25	90.31, 131.00	2802.12, 4088.41
	p-value (one-sided)				0.813	
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	7.49	7.10	0.46	105.51 (154.78)	1616.49 (154.78)
	95% CI	5.84, 9.61	5.05, 9.97	0.32, 0.66	69.43, 160.34	1056.68, 2472.89

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.

Note: mCC = 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	83.31	624.33	83.65	13.34 (58.78)	99.59 (58.78)
	95% CI	73.59, 94.32	526.76, 739.97	70.36, 99.44	10.82, 16.46	80.55, 123.13
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	143.74	755.98	141.78	19.01 (74.38)	101.38 (74.38)
	95% CI	122.69, 168.40	614.56, 929.93	114.18, 176.07	14.66, 24.66	77.58, 132.48
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	304.05	592.47	183.36	51.32 (32.54)	165.82 (32.54)
	95% CI	282.86, 326.84	536.87, 653.82	165.79, 202.80	45.44, 57.96	146.55, 187.62
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	384.46	713.22	278.42	53.90 (37.65)	138.08 (37.65)
	95% CI	352.41, 419.41	636.87, 798.72	247.25, 313.53	46.74, 62.16	119.23, 159.92
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	119.55	1102.86	105.13	10.84 (46.61)	113.71 (46.61)
	95% CI	108.07, 132.25	960.79, 1265.93	91.34, 121.01	9.14, 12.85	95.68, 135.14
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	151.76	1168.00	151.26	12.99 (73.83)	100.33 (73.83)
	95% CI	129.66, 177.64	951.26, 1434.13	121.98, 187.57	10.04, 16.82	76.90, 130.89
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
COHb (%) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	2.47	5.49	2.49	44.93 (17.30)	99.31 (17.30)
	95% CI	2.37, 2.57	5.20, 5.80	2.35, 2.63	42.06, 47.99	92.89, 106.18
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	2.97	5.73	3.05	51.73 (19.03)	97.11 (19.03)
	95% CI	2.83, 3.11	5.40, 6.08	2.87, 3.25	48.05, 55.68	89.99, 104.79
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	37.02	85.03	30.95	43.54 (26.16)	119.63 (26.16)
	95% CI	34.91, 39.26	78.50, 92.11	28.52, 33.59	39.45, 48.06	108.22, 132.24
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	22.46	96.79	14.92	23.20 (86.81)	150.53 (86.81)
	95% CI	18.77, 26.87	76.68, 122.18	11.67, 19.07	17.31, 31.10	111.17, 203.82
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Exhaled CO (ppm)						
Day 5	n	76	41	39		
	LS Mean	2.28	15.23	3.12	-12.94	-0.84
	95% CI	1.33, 3.24	13.93, 16.53	1.79, 4.45	-14.55, -11.33	-2.47, 0.79
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	LS Mean	2.35	11.65	2.60	-9.30	-0.24
	95% CI	1.45, 3.26	10.47, 12.83	1.36, 3.84	-10.78, -7.82	-1.77, 1.28
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	47.26	119.25	43.09	39.63 (31.43)	109.68 (31.43)
	95% CI	44.06, 50.69	108.35, 131.24	39.09, 47.50	35.22, 44.60	97.32, 123.61
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	86.41	167.10	91.71	51.71 (39.53)	94.22 (39.53)
	95% CI	78.89, 94.64	148.32, 188.26	80.98, 103.85	44.54, 60.04	80.80, 109.87
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	1.18	4.39	0.15	26.96 (62.08)	786.47 (62.08)
	95% CI	1.03, 1.35	3.67, 5.25	0.12, 0.19	21.65, 33.56	629.72, 982.23
	p-value (one-sided)				<.001	
Day 90	n	69	41	36		
	Geometric LS Mean (CV%)	1.34	4.67	0.29	28.72 (92.80)	462.16 (92.80)
	95% CI	1.11, 1.62	3.65, 5.98	0.22, 0.38	21.09, 39.10	335.24, 637.12
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	1.96	9.72	2.27	20.17 (44.82)	86.24 (44.82)
	95% CI	1.77, 2.17	8.51, 11.11	1.98, 2.61	17.11, 23.78	72.90, 102.01
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	2.09	9.90	2.42	21.10 (58.04)	86.19 (58.04)
	95% CI	1.83, 2.38	8.36, 11.70	2.03, 2.89	17.08, 26.05	69.25, 107.27
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	3.12	54.20	2.97	5.75 (39.28)	104.73 (39.28)
	95% CI	2.85, 3.40	48.18, 60.96	2.63, 3.36	4.97, 6.65	90.27, 121.50
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	3.57	57.11	4.37	6.25 (81.73)	81.67 (81.73)
	95% CI	3.00, 4.24	45.73, 71.34	3.45, 5.53	4.72, 8.27	61.06, 109.22
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	1.97	14.28	2.15	13.79 (33.94)	91.70 (33.94)
	95% CI	1.82, 2.13	12.88, 15.83	1.93, 2.39	12.15, 15.66	80.58, 104.35
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	2.35	15.24	2.76	15.40 (47.18)	85.22 (47.18)
	95% CI	2.10, 2.62	13.26, 17.53	2.37, 3.20	12.92, 18.36	71.02, 102.24
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	39	39		
	Geometric LS Mean (CV%)	52.01	116.30	50.55	44.72 (50.13)	102.89 (50.13)
	95% CI	46.69, 57.94	99.63, 135.75	43.49, 58.75	37.07, 53.96	85.56, 123.74
	p-value (one-sided)				<.001	
Day 90	n	69	40	37		
	Geometric LS Mean (CV%)	70.01	118.22	80.16	59.22 (103.49)	87.34 (103.49)
	95% CI	57.10, 85.83	89.44, 156.25	60.68, 105.89	41.97, 83.55	61.91, 123.19
	p-value (one-sided)				0.002	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	12.39	67.68	11.58	18.31 (32.50)	107.03 (32.50)
	95% CI	11.53, 13.33	61.33, 74.68	10.47, 12.81	16.21, 20.68	94.60, 121.08
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	7.82	85.65	8.54	9.13 (78.39)	91.50 (78.39)
	95% CI	6.62, 9.23	69.07, 106.20	6.81, 10.71	6.96, 11.97	69.22, 120.96
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	1146.08	2260.25	1121.99	50.71 (34.69)	102.15 (34.69)
	95% CI	1061.33, 1237.59	2035.59, 2509.71	1008.22, 1248.61	44.56, 57.70	89.59, 116.47
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	1709.85	3848.40	1695.85	44.43 (51.62)	100.83 (51.62)
	95% CI	1522.21, 1920.60	3308.78, 4476.01	1447.29, 1987.10	36.74, 53.72	82.87, 122.67
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	20.78	75.63	18.79	27.48 (43.92)	110.61 (43.92)
	95% CI	18.88, 22.88	66.37, 86.17	16.44, 21.48	23.39, 32.28	93.86, 130.35
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	29.90	90.33	31.10	33.09 (68.99)	96.12 (68.99)
	95% CI	25.74, 34.72	74.40, 109.67	25.35, 38.15	25.93, 42.24	74.61, 123.82
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	126.29	287.46	115.28	43.93 (35.00)	109.55 (35.00)
	95% CI	116.88, 136.46	258.66, 319.47	103.49, 128.40	38.56, 50.05	95.97, 125.06
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	159.24	316.18	165.87	50.36 (42.38)	96.00 (42.38)
	95% CI	144.50, 175.47	278.63, 358.77	145.25, 189.41	42.96, 59.04	81.46, 113.13
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	2540.50	2935.77	2682.99	86.54 (30.71)	94.69 (30.71)
	95% CI	2372.46, 2720.45	2671.35, 3226.37	2438.47, 2952.02	77.08, 97.15	84.19, 106.49
	p-value (one-sided)				0.007	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	3343.18	3008.70	3651.19	111.12 (63.58)	91.56 (63.58)
	95% CI	2908.76, 3842.47	2504.57, 3614.31	3015.90, 4420.31	88.41, 139.65	72.28, 116.00
	p-value (one-sided)				0.818	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	6.06	5.20	0.16	116.47 (43.96)	3798.06 (43.96)
	95% CI	5.50, 6.67	4.56, 5.93	0.13, 0.19	99.14, 136.84	3224.43, 4473.73
	p-value (one-sided)				0.968	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	6.71	6.48	0.40	103.60 (166.84)	1683.97 (166.84)
	95% CI	5.09, 8.85	4.52, 9.28	0.27, 0.59	66.02, 162.55	1056.64, 2683.74

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (ng) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	95.33	753.98	99.92	12.64 (62.41)	95.40 (62.41)
	95% CI	83.65, 108.63	630.77, 901.25	83.29, 119.88	10.14, 15.76	76.31, 119.27
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	159.87	798.47	156.10	20.02 (73.03)	102.41 (73.03)
	95% CI	136.77, 186.87	651.38, 978.78	126.11, 193.23	15.50, 25.86	78.69, 133.30
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ug) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	349.27	716.75	220.73	48.73 (36.23)	158.23 (36.23)
	95% CI	322.42, 378.35	642.45, 799.64	197.45, 246.75	42.58, 55.77	138.01, 181.42
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	425.94	757.48	305.78	56.23 (41.80)	139.30 (41.80)
	95% CI	387.04, 468.74	668.38, 858.46	268.27, 348.52	48.05, 65.80	118.49, 163.75
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (ng) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	137.49	1346.97	126.30	10.21 (52.52)	108.86 (52.52)
	95% CI	122.87, 153.85	1155.54, 1570.11	108.00, 147.71	8.44, 12.34	89.83, 131.92
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	169.26	1240.44	166.59	13.64 (70.99)	101.60 (70.99)
	95% CI	145.32, 197.13	1017.00, 1512.98	135.26, 205.19	10.63, 17.52	78.53, 131.44
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (ng)						
Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	42.93	105.80	37.40	40.57 (31.17)	114.78 (31.17)
	95% CI	40.05, 46.02	96.25, 116.30	33.95, 41.21	36.10, 45.60	101.93, 129.24
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	25.14	103.75	16.45	24.23 (88.28)	152.84 (88.28)
	95% CI	20.97, 30.14	81.93, 131.38	12.83, 21.09	18.01, 32.61	112.45, 207.72
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	54.51	147.78	51.57	36.88 (40.72)	105.69 (40.72)
	95% CI	49.85, 59.60	130.84, 166.91	45.54, 58.40	31.73, 42.87	90.74, 123.12
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	96.02	178.30	100.52	53.86 (46.33)	95.53 (46.33)
	95% CI	86.43, 106.68	155.43, 204.54	87.04, 116.08	45.32, 64.00	79.97, 114.11
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (ng) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	1.36	5.37	0.18	25.39 (65.38)	752.55 (65.38)
	95% CI	1.19, 1.57	4.46, 6.47	0.14, 0.22	20.19, 31.92	596.57, 949.31
	p-value (one-sided)				<.001	
Day 90	n	69	41	36		
	Geometric LS Mean (CV%)	1.50	5.01	0.32	29.93 (88.93)	469.57 (88.93)
	95% CI	1.24, 1.80	3.94, 6.36	0.24, 0.42	22.19, 40.35	344.11, 640.78
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (ng) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	2.25	11.75	2.72	19.17 (48.39)	82.95 (48.39)
	95% CI	2.02, 2.51	10.18, 13.56	2.34, 3.15	16.06, 22.87	69.27, 99.33
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	2.30	10.41	2.68	22.09 (62.02)	85.88 (62.02)
	95% CI	2.00, 2.64	8.72, 12.44	2.22, 3.23	17.66, 27.62	68.14, 108.23
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (ng) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	3.58	65.43	3.55	5.47 (43.83)	100.95 (43.83)
	95% CI	3.25, 3.95	57.43, 74.55	3.10, 4.06	4.65, 6.44	85.64, 118.99
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	3.92	60.50	4.87	6.48 (82.51)	80.54 (82.51)
	95% CI	3.29, 4.66	48.34, 75.71	3.84, 6.17	4.88, 8.60	60.12, 107.89
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (ng) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	2.26	17.30	2.57	13.07 (38.26)	88.09 (38.26)
	95% CI	2.07, 2.46	15.42, 19.41	2.28, 2.89	11.34, 15.06	76.22, 101.81
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	2.59	16.07	3.06	16.13 (49.85)	84.76 (49.85)
	95% CI	2.31, 2.91	13.88, 18.61	2.62, 3.57	13.41, 19.39	70.01, 102.61
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (ng) Day 5	n	76	39	39		
	Geometric LS Mean (CV%)	59.74	140.19	60.56	42.62 (50.69)	98.66 (50.69)
	95% CI	53.57, 66.62	119.93, 163.87	52.02, 70.49	35.26, 51.51	81.89, 118.87
	p-value (one-sided)				<.001	
Day 90	n	69	40	37		
	Geometric LS Mean (CV%)	78.43	126.01	88.36	62.25 (101.07)	88.76 (101.07)
	95% CI	64.19, 95.84	95.79, 165.74	67.20, 116.19	44.38, 87.31	63.29, 124.49
	p-value (one-sided)				0.003	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ug) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	14.30	83.10	14.00	17.21 (37.01)	102.15 (37.01)
	95% CI	13.17, 15.52	74.34, 92.89	12.49, 15.69	14.99, 19.74	88.85, 117.44
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	8.72	91.46	9.41	9.54 (75.68)	92.71 (75.68)
	95% CI	7.43, 10.25	74.18, 112.77	7.55, 11.72	7.33, 12.41	70.68, 121.60
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (ng) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	1324.93	2778.02	1355.94	47.69 (39.86)	97.71 (39.86)
	95% CI	1213.99, 1446.02	2465.85, 3129.70	1200.49, 1531.52	41.16, 55.26	84.15, 113.47
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	1912.45	4120.82	1867.97	46.41 (51.39)	102.38 (51.39)
	95% CI	1703.65, 2146.83	3545.27, 4789.80	1595.20, 2187.37	38.41, 56.07	84.22, 124.45
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 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	76	41	39		
	Geometric LS Mean (CV%)	23.86	91.39	22.40	26.10 (46.52)	106.49 (46.52)
	95% CI	21.56, 26.39	79.65, 104.86	19.45, 25.80	22.02, 30.94	89.57, 126.61
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	33.26	95.64	34.15	34.77 (71.68)	97.40 (71.68)
	95% CI	28.51, 38.80	78.29, 116.83	27.65, 42.16	27.03, 44.73	75.03, 126.44
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ug) Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	144.49	345.98	137.84	41.76 (38.27)	104.82 (38.27)
	95% CI	132.82, 157.19	308.36, 388.19	122.59, 155.00	36.24, 48.13	90.77, 121.05
	p-value (one-sided)				<.001	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	175.75	334.88	183.46	52.48 (49.59)	95.80 (49.59)
	95% CI	157.15, 196.56	289.32, 387.60	157.40, 213.82	43.68, 63.06	79.28, 115.76
	p-value (one-sided)				<.001	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (ng)						
Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	2932.12	3626.87	3209.90	80.84 (38.40)	91.35 (38.40)
	95% CI	2694.67, 3190.48	3230.70, 4071.62	2851.80, 3612.97	70.11, 93.22	79.01, 105.61
	p-value (one-sided)				0.002	
Day 90						
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	3761.08	3236.78	4044.83	116.20 (64.68)	92.98 (64.68)
	95% CI	3266.27, 4330.84	2690.74, 3893.62	3331.51, 4910.87	92.18, 146.47	73.18, 118.14
	p-value (one-sided)				0.899	

Note: Adjusted geometric 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; 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 and Day 90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg)						
Day 5	n	76	41	39		
	Geometric LS Mean (CV%)	6.98	6.36	0.19	109.73 (46.42)	3638.87 (46.42)
	95% CI	6.31, 7.72	5.54, 7.30	0.16, 0.23	92.63, 129.99	3063.68, 4322.05
	p-value (one-sided)				0.860	
Day 90	n	69	41	37		
	Geometric LS Mean (CV%)	7.53	6.96	0.44	108.12 (158.74)	1713.38 (158.74)
	95% CI	5.76, 9.85	4.91, 9.88	0.30, 0.64	69.75, 167.58	1089.46, 2694.61

Note: Adjusted geometric 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; 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	83.21	617.04	83.57	13.49 (58.68)	99.57 (58.68)
	95% CI	73.51, 94.19	521.87, 729.55	70.32, 99.32	10.96, 16.60	80.56, 123.06
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	138.44	756.01	141.64	18.31 (74.26)	97.74 (74.26)
	95% CI	117.61, 162.95	614.65, 929.89	114.09, 175.84	14.08, 23.82	74.61, 128.05
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	304.56	601.11	183.61	50.67 (32.72)	165.87 (32.72)
	95% CI	283.22, 327.50	545.07, 662.91	165.93, 203.18	44.88, 57.20	146.50, 187.81
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	387.19	712.60	278.26	54.33 (37.77)	139.14 (37.77)
	95% CI	353.87, 423.64	636.07, 798.33	247.01, 313.47	47.02, 62.79	119.90, 161.48
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	119.18	1086.89	104.83	10.97 (46.63)	113.70 (46.63)
	95% CI	107.73, 131.85	948.47, 1245.51	91.07, 120.66	9.26, 12.99	95.67, 135.12
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	142.64	1167.40	151.19	12.22 (72.83)	94.34 (72.83)
	95% CI	121.49, 167.47	952.82, 1430.29	122.21, 187.05	9.44, 15.82	72.32, 123.07
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
COHb (%) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	2.47	5.49	2.49	44.94 (17.24)	99.31 (17.24)
	95% CI	2.37, 2.57	5.21, 5.79	2.35, 2.63	42.11, 47.97	92.91, 106.15
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	2.94	5.73	3.05	51.31 (18.95)	96.30 (18.95)
	95% CI	2.80, 3.09	5.40, 6.08	2.87, 3.25	47.63, 55.26	89.20, 103.96
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	36.95	84.57	30.89	43.69 (26.09)	119.61 (26.09)
	95% CI	34.85, 39.17	78.17, 91.51	28.47, 33.51	39.62, 48.17	108.23, 132.19
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	21.89	96.86	14.93	22.60 (85.85)	146.59 (85.85)
	95% CI	18.23, 26.29	76.88, 122.03	11.71, 19.04	16.85, 30.32	108.19, 198.62
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Exhaled CO (ppm)						
Day 5	n	76	42	39		
	LS Mean	2.29	15.39	3.14	-13.10	-0.85
	95% CI	1.33, 3.25	14.10, 16.68	1.81, 4.47	-14.70, -11.50	-2.49, 0.79
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	LS Mean	2.29	11.65	2.60	-9.36	-0.31
	95% CI	1.35, 3.23	10.46, 12.84	1.35, 3.85	-10.88, -7.85	-1.87, 1.24
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	47.34	120.83	43.17	39.18 (31.60)	109.65 (31.60)
	95% CI	44.12, 50.79	109.84, 132.91	39.14, 47.61	34.82, 44.07	97.23, 123.66
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	85.68	167.27	92.05	51.23 (39.60)	93.09 (39.60)
	95% CI	78.00, 94.12	148.45, 188.47	81.26, 104.26	44.04, 59.58	79.66, 108.77
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	1.18	4.38	0.15	27.02 (61.84)	786.46 (61.84)
	95% CI	1.03, 1.35	3.67, 5.22	0.12, 0.19	21.75, 33.55	630.18, 981.50
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	1.35	4.63	0.28	29.24 (95.45)	487.36 (95.45)
	95% CI	1.11, 1.66	3.60, 5.95	0.21, 0.37	21.26, 40.20	350.98, 676.72
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	1.96	9.76	2.28	20.10 (44.68)	86.22 (44.68)
	95% CI	1.78, 2.17	8.56, 11.14	1.98, 2.61	17.08, 23.64	72.93, 101.94
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	1.98	9.91	2.43	20.02 (55.58)	81.77 (55.58)
	95% CI	1.74, 2.26	8.43, 11.65	2.04, 2.88	16.30, 24.58	66.11, 101.14
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	3.12	54.64	2.98	5.70 (39.23)	104.70 (39.23)
	95% CI	2.85, 3.40	48.65, 61.38	2.63, 3.36	4.93, 6.59	90.26, 121.44
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	3.45	57.05	4.37	6.05 (80.48)	78.92 (80.48)
	95% CI	2.89, 4.11	45.79, 71.06	3.46, 5.51	4.57, 8.00	59.04, 105.48
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	1.97	14.43	2.15	13.66 (33.99)	91.67 (33.99)
	95% CI	1.82, 2.13	13.03, 15.97	1.93, 2.39	12.04, 15.49	80.53, 104.33
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	2.31	15.22	2.76	15.20 (47.25)	83.95 (47.25)
	95% CI	2.07, 2.59	13.23, 17.50	2.37, 3.20	12.72, 18.15	69.81, 100.94
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	40	39		
	Geometric LS Mean (CV%)	52.17	119.11	50.75	43.80 (50.51)	102.80 (50.51)
	95% CI	46.80, 58.15	102.11, 138.93	43.61, 59.04	36.31, 52.83	85.37, 123.79
	p-value (one-sided)				<.001	
Day 90	n	65	40	37		
	Geometric LS Mean (CV%)	72.11	118.51	80.38	60.84 (104.18)	89.70 (104.18)
	95% CI	58.39, 89.04	89.54, 156.85	60.76, 106.33	42.89, 86.30	63.25, 127.22
	p-value (one-sided)				0.003	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	12.43	68.18	11.61	18.23 (32.43)	107.03 (32.43)
	95% CI	11.56, 13.36	61.87, 75.13	10.50, 12.84	16.16, 20.56	94.63, 121.05
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	7.60	85.58	8.54	8.88 (75.88)	88.99 (75.88)
	95% CI	6.43, 8.98	69.39, 105.54	6.85, 10.65	6.80, 11.60	67.60, 117.14
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	1145.94	2285.36	1121.87	50.14 (34.79)	102.15 (34.79)
	95% CI	1060.99, 1237.70	2060.10, 2535.25	1007.81, 1248.84	44.09, 57.02	89.55, 116.51
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	1725.78	3845.92	1694.91	44.87 (52.45)	101.82 (52.45)
	95% CI	1528.26, 1948.83	3299.40, 4482.95	1443.16, 1990.57	36.93, 54.53	83.27, 124.50
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	20.79	76.46	18.80	27.19 (43.93)	110.59 (43.93)
	95% CI	18.89, 22.89	67.20, 86.99	16.45, 21.49	23.17, 31.91	93.84, 130.33
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	29.66	90.58	31.25	32.75 (66.73)	94.93 (66.73)
	95% CI	25.53, 34.46	75.00, 109.39	25.61, 38.12	25.76, 41.63	74.00, 121.76
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	126.41	293.61	115.40	43.06 (35.59)	109.54 (35.59)
	95% CI	116.85, 136.76	264.09, 326.43	103.43, 128.76	37.75, 49.10	95.76, 125.30
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	158.80	316.54	166.11	50.17 (41.12)	95.60 (41.12)
	95% CI	144.07, 175.04	279.92, 357.95	145.99, 189.00	42.90, 58.66	81.35, 112.35
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	2547.36	2967.89	2693.82	85.83 (30.78)	94.56 (30.78)
	95% CI	2378.56, 2728.13	2702.17, 3259.75	2447.67, 2964.72	76.49, 96.31	84.06, 106.38
	p-value (one-sided)				0.005	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	3247.08	2991.79	3612.05	108.53 (63.72)	89.90 (63.72)
	95% CI	2812.62, 3748.65	2488.31, 3597.13	2983.14, 4373.54	86.04, 136.90	70.78, 114.16
	p-value (one-sided)				0.757	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	6.06	5.23	0.16	116.00 (43.83)	3797.93 (43.83)
	95% CI	5.51, 6.68	4.59, 5.95	0.13, 0.19	98.91, 136.04	3225.82, 4471.49
	p-value (one-sided)				0.966	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	6.86	6.46	0.40	106.29 (170.90)	1728.08 (170.90)
	95% CI	5.14, 9.16	4.48, 9.29	0.27, 0.59	66.98, 168.66	1072.27, 2784.97

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	95.28	747.09	99.88	12.75 (62.25)	95.39 (62.25)
	95% CI	83.63, 108.54	626.63, 890.72	83.29, 119.78	10.25, 15.86	76.33, 119.20
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	153.24	798.92	156.19	19.18 (72.79)	98.11 (72.79)
	95% CI	130.52, 179.91	652.02, 978.91	126.25, 193.24	14.81, 24.84	75.22, 127.97
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ug) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	350.10	730.08	221.15	47.95 (36.50)	158.31 (36.50)
	95% CI	323.01, 379.46	654.82, 813.99	197.68, 247.40	41.91, 54.87	137.94, 181.68
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	426.73	758.35	305.98	56.27 (42.16)	139.46 (42.16)
	95% CI	386.31, 471.38	668.42, 860.39	268.16, 349.14	47.93, 66.06	118.27, 164.45
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	137.25	1329.96	126.09	10.32 (52.48)	108.85 (52.48)
	95% CI	122.66, 153.56	1143.16, 1547.27	107.83, 147.44	8.55, 12.45	89.83, 131.89
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	158.27	1241.89	166.79	12.74 (70.60)	94.89 (70.60)
	95% CI	135.35, 185.07	1019.03, 1513.48	135.54, 205.25	9.91, 16.39	73.23, 122.96
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (ng)						
Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	42.93	105.32	37.40	40.76 (31.11)	114.76 (31.11)
	95% CI	40.05, 46.01	95.94, 115.62	33.96, 41.20	36.31, 45.76	101.94, 129.19
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	24.38	104.14	16.51	23.41 (87.26)	147.61 (87.26)
	95% CI	20.25, 29.34	82.40, 131.60	12.91, 21.13	17.38, 31.52	108.53, 200.74
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	54.63	150.23	51.71	36.36 (40.91)	105.65 (40.91)
	95% CI	49.95, 59.76	133.13, 169.54	45.63, 58.60	31.30, 42.24	90.64, 123.15
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	94.86	178.76	100.97	53.06 (46.37)	93.94 (46.37)
	95% CI	85.09, 105.74	155.82, 205.08	87.42, 116.63	44.56, 63.18	78.47, 112.46
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	1.36	5.37	0.18	25.42 (65.12)	752.55 (65.12)
	95% CI	1.19, 1.57	4.46, 6.45	0.15, 0.22	20.27, 31.89	597.03, 948.57
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	1.50	4.97	0.31	30.24 (91.09)	491.06 (91.09)
	95% CI	1.24, 1.82	3.90, 6.33	0.23, 0.40	22.23, 41.14	357.65, 674.21
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	2.26	11.84	2.72	19.05 (48.26)	82.92 (48.26)
	95% CI	2.03, 2.51	10.28, 13.63	2.34, 3.15	16.00, 22.69	69.28, 99.24
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	2.18	10.44	2.69	20.86 (59.90)	81.07 (59.90)
	95% CI	1.90, 2.50	8.78, 12.41	2.24, 3.23	16.75, 25.97	64.63, 101.69
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (ng)						
Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	3.58	66.17	3.55	5.42 (43.82)	100.88 (43.82)
	95% CI	3.25, 3.95	58.17, 75.26	3.10, 4.07	4.61, 6.36	85.59, 118.91
	p-value (one-sided)				<.001	
Day 90						
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	3.77	60.49	4.87	6.24 (81.63)	77.51 (81.63)
	95% CI	3.16, 4.51	48.42, 75.56	3.85, 6.16	4.70, 8.29	57.82, 103.89
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	2.26	17.53	2.57	12.92 (38.35)	88.03 (38.35)
	95% CI	2.08, 2.47	15.64, 19.65	2.28, 2.90	11.21, 14.87	76.14, 101.77
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	2.54	16.08	3.06	15.81 (49.88)	82.96 (49.88)
	95% CI	2.26, 2.86	13.88, 18.62	2.62, 3.58	13.12, 19.05	68.38, 100.65
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (ng) Day 5	n	76	40	39		
	Geometric LS Mean (CV%)	59.98	144.15	60.86	41.61 (51.21)	98.55 (51.21)
	95% CI	53.73, 66.95	123.38, 168.42	52.21, 70.95	34.42, 50.30	81.66, 118.93
	p-value (one-sided)				<.001	
Day 90	n	65	40	37		
	Geometric LS Mean (CV%)	80.38	126.73	88.86	63.43 (101.84)	90.46 (101.84)
	95% CI	65.31, 98.93	96.19, 166.96	67.47, 117.02	44.97, 89.46	64.14, 127.58
	p-value (one-sided)				0.005	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ug) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	14.35	83.94	14.05	17.10 (36.94)	102.15 (36.94)
	95% CI	13.22, 15.57	75.20, 93.69	12.54, 15.74	14.92, 19.59	88.87, 117.42
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	8.44	91.61	9.42	9.21 (73.43)	89.54 (73.43)
	95% CI	7.18, 9.92	74.67, 112.39	7.60, 11.68	7.10, 11.95	68.52, 117.02
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	1326.41	2815.66	1357.47	47.11 (39.96)	97.71 (39.96)
	95% CI	1215.11, 1447.91	2502.07, 3168.56	1201.51, 1533.67	40.69, 54.54	84.12, 113.50
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	1918.76	4125.98	1870.75	46.50 (52.03)	102.57 (52.03)
	95% CI	1700.92, 2164.50	3543.67, 4803.97	1594.73, 2194.55	38.32, 56.43	84.01, 125.22
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 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	76	42	39		
	Geometric LS Mean (CV%)	23.88	92.65	22.43	25.77 (46.59)	106.45 (46.59)
	95% CI	21.58, 26.42	80.87, 106.15	19.48, 25.84	21.77, 30.51	89.51, 126.58
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	32.84	96.15	34.37	34.16 (69.43)	95.54 (69.43)
	95% CI	28.13, 38.33	79.11, 116.86	27.99, 42.21	26.65, 43.77	73.89, 123.53
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ug) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	144.79	354.72	138.15	40.82 (38.93)	104.80 (38.93)
	95% CI	132.91, 157.73	316.03, 398.15	122.63, 155.64	35.38, 47.09	90.54, 121.31
	p-value (one-sided)				<.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	174.45	336.03	183.98	51.91 (48.74)	94.82 (48.74)
	95% CI	155.72, 195.43	290.95, 388.09	158.21, 213.94	43.24, 62.33	78.54, 114.48
	p-value (one-sided)				<.001	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (ng) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	2942.90	3679.22	3227.72	79.99 (38.51)	91.18 (38.51)
	95% CI	2704.04, 3202.86	3279.99, 4127.05	2866.52, 3634.43	69.40, 92.19	78.83, 105.45
	p-value (one-sided)				0.001	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	3632.36	3219.42	4014.64	112.83 (64.80)	90.48 (64.80)
	95% CI	3140.10, 4201.77	2674.75, 3875.01	3306.13, 4874.98	89.20, 142.71	71.03, 115.26
	p-value (one-sided)				0.844	

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.

Note: mCC = 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 and Day 90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg) Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	7.00	6.41	0.19	109.18 (46.28)	3638.56 (46.28)
	95% CI	6.32, 7.74	5.59, 7.34	0.16, 0.23	92.33, 129.10	3064.82, 4319.70
	p-value (one-sided)				0.849	
Day 90	n	65	41	37		
	Geometric LS Mean (CV%)	7.65	6.96	0.44	110.04 (162.20)	1743.97 (162.20)
	95% CI	5.78, 10.13	4.88, 9.91	0.30, 0.64	70.25, 172.35	1097.34, 2771.64

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.

Note: mCC = 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.11 (31.74)		5.17 (31.51)		5.15 (27.16)	
	95% CI of Geometric Mean	4.75, 5.49		4.70, 5.70		4.72, 5.62	
	Median	5.10		5.40		5.10	
	Q25, Q75	4.20, 6.30		4.40, 6.30		4.20, 6.30	
	Min, Max	2.1, 9.7		2.4, 10.3		3.1, 8.3	
	Mean (SD)	5.35 (1.629)		5.41 (1.588)		5.33 (1.403)	
	95% CI of Mean	4.97, 5.72		4.91, 5.91		4.87, 5.79	

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.52 (13.28)		5.06 (31.18)		2.65 (11.84)	
	95% CI of Geometric Mean	2.44, 2.60		4.60, 5.57		2.54, 2.76	
	Median	2.60	-48.85	5.10	1.04	2.70	-48.89
	Q25, Q75	2.40, 2.70	-58.73, -41.59	4.10, 6.30	-11.11, 8.51	2.40, 2.90	-57.81, -38.10
	Min, Max	1.7, 3.4	-73.3, -14.8	2.8, 10.0	-35.5, 25.7	1.9, 3.4	-65.8, -15.6
	Mean (SD)	2.54 (0.325)	-48.84 (13.749)	5.30 (1.618)	-1.04 (14.437)	2.67 (0.314)	-47.06 (13.210)
	95% CI of Mean	2.46, 2.62	-51.99, -45.69	4.79, 5.80	-5.55, 3.46	2.56, 2.77	-51.34, -42.77

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.33 (13.37)		5.29 (30.85)		2.42 (15.35)	
	95% CI of Geometric Mean	2.25, 2.41		4.81, 5.82		2.30, 2.55	
	Median	2.35	-52.94	5.15	0.00	2.40	-55.17
	Q25, Q75	2.20, 2.55	-60.75, -45.68	4.30, 6.80	-7.35, 15.15	2.20, 2.60	-62.00, -45.65
	Min, Max	1.6, 3.1	-78.4, -18.5	2.9, 9.0	-27.4, 47.8	1.9, 4.6	-72.4, -8.8
	Mean (SD)	2.35 (0.303)	-52.46 (13.621)	5.53 (1.696)	3.59 (16.859)	2.45 (0.442)	-50.90 (15.369)
	95% CI of Mean	2.27, 2.42	-55.58, -49.34	5.00, 6.07	-1.67, 8.84	2.30, 2.60	-55.89, -45.92

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.34 (13.69)		5.11 (31.02)		2.33 (13.22)	
	95% CI of Geometric Mean	2.27, 2.42		4.64, 5.62		2.23, 2.44	
	Median	2.40	-52.89	4.95	0.00	2.30	-54.10
	Q25, Q75	2.15, 2.60	-61.42, -44.19	4.10, 6.00	-12.62, 11.32	2.10, 2.60	-61.54, -46.00
	Min, Max	1.4, 3.1	-78.4, -4.8	2.9, 9.4	-32.9, 39.4	1.8, 3.0	-73.4, -11.8
	Mean (SD)	2.37 (0.310)	-51.83 (15.287)	5.35 (1.703)	0.16 (17.377)	2.35 (0.313)	-52.98 (13.315)
	95% CI of Mean	2.29, 2.44	-55.33, -48.33	4.81, 5.88	-5.26, 5.58	2.24, 2.46	-57.30, -48.66

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.39 (14.49)		5.28 (30.20)		2.44 (11.00)	
	95% CI of Geometric Mean	2.31, 2.48		4.81, 5.79		2.35, 2.54	
	Median	2.45	-51.44	5.50	2.39	2.50	-53.85
	Q25, Q75	2.25, 2.70	-61.62, -43.49	4.30, 6.50	-8.06, 14.89	2.30, 2.60	-58.82, -41.67
	Min, Max	1.5, 3.1	-77.5, 14.8	2.5, 9.7	-29.6, 36.4	1.9, 3.1	-75.3, -14.7
	Mean (SD)	2.42 (0.323)	-50.64 (16.571)	5.50 (1.571)	3.24 (15.964)	2.46 (0.270)	-50.75 (13.378)
	95% CI of Mean	2.34, 2.49	-54.43, -46.85	5.01, 5.99	-1.74, 8.22	2.37, 2.55	-55.10, -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 / THS 2.2 Menthol arms or the last assessment prior to 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - Within 15							
Min Prior To Smoking	n	76	76	41	41		
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	2.57 (11.75)		3.97 (21.54)			
	95% CI of Geometric Mean	2.50, 2.65		3.71, 4.25			
	Median	2.60	-47.50	4.00	-22.22		
	Q25, Q75	2.40, 2.80	-57.28, -39.57	3.50, 4.50	-33.33, -14.89		
	Min, Max	1.9, 3.2	-74.4, 4.8	2.6, 6.5	-44.4, 17.2		
	Mean (SD)	2.59 (0.298)	-47.29 (16.120)	4.06 (0.891)	-21.69 (14.913)		
	95% CI of Mean	2.52, 2.66	-50.98, -43.60	3.77, 4.35	-26.40, -16.98		

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 08:00 - 09:30	n					39	39
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					2.66 (12.65)	
	95% CI of Geometric Mean					2.55, 2.77	
	Median					2.70	-47.92
	Q25, Q75					2.50, 3.00	-57.14, -37.50
	Min, Max					1.9, 3.2	-67.9, -8.8
	Mean (SD)					2.68 (0.326)	-46.40 (15.295)
	95% CI of Mean					2.57, 2.79	-51.36, -41.44

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 12:00 - 13:30	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.62 (12.28)		5.19 (30.87)		2.57 (12.55)	
	95% CI of Geometric Mean	2.54, 2.69		4.71, 5.71		2.47, 2.68	
	Median	2.70	-47.24	5.00	6.82	2.60	-51.06
	Q25, Q75	2.50, 2.80	-59.69, -38.83	4.10, 6.70	-8.86, 15.22	2.40, 2.80	-56.90, -41.67
	Min, Max	1.6, 3.3	-73.3, 23.8	2.7, 10.4	-38.4, 44.4	2.0, 3.3	-71.6, -2.9
	Mean (SD)	2.63 (0.302)	-46.37 (16.960)	5.43 (1.691)	2.75 (20.604)	2.59 (0.326)	-47.81 (16.267)
	95% CI of Mean	2.56, 2.71	-50.25, -42.48	4.89, 5.97	-3.76, 9.26	2.48, 2.70	-53.09, -42.53

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 16:00 - 17:30	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.50 (15.52)		5.33 (30.90)		2.54 (13.34)	
	95% CI of Geometric Mean	2.41, 2.59		4.84, 5.87		2.43, 2.66	
	Median	2.60	-50.00	5.10	4.65	2.50	-51.22
	Q25, Q75	2.35, 2.75	-59.57, -42.16	4.50, 6.70	-6.25, 13.21	2.30, 2.70	-58.93, -40.48
	Min, Max	1.2, 3.3	-75.3, -4.5	2.4, 10.4	-26.0, 35.1	2.0, 3.4	-71.6, -2.9
	Mean (SD)	2.52 (0.346)	-48.89 (15.541)	5.57 (1.696)	4.50 (15.975)	2.57 (0.352)	-48.34 (16.224)
	95% CI of Mean	2.44, 2.61	-52.44, -45.33	5.03, 6.11	-0.54, 9.55	2.45, 2.69	-53.60, -43.07

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 20:00 - 21:30	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.48 (14.16)		5.55 (29.83)		2.50 (15.50)	
	95% CI of Geometric Mean	2.40, 2.57		5.06, 6.08		2.38, 2.64	
	Median	2.50	-49.53	5.65	7.05	2.40	-53.66
	Q25, Q75	2.30, 2.70	-60.16, -41.24	4.40, 7.10	-2.13, 16.39	2.40, 2.80	-60.00, -41.67
	Min, Max	1.4, 3.2	-78.4, -4.8	2.7, 9.5	-32.9, 51.9	1.7, 3.4	-70.4, -8.8
	Mean (SD)	2.50 (0.327)	-49.24 (15.099)	5.78 (1.648)	8.90 (18.963)	2.53 (0.383)	-49.11 (16.379)
	95% CI of Mean	2.42, 2.58	-52.69, -45.78	5.26, 6.30	2.98, 14.81	2.40, 2.66	-54.42, -43.80

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 10 AM 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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.16 (30.46)		5.16 (31.85)		5.15 (27.16)	
	95% CI of Geometric Mean	4.81, 5.54		4.67, 5.69		4.72, 5.62	
	Median	5.10		5.40		5.10	
	Q25, Q75	4.20, 6.30		4.40, 6.30		4.20, 6.30	
	Min, Max	2.1, 9.7		2.4, 10.3		3.1, 8.3	
	Mean (SD)	5.39 (1.609)		5.40 (1.606)		5.33 (1.403)	
	95% CI of Mean	5.01, 5.77		4.88, 5.91		4.87, 5.79	

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 10 AM 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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.89 (13.18)		6.00 (25.33)		2.87 (12.34)	
	95% CI of Geometric Mean	2.80, 2.99		5.54, 6.50		2.75, 2.99	
	Median	3.00	-42.58	6.10	12.96	2.90	-45.90
	Q25, Q75	2.70, 3.20	-53.62, -32.35	5.30, 6.70	0.00, 35.94	2.70, 3.20	-54.00, -28.95
	Min, Max	2.1, 4.2	-72.2, 33.3	3.7, 11.4	-32.0, 117.9	2.2, 3.4	-71.1, -6.3
	Mean (SD)	2.92 (0.376)	-41.14 (18.936)	6.19 (1.593)	20.15 (32.154)	2.89 (0.349)	-41.78 (17.418)
	95% CI of Mean	2.83, 3.01	-45.53, -36.75	5.68, 6.70	9.99, 30.30	2.77, 3.01	-47.43, -36.13

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 10 AM 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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.16 (30.12)		5.16 (31.85)		5.08 (26.28)	
	95% CI of Geometric Mean	4.80, 5.53		4.67, 5.69		4.67, 5.54	
	Median	5.10		5.40		5.05	
	Q25, Q75	4.20, 6.30		4.40, 6.30		4.20, 6.10	
	Min, Max	2.1, 9.7		2.4, 10.3		3.1, 8.1	
	Mean (SD)	5.38 (1.590)		5.40 (1.606)		5.25 (1.333)	
	95% CI of Mean	5.00, 5.76		4.88, 5.91		4.81, 5.69	

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 10 AM 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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.98 (13.36)		5.87 (25.59)		3.04 (18.43)	
	95% CI of Geometric Mean	2.88, 3.08		5.42, 6.37		2.86, 3.24	
	Median	2.90	-44.90	6.10	9.30	2.95	-46.85
	Q25, Q75	2.70, 3.20	-52.38, -25.93	4.90, 6.80	-4.41, 31.03	2.70, 3.20	-51.79, -25.58
	Min, Max	2.3, 5.6	-69.4, 47.6	3.3, 11.8	-31.1, 118.5	2.3, 5.3	-67.1, 46.9
	Mean (SD)	3.01 (0.454)	-39.19 (21.030)	6.06 (1.556)	17.68 (32.349)	3.10 (0.657)	-36.78 (23.157)
	95% CI of Mean	2.89, 3.12	-44.17, -34.21	5.56, 6.55	7.46, 27.89	2.88, 3.32	-44.40, -29.16

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 10 AM 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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.15 (31.10)		5.16 (31.85)		5.03 (25.72)	
	95% CI of Geometric Mean	4.79, 5.54		4.67, 5.69		4.62, 5.48	
	Median	5.10		5.40		5.00	
	Q25, Q75	4.20, 6.30		4.40, 6.30		4.20, 6.10	
	Min, Max	2.1, 9.7		2.4, 10.3		3.1, 8.1	
	Mean (SD)	5.39 (1.640)		5.40 (1.606)		5.19 (1.292)	
	95% CI of Mean	4.99, 5.78		4.88, 5.91		4.75, 5.62	

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 10 AM 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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.97 (12.22)		5.73 (28.18)		3.04 (20.22)	
	95% CI of Geometric Mean	2.88, 3.06		5.24, 6.25		2.84, 3.26	
	Median	2.90	-41.41	6.00	10.13	2.90	-41.67
	Q25, Q75	2.70, 3.20	-53.03, -28.95	4.30, 6.80	-5.71, 29.79	2.70, 3.20	-51.11, -25.53
	Min, Max	2.4, 4.3	-71.9, 52.4	3.2, 11.9	-31.3, 89.7	2.2, 5.3	-65.4, 14.7
	Mean (SD)	2.99 (0.382)	-39.18 (21.121)	5.95 (1.687)	14.17 (27.981)	3.11 (0.697)	-36.34 (20.951)
	95% CI of Mean	2.89, 3.09	-44.22, -34.14	5.41, 6.48	5.33, 23.01	2.87, 3.34	-43.33, -29.35

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Baseline	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	5.23 (25.02)	4.95 (39.27)	5.26 (30.28)	5.06 (34.11)	5.13 (29.95)	5.17 (24.07)
	95% CI of Geometric Mean	4.85, 5.65	4.32, 5.66	4.65, 5.94	4.26, 6.00	4.50, 5.85	4.57, 5.85
	Median	5.10	5.10	5.60	5.30	5.05	5.20
	Q25, Q75	4.30, 6.30	3.90, 6.30	4.50, 6.30	4.40, 6.20	4.20, 6.10	4.30, 6.40
	Min, Max	3.2, 9.4	2.1, 9.7	2.7, 10.3	2.4, 7.8	3.1, 8.3	3.2, 7.6
	Mean (SD)	5.39 (1.381)	5.29 (1.926)	5.48 (1.607)	5.31 (1.604)	5.35 (1.555)	5.31 (1.227)
	95% CI of Mean	4.96, 5.82	4.60, 5.98	4.81, 6.14	4.48, 6.14	4.65, 6.04	4.67, 5.94

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 1	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.61 (10.02)	2.41 (15.70)	5.15 (30.10)	4.94 (33.53)	2.70 (12.01)	2.58 (11.49)
	95% CI of Geometric Mean	2.52, 2.69	2.28, 2.55	4.56, 5.82	4.17, 5.84	2.56, 2.85	2.43, 2.75
	Median	2.60	2.40	5.20	5.10	2.70	2.60
	Q25, Q75	2.50, 2.70	2.10, 2.70	4.30, 6.30	4.00, 6.00	2.40, 2.90	2.40, 2.70
	Min, Max	2.1, 3.4	1.7, 3.1	3.0, 10.0	2.8, 8.8	2.3, 3.4	1.9, 3.1
	Mean (SD)	2.62 (0.267)	2.44 (0.367)	5.37 (1.589)	5.19 (1.703)	2.72 (0.331)	2.60 (0.286)
	95% CI of Mean	2.53, 2.71	2.30, 2.57	4.71, 6.03	4.31, 6.07	2.57, 2.87	2.45, 2.75

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 1							
	n	43	33	25	17	22	17
	Median	-48.08	-49.02	-1.56	3.85	-48.10	-53.85
	Q25, Q75	-56.52, -40.48	-60.94, -41.67	-6.06, 6.98	-11.36, 8.51	-55.36, -37.50	-57.81, -41.46
	Min, Max	-73.3, -18.8	-72.9, -14.8	-29.5, 20.9	-35.5, 25.7	-65.8, -17.6	-64.5, -15.6
	Mean (SD)	-48.77 (12.002)	-48.93 (15.937)	-1.11 (13.138)	-0.95 (16.589)	-45.80 (13.689)	-48.68 (12.787)
	95% CI of Mean	-52.47, -45.08	-54.58, -43.27	-6.53, 4.32	-9.48, 7.58	-51.87, -39.73	-55.26, -42.10

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 2							
	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.39 (9.43)	2.26 (16.90)	5.34 (26.61)	5.22 (37.27)	2.45 (10.56)	2.39 (20.30)
	95% CI of Geometric Mean	2.31, 2.46	2.12, 2.40	4.79, 5.95	4.34, 6.29	2.33, 2.57	2.15, 2.65
	Median	2.30	2.40	5.20	5.10	2.40	2.30
	Q25, Q75	2.20, 2.60	2.10, 2.50	4.30, 6.70	4.40, 6.80	2.30, 2.60	2.10, 2.50
	Min, Max	1.9, 2.9	1.6, 3.1	3.5, 8.6	2.9, 9.0	2.0, 3.1	1.9, 4.6
	Mean (SD)	2.40 (0.225)	2.29 (0.377)	5.52 (1.486)	5.55 (2.015)	2.46 (0.264)	2.44 (0.611)
	95% CI of Mean	2.32, 2.47	2.15, 2.43	4.90, 6.14	4.51, 6.59	2.34, 2.58	2.12, 2.76

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 2							
	n	43	33	25	17	22	17
	Median	-51.92	-52.94	0.00	0.00	-53.14	-55.74
	Q25, Q75	-61.76, -45.24	-59.74, -45.71	-7.35, 10.61	-6.38, 20.51	-60.78, -42.86	-62.00, -46.34
	Min, Max	-75.6, -18.8	-78.4, -18.5	-18.5, 33.3	-27.4, 47.8	-70.4, -8.8	-72.4, -11.5
	Mean (SD)	-53.00 (11.554)	-51.76 (16.085)	2.59 (15.063)	5.04 (19.600)	-50.17 (15.828)	-51.85 (15.181)
	95% CI of Mean	-56.56, -49.44	-57.47, -46.05	-3.63, 8.82	-5.04, 15.13	-57.20, -43.15	-59.66, -44.04

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 3	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.41 (9.62)	2.26 (17.17)	5.13 (26.21)	5.08 (38.13)	2.39 (13.43)	2.25 (12.50)
	95% CI of Geometric Mean	2.33, 2.49	2.12, 2.41	4.61, 5.71	4.19, 6.14	2.25, 2.54	2.11, 2.41
	Median	2.40	2.30	5.10	4.90	2.40	2.20
	Q25, Q75	2.20, 2.60	2.10, 2.40	4.10, 5.90	4.10, 6.20	2.10, 2.70	2.10, 2.40
	Min, Max	2.0, 3.0	1.4, 3.1	3.5, 9.0	2.9, 9.4	1.8, 3.0	1.8, 2.8
	Mean (SD)	2.42 (0.232)	2.29 (0.381)	5.30 (1.435)	5.42 (2.081)	2.41 (0.323)	2.27 (0.289)
	95% CI of Mean	2.34, 2.50	2.15, 2.43	4.70, 5.90	4.34, 6.49	2.27, 2.56	2.12, 2.42

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 3							
	n	43	33	25	17	22	17
	Median	-51.92	-52.94	-6.25	5.13	-52.53	-57.81
	Q25, Q75	-60.29, -44.44	-63.49, -44.12	-12.62, 4.26	-10.26, 13.04	-58.90, -41.94	-64.00, -47.83
	Min, Max	-75.6, -25.0	-78.4, -4.8	-29.6, 39.4	-32.9, 32.9	-73.4, -11.8	-71.1, -28.1
	Mean (SD)	-52.50 (11.635)	-50.96 (19.200)	-1.07 (17.220)	1.97 (17.975)	-51.37 (14.550)	-55.07 (11.620)
	95% CI of Mean	-56.09, -48.91	-57.77, -44.14	-8.19, 6.04	-7.27, 11.22	-57.83, -44.92	-61.04, -49.09

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 4	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.49 (7.43)	2.28 (19.38)	5.28 (24.52)	5.27 (38.19)	2.47 (10.80)	2.41 (11.42)
	95% CI of Geometric Mean	2.43, 2.55	2.12, 2.44	4.78, 5.84	4.36, 6.38	2.35, 2.60	2.27, 2.56
	Median	2.50	2.30	5.40	5.70	2.50	2.40
	Q25, Q75	2.40, 2.70	2.00, 2.60	4.30, 6.30	4.50, 6.60	2.30, 2.70	2.30, 2.50
	Min, Max	2.1, 2.8	1.5, 3.1	3.2, 8.7	2.5, 9.7	2.0, 3.0	1.9, 3.1
	Mean (SD)	2.49 (0.182)	2.32 (0.426)	5.43 (1.316)	5.60 (1.926)	2.49 (0.265)	2.42 (0.280)
	95% CI of Mean	2.43, 2.55	2.16, 2.47	4.88, 5.98	4.60, 6.60	2.36, 2.61	2.27, 2.57

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 4							
	n	43	33	25	17	22	17
	Median	-49.06	-53.70	-1.64	4.17	-52.03	-53.85
	Q25, Q75	-60.32, -42.86	-63.41, -44.12	-11.11, 14.89	-1.69, 14.29	-58.33, -38.89	-60.94, -45.24
	Min, Max	-74.4, -21.9	-77.5, 14.8	-24.6, 36.4	-29.6, 32.6	-75.3, -14.7	-68.4, -31.3
	Mean (SD)	-50.89 (12.500)	-50.32 (20.936)	1.73 (16.144)	5.46 (15.916)	-49.60 (15.187)	-52.25 (10.867)
	95% CI of Mean	-54.74, -47.04	-57.75, -42.89	-4.94, 8.40	-2.72, 13.65	-56.34, -42.86	-57.84, -46.66

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 5 - Within 15 Min Prior To Smoking							
	n	43	33	24	17		
	Missing, n (%)	0	0	1 (4.0)	0		
	BLOQ, n (%)	0	0	0	0		
	Geometric Mean (CV%)	2.64 (9.73)	2.49 (13.47)	4.01 (21.95)	3.92 (21.56)		
	95% CI of Geometric Mean	2.55, 2.72	2.37, 2.62	3.65, 4.40	3.51, 4.38		
	Median	2.60	2.50	4.00	4.00		
	Q25, Q75	2.50, 2.80	2.20, 2.80	3.50, 4.45	3.40, 4.60		
	Min, Max	2.2, 3.2	1.9, 3.1	2.9, 6.5	2.6, 6.0		
	Mean (SD)	2.65 (0.261)	2.52 (0.329)	4.10 (0.933)	4.01 (0.855)		
	95% CI of Mean	2.56, 2.73	2.39, 2.64	3.70, 4.50	3.56, 4.45		

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 5 - Within 15 Min Prior To Smoking							
	n	43	33	24	17		
	Median	-46.94	-48.15	-22.57	-22.08		
	Q25, Q75	-57.63, -37.78	-56.52, -40.38	-33.85, -11.87	-32.88, -16.95		
	Min, Max	-74.4, -17.6	-74.2, 4.8	-44.4, 7.4	-41.0, 17.2		
	Mean (SD)	-47.91 (13.233)	-46.49 (19.443)	-22.11 (14.631)	-21.10 (15.737)		
	95% CI of Mean	-51.99, -43.83	-53.39, -39.59	-28.30, -15.93	-29.19, -13.00		

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 5 - 08:00 - 09:30	n					22	17
	BLOQ, n (%)					0	0
	Geometric Mean (CV%)					2.71 (10.89)	2.59 (14.52)
	95% CI of Geometric Mean					2.58, 2.85	2.40, 2.79
	Median					2.70	2.60
	Q25, Q75					2.50, 3.00	2.30, 2.80
	Min, Max					2.1, 3.2	1.9, 3.2
	Mean (SD)					2.73 (0.290)	2.61 (0.366)
	95% CI of Mean					2.59, 2.86	2.42, 2.80

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 5 - 08:00 - 09:30							
	n					22	17
	Median					-48.96	-47.62
	Q25, Q75					-56.16, -33.33	-59.38, -43.90
	Min, Max					-67.9, -8.8	-65.8, -12.5
	Mean (SD)					-44.99 (16.024)	-48.22 (14.570)
	95% CI of Mean					-52.10, -37.88	-55.72, -40.73

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 5 - 12:00 - 13:30							
	n	43	33	24	17	22	17
	Missing, n (%)	0	0	1 (4.0)	0	0	0
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.69 (8.36)	2.52 (15.41)	5.14 (27.66)	5.26 (35.91)	2.65 (12.10)	2.48 (12.54)
	95% CI of Geometric Mean	2.62, 2.77	2.38, 2.67	4.58, 5.77	4.39, 6.29	2.50, 2.80	2.32, 2.65
	Median	2.70	2.60	5.00	5.00	2.60	2.50
	Q25, Q75	2.50, 2.80	2.20, 2.80	4.05, 6.80	4.50, 6.70	2.50, 2.80	2.30, 2.70
	Min, Max	2.3, 3.3	1.6, 3.0	3.2, 8.3	2.7, 10.4	2.1, 3.3	2.0, 3.1
	Mean (SD)	2.70 (0.228)	2.55 (0.363)	5.33 (1.452)	5.57 (2.019)	2.66 (0.326)	2.50 (0.311)
	95% CI of Mean	2.62, 2.78	2.41, 2.68	4.71, 5.94	4.53, 6.61	2.51, 2.81	2.34, 2.66

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 5 - 12:00 - 13:30							
	n	43	33	24	17	22	17
	Median	-46.15	-48.72	-3.15	10.26	-49.92	-52.46
	Q25, Q75	-59.09, -37.78	-60.94, -40.00	-11.06, 13.25	2.17, 15.22	-56.67, -35.90	-57.81, -48.78
	Min, Max	-73.3, -17.6	-73.2, 23.8	-36.9, 44.4	-38.4, 35.1	-71.6, -2.9	-69.7, -15.6
	Mean (SD)	-46.83 (13.562)	-45.76 (20.787)	0.56 (21.845)	5.83 (18.924)	-45.64 (18.568)	-50.62 (12.693)
	95% CI of Mean	-51.01, -42.65	-53.13, -38.38	-8.66, 9.79	-3.90, 15.57	-53.87, -37.40	-57.15, -44.09

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 5 - 16:00 - 17:30							
	n	43	33	24	17	22	17
	Missing, n (%)	0	0	1 (4.0)	0	0	0
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.62 (8.98)	2.34 (19.63)	5.42 (27.17)	5.20 (36.42)	2.56 (12.45)	2.53 (14.78)
	95% CI of Geometric Mean	2.55, 2.70	2.18, 2.51	4.84, 6.07	4.33, 6.24	2.42, 2.71	2.34, 2.73
	Median	2.60	2.50	5.10	5.00	2.50	2.50
	Q25, Q75	2.50, 2.80	2.10, 2.70	4.50, 7.20	4.40, 6.50	2.30, 2.70	2.30, 2.70
	Min, Max	2.2, 3.3	1.2, 3.0	3.4, 8.0	2.4, 10.4	2.1, 3.3	2.0, 3.4
	Mean (SD)	2.63 (0.236)	2.38 (0.414)	5.61 (1.505)	5.51 (1.983)	2.58 (0.334)	2.55 (0.383)
	95% CI of Mean	2.56, 2.71	2.23, 2.53	4.97, 6.25	4.49, 6.54	2.42, 2.73	2.35, 2.75

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 5 - 16:00 - 17:30							
	n	43	33	24	17	22	17
	Median	-48.08	-51.85	3.89	4.84	-50.41	-52.73
	Q25, Q75	-58.82, -41.46	-60.32, -43.14	-6.92, 19.66	-4.55, 12.82	-58.82, -35.90	-58.93, -41.30
	Min, Max	-70.0, -12.5	-75.3, -4.5	-22.3, 30.3	-26.0, 35.1	-71.6, -2.9	-71.1, -10.5
	Mean (SD)	-48.21 (13.587)	-49.77 (17.955)	4.86 (16.475)	4.00 (15.728)	-47.73 (17.015)	-49.13 (15.621)
	95% CI of Mean	-52.40, -44.03	-56.14, -43.40	-2.10, 11.82	-4.09, 12.09	-55.28, -40.18	-57.17, -41.10

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 5 - 20:00 - 21:30							
	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.59 (9.15)	2.35 (17.45)	5.81 (24.26)	5.19 (36.43)	2.61 (13.11)	2.37 (17.11)
	95% CI of Geometric Mean	2.51, 2.67	2.20, 2.50	5.26, 6.42	4.32, 6.23	2.45, 2.77	2.17, 2.60
	Median	2.60	2.40	5.90	4.90	2.55	2.40
	Q25, Q75	2.50, 2.70	2.10, 2.70	4.70, 7.10	4.20, 7.10	2.40, 2.80	2.20, 2.70
	Min, Max	2.2, 3.2	1.4, 2.9	4.1, 8.9	2.7, 9.5	2.1, 3.4	1.7, 3.0
	Mean (SD)	2.60 (0.238)	2.38 (0.385)	5.97 (1.425)	5.50 (1.943)	2.63 (0.353)	2.41 (0.395)
	95% CI of Mean	2.52, 2.68	2.24, 2.52	5.38, 6.57	4.50, 6.50	2.47, 2.79	2.20, 2.61

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 10 AM 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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 5 - 20:00 - 21:30							
	n	43	33	25	17	22	17
	Median	-48.08	-51.85	9.26	3.85	-50.41	-54.76
	Q25, Q75	-57.35, -42.22	-60.94, -38.24	0.00, 21.05	-7.69, 13.79	-58.62, -35.90	-62.50, -48.94
	Min, Max	-73.4, -15.6	-78.4, -4.8	-26.2, 51.9	-32.9, 34.0	-70.4, -8.8	-69.7, -9.4
	Mean (SD)	-48.99 (12.675)	-49.56 (17.979)	12.13 (19.357)	4.13 (17.858)	-46.62 (17.565)	-52.33 (14.584)
	95% CI of Mean	-52.90, -45.09	-55.94, -43.18	4.14, 20.13	-5.05, 13.32	-54.42, -38.83	-59.83, -44.82

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 10 AM 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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Baseline							
	n	42	32	24	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	5.23 (25.33)	5.07 (36.68)	5.23 (30.86)	5.06 (34.11)	5.13 (29.95)	5.17 (24.07)
	95% CI of Geometric Mean	4.83, 5.66	4.46, 5.77	4.60, 5.95	4.26, 6.00	4.50, 5.85	4.57, 5.85
	Median	5.10	5.15	5.50	5.30	5.05	5.20
	Q25, Q75	4.30, 6.30	4.00, 6.35	4.40, 6.35	4.40, 6.20	4.20, 6.10	4.30, 6.40
	Min, Max	3.2, 9.4	2.1, 9.7	2.7, 10.3	2.4, 7.8	3.1, 8.3	3.2, 7.6
	Mean (SD)	5.39 (1.398)	5.38 (1.874)	5.46 (1.639)	5.31 (1.604)	5.35 (1.555)	5.31 (1.227)
	95% CI of Mean	4.95, 5.83	4.70, 6.06	4.76, 6.16	4.48, 6.14	4.65, 6.04	4.67, 5.94

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 10 AM 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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Day 30	n	42	32	24	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	3.04 (9.58)	2.71 (14.48)	6.12 (23.15)	5.84 (28.69)	2.93 (11.37)	2.79 (13.32)
	95% CI of Geometric Mean	2.95, 3.14	2.57, 2.86	5.55, 6.74	5.05, 6.75	2.78, 3.08	2.60, 2.99
	Median	3.00	2.80	6.20	5.90	2.90	2.80
	Q25, Q75	2.90, 3.20	2.35, 3.00	5.15, 7.15	5.30, 6.60	2.70, 3.30	2.50, 3.10
	Min, Max	2.5, 4.2	2.1, 3.3	3.7, 9.5	3.7, 11.4	2.4, 3.4	2.2, 3.4
	Mean (SD)	3.05 (0.309)	2.74 (0.383)	6.27 (1.428)	6.07 (1.840)	2.95 (0.328)	2.81 (0.369)
	95% CI of Mean	2.95, 3.16	2.59, 2.88	5.66, 6.88	5.12, 7.02	2.80, 3.10	2.62, 3.01

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 10 AM 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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 30							
	n	42	32	24	17	22	17
	Median	-41.34	-44.02	12.30	14.81	-41.55	-46.43
	Q25, Q75	-51.67, -29.55	-58.32, -35.77	3.11, 42.53	-4.55, 27.59	-53.33, -23.81	-54.00, -33.33
	Min, Max	-67.0, -7.9	-72.2, 33.3	-32.0, 96.3	-28.2, 117.9	-71.1, -6.3	-68.4, -9.4
	Mean (SD)	-39.88 (15.516)	-42.79 (22.825)	20.41 (30.316)	19.78 (35.542)	-39.97 (18.978)	-44.12 (15.411)
	95% CI of Mean	-44.72, -35.04	-51.02, -34.56	7.60, 33.21	1.50, 38.06	-48.39, -31.55	-52.05, -36.19

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 10 AM 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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Baseline	n	41	30	24	17	21	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	5.20 (24.58)	5.10 (37.03)	5.23 (30.86)	5.06 (34.11)	5.02 (28.50)	5.17 (24.07)
	95% CI of Geometric Mean	4.81, 5.62	4.46, 5.84	4.60, 5.95	4.26, 6.00	4.41, 5.70	4.57, 5.85
	Median	5.10	5.15	5.50	5.30	5.00	5.20
	Q25, Q75	4.30, 6.30	4.10, 6.40	4.40, 6.35	4.40, 6.20	4.20, 6.00	4.30, 6.40
	Min, Max	3.2, 9.4	2.1, 9.7	2.7, 10.3	2.4, 7.8	3.1, 8.1	3.2, 7.6
	Mean (SD)	5.35 (1.346)	5.42 (1.898)	5.46 (1.639)	5.31 (1.604)	5.20 (1.442)	5.31 (1.227)
	95% CI of Mean	4.92, 5.78	4.70, 6.13	4.76, 6.16	4.48, 6.14	4.54, 5.87	4.67, 5.94

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 10 AM 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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Day 60	n	41	30	24	17	21	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.99 (13.79)	2.96 (12.95)	5.77 (23.61)	6.02 (28.78)	3.13 (22.17)	2.93 (12.15)
	95% CI of Geometric Mean	2.86, 3.13	2.82, 3.11	5.23, 6.38	5.20, 6.96	2.83, 3.47	2.75, 3.13
	Median	2.90	2.90	5.85	6.10	3.00	2.90
	Q25, Q75	2.70, 3.20	2.70, 3.30	4.85, 6.85	5.50, 6.80	2.60, 3.20	2.70, 3.20
	Min, Max	2.4, 5.6	2.3, 4.0	3.3, 8.4	3.7, 11.8	2.6, 5.3	2.3, 3.6
	Mean (SD)	3.02 (0.498)	2.99 (0.394)	5.92 (1.315)	6.25 (1.871)	3.21 (0.815)	2.95 (0.356)
	95% CI of Mean	2.86, 3.18	2.83, 3.14	5.36, 6.48	5.29, 7.22	2.84, 3.59	2.77, 3.14

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 10 AM 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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
% Change from baseline to Day 60							
	n	41	30	24	17	21	17
	Median	-44.83	-45.19	8.35	14.81	-42.22	-47.54
	Q25, Q75	-53.03, -28.57	-51.95, -25.00	-5.74, 29.17	-1.61, 31.03	-52.38, -14.29	-49.09, -29.79
	Min, Max	-66.3, 33.3	-69.4, 47.6	-31.1, 118.5	-12.8, 100.0	-67.1, 46.9	-63.2, -13.2
	Mean (SD)	-39.88 (18.990)	-38.25 (23.844)	14.31 (32.723)	22.42 (32.187)	-32.70 (28.334)	-41.82 (13.703)
	95% CI of Mean	-45.88, -33.88	-47.15, -29.34	0.49, 28.14	5.87, 38.98	-45.61, -19.80	-48.87, -34.77

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 10 AM 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=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Baseline	n	39	31	24	17	21	16
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	5.22 (25.78)	5.06 (37.30)	5.23 (30.86)	5.06 (34.11)	5.02 (28.50)	5.05 (22.54)
	95% CI of Geometric Mean	4.80, 5.67	4.43, 5.79	4.60, 5.95	4.26, 6.00	4.41, 5.70	4.48, 5.69
	Median	5.10	5.10	5.50	5.30	5.00	5.10
	Q25, Q75	4.20, 6.30	3.90, 6.40	4.40, 6.35	4.40, 6.20	4.20, 6.00	4.25, 6.25
	Min, Max	3.2, 9.4	2.1, 9.7	2.7, 10.3	2.4, 7.8	3.1, 8.1	3.2, 7.0
	Mean (SD)	5.39 (1.422)	5.38 (1.905)	5.46 (1.639)	5.31 (1.604)	5.20 (1.442)	5.16 (1.110)
	95% CI of Mean	4.92, 5.86	4.68, 6.09	4.76, 6.16	4.48, 6.14	4.54, 5.87	4.57, 5.76

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 10 AM 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=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Day 90	n	39	31	24	17	21	16
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	3.00 (13.44)	2.93 (10.60)	5.60 (25.60)	5.91 (32.09)	3.17 (24.08)	2.88 (12.61)
	95% CI of Geometric Mean	2.86, 3.13	2.82, 3.05	5.03, 6.24	5.03, 6.95	2.84, 3.53	2.69, 3.09
	Median	2.90	3.00	5.70	6.10	3.10	2.90
	Q25, Q75	2.70, 3.30	2.70, 3.20	4.30, 6.85	5.30, 6.60	2.70, 3.30	2.70, 3.10
	Min, Max	2.4, 4.3	2.4, 3.6	3.9, 8.7	3.2, 11.9	2.2, 5.3	2.3, 3.7
	Mean (SD)	3.02 (0.431)	2.95 (0.312)	5.78 (1.454)	6.19 (1.993)	3.26 (0.847)	2.91 (0.368)
	95% CI of Mean	2.88, 3.17	2.83, 3.07	5.16, 6.39	5.16, 7.22	2.87, 3.65	2.71, 3.11

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 10 AM 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=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
% Change from baseline to Day 90							
	n	39	31	24	17	21	16
	Median	-41.30	-42.31	6.85	10.34	-41.67	-42.01
	Q25, Q75	-53.03, -33.33	-56.52, -27.78	-9.10, 18.68	-2.74, 30.43	-48.33, -12.07	-51.67, -28.59
	Min, Max	-70.2, 0.0	-71.9, 52.4	-31.3, 69.7	-15.4, 89.7	-65.4, 14.7	-64.6, -12.5
	Mean (SD)	-40.56 (15.933)	-37.45 (26.437)	9.91 (25.783)	20.19 (30.595)	-32.86 (24.231)	-40.92 (15.204)
	95% CI of Mean	-45.73, -35.39	-47.15, -27.74	-0.98, 20.80	4.45, 35.92	-43.89, -21.82	-49.03, -32.82

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 10 AM 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**

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
Baseline							
	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	4.61 (29.01)	5.69 (30.96)	4.92 (34.55)	5.50 (27.05)	4.82 (27.55)	5.52 (25.57)
	95% CI of Geometric Mean	4.20, 5.06	5.14, 6.30	4.25, 5.69	4.83, 6.26	4.25, 5.48	4.88, 6.23
	Median	4.50	5.90	5.30	5.60	4.95	5.60
	Q25, Q75	3.90, 5.40	4.90, 6.80	4.30, 6.40	4.60, 6.20	3.95, 6.10	4.60, 7.00
	Min, Max	2.2, 8.5	2.1, 9.7	2.4, 7.7	3.3, 10.3	3.1, 7.9	3.6, 8.3
	Mean (SD)	4.79 (1.374)	5.93 (1.690)	5.17 (1.553)	5.69 (1.624)	4.99 (1.315)	5.68 (1.440)
	95% CI of Mean	4.34, 5.25	5.36, 6.50	4.49, 5.85	4.91, 6.48	4.37, 5.61	4.99, 6.38

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 1	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.50 (11.57)	2.54 (15.02)	4.84 (33.24)	5.35 (28.35)	2.62 (8.70)	2.68 (14.58)
	95% CI of Geometric Mean	2.41, 2.61	2.41, 2.67	4.20, 5.57	4.68, 6.13	2.51, 2.73	2.50, 2.88
	Median	2.60	2.60	5.00	5.20	2.60	2.70
	Q25, Q75	2.40, 2.70	2.40, 2.80	3.50, 6.30	4.20, 6.30	2.40, 2.75	2.40, 3.00
	Min, Max	1.8, 3.1	1.7, 3.4	2.8, 8.8	3.1, 10.0	2.3, 3.2	1.9, 3.4
	Mean (SD)	2.52 (0.278)	2.56 (0.370)	5.08 (1.604)	5.56 (1.638)	2.63 (0.234)	2.71 (0.382)
	95% CI of Mean	2.43, 2.62	2.43, 2.69	4.38, 5.78	4.76, 6.35	2.51, 2.74	2.52, 2.90

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 1							
	n	39	37	23	19	20	19
	Median	-45.65	-53.70	3.28	0.00	-48.40	-51.72
	Q25, Q75	-53.66, -35.14	-63.24, -47.06	-11.11, 13.11	-12.90, 7.69	-54.73, -32.07	-60.24, -40.48
	Min, Max	-67.1, -14.8	-73.3, -19.0	-30.1, 25.7	-35.5, 20.9	-65.8, -15.6	-64.5, -30.8
	Mean (SD)	-44.08 (13.643)	-53.86 (12.118)	-0.52 (15.153)	-1.67 (13.905)	-43.95 (15.067)	-50.32 (10.332)
	95% CI of Mean	-48.51, -39.65	-57.91, -49.82	-7.08, 6.04	-8.38, 5.03	-51.01, -36.90	-55.31, -45.34

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 2							
	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.31 (13.10)	2.35 (13.80)	5.10 (33.39)	5.54 (27.71)	2.44 (18.67)	2.40 (11.38)
	95% CI of Geometric Mean	2.21, 2.42	2.24, 2.46	4.42, 5.87	4.85, 6.32	2.23, 2.67	2.27, 2.54
	Median	2.30	2.40	5.10	5.30	2.40	2.40
	Q25, Q75	2.20, 2.50	2.20, 2.60	4.10, 6.80	4.40, 7.50	2.20, 2.60	2.20, 2.60
	Min, Max	1.6, 3.1	1.7, 3.1	2.9, 9.0	3.8, 8.9	1.9, 4.6	1.9, 2.9
	Mean (SD)	2.33 (0.292)	2.37 (0.318)	5.36 (1.750)	5.74 (1.651)	2.49 (0.565)	2.42 (0.272)
	95% CI of Mean	2.23, 2.43	2.26, 2.48	4.60, 6.12	4.94, 6.54	2.22, 2.75	2.28, 2.55

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 10 AM 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**

	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 2							
	n	39	37	23	19	20	19
	Median	-50.94	-55.07	2.27	0.00	-50.56	-60.00
	Q25, Q75	-57.63, -41.03	-66.67, -50.98	-7.35, 19.67	-8.33, 14.58	-59.15, -39.05	-63.33, -45.65
	Min, Max	-74.1, -18.5	-78.4, -19.0	-27.4, 47.8	-18.5, 33.3	-69.6, -8.8	-72.4, -30.6
	Mean (SD)	-48.19 (13.466)	-56.97 (12.428)	5.22 (18.767)	1.60 (14.468)	-46.99 (17.508)	-55.03 (11.836)
	95% CI of Mean	-52.56, -43.82	-61.11, -52.82	-2.90, 13.34	-5.37, 8.58	-55.19, -38.79	-60.74, -49.32

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 3							
	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.33 (13.14)	2.36 (14.40)	4.81 (33.25)	5.49 (27.15)	2.30 (13.73)	2.37 (12.86)
	95% CI of Geometric Mean	2.23, 2.44	2.24, 2.48	4.18, 5.54	4.82, 6.25	2.15, 2.46	2.22, 2.52
	Median	2.40	2.40	4.90	5.10	2.20	2.40
	Q25, Q75	2.20, 2.50	2.10, 2.60	3.70, 5.90	4.40, 7.10	2.10, 2.60	2.20, 2.60
	Min, Max	1.4, 3.0	1.6, 3.1	2.9, 9.4	3.8, 9.0	1.8, 3.0	1.8, 3.0
	Mean (SD)	2.35 (0.284)	2.38 (0.339)	5.07 (1.759)	5.68 (1.614)	2.32 (0.326)	2.38 (0.305)
	95% CI of Mean	2.25, 2.45	2.26, 2.50	4.30, 5.84	4.90, 6.47	2.16, 2.48	2.23, 2.54

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 3							
	n	39	37	23	19	20	19
	Median	-50.00	-55.07	-6.25	0.00	-53.72	-56.90
	Q25, Q75	-58.62, -38.64	-66.67, -50.00	-13.95, 13.11	-12.62, 10.26	-60.36, -41.76	-64.29, -47.62
	Min, Max	-74.1, -6.3	-78.4, -4.8	-32.9, 37.0	-29.6, 39.4	-73.4, -11.8	-71.6, -36.1
	Mean (SD)	-47.32 (15.510)	-56.59 (13.696)	-0.57 (18.340)	1.04 (16.588)	-50.29 (15.095)	-55.82 (10.826)
	95% CI of Mean	-52.35, -42.28	-61.16, -52.02	-8.50, 7.37	-6.96, 9.04	-57.36, -43.22	-61.04, -50.60

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 4							
	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.37 (15.12)	2.42 (13.92)	5.09 (36.54)	5.52 (20.69)	2.45 (10.15)	2.44 (12.11)
	95% CI of Geometric Mean	2.25, 2.49	2.30, 2.54	4.36, 5.94	4.99, 6.09	2.33, 2.58	2.29, 2.59
	Median	2.40	2.50	5.40	5.60	2.40	2.50
	Q25, Q75	2.30, 2.60	2.20, 2.70	3.80, 6.70	4.50, 6.30	2.25, 2.70	2.30, 2.60
	Min, Max	1.5, 3.1	1.6, 3.1	2.5, 9.7	4.3, 8.7	2.1, 2.9	1.9, 3.1
	Mean (SD)	2.39 (0.327)	2.44 (0.321)	5.39 (1.822)	5.63 (1.238)	2.47 (0.250)	2.45 (0.296)
	95% CI of Mean	2.28, 2.50	2.33, 2.55	4.60, 6.18	5.03, 6.23	2.34, 2.59	2.31, 2.60

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 4							
	n	39	37	23	19	20	19
	Median	-48.08	-55.00	4.17	1.61	-51.37	-55.17
	Q25, Q75	-57.81, -37.84	-64.71, -47.83	-4.92, 18.03	-13.92, 13.95	-57.14, -38.17	-62.00, -46.81
	Min, Max	-72.9, 14.8	-77.5, -4.8	-29.6, 32.6	-24.6, 36.4	-73.4, -14.7	-75.3, -38.1
	Mean (SD)	-46.16 (17.534)	-55.37 (14.241)	4.69 (16.045)	1.50 (16.123)	-47.21 (14.737)	-54.49 (10.948)
	95% CI of Mean	-51.85, -40.47	-60.12, -50.62	-2.26, 11.63	-6.28, 9.27	-54.11, -40.30	-59.77, -49.21

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 5 - Within 15							
Min Prior To							
Smoking							
	n	39	37	23	18		
	Missing, n (%)	0	0	0	1 (5.3)		
	BLOQ, n (%)	0	0	0	0		
	Geometric Mean (CV%)	2.58 (11.52)	2.57 (12.16)	3.88 (21.56)	4.10 (21.73)		
	95% CI of Geometric Mean	2.48, 2.68	2.46, 2.68	3.53, 4.26	3.68, 4.56		
	Median	2.60	2.60	4.00	4.00		
	Q25, Q75	2.40, 2.80	2.40, 2.80	3.40, 4.40	3.60, 4.60		
	Min, Max	2.0, 3.2	1.9, 3.2	2.6, 6.0	2.9, 6.5		
	Mean (SD)	2.59 (0.291)	2.59 (0.309)	3.96 (0.847)	4.19 (0.953)		
	95% CI of Mean	2.49, 2.69	2.48, 2.70	3.59, 4.33	3.71, 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 / THS 2.2 Menthol arms or the last assessment prior to 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 5 - Within 15 Min Prior To Smoking							
	n	39	37	23	18		
	Median	-44.90	-55.32	-22.22	-22.33		
	Q25, Q75	-50.98, -33.33	-60.87, -43.14	-32.86, -14.89	-35.71, -12.12		
	Min, Max	-70.6, 0.0	-74.4, 4.8	-38.9, 17.2	-44.4, 3.2		
	Mean (SD)	-42.18 (15.631)	-52.68 (15.011)	-19.93 (15.285)	-23.94 (14.539)		
	95% CI of Mean	-47.25, -37.11	-57.69, -47.67	-26.55, -13.32	-31.18, -16.71		

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 5 - 08:00 - 09:30	n					20	19
	BLOQ, n (%)					0	0
	Geometric Mean (CV%)					2.66 (12.58)	2.65 (13.06)
	95% CI of Geometric Mean					2.50, 2.83	2.49, 2.83
	Median					2.70	2.60
	Q25, Q75					2.45, 2.95	2.50, 3.00
	Min, Max					2.1, 3.2	1.9, 3.2
	Mean (SD)					2.68 (0.328)	2.67 (0.334)
	95% CI of Mean					2.52, 2.84	2.51, 2.84

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 5 - 08:00 - 09:30							
	n					20	19
	Median					-46.97	-50.00
	Q25, Q75					-56.25, -30.60	-62.00, -40.00
	Min, Max					-67.1, -8.8	-67.9, -25.0
	Mean (SD)					-42.69 (16.575)	-50.30 (13.132)
	95% CI of Mean					-50.45, -34.93	-56.64, -43.97

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 5 - 12:00 - 13:30							
	n	39	37	23	18	20	19
	Missing, n (%)	0	0	0	1 (5.3)	0	0
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.58 (13.61)	2.65 (10.70)	4.99 (34.92)	5.46 (24.99)	2.61 (11.64)	2.54 (13.60)
	95% CI of Geometric Mean	2.46, 2.70	2.56, 2.75	4.30, 5.78	4.82, 6.17	2.47, 2.76	2.37, 2.71
	Median	2.60	2.70	4.70	5.00	2.70	2.50
	Q25, Q75	2.40, 2.80	2.50, 2.80	3.90, 6.90	4.70, 6.70	2.45, 2.80	2.30, 2.80
	Min, Max	1.6, 3.3	1.9, 3.1	2.7, 10.4	3.6, 8.6	2.1, 3.3	2.0, 3.3
	Mean (SD)	2.60 (0.328)	2.67 (0.272)	5.28 (1.888)	5.62 (1.430)	2.63 (0.301)	2.56 (0.355)
	95% CI of Mean	2.49, 2.71	2.57, 2.76	4.46, 6.10	4.90, 6.33	2.48, 2.77	2.38, 2.73

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 5 - 12:00 - 13:30							
	n	39	37	23	18	20	19
	Median	-43.48	-51.06	6.82	5.62	-49.92	-55.36
	Q25, Q75	-51.72, -33.33	-62.12, -43.48	-6.98, 17.14	-12.28, 15.22	-54.60, -35.86	-60.00, -44.00
	Min, Max	-67.1, 0.0	-73.3, 23.8	-38.4, 44.4	-36.9, 42.4	-68.4, -2.9	-71.6, -21.4
	Mean (SD)	-42.07 (15.497)	-50.89 (17.456)	3.41 (20.001)	1.91 (21.906)	-43.70 (17.317)	-52.13 (14.268)
	95% CI of Mean	-47.10, -37.04	-56.72, -45.07	-5.25, 12.06	-8.99, 12.81	-51.81, -35.59	-59.02, -45.25

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 5 - 16:00 - 17:30							
	n	39	37	23	18	20	19
	Missing, n (%)	0	0	0	1 (5.3)	0	0
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.44 (17.42)	2.56 (13.08)	5.14 (35.56)	5.58 (24.12)	2.61 (13.70)	2.48 (12.71)
	95% CI of Geometric Mean	2.30, 2.59	2.44, 2.67	4.42, 5.97	4.95, 6.28	2.45, 2.79	2.32, 2.64
	Median	2.50	2.60	4.60	5.15	2.60	2.40
	Q25, Q75	2.20, 2.70	2.40, 2.80	3.90, 7.10	4.50, 6.60	2.45, 2.80	2.30, 2.60
	Min, Max	1.2, 3.3	1.7, 3.0	2.4, 10.4	4.1, 8.7	2.0, 3.4	2.1, 3.3
	Mean (SD)	2.47 (0.375)	2.58 (0.310)	5.44 (1.893)	5.73 (1.442)	2.64 (0.364)	2.49 (0.333)
	95% CI of Mean	2.35, 2.60	2.47, 2.68	4.62, 6.26	5.01, 6.46	2.46, 2.81	2.33, 2.66

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 5 - 16:00 - 17:30							
	n	39	37	23	18	20	19
	Median	-46.94	-51.85	6.98	1.04	-49.59	-55.32
	Q25, Q75	-57.14, -35.90	-62.12, -45.24	-4.55, 16.39	-7.59, 12.82	-56.25, -29.18	-63.33, -41.30
	Min, Max	-72.9, -4.5	-75.3, -19.0	-26.0, 35.1	-22.3, 30.3	-68.4, -2.9	-71.6, -26.2
	Mean (SD)	-44.56 (17.114)	-53.45 (12.345)	5.76 (16.509)	2.89 (15.584)	-43.45 (17.789)	-53.48 (12.930)
	95% CI of Mean	-50.12, -39.01	-57.57, -49.33	-1.38, 12.91	-4.86, 10.65	-51.78, -35.12	-59.72, -47.25

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 5 - 20:00 - 21:30							
	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.42 (15.05)	2.54 (12.88)	5.28 (32.41)	5.90 (25.95)	2.48 (14.37)	2.52 (16.98)
	95% CI of Geometric Mean	2.30, 2.55	2.43, 2.66	4.60, 6.06	5.21, 6.67	2.32, 2.66	2.32, 2.74
	Median	2.50	2.70	4.90	5.90	2.40	2.50
	Q25, Q75	2.30, 2.60	2.30, 2.80	4.20, 7.10	4.60, 7.60	2.30, 2.75	2.40, 2.80
	Min, Max	1.4, 3.0	1.9, 3.2	2.7, 9.5	4.1, 8.9	1.9, 3.1	1.7, 3.4
	Mean (SD)	2.45 (0.330)	2.56 (0.317)	5.53 (1.725)	6.08 (1.543)	2.51 (0.352)	2.56 (0.421)
	95% CI of Mean	2.33, 2.56	2.45, 2.67	4.78, 6.29	5.33, 6.83	2.34, 2.67	2.35, 2.77

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 10 AM 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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 5 - 20:00 - 21:30							
	n	39	37	23	19	20	19
	Median	-47.17	-53.97	9.30	3.85	-52.08	-54.79
	Q25, Q75	-55.56, -36.11	-63.24, -44.23	-3.13, 16.39	-2.13, 21.05	-57.48, -37.03	-66.00, -45.83
	Min, Max	-74.1, -9.1	-78.4, -4.8	-32.9, 51.9	-26.2, 43.8	-69.6, -8.8	-70.4, -19.0
	Mean (SD)	-45.42 (15.153)	-53.27 (14.143)	9.13 (19.869)	8.61 (18.342)	-46.05 (17.787)	-52.34 (14.526)
	95% CI of Mean	-50.33, -40.50	-57.99, -48.55	0.54, 17.73	-0.24, 17.45	-54.37, -37.72	-59.34, -45.33

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 10 AM 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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Baseline							
	n	38	36	23	18	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	4.70 (26.48)	5.69 (31.41)	4.92 (34.55)	5.48 (27.81)	4.82 (27.55)	5.52 (25.57)
	95% CI of Geometric Mean	4.31, 5.13	5.13, 6.32	4.25, 5.69	4.78, 6.28	4.25, 5.48	4.88, 6.23
	Median	4.50	5.90	5.30	5.50	4.95	5.60
	Q25, Q75	3.90, 5.40	4.80, 6.85	4.30, 6.40	4.60, 6.20	3.95, 6.10	4.60, 7.00
	Min, Max	2.7, 8.5	2.1, 9.7	2.4, 7.7	3.3, 10.3	3.1, 7.9	3.6, 8.3
	Mean (SD)	4.86 (1.323)	5.94 (1.712)	5.17 (1.553)	5.68 (1.670)	4.99 (1.315)	5.68 (1.440)
	95% CI of Mean	4.42, 5.30	5.36, 6.53	4.49, 5.85	4.85, 6.52	4.37, 5.61	4.99, 6.38

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 10 AM 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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 30	n	38	36	23	18	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.83 (13.48)	2.96 (12.59)	5.66 (28.67)	6.47 (18.42)	2.86 (11.88)	2.88 (13.11)
	95% CI of Geometric Mean	2.70, 2.96	2.84, 3.10	5.00, 6.39	5.90, 7.09	2.70, 3.02	2.70, 3.07
	Median	2.90	3.00	5.70	6.25	2.90	2.90
	Q25, Q75	2.70, 3.00	2.80, 3.20	4.50, 6.70	5.70, 7.30	2.70, 3.15	2.50, 3.30
	Min, Max	2.1, 3.9	2.1, 4.2	3.7, 11.4	4.8, 9.5	2.2, 3.4	2.3, 3.4
	Mean (SD)	2.85 (0.377)	2.99 (0.366)	5.88 (1.778)	6.58 (1.261)	2.88 (0.336)	2.90 (0.370)
	95% CI of Mean	2.72, 2.98	2.86, 3.11	5.11, 6.66	5.95, 7.21	2.71, 3.04	2.72, 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 10 AM 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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 30							
	n	38	36	23	18	20	19
	Median	-39.01	-49.18	6.56	15.18	-41.57	-48.28
	Q25, Q75	-47.17, -25.64	-55.30, -37.25	0.00, 27.59	-4.84, 49.12	-49.60, -27.26	-54.79, -33.33
	Min, Max	-70.5, 0.0	-72.2, 33.3	-14.1, 96.3	-32.0, 117.9	-65.8, -6.3	-71.1, -12.8
	Mean (SD)	-37.28 (18.000)	-45.22 (19.288)	17.75 (27.909)	23.21 (37.509)	-38.35 (17.800)	-45.39 (16.710)
	95% CI of Mean	-43.20, -31.35	-51.75, -38.68	5.68, 29.82	4.55, 41.86	-46.69, -30.02	-53.45, -37.33

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 10 AM 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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Baseline	n	36	35	23	18	20	18
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	4.75 (26.73)	5.61 (31.22)	4.92 (34.55)	5.48 (27.81)	4.82 (27.55)	5.39 (24.16)
	95% CI of Geometric Mean	4.34, 5.19	5.05, 6.24	4.25, 5.69	4.78, 6.28	4.25, 5.48	4.79, 6.07
	Median	4.55	5.40	5.30	5.50	4.95	5.30
	Q25, Q75	3.90, 5.60	4.70, 6.80	4.30, 6.40	4.60, 6.20	3.95, 6.10	4.60, 6.50
	Min, Max	2.7, 8.5	2.1, 9.7	2.4, 7.7	3.3, 10.3	3.1, 7.9	3.6, 8.1
	Mean (SD)	4.91 (1.339)	5.86 (1.700)	5.17 (1.553)	5.68 (1.670)	4.99 (1.315)	5.54 (1.330)
	95% CI of Mean	4.45, 5.37	5.27, 6.45	4.49, 5.85	4.85, 6.52	4.37, 5.61	4.87, 6.21

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 10 AM 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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Day 60	n	36	35	23	18	20	18
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.91 (11.26)	3.06 (14.96)	5.51 (30.67)	6.38 (14.26)	3.02 (19.52)	3.06 (17.69)
	95% CI of Geometric Mean	2.79, 3.02	2.90, 3.22	4.83, 6.28	5.94, 6.85	2.76, 3.32	2.80, 3.35
	Median	2.80	3.10	5.70	6.30	2.85	3.00
	Q25, Q75	2.70, 3.20	2.80, 3.30	4.20, 6.90	5.90, 6.80	2.65, 3.20	2.80, 3.30
	Min, Max	2.5, 4.0	2.3, 5.6	3.3, 11.8	4.8, 8.4	2.5, 5.3	2.3, 5.1
	Mean (SD)	2.93 (0.347)	3.09 (0.535)	5.76 (1.883)	6.44 (0.915)	3.09 (0.709)	3.11 (0.613)
	95% CI of Mean	2.80, 3.05	2.90, 3.28	4.94, 6.58	5.98, 6.90	2.75, 3.42	2.80, 3.42

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 10 AM 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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
% Change from baseline to Day 60							
	n	36	35	23	18	20	18
	Median	-37.95	-48.53	6.85	14.15	-41.94	-48.11
	Q25, Q75	-47.11, -24.38	-56.06, -30.43	-5.13, 25.00	0.00, 33.33	-50.48, -19.00	-53.33, -29.79
	Min, Max	-69.4, 7.4	-66.3, 47.6	-29.8, 118.5	-31.1, 89.7	-67.1, 46.9	-63.2, 6.3
	Mean (SD)	-36.44 (16.992)	-42.01 (24.437)	16.32 (35.879)	19.41 (28.119)	-33.16 (26.601)	-40.80 (18.540)
	95% CI of Mean	-42.20, -30.69	-50.41, -33.61	0.80, 31.84	5.42, 33.40	-45.62, -20.71	-50.02, -31.58

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 10 AM 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=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Baseline							
	n	36	34	23	18	20	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	4.70 (27.23)	5.67 (32.18)	4.92 (34.55)	5.48 (27.81)	4.82 (27.55)	5.28 (23.21)
	95% CI of Geometric Mean	4.29, 5.15	5.08, 6.33	4.25, 5.69	4.78, 6.28	4.25, 5.48	4.69, 5.95
	Median	4.50	5.90	5.30	5.50	4.95	5.00
	Q25, Q75	3.90, 5.60	4.70, 6.80	4.30, 6.40	4.60, 6.20	3.95, 6.10	4.60, 6.00
	Min, Max	2.7, 8.5	2.1, 9.7	2.4, 7.7	3.3, 10.3	3.1, 7.9	3.6, 8.1
	Mean (SD)	4.87 (1.359)	5.93 (1.753)	5.17 (1.553)	5.68 (1.670)	4.99 (1.315)	5.42 (1.265)
	95% CI of Mean	4.41, 5.34	5.32, 6.55	4.49, 5.85	4.85, 6.52	4.37, 5.61	4.76, 6.07

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 10 AM 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=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Day 90	n	36	34	23	18	20	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	2.90 (11.94)	3.05 (12.15)	5.35 (32.95)	6.26 (17.94)	3.01 (19.52)	3.08 (21.57)
	95% CI of Geometric Mean	2.78, 3.02	2.91, 3.18	4.65, 6.15	5.72, 6.84	2.75, 3.30	2.75, 3.44
	Median	2.90	3.00	5.30	6.20	3.00	2.90
	Q25, Q75	2.65, 3.10	2.80, 3.20	4.10, 6.80	5.80, 6.90	2.75, 3.15	2.70, 3.20
	Min, Max	2.4, 4.3	2.4, 4.0	3.2, 11.9	4.1, 8.7	2.2, 5.3	2.3, 5.1
	Mean (SD)	2.92 (0.371)	3.07 (0.384)	5.63 (1.991)	6.35 (1.124)	3.07 (0.669)	3.15 (0.748)
	95% CI of Mean	2.79, 3.05	2.93, 3.21	4.76, 6.50	5.79, 6.91	2.75, 3.39	2.76, 3.54

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 10 AM 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**

		THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Timepoint	Statistic						
% Change from baseline to Day 90							
	n	36	34	23	18	20	17
	Median	-35.56	-46.23	2.56	11.35	-39.86	-45.21
	Q25, Q75	-50.47, -24.77	-56.52, -38.10	-8.89, 20.37	1.69, 30.43	-51.34, -18.29	-48.33, -26.19
	Min, Max	-69.4, 11.1	-71.9, 52.4	-31.3, 70.8	-31.1, 89.7	-64.6, 14.7	-65.4, -6.3
	Mean (SD)	-35.47 (19.527)	-43.10 (22.305)	11.59 (27.132)	17.47 (29.479)	-33.92 (23.139)	-39.20 (18.323)
	95% CI of Mean	-42.09, -28.86	-50.89, -35.32	-0.15, 23.33	2.80, 32.13	-44.75, -23.08	-48.63, -29.78

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.10 (31.39)		5.17 (31.51)		5.13 (26.87)	
	95% CI of Geometric Mean	4.76, 5.47		4.70, 5.70		4.71, 5.59	
	Median	5.10		5.40		5.05	
	Q25, Q75	4.20, 6.30		4.40, 6.30		4.25, 6.20	
	Min, Max	2.1, 9.7		2.4, 10.3		3.1, 8.3	
	Mean (SD)	5.34 (1.612)		5.41 (1.588)		5.31 (1.390)	
	95% CI of Mean	4.97, 5.71		4.91, 5.91		4.86, 5.76	

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.53 (13.25)		5.06 (31.18)		2.63 (12.25)	
	95% CI of Geometric Mean	2.45, 2.61		4.60, 5.57		2.53, 2.74	
	Median	2.60	-48.47	5.10	1.04	2.65	-50.31
	Q25, Q75	2.40, 2.70	-58.73, -41.51	4.10, 6.30	-11.11, 8.51	2.40, 2.90	-56.76, -38.84
	Min, Max	1.7, 3.4	-73.3, -14.8	2.8, 10.0	-35.5, 25.7	1.9, 3.4	-65.8, -15.6
	Mean (SD)	2.55 (0.324)	-48.65 (13.661)	5.30 (1.618)	-1.04 (14.437)	2.65 (0.322)	-47.24 (13.090)
	95% CI of Mean	2.47, 2.63	-51.74, -45.57	4.79, 5.80	-5.55, 3.46	2.54, 2.76	-51.43, -43.05

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.34 (13.37)		5.29 (30.85)		2.41 (15.45)	
	95% CI of Geometric Mean	2.26, 2.41		4.81, 5.82		2.29, 2.54	
	Median	2.40	-52.94	5.15	0.00	2.40	-55.46
	Q25, Q75	2.20, 2.60	-59.74, -45.65	4.30, 6.80	-7.35, 15.15	2.20, 2.60	-61.39, -45.74
	Min, Max	1.6, 3.1	-78.4, -18.5	2.9, 9.0	-27.4, 47.8	1.9, 4.6	-72.4, -8.8
	Mean (SD)	2.36 (0.304)	-52.30 (13.601)	5.53 (1.696)	3.59 (16.859)	2.44 (0.442)	-51.04 (15.196)
	95% CI of Mean	2.28, 2.43	-55.37, -49.22	5.00, 6.07	-1.67, 8.84	2.29, 2.59	-55.91, -46.18

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.36 (13.80)		5.11 (31.02)		2.32 (13.27)	
	95% CI of Geometric Mean	2.28, 2.43		4.64, 5.62		2.22, 2.43	
	Median	2.40	-52.69	4.95	0.00	2.30	-54.92
	Q25, Q75	2.20, 2.60	-60.94, -44.19	4.10, 6.00	-12.62, 11.32	2.10, 2.55	-61.13, -46.08
	Min, Max	1.4, 3.1	-78.4, -4.8	2.9, 9.4	-32.9, 39.4	1.8, 3.0	-73.4, -11.8
	Mean (SD)	2.38 (0.314)	-51.59 (15.210)	5.35 (1.703)	0.16 (17.377)	2.34 (0.314)	-53.07 (13.155)
	95% CI of Mean	2.30, 2.45	-55.02, -48.15	4.81, 5.88	-5.26, 5.58	2.24, 2.45	-57.28, -48.86

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.40 (14.47)		5.28 (30.20)		2.43 (11.32)	
	95% CI of Geometric Mean	2.32, 2.49		4.81, 5.79		2.34, 2.53	
	Median	2.50	-51.40	5.50	2.39	2.45	-54.20
	Q25, Q75	2.30, 2.70	-61.54, -42.86	4.30, 6.50	-8.06, 14.89	2.25, 2.60	-58.58, -41.89
	Min, Max	1.5, 3.1	-77.5, 14.8	2.5, 9.7	-29.6, 36.4	1.9, 3.1	-75.3, -14.7
	Mean (SD)	2.42 (0.323)	-50.45 (16.452)	5.50 (1.571)	3.24 (15.964)	2.45 (0.276)	-50.90 (13.237)
	95% CI of Mean	2.35, 2.50	-54.17, -46.74	5.01, 5.99	-1.74, 8.22	2.35, 2.54	-55.14, -46.66

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - Within 15							
Min Prior To Smoking	n	77	77	41	41		
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	2.58 (11.72)		3.97 (21.54)			
	95% CI of Geometric Mean	2.50, 2.65		3.71, 4.25			
	Median	2.60	-47.83	4.00	-22.22		
	Q25, Q75	2.40, 2.80	-57.14, -40.00	3.50, 4.50	-33.33, -14.89		
	Min, Max	1.9, 3.2	-74.4, 4.8	2.6, 6.5	-44.4, 17.2		
	Mean (SD)	2.59 (0.297)	-47.33 (16.017)	4.06 (0.891)	-21.69 (14.913)		
	95% CI of Mean	2.52, 2.67	-50.97, -43.69	3.77, 4.35	-26.40, -16.98		

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 08:00 - 09:30	n					39	39
	Missing, n (%)					1 (2.5)	1 (2.5)
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					2.66 (12.65)	
	95% CI of Geometric Mean					2.55, 2.77	
	Median					2.70	-47.92
	Q25, Q75					2.50, 3.00	-57.14, -37.50
	Min, Max					1.9, 3.2	-67.9, -8.8
	Mean (SD)					2.68 (0.326)	-46.40 (15.295)
	95% CI of Mean					2.57, 2.79	-51.36, -41.44

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 12:00 - 13:30	n	77	77	41	41	39	39
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.62 (12.22)		5.19 (30.87)		2.57 (12.55)	
	95% CI of Geometric Mean	2.54, 2.70		4.71, 5.71		2.47, 2.68	
	Median	2.70	-48.33	5.00	6.82	2.60	-51.06
	Q25, Q75	2.50, 2.80	-59.09, -38.89	4.10, 6.70	-8.86, 15.22	2.40, 2.80	-56.90, -41.67
	Min, Max	1.6, 3.3	-73.3, 23.8	2.7, 10.4	-38.4, 44.4	2.0, 3.3	-71.6, -2.9
	Mean (SD)	2.64 (0.300)	-46.41 (16.853)	5.43 (1.691)	2.75 (20.604)	2.59 (0.326)	-47.81 (16.267)
	95% CI of Mean	2.56, 2.71	-50.24, -42.58	4.89, 5.97	-3.76, 9.26	2.48, 2.70	-53.09, -42.53

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 16:00 - 17:30	n	77	77	41	41	39	39
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.50 (15.48)		5.33 (30.90)		2.54 (13.34)	
	95% CI of Geometric Mean	2.41, 2.59		4.84, 5.87		2.43, 2.66	
	Median	2.60	-50.00	5.10	4.65	2.50	-51.22
	Q25, Q75	2.40, 2.80	-58.82, -42.86	4.50, 6.70	-6.25, 13.21	2.30, 2.70	-58.93, -40.48
	Min, Max	1.2, 3.3	-75.3, -4.5	2.4, 10.4	-26.0, 35.1	2.0, 3.4	-71.6, -2.9
	Mean (SD)	2.53 (0.346)	-48.90 (15.439)	5.57 (1.696)	4.50 (15.975)	2.57 (0.352)	-48.34 (16.224)
	95% CI of Mean	2.44, 2.61	-52.41, -45.39	5.03, 6.11	-0.54, 9.55	2.45, 2.69	-53.60, -43.07

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 20:00 - 21:30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.49 (14.15)		5.55 (29.83)		2.49 (15.72)	
	95% CI of Geometric Mean	2.41, 2.57		5.06, 6.08		2.36, 2.62	
	Median	2.55	-48.64	5.65	7.05	2.40	-54.10
	Q25, Q75	2.30, 2.70	-60.00, -41.18	4.40, 7.10	-2.13, 16.39	2.35, 2.80	-59.31, -42.57
	Min, Max	1.4, 3.2	-78.4, -4.8	2.7, 9.5	-32.9, 51.9	1.7, 3.4	-70.4, -8.8
	Mean (SD)	2.51 (0.328)	-49.04 (14.990)	5.78 (1.648)	8.90 (18.963)	2.52 (0.387)	-49.30 (16.210)
	95% CI of Mean	2.43, 2.59	-52.43, -45.66	5.26, 6.30	2.98, 14.81	2.39, 2.65	-54.48, -44.11

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.88 (12.92)		6.00 (25.02)		2.84 (13.46)	
	95% CI of Geometric Mean	2.80, 2.97		5.55, 6.48		2.72, 2.97	
	Median	2.90	-42.58	6.00	12.30	2.90	-45.90
	Q25, Q75	2.70, 3.10	-53.62, -32.35	5.30, 6.70	0.00, 35.94	2.65, 3.20	-54.40, -29.06
	Min, Max	2.1, 4.2	-72.2, 33.3	3.7, 11.4	-32.0, 117.9	2.0, 3.4	-71.1, -6.3
	Mean (SD)	2.91 (0.369)	-40.53 (19.693)	6.18 (1.574)	19.67 (31.911)	2.87 (0.372)	-42.15 (17.350)
	95% CI of Mean	2.82, 3.00	-44.97, -36.08	5.69, 6.68	9.72, 29.61	2.74, 2.99	-47.70, -36.59

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.99 (13.70)		5.87 (25.27)		2.99 (19.51)	
	95% CI of Geometric Mean	2.90, 3.09		5.43, 6.35		2.81, 3.19	
	Median	2.90	-44.11	6.00	8.42	2.90	-47.77
	Q25, Q75	2.70, 3.20	-52.38, -25.58	4.90, 6.80	-4.41, 31.03	2.60, 3.20	-52.86, -27.08
	Min, Max	2.3, 5.6	-69.4, 47.6	3.3, 11.8	-31.1, 118.5	2.0, 5.3	-71.1, 46.9
	Mean (SD)	3.02 (0.469)	-37.89 (23.036)	6.05 (1.537)	17.26 (32.068)	3.05 (0.671)	-38.13 (23.389)
	95% CI of Mean	2.91, 3.13	-43.09, -32.69	5.57, 6.54	7.26, 27.25	2.83, 3.27	-45.62, -30.65

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.99 (12.80)		5.73 (27.83)		2.97 (21.17)	
	95% CI of Geometric Mean	2.90, 3.08		5.26, 6.25		2.78, 3.19	
	Median	3.00	-41.24	6.00	8.29	2.90	-43.82
	Q25, Q75	2.70, 3.20	-52.94, -28.95	4.30, 6.80	-5.71, 29.79	2.65, 3.15	-54.15, -25.86
	Min, Max	2.4, 4.4	-71.9, 52.4	3.2, 11.9	-31.3, 89.7	2.0, 5.3	-71.1, 14.7
	Mean (SD)	3.01 (0.407)	-38.22 (21.417)	5.95 (1.667)	13.83 (27.724)	3.04 (0.708)	-38.52 (21.635)
	95% CI of Mean	2.91, 3.11	-43.06, -33.39	5.42, 6.47	5.19, 22.48	2.81, 3.27	-45.44, -31.60

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.11 (31.74)		5.17 (31.51)		5.15 (27.16)	
	95% CI of Geometric Mean	4.75, 5.49		4.70, 5.70		4.72, 5.62	
	Median	5.10		5.40		5.10	
	Q25, Q75	4.20, 6.30		4.40, 6.30		4.20, 6.30	
	Min, Max	2.1, 9.7		2.4, 10.3		3.1, 8.3	
	Mean (SD)	5.35 (1.629)		5.41 (1.588)		5.33 (1.403)	
	95% CI of Mean	4.97, 5.72		4.91, 5.91		4.87, 5.79	

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.52 (13.28)		5.06 (31.18)		2.65 (11.84)	
	95% CI of Geometric Mean	2.44, 2.60		4.60, 5.57		2.54, 2.76	
	Median	2.60	-48.85	5.10	1.04	2.70	-48.89
	Q25, Q75	2.40, 2.70	-58.73, -41.59	4.10, 6.30	-11.11, 8.51	2.40, 2.90	-57.81, -38.10
	Min, Max	1.7, 3.4	-73.3, -14.8	2.8, 10.0	-35.5, 25.7	1.9, 3.4	-65.8, -15.6
	Mean (SD)	2.54 (0.325)	-48.84 (13.749)	5.30 (1.618)	-1.04 (14.437)	2.67 (0.314)	-47.06 (13.210)
	95% CI of Mean	2.46, 2.62	-51.99, -45.69	4.79, 5.80	-5.55, 3.46	2.56, 2.77	-51.34, -42.77

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.33 (13.37)		5.29 (30.85)		2.42 (15.35)	
	95% CI of Geometric Mean	2.25, 2.41		4.81, 5.82		2.30, 2.55	
	Median	2.35	-52.94	5.15	0.00	2.40	-55.17
	Q25, Q75	2.20, 2.55	-60.75, -45.68	4.30, 6.80	-7.35, 15.15	2.20, 2.60	-62.00, -45.65
	Min, Max	1.6, 3.1	-78.4, -18.5	2.9, 9.0	-27.4, 47.8	1.9, 4.6	-72.4, -8.8
	Mean (SD)	2.35 (0.303)	-52.46 (13.621)	5.53 (1.696)	3.59 (16.859)	2.45 (0.442)	-50.90 (15.369)
	95% CI of Mean	2.27, 2.42	-55.58, -49.34	5.00, 6.07	-1.67, 8.84	2.30, 2.60	-55.89, -45.92

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.34 (13.69)		5.11 (31.02)		2.33 (13.22)	
	95% CI of Geometric Mean	2.27, 2.42		4.64, 5.62		2.23, 2.44	
	Median	2.40	-52.89	4.95	0.00	2.30	-54.10
	Q25, Q75	2.15, 2.60	-61.42, -44.19	4.10, 6.00	-12.62, 11.32	2.10, 2.60	-61.54, -46.00
	Min, Max	1.4, 3.1	-78.4, -4.8	2.9, 9.4	-32.9, 39.4	1.8, 3.0	-73.4, -11.8
	Mean (SD)	2.37 (0.310)	-51.83 (15.287)	5.35 (1.703)	0.16 (17.377)	2.35 (0.313)	-52.98 (13.315)
	95% CI of Mean	2.29, 2.44	-55.33, -48.33	4.81, 5.88	-5.26, 5.58	2.24, 2.46	-57.30, -48.66

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.39 (14.49)		5.28 (30.20)		2.44 (11.00)	
	95% CI of Geometric Mean	2.31, 2.48		4.81, 5.79		2.35, 2.54	
	Median	2.45	-51.44	5.50	2.39	2.50	-53.85
	Q25, Q75	2.25, 2.70	-61.62, -43.49	4.30, 6.50	-8.06, 14.89	2.30, 2.60	-58.82, -41.67
	Min, Max	1.5, 3.1	-77.5, 14.8	2.5, 9.7	-29.6, 36.4	1.9, 3.1	-75.3, -14.7
	Mean (SD)	2.42 (0.323)	-50.64 (16.571)	5.50 (1.571)	3.24 (15.964)	2.46 (0.270)	-50.75 (13.378)
	95% CI of Mean	2.34, 2.49	-54.43, -46.85	5.01, 5.99	-1.74, 8.22	2.37, 2.55	-55.10, -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 / THS 2.2 Menthol arms or the last assessment prior to 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - Within 15							
Min Prior To							
Smoking	n	76	76	41	41		
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	2.57 (11.75)		3.97 (21.54)			
	95% CI of Geometric Mean	2.50, 2.65		3.71, 4.25			
	Median	2.60	-47.50	4.00	-22.22		
	Q25, Q75	2.40, 2.80	-57.28, -39.57	3.50, 4.50	-33.33, -14.89		
	Min, Max	1.9, 3.2	-74.4, 4.8	2.6, 6.5	-44.4, 17.2		
	Mean (SD)	2.59 (0.298)	-47.29 (16.120)	4.06 (0.891)	-21.69 (14.913)		
	95% CI of Mean	2.52, 2.66	-50.98, -43.60	3.77, 4.35	-26.40, -16.98		

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 08:00 - 09:30	n					39	39
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					2.66 (12.65)	
	95% CI of Geometric Mean					2.55, 2.77	
	Median					2.70	-47.92
	Q25, Q75					2.50, 3.00	-57.14, -37.50
	Min, Max					1.9, 3.2	-67.9, -8.8
	Mean (SD)					2.68 (0.326)	-46.40 (15.295)
	95% CI of Mean					2.57, 2.79	-51.36, -41.44

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 12:00 - 13:30	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.62 (12.28)		5.19 (30.87)		2.57 (12.55)	
	95% CI of Geometric Mean	2.54, 2.69		4.71, 5.71		2.47, 2.68	
	Median	2.70	-47.24	5.00	6.82	2.60	-51.06
	Q25, Q75	2.50, 2.80	-59.69, -38.83	4.10, 6.70	-8.86, 15.22	2.40, 2.80	-56.90, -41.67
	Min, Max	1.6, 3.3	-73.3, 23.8	2.7, 10.4	-38.4, 44.4	2.0, 3.3	-71.6, -2.9
	Mean (SD)	2.63 (0.302)	-46.37 (16.960)	5.43 (1.691)	2.75 (20.604)	2.59 (0.326)	-47.81 (16.267)
	95% CI of Mean	2.56, 2.71	-50.25, -42.48	4.89, 5.97	-3.76, 9.26	2.48, 2.70	-53.09, -42.53

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 16:00 - 17:30	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.50 (15.52)		5.33 (30.90)		2.54 (13.34)	
	95% CI of Geometric Mean	2.41, 2.59		4.84, 5.87		2.43, 2.66	
	Median	2.60	-50.00	5.10	4.65	2.50	-51.22
	Q25, Q75	2.35, 2.75	-59.57, -42.16	4.50, 6.70	-6.25, 13.21	2.30, 2.70	-58.93, -40.48
	Min, Max	1.2, 3.3	-75.3, -4.5	2.4, 10.4	-26.0, 35.1	2.0, 3.4	-71.6, -2.9
	Mean (SD)	2.52 (0.346)	-48.89 (15.541)	5.57 (1.696)	4.50 (15.975)	2.57 (0.352)	-48.34 (16.224)
	95% CI of Mean	2.44, 2.61	-52.44, -45.33	5.03, 6.11	-0.54, 9.55	2.45, 2.69	-53.60, -43.07

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 20:00 - 21:30	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.48 (14.16)		5.55 (29.83)		2.50 (15.50)	
	95% CI of Geometric Mean	2.40, 2.57		5.06, 6.08		2.38, 2.64	
	Median	2.50	-49.53	5.65	7.05	2.40	-53.66
	Q25, Q75	2.30, 2.70	-60.16, -41.24	4.40, 7.10	-2.13, 16.39	2.40, 2.80	-60.00, -41.67
	Min, Max	1.4, 3.2	-78.4, -4.8	2.7, 9.5	-32.9, 51.9	1.7, 3.4	-70.4, -8.8
	Mean (SD)	2.50 (0.327)	-49.24 (15.099)	5.78 (1.648)	8.90 (18.963)	2.53 (0.383)	-49.11 (16.379)
	95% CI of Mean	2.42, 2.58	-52.69, -45.78	5.26, 6.30	2.98, 14.81	2.40, 2.66	-54.42, -43.80

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 10 AM 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=63)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	63		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.14 (30.83)		5.16 (31.85)		5.08 (26.28)	
	95% CI of Geometric Mean	4.76, 5.55		4.67, 5.69		4.67, 5.54	
	Median	5.10		5.40		5.05	
	Q25, Q75	4.20, 6.30		4.40, 6.30		4.20, 6.10	
	Min, Max	2.1, 9.7		2.4, 10.3		3.1, 8.1	
	Mean (SD)	5.37 (1.612)		5.40 (1.606)		5.25 (1.333)	
	95% CI of Mean	4.96, 5.79		4.88, 5.91		4.81, 5.69	

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 10 AM 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=63)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	63	63	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.88 (12.38)		6.00 (25.33)		2.88 (12.14)	
	95% CI of Geometric Mean	2.78, 2.97		5.54, 6.50		2.76, 3.00	
	Median	3.00	-42.31	6.10	12.96	2.90	-44.52
	Q25, Q75	2.70, 3.20	-53.62, -32.61	5.30, 6.70	0.00, 35.94	2.70, 3.20	-53.33, -28.95
	Min, Max	2.1, 3.5	-72.2, 33.3	3.7, 11.4	-32.0, 117.9	2.2, 3.4	-68.4, -6.3
	Mean (SD)	2.90 (0.337)	-41.30 (18.923)	6.19 (1.593)	20.15 (32.154)	2.90 (0.344)	-41.01 (16.963)
	95% CI of Mean	2.81, 2.99	-46.07, -36.53	5.68, 6.70	9.99, 30.30	2.78, 3.02	-46.59, -35.43

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 10 AM 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=65)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.19 (29.96)		5.16 (31.85)		5.08 (26.28)	
	95% CI of Geometric Mean	4.83, 5.59		4.67, 5.69		4.67, 5.54	
	Median	5.20		5.40		5.05	
	Q25, Q75	4.30, 6.30		4.40, 6.30		4.20, 6.10	
	Min, Max	2.1, 9.7		2.4, 10.3		3.1, 8.1	
	Mean (SD)	5.41 (1.575)		5.40 (1.606)		5.25 (1.333)	
	95% CI of Mean	5.02, 5.81		4.88, 5.91		4.81, 5.69	

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 10 AM 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=65)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	65	65	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.99 (13.55)		5.87 (25.59)		3.04 (18.43)	
	95% CI of Geometric Mean	2.88, 3.09		5.42, 6.37		2.86, 3.24	
	Median	2.90	-45.10	6.10	9.30	2.95	-46.85
	Q25, Q75	2.70, 3.20	-52.38, -29.27	4.90, 6.80	-4.41, 31.03	2.70, 3.20	-51.79, -25.58
	Min, Max	2.3, 5.6	-67.9, 47.6	3.3, 11.8	-31.1, 118.5	2.3, 5.3	-67.1, 46.9
	Mean (SD)	3.02 (0.464)	-39.49 (21.263)	6.06 (1.556)	17.68 (32.349)	3.10 (0.657)	-36.78 (23.157)
	95% CI of Mean	2.90, 3.14	-44.77, -34.22	5.56, 6.55	7.46, 27.89	2.88, 3.32	-44.40, -29.16

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 10 AM 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=65)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.13 (30.62)		5.16 (31.85)		5.03 (25.72)	
	95% CI of Geometric Mean	4.76, 5.53		4.67, 5.69		4.62, 5.48	
	Median	5.10		5.40		5.00	
	Q25, Q75	4.20, 6.30		4.40, 6.30		4.20, 6.10	
	Min, Max	2.1, 9.7		2.4, 10.3		3.1, 8.1	
	Mean (SD)	5.36 (1.600)		5.40 (1.606)		5.19 (1.292)	
	95% CI of Mean	4.95, 5.76		4.88, 5.91		4.75, 5.62	

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 10 AM 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=65)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	65	65	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.94 (11.40)		5.73 (28.18)		3.04 (20.22)	
	95% CI of Geometric Mean	2.86, 3.03		5.24, 6.25		2.84, 3.26	
	Median	2.90	-41.51	6.00	10.13	2.90	-41.67
	Q25, Q75	2.70, 3.10	-53.03, -30.43	4.30, 6.80	-5.71, 29.79	2.70, 3.20	-51.11, -25.53
	Min, Max	2.4, 4.3	-71.9, 52.4	3.2, 11.9	-31.3, 89.7	2.2, 5.3	-65.4, 14.7
	Mean (SD)	2.96 (0.352)	-39.52 (21.071)	5.95 (1.687)	14.17 (27.981)	3.11 (0.697)	-36.34 (20.951)
	95% CI of Mean	2.87, 3.05	-44.74, -34.29	5.41, 6.48	5.33, 23.01	2.87, 3.34	-43.33, -29.35

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	653.78 (115.03)		737.29 (114.14)		614.87 (122.18)	
	95% CI of Geometric Mean	530.04, 806.39		554.67, 980.04		451.06, 838.16	
	Median	708.14		756.44		562.84	
	Q25, Q75	267.73, 1473.25		307.86, 1826.20		234.01, 1405.14	
	Min, Max	80.8, 4067.8		145.8, 3506.2		139.2, 2896.8	
	Mean (SD)	948.00 (786.107)		1072.36 (901.976)		933.39 (818.265)	
	95% CI of Mean	768.36, 1127.64		791.28, 1353.44		668.13, 1198.64	

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	242.57 (77.20)		627.24 (131.96)		223.52 (94.27)	
	95% CI of Geometric Mean	207.48, 283.59		458.70, 857.71		172.60, 289.45	
	Median	278.15	-64.51	584.28	-9.79	223.05	-66.27
	Q25, Q75	138.57, 393.53	-75.52, -46.15	273.90, 1462.96	-18.05, -3.34	143.31, 348.04	-75.70, -49.06
	Min, Max	64.9, 1279.8	-89.8, 358.2	77.2, 4339.6	-62.2, 43.1	31.3, 928.1	-85.7, 9.1
	Mean (SD)	303.36 (215.669)	-54.07 (51.809)	991.54 (982.046)	-12.50 (19.733)	297.24 (229.040)	-59.26 (21.430)
	95% CI of Mean	254.07, 352.65	-65.91, -42.23	685.51, 1297.57	-18.65, -6.34	222.99, 371.49	-66.21, -52.31

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	87.99 (39.48)		548.51 (143.67)		90.66 (56.16)	
	95% CI of Geometric Mean	80.66, 95.99		394.43, 762.77		76.50, 107.43	
	Median	91.49	-87.24	606.21	-25.66	87.10	-84.24
	Q25, Q75	67.39, 114.55	-92.02, -75.31	245.12, 1320.00	-35.34, -12.82	66.23, 110.13	-93.57, -66.07
	Min, Max	36.2, 211.1	-97.7, 18.4	46.3, 4273.4	-72.0, 44.6	33.3, 390.0	-97.1, -13.1
	Mean (SD)	94.34 (35.498)	-81.66 (17.001)	891.26 (884.476)	-21.90 (23.798)	105.27 (69.114)	-77.96 (19.758)
	95% CI of Mean	86.23, 102.46	-85.55, -77.77	615.63, 1166.88	-29.32, -14.47	82.86, 127.68	-84.37, -71.55

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	84.53 (37.97)		600.28 (138.60)		91.77 (53.73)	
	95% CI of Geometric Mean	77.73, 91.93		434.75, 828.84		77.94, 108.04	
	Median	86.06	-88.23	590.79	-17.61	86.21	-87.04
	Q25, Q75	63.17, 111.30	-93.65, -70.98	298.50, 1291.05	-33.43, 5.88	65.96, 125.49	-94.30, -61.57
	Min, Max	40.7, 194.8	-97.6, 51.0	64.2, 4277.4	-68.5, 105.6	30.7, 370.7	-97.2, -2.2
	Mean (SD)	90.28 (33.452)	-81.27 (19.898)	985.51 (1036.662)	-13.24 (32.462)	105.11 (64.996)	-75.27 (24.600)
	95% CI of Mean	82.63, 97.93	-85.83, -76.72	662.46, 1308.56	-23.36, -3.11	84.04, 126.19	-83.25, -67.30

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	73.84 (42.90)		577.44 (133.52)		76.57 (51.10)	
	95% CI of Geometric Mean	67.21, 81.11		421.30, 791.44		65.49, 89.51	
	Median	77.00	-88.84	533.59	-20.43	76.10	-86.57
	Q25, Q75	56.50, 94.44	-94.86, -76.36	287.13, 1433.82	-37.55, -3.62	52.63, 96.15	-94.64, -66.46
	Min, Max	31.3, 173.8	-97.9, 43.0	96.6, 3256.8	-59.2, 33.9	30.5, 242.7	-97.9, -36.8
	Mean (SD)	80.13 (32.798)	-82.66 (19.461)	912.26 (856.448)	-18.58 (22.615)	86.26 (47.364)	-80.77 (16.651)
	95% CI of Mean	72.63, 87.63	-87.11, -78.21	645.37, 1179.15	-25.63, -11.53	70.90, 101.62	-86.17, -75.37

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 10 AM 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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	81.71 (35.50)		622.58 (132.98)		80.72 (41.57)	
	95% CI of Geometric Mean	75.52, 88.41		454.60, 852.64		70.92, 91.88	
	Median	81.39	-86.85	607.12	-17.42	81.43	-86.78
	Q25, Q75	66.49, 105.55	-94.47, -74.50	248.98, 1504.67	-28.70, -3.45	65.45, 97.09	-94.98, -65.48
	Min, Max	27.3, 150.6	-98.3, 37.3	109.2, 3901.1	-53.6, 113.6	30.7, 202.4	-98.1, -35.9
	Mean (SD)	86.43 (28.659)	-80.54 (20.866)	992.22 (972.694)	-11.98 (28.782)	87.20 (36.178)	-78.67 (18.978)
	95% CI of Mean	79.88, 92.99	-85.31, -75.76	689.10, 1295.34	-20.96, -3.01	75.47, 98.93	-84.83, -72.52

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 10 AM 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 2**

Timepoint	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	654.38 (116.78)		753.74 (114.14)		614.87 (122.18)	
	95% CI of Geometric Mean	527.84, 811.24		564.97, 1005.56		451.06, 838.16	
	Median	708.14		780.53		562.84	
	Q25, Q75	262.73, 1519.32		334.25, 1826.20		234.01, 1405.14	
	Min, Max	80.8, 4067.8		145.8, 3506.2		139.2, 2896.8	
	Mean (SD)	954.71 (794.153)		1091.24 (904.744)		933.39 (818.265)	
	95% CI of Mean	770.71, 1138.70		805.66, 1376.82		668.13, 1198.64	

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 10 AM 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 2**

Timepoint	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	139.19 (61.13)		790.61 (124.30)		158.15 (68.78)	
	95% CI of Geometric Mean	122.16, 158.61		582.74, 1072.64		129.25, 193.50	
	Median	143.41	-80.99	875.78	8.43	176.40	-70.87
	Q25, Q75	96.06, 196.92	-88.83, -51.79	290.57, 1815.13	-5.69, 29.22	100.00, 262.65	-87.94, -52.59
	Min, Max	39.1, 708.2	-96.9, 37.5	135.5, 4058.8	-68.2, 151.5	46.3, 492.2	-97.9, 28.5
	Mean (SD)	163.89 (110.046)	-67.93 (30.046)	1190.80 (1028.235)	13.72 (46.766)	188.55 (109.500)	-60.26 (35.775)
	95% CI of Mean	138.39, 189.39	-74.89, -60.96	866.25, 1515.36	-1.05, 28.49	153.05, 224.05	-71.87, -48.66

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 10 AM 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 3**

Timepoint	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	664.28 (115.59)		753.74 (114.14)		632.38 (121.47)	
	95% CI of Geometric Mean	534.15, 826.10		564.97, 1005.56		462.45, 864.74	
	Median	725.72		780.53		658.34	
	Q25, Q75	272.73, 1519.32		334.25, 1826.20		256.72, 1405.14	
	Min, Max	80.8, 4067.8		145.8, 3506.2		139.2, 2896.8	
	Mean (SD)	962.52 (795.445)		1091.24 (904.744)		952.38 (820.488)	
	95% CI of Mean	774.24, 1150.81		805.66, 1376.82		682.69, 1222.08	

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 10 AM 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 3**

Timepoint	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	142.50 (59.77)		799.06 (109.15)		148.73 (67.73)	
	95% CI of Geometric Mean	125.02, 162.42		604.18, 1056.80		121.53, 182.03	
	Median	139.64	-83.13	820.51	3.54	143.62	-72.82
	Q25, Q75	98.60, 202.07	-89.98, -49.45	426.71, 1574.64	-11.66, 28.75	90.42, 207.92	-92.95, -39.23
	Min, Max	41.7, 759.7	-95.9, 29.7	182.8, 3539.7	-74.4, 171.5	39.4, 905.4	-95.9, 61.1
	Mean (SD)	168.68 (122.805)	-69.13 (27.675)	1142.03 (946.058)	15.09 (49.173)	182.56 (149.413)	-60.09 (40.969)
	95% CI of Mean	139.60, 197.75	-75.69, -62.58	843.41, 1440.65	-0.44, 30.61	133.45, 231.68	-73.56, -46.62

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 10 AM 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 4**

Timepoint	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	645.95 (118.98)		753.74 (114.14)		611.58 (119.59)	
	95% CI of Geometric Mean	516.35, 808.07		564.97, 1005.56		446.69, 837.33	
	Median	686.10		780.53		562.84	
	Q25, Q75	260.25, 1519.32		334.25, 1826.20		256.72, 1386.83	
	Min, Max	80.8, 4067.8		145.8, 3506.2		139.2, 2896.8	
	Mean (SD)	953.14 (807.856)		1091.24 (904.744)		919.22 (805.566)	
	95% CI of Mean	760.51, 1145.77		805.66, 1376.82		650.62, 1187.81	

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 10 AM 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 4**

Timepoint	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	141.74 (76.23)		785.27 (126.46)		136.83 (57.80)	
	95% CI of Geometric Mean	120.62, 166.57		576.82, 1069.04		114.40, 163.66	
	Median	122.80	-79.24	936.64	-1.47	132.28	-74.59
	Q25, Q75	98.23, 196.85	-89.47, -53.62	376.12, 1655.48	-15.60, 37.74	93.63, 175.36	-91.06, -48.38
	Min, Max	30.7, 3645.2	-96.9, 179.1	77.9, 3942.3	-53.0, 278.8	58.6, 473.8	-96.8, 21.2
	Mean (SD)	208.38 (428.550)	-64.30 (41.414)	1201.01 (1071.605)	15.68 (63.221)	159.09 (99.861)	-66.12 (29.207)
	95% CI of Mean	106.19, 310.57	-74.18, -54.42	862.77, 1539.26	-4.28, 35.64	125.79, 192.39	-75.86, -56.38

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 10 AM 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 (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	786.75 (133.34)	874.37 (122.19)	738.62 (115.98)
	95% CI of Geometric Mean	624.48, 991.17	649.15, 1177.73	547.58, 996.31
	Median	976.10	798.21	592.90
	Q25, Q75	311.78, 1906.81	397.35, 2193.53	321.98, 1813.53
	Min, Max	86.4, 5905.7	142.6, 4025.8	161.7, 3676.8
	Mean (SD)	1218.98 (1086.046)	1314.24 (1129.190)	1090.99 (931.034)
	95% CI of Mean	970.80, 1467.16	962.36, 1666.13	789.18, 1392.80

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 10 AM 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 (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	281.92 (82.54)	752.14 (150.10)	244.39 (101.42)
	95% CI of Geometric Mean	239.11, 332.41	536.18, 1055.07	186.07, 320.98
	Median	315.55	668.06	248.35
	Q25, Q75	167.24, 479.46	308.90, 1838.22	156.33, 454.20
	Min, Max	73.5, 1758.6	78.9, 5857.6	26.1, 1598.5
	Mean (SD)	362.90 (285.312)	1281.11 (1371.360)	332.92 (282.717)
	95% CI of Mean	297.70, 428.10	853.76, 1708.46	241.27, 424.57

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 10 AM 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 (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	104.18 (43.23)	683.62 (156.99)	105.52 (49.56)
	95% CI of Geometric Mean	94.77, 114.51	483.01, 967.56	90.64, 122.83
	Median	104.89	739.17	109.62
	Q25, Q75	81.20, 130.40	273.56, 1750.32	80.75, 139.45
	Min, Max	33.6, 278.5	86.1, 5620.5	36.6, 344.4
	Mean (SD)	113.48 (49.884)	1203.26 (1340.439)	117.88 (62.142)
	95% CI of Mean	102.07, 124.88	785.54, 1620.97	97.73, 138.03

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 10 AM 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 (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	102.60 (39.75)	733.20 (152.75)	110.70 (46.63)
	95% CI of Geometric Mean	94.00, 111.99	520.86, 1032.08	95.87, 127.82
	Median	100.78	764.95	108.60
	Q25, Q75	84.88, 127.08	277.51, 1932.56	86.10, 153.00
	Min, Max	38.9, 279.1	95.6, 5341.4	44.9, 327.5
	Mean (SD)	110.35 (44.585)	1265.53 (1331.557)	122.36 (61.018)
	95% CI of Mean	100.16, 120.54	850.58, 1680.47	102.58, 142.15

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 10 AM 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 (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	90.15 (41.66)	659.65 (141.07)	88.84 (42.60)
	95% CI of Geometric Mean	82.27, 98.79	476.07, 914.00	77.82, 101.41
	Median	88.78	750.84	83.15
	Q25, Q75	67.98, 121.02	245.58, 1744.90	65.70, 123.90
	Min, Max	32.9, 197.6	84.5, 4586.4	36.1, 207.5
	Mean (SD)	97.40 (38.522)	1068.52 (1033.857)	96.30 (39.765)
	95% CI of Mean	88.59, 106.20	746.35, 1390.70	83.41, 109.20

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 10 AM 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 (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	95.54 (37.04)	771.53 (140.36)	98.54 (39.51)
	95% CI of Geometric Mean	88.02, 103.70	557.37, 1067.96	87.10, 111.50
	Median	102.43	730.95	99.35
	Q25, Q75	81.65, 126.15	268.15, 1973.40	79.25, 135.50
	Min, Max	34.3, 181.1	140.1, 5152.3	47.8, 202.3
	Mean (SD)	101.19 (32.025)	1277.63 (1310.796)	105.56 (39.248)
	95% CI of Mean	93.87, 108.51	869.16, 1686.11	92.83, 118.28

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 10 AM 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 (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	783.35 (134.34)	886.46 (123.70)	738.62 (115.98)
	95% CI of Geometric Mean	619.12, 991.13	654.02, 1201.52	547.58, 996.31
	Median	976.10	839.38	592.90
	Q25, Q75	310.21, 1881.08	397.35, 2193.53	321.98, 1813.53
	Min, Max	86.4, 5905.7	142.6, 4025.8	161.7, 3676.8
	Mean (SD)	1218.43 (1092.287)	1334.16 (1135.728)	1090.99 (931.034)
	95% CI of Mean	965.36, 1471.50	975.67, 1692.64	789.18, 1392.80

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 10 AM 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 (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	164.66 (65.33)	914.04 (141.76)	169.17 (70.81)
	95% CI of Geometric Mean	143.41, 189.05	656.26, 1273.08	137.59, 208.01
	Median	176.48	863.55	180.94
	Q25, Q75	99.15, 235.76	395.56, 1941.84	94.50, 255.14
	Min, Max	47.6, 977.1	86.7, 7449.7	46.9, 606.4
	Mean (SD)	199.13 (149.217)	1495.77 (1552.580)	204.12 (125.686)
	95% CI of Mean	164.55, 233.70	1005.71, 1985.83	163.37, 244.87

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 10 AM 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 (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	795.98 (132.80)	886.46 (123.70)	757.27 (115.79)
	95% CI of Geometric Mean	626.99, 1010.52	654.02, 1201.52	559.25, 1025.40
	Median	982.78	839.38	707.25
	Q25, Q75	313.35, 1881.08	397.35, 2193.53	323.96, 1813.53
	Min, Max	86.4, 5905.7	142.6, 4025.8	161.7, 3676.8
	Mean (SD)	1227.44 (1092.791)	1334.16 (1135.728)	1112.16 (933.968)
	95% CI of Mean	968.78, 1486.11	975.67, 1692.64	805.17, 1419.15

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 10 AM 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 (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	164.29 (66.24)	911.80 (116.46)	168.96 (88.58)
	95% CI of Geometric Mean	142.43, 189.51	680.76, 1221.25	131.56, 216.99
	Median	164.85	883.41	178.65
	Q25, Q75	105.67, 241.23	387.59, 2058.86	140.35, 253.67
	Min, Max	52.3, 1130.2	162.7, 4793.5	16.4, 1451.2
	Mean (SD)	200.43 (159.460)	1353.78 (1204.401)	224.33 (229.830)
	95% CI of Mean	162.68, 238.18	973.61, 1733.94	148.78, 299.88

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 10 AM 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 (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	764.05 (137.29)	886.46 (123.70)	739.22 (115.88)
	95% CI of Geometric Mean	597.77, 976.58	654.02, 1201.52	543.46, 1005.50
	Median	898.92	839.38	592.90
	Q25, Q75	308.71, 1881.08	397.35, 2193.53	323.96, 1763.57
	Min, Max	86.4, 5905.7	142.6, 4025.8	161.7, 3676.8
	Mean (SD)	1208.33 (1113.046)	1334.16 (1135.728)	1092.26 (938.651)
	95% CI of Mean	942.93, 1473.73	975.67, 1692.64	779.30, 1405.23

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 10 AM 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 (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	159.97 (84.52)	852.65 (131.18)	154.94 (72.24)
	95% CI of Geometric Mean	134.27, 190.57	621.76, 1169.27	124.83, 192.30
	Median	138.81	912.38	158.24
	Q25, Q75	102.70, 233.22	380.13, 1955.49	100.50, 240.98
	Min, Max	33.8, 3357.2	138.3, 5107.9	41.7, 700.7
	Mean (SD)	236.25 (408.035)	1334.33 (1255.201)	190.92 (137.828)
	95% CI of Mean	138.95, 333.55	938.14, 1730.53	144.96, 236.88

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Baseline	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	708.52 (109.95)	588.73 (122.40)	716.55 (128.18)	768.89 (98.34)	437.96 (100.99)	953.83 (119.12)
	95% CI of Geometric Mean	538.73, 931.82	419.34, 826.55	477.00, 1076.41	503.73, 1173.62	301.98, 635.16	588.31, 1546.43
	Median	822.77	601.55	732.35	780.53	316.58	1372.05
	Q25, Q75	293.43, 1607.20	254.50, 1335.04	274.66, 1760.56	424.24, 1826.20	213.22, 828.36	328.82, 1876.08
	Min, Max	116.3, 4067.8	80.8, 3223.8	165.5, 3506.2	145.8, 2865.2	139.2, 2258.1	196.9, 2896.8
	Mean (SD)	995.49 (793.174)	886.12 (784.632)	1100.24 (987.750)	1031.36 (786.303)	632.97 (619.249)	1322.16 (895.661)
	95% CI of Mean	751.38, 1239.60	607.90, 1164.35	692.52, 1507.97	627.08, 1435.65	358.41, 907.54	861.65, 1782.68

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 1	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	247.09 (78.86)	236.80 (76.41)	602.24 (141.43)	665.90 (123.86)	170.88 (89.07)	316.39 (82.20)
	95% CI of Geometric Mean	199.48, 306.06	186.18, 301.17	390.72, 928.27	405.60, 1093.25	121.77, 239.81	218.67, 457.77
	Median	283.65	254.52	558.94	609.62	171.55	300.31
	Q25, Q75	135.00, 378.77	146.20, 404.15	262.30, 1432.58	316.93, 1560.84	90.91, 271.37	203.59, 544.21
	Min, Max	64.9, 1279.8	70.1, 969.9	77.2, 4339.6	84.7, 3261.3	31.3, 899.5	54.4, 928.1
	Mean (SD)	311.90 (233.447)	292.23 (193.033)	991.44 (1051.485)	991.69 (901.599)	224.34 (187.846)	391.58 (248.017)
	95% CI of Mean	240.05, 383.75	223.78, 360.68	557.40, 1425.47	528.13, 1455.26	141.04, 307.63	264.06, 519.11

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 1							
	n	43	33	25	17	22	17
	Median	-67.56	-59.29	-9.41	-10.84	-57.62	-72.37
	Q25, Q75	-75.32, -47.28	-76.13, -39.88	-16.90, -0.85	-18.05, -4.80	-73.19, -44.57	-75.74, -57.68
	Min, Max	-86.8, -18.7	-89.8, 358.2	-62.2, 23.8	-46.2, 43.1	-79.1, 9.1	-85.7, -4.7
	Mean (SD)	-61.12 (18.459)	-44.88 (75.431)	-13.36 (19.628)	-11.23 (20.423)	-57.13 (20.378)	-62.02 (23.050)
	95% CI of Mean	-66.81, -55.44	-71.63, -18.13	-21.46, -5.25	-21.74, -0.73	-66.17, -48.09	-73.87, -50.16

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 2	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	82.75 (42.52)	95.32 (34.05)	546.06 (158.39)	552.14 (129.68)	80.75 (51.29)	105.31 (59.42)
	95% CI of Geometric Mean	72.99, 93.81	84.76, 107.20	343.87, 867.13	331.34, 920.07	65.17, 100.04	79.37, 139.72
	Median	80.91	95.24	627.41	400.40	78.80	102.67
	Q25, Q75	59.88, 109.89	79.49, 115.74	233.85, 1253.81	274.30, 1323.12	60.75, 91.84	69.93, 126.90
	Min, Max	36.2, 211.1	43.1, 172.4	46.3, 4273.4	105.9, 2639.8	33.3, 254.0	44.6, 390.0
	Mean (SD)	89.77 (37.828)	100.29 (31.792)	918.92 (961.284)	850.58 (784.594)	91.31 (53.450)	123.33 (83.550)
	95% CI of Mean	78.13, 101.42	89.02, 111.57	522.11, 1315.72	447.17, 1253.99	67.61, 115.01	80.37, 166.29

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 2							
	n	43	33	25	17	22	17
	Median	-89.85	-82.77	-21.23	-34.13	-74.10	-92.28
	Q25, Q75	-92.92, -81.34	-90.84, -71.84	-31.06, -12.82	-36.18, -13.01	-92.78, -64.50	-93.80, -77.33
	Min, Max	-97.7, -49.1	-95.8, 18.4	-72.0, 21.9	-61.7, 44.6	-97.1, -13.1	-96.1, -58.6
	Mean (SD)	-84.73 (11.897)	-77.66 (21.506)	-20.46 (21.708)	-24.00 (27.139)	-72.54 (22.796)	-84.98 (12.341)
	95% CI of Mean	-88.40, -81.06	-85.29, -70.03	-29.43, -11.50	-37.96, -10.04	-82.65, -62.42	-91.33, -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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 3	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	76.52 (40.01)	96.25 (30.71)	572.00 (146.97)	644.43 (132.32)	85.89 (56.71)	99.97 (49.93)
	95% CI of Geometric Mean	67.96, 86.16	86.53, 107.07	367.37, 890.61	384.20, 1080.90	67.96, 108.55	78.44, 127.42
	Median	78.00	93.28	625.57	391.52	82.35	86.51
	Q25, Q75	55.62, 100.98	79.24, 121.95	295.56, 1291.67	333.89, 1286.50	63.21, 97.85	72.57, 137.36
	Min, Max	40.7, 194.8	47.6, 186.3	64.2, 4277.4	159.2, 3755.2	30.7, 370.7	39.1, 248.8
	Mean (SD)	82.42 (33.783)	100.53 (30.555)	941.04 (983.804)	1050.91 (1137.716)	100.48 (72.907)	111.11 (54.672)
	95% CI of Mean	72.02, 92.82	89.69, 111.37	534.94, 1347.14	465.94, 1635.87	68.15, 132.81	82.99, 139.22

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 3							
	n	43	33	25	17	22	17
	Median	-89.15	-81.29	-18.00	-15.47	-75.22	-93.02
	Q25, Q75	-93.84, -80.61	-90.91, -66.79	-33.18, 0.00	-41.91, 9.83	-93.10, -57.21	-94.95, -77.93
	Min, Max	-97.6, -49.0	-96.6, 51.0	-68.5, 42.1	-54.9, 105.6	-97.2, -2.2	-95.4, -50.2
	Mean (SD)	-85.30 (11.957)	-76.02 (26.269)	-16.72 (23.714)	-8.11 (42.544)	-68.44 (28.076)	-84.11 (15.984)
	95% CI of Mean	-88.99, -81.62	-85.34, -66.70	-26.51, -6.93	-29.99, 13.77	-80.90, -55.99	-92.34, -75.89

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 4	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	64.12 (40.60)	88.75 (37.87)	550.73 (143.83)	619.09 (124.09)	67.88 (48.55)	89.48 (50.55)
	95% CI of Geometric Mean	56.85, 72.31	77.95, 101.06	355.72, 852.63	376.86, 1017.03	55.35, 83.24	70.02, 114.35
	Median	65.70	85.91	550.98	420.94	73.42	84.03
	Q25, Q75	47.62, 84.89	67.28, 115.47	277.78, 1192.31	316.86, 1603.56	49.50, 88.50	70.82, 101.63
	Min, Max	31.3, 130.7	43.9, 173.8	96.6, 3256.8	128.9, 2761.6	30.5, 182.0	41.7, 242.7
	Mean (SD)	68.96 (26.431)	94.68 (34.907)	897.55 (894.289)	933.90 (824.097)	75.18 (36.635)	100.60 (56.385)
	95% CI of Mean	60.82, 77.10	82.29, 107.06	528.40, 1266.70	510.19, 1357.62	58.94, 91.43	71.60, 129.59

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 4							
	n	43	33	25	17	22	17
	Median	-90.98	-82.77	-18.59	-22.27	-77.90	-93.88
	Q25, Q75	-95.54, -82.12	-93.89, -68.15	-40.37, -6.12	-36.67, 6.58	-94.44, -65.13	-95.40, -81.06
	Min, Max	-97.8, -51.2	-97.9, 43.0	-52.1, 16.4	-59.2, 33.9	-97.9, -36.8	-97.1, -47.7
	Mean (SD)	-87.43 (10.825)	-76.44 (25.755)	-20.54 (20.371)	-15.70 (25.948)	-77.10 (17.410)	-85.52 (14.772)
	95% CI of Mean	-90.77, -84.10	-85.57, -67.30	-28.95, -12.13	-29.05, -2.35	-84.82, -69.38	-93.12, -77.92

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 5	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	69.74 (33.51)	100.44 (25.06)	594.25 (134.46)	666.72 (136.54)	75.97 (40.27)	87.31 (43.02)
	95% CI of Geometric Mean	63.08, 77.11	92.02, 109.63	390.67, 903.89	393.44, 1129.81	63.97, 90.22	70.64, 107.91
	Median	67.84	99.80	611.97	467.39	82.53	76.69
	Q25, Q75	59.24, 86.54	86.96, 119.54	246.01, 1393.94	325.42, 1719.96	64.60, 94.85	72.15, 102.04
	Min, Max	27.3, 150.6	60.3, 150.6	134.1, 3814.6	109.2, 3901.1	30.7, 149.0	41.7, 202.4
	Mean (SD)	73.41 (24.159)	103.41 (25.178)	940.88 (923.177)	1067.72 (1065.790)	81.10 (28.210)	95.09 (44.124)
	95% CI of Mean	65.97, 80.85	94.47, 112.34	559.81, 1321.95	519.74, 1615.71	68.59, 93.62	72.39, 117.78

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 5							
	n	43	33	25	17	22	17
	Median	-89.48	-80.19	-18.37	-12.82	-69.50	-93.29
	Q25, Q75	-94.72, -83.29	-91.63, -62.08	-26.83, -10.43	-28.70, -3.45	-93.79, -56.74	-95.12, -77.03
	Min, Max	-98.3, -42.7	-97.0, 37.3	-40.8, 43.8	-53.6, 113.6	-98.1, -35.9	-97.5, -48.0
	Mean (SD)	-85.73 (13.132)	-73.77 (26.656)	-15.29 (18.752)	-7.12 (39.410)	-73.20 (20.474)	-85.76 (14.512)
	95% CI of Mean	-89.78, -81.69	-83.22, -64.31	-23.03, -7.54	-27.39, 13.14	-82.28, -64.11	-93.23, -78.30

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Baseline	n	42	32	24	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	702.71 (111.59)	595.94 (124.91)	743.18 (128.95)	768.89 (98.34)	437.96 (100.99)	953.83 (119.12)
	95% CI of Geometric Mean	530.97, 930.01	420.13, 845.32	489.34, 1128.71	503.73, 1173.62	301.98, 635.16	588.31, 1546.43
	Median	814.54	604.64	762.92	780.53	316.58	1372.05
	Q25, Q75	293.43, 1607.20	245.73, 1427.18	259.29, 1809.84	424.24, 1826.20	213.22, 828.36	328.82, 1876.08
	Min, Max	116.3, 4067.8	80.8, 3223.8	165.5, 3506.2	145.8, 2865.2	139.2, 2258.1	196.9, 2896.8
	Mean (SD)	995.36 (802.788)	901.35 (792.217)	1133.65 (994.463)	1031.36 (786.303)	632.97 (619.249)	1322.16 (895.661)
	95% CI of Mean	745.19, 1245.53	615.72, 1186.98	713.72, 1553.58	627.08, 1435.65	358.41, 907.54	861.65, 1782.68

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Day 30	n	42	32	24	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	127.51 (70.04)	156.18 (46.49)	754.43 (131.35)	844.67 (119.41)	133.69 (70.48)	196.56 (59.33)
	95% CI of Geometric Mean	104.72, 155.25	133.15, 183.18	494.30, 1151.44	520.57, 1370.53	100.88, 177.17	148.20, 260.69
	Median	142.19	151.05	945.35	669.61	140.77	204.41
	Q25, Q75	85.31, 189.31	114.74, 199.14	276.08, 1528.87	370.97, 2033.25	78.74, 227.81	116.82, 295.58
	Min, Max	39.1, 601.6	79.1, 708.2	135.5, 4058.8	182.4, 2864.7	46.3, 420.5	82.0, 492.2
	Mean (SD)	155.39 (109.412)	175.04 (111.619)	1168.97 (1094.256)	1221.62 (959.265)	160.45 (97.397)	224.91 (116.343)
	95% CI of Mean	121.29, 189.49	134.79, 215.29	706.90, 1631.04	728.41, 1714.84	117.26, 203.63	165.09, 284.73

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 30							
	n	42	32	24	17	22	17
	Median	-83.64	-67.60	6.98	10.99	-64.90	-87.34
	Q25, Q75	-88.83, -64.46	-88.32, -45.57	-9.43, 22.67	-5.62, 31.30	-72.61, -55.32	-90.14, -44.52
	Min, Max	-96.9, 37.5	-95.3, 16.4	-68.2, 151.5	-63.8, 135.0	-97.9, 24.2	-94.6, 28.5
	Mean (SD)	-72.58 (29.164)	-61.82 (30.548)	8.39 (40.635)	21.25 (54.690)	-57.97 (32.397)	-63.23 (40.565)
	95% CI of Mean	-81.67, -63.48	-72.84, -50.80	-8.78, 25.55	-6.87, 49.37	-72.34, -43.60	-84.09, -42.37

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Baseline	n	41	30	24	17	21	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	685.56 (111.24)	636.25 (124.27)	743.18 (128.95)	768.89 (98.34)	453.40 (101.73)	953.83 (119.12)
	95% CI of Geometric Mean	516.45, 910.04	443.53, 912.72	489.34, 1128.71	503.73, 1173.62	308.92, 665.44	588.31, 1546.43
	Median	806.30	649.15	762.92	780.53	330.29	1372.05
	Q25, Q75	293.43, 1427.18	260.25, 1519.32	259.29, 1809.84	424.24, 1826.20	232.50, 828.36	328.82, 1876.08
	Min, Max	116.3, 4067.8	80.8, 3223.8	165.5, 3506.2	145.8, 2865.2	139.2, 2258.1	196.9, 2896.8
	Mean (SD)	974.22 (803.157)	946.53 (798.179)	1133.65 (994.463)	1031.36 (786.303)	653.04 (627.168)	1322.16 (895.661)
	95% CI of Mean	720.71, 1227.74	648.48, 1244.58	713.72, 1553.58	627.08, 1435.65	367.55, 938.53	861.65, 1782.68

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Day 60	n	41	30	24	17	21	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	148.65 (63.72)	134.51 (54.64)	744.47 (109.07)	883.01 (112.36)	159.85 (67.01)	136.06 (69.52)
	95% CI of Geometric Mean	123.63, 178.72	111.13, 162.80	512.27, 1081.93	554.89, 1405.16	121.15, 210.91	98.52, 187.91
	Median	144.09	135.92	759.44	867.49	145.16	138.89
	Q25, Q75	104.17, 203.90	87.72, 196.05	378.21, 1437.10	429.36, 1898.12	122.94, 207.92	79.24, 196.58
	Min, Max	48.1, 759.7	41.7, 483.9	188.1, 3539.7	182.8, 3001.7	59.0, 905.4	39.4, 370.6
	Mean (SD)	180.00 (143.314)	153.20 (87.433)	1059.76 (909.202)	1258.17 (1012.310)	198.90 (181.580)	162.38 (98.118)
	95% CI of Mean	134.76, 225.24	120.55, 185.86	675.83, 1443.68	737.69, 1778.66	116.24, 281.56	111.92, 212.83

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
% Change from baseline to Day 60							
	n	41	30	24	17	21	17
	Median	-79.75	-83.80	0.84	20.18	-67.73	-87.56
	Q25, Q75	-89.98, -55.13	-88.97, -45.91	-14.23, 17.96	-1.20, 30.51	-74.90, -38.05	-94.13, -69.38
	Min, Max	-95.2, 16.5	-95.9, 29.7	-74.4, 171.5	-39.2, 146.2	-95.9, 45.6	-95.3, 61.1
	Mean (SD)	-70.37 (25.005)	-67.44 (31.324)	9.66 (50.068)	22.75 (48.321)	-49.81 (39.685)	-72.79 (40.036)
	95% CI of Mean	-78.27, -62.47	-79.14, -55.74	-11.49, 30.81	-2.10, 47.60	-67.88, -31.74	-93.38, -52.20

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Baseline	n	39	31	24	17	21	16
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	707.25 (115.22)	576.32 (124.32)	743.18 (128.95)	768.89 (98.34)	453.40 (101.73)	905.81 (120.19)
	95% CI of Geometric Mean	525.02, 952.74	404.28, 821.56	489.34, 1128.71	503.73, 1173.62	308.92, 665.44	547.33, 1499.09
	Median	806.30	601.55	762.92	780.53	330.29	1346.82
	Q25, Q75	293.43, 1692.87	236.97, 1335.04	259.29, 1809.84	424.24, 1826.20	232.50, 828.36	317.59, 1794.04
	Min, Max	116.3, 4067.8	80.8, 3223.8	165.5, 3506.2	145.8, 2865.2	139.2, 2258.1	196.9, 2896.8
	Mean (SD)	1014.34 (825.201)	876.14 (792.156)	1133.65 (994.463)	1031.36 (786.303)	653.04 (627.168)	1268.58 (896.446)
	95% CI of Mean	746.84, 1281.85	585.57, 1166.71	713.72, 1553.58	627.08, 1435.65	367.55, 938.53	790.89, 1746.26

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Day 90	n	39	31	24	17	21	16
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	140.80 (72.08)	142.94 (82.94)	733.78 (120.49)	864.16 (139.70)	151.68 (65.66)	119.53 (44.33)
	95% CI of Geometric Mean	114.17, 173.66	109.62, 186.38	491.93, 1094.53	506.16, 1475.36	115.49, 199.20	95.38, 149.80
	Median	135.29	117.65	945.08	516.62	151.98	127.50
	Q25, Q75	93.11, 211.76	100.60, 174.84	384.86, 1349.38	324.56, 2838.71	93.63, 212.43	92.34, 143.76
	Min, Max	30.7, 515.2	66.1, 3645.2	77.9, 3942.3	254.4, 3591.7	59.2, 473.8	58.6, 280.6
	Mean (SD)	172.76 (119.515)	253.19 (632.922)	1069.93 (936.322)	1386.07 (1244.360)	181.22 (119.603)	130.05 (57.228)
	95% CI of Mean	134.02, 211.51	21.03, 485.36	674.56, 1465.31	746.27, 2025.86	126.77, 235.67	99.55, 160.55

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
% Change from baseline to Day 90							
	n	39	31	24	17	21	16
	Median	-84.04	-71.23	-1.27	-5.92	-60.98	-90.52
	Q25, Q75	-90.49, -54.27	-88.51, -49.52	-18.99, 39.83	-13.05, 37.74	-79.14, -43.20	-93.85, -70.63
	Min, Max	-96.9, 4.9	-95.3, 179.1	-53.0, 84.4	-49.5, 278.8	-92.2, 21.2	-96.8, -21.5
	Mean (SD)	-69.83 (28.274)	-57.36 (53.316)	4.54 (35.427)	31.39 (87.975)	-56.41 (30.691)	-78.86 (22.053)
	95% CI of Mean	-79.00, -60.66	-76.92, -37.79	-10.42, 19.51	-13.84, 76.63	-70.39, -42.44	-90.61, -67.10

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Baseline	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	451.47 (107.88)	965.87 (94.32)	621.64 (97.11)	906.45 (131.70)	545.03 (117.44)	698.08 (129.03)
	95% CI of Geometric Mean	339.58, 600.22	740.30, 1260.18	436.99, 884.30	558.99, 1469.88	352.52, 842.65	433.18, 1124.95
	Median	398.83	1189.05	674.05	1361.11	542.07	562.84
	Q25, Q75	231.54, 994.44	627.77, 1692.87	334.25, 950.64	298.50, 1884.62	231.25, 1379.44	258.71, 2059.93
	Min, Max	80.8, 2071.4	172.3, 4067.8	145.8, 2547.8	217.8, 3506.2	139.2, 2258.1	196.9, 2896.8
	Mean (SD)	659.82 (604.003)	1251.77 (847.072)	839.92 (669.136)	1353.74 (1073.898)	796.68 (653.523)	1077.29 (959.201)
	95% CI of Mean	464.02, 855.62	969.33, 1534.20	550.56, 1129.28	836.14, 1871.35	490.82, 1102.54	614.97, 1539.62

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 1	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	194.87 (82.18)	305.53 (61.69)	495.84 (113.34)	833.72 (144.89)	198.54 (79.42)	253.21 (110.12)
	95% CI of Geometric Mean	154.39, 245.97	252.82, 369.22	334.68, 734.59	499.34, 1392.02	143.12, 275.42	164.79, 389.07
	Median	155.50	325.94	517.56	1120.88	220.98	256.05
	Q25, Q75	106.45, 369.05	221.70, 406.59	270.88, 1000.00	291.85, 1768.39	138.15, 303.65	143.41, 544.21
	Min, Max	70.1, 969.9	64.9, 1279.8	77.2, 2308.1	183.2, 4339.6	31.3, 701.5	54.4, 928.1
	Mean (SD)	253.72 (204.395)	355.68 (217.534)	699.14 (568.948)	1345.50 (1248.835)	242.04 (151.349)	355.35 (282.167)
	95% CI of Mean	187.46, 319.99	283.15, 428.22	453.10, 945.17	743.58, 1947.43	171.20, 312.87	219.34, 491.35

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19	>19	10-19	>19	10-19	>19
		cig/day (N=39)	cig/day (N=37)	cig/day (N=23)	cig/day (N=19)	cig/day (N=20)	cig/day (N=19)
% Change from baseline to Day 1							
	n	39	37	23	19	20	19
	Median	-57.38	-70.38	-10.84	-5.84	-67.70	-66.27
	Q25, Q75	-70.32, -39.88	-76.43, -56.82	-33.69, -6.24	-15.88, 0.00	-77.83, -45.93	-74.66, -51.86
	Min, Max	-86.8, 358.2	-89.8, -4.4	-62.2, 8.4	-46.8, 43.1	-85.7, 9.1	-77.2, -38.2
	Mean (SD)	-44.55 (68.971)	-64.10 (19.212)	-17.86 (18.405)	-6.01 (19.794)	-57.05 (27.162)	-61.58 (13.404)
	95% CI of Mean	-66.92, -22.19	-70.51, -57.69	-25.82, -9.89	-15.55, 3.54	-69.77, -44.34	-68.05, -55.12

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 2	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	83.93 (35.85)	92.49 (42.93)	436.11 (132.34)	724.01 (148.52)	80.55 (39.56)	102.67 (69.44)
	95% CI of Geometric Mean	74.98, 93.94	80.63, 106.08	282.27, 673.80	430.34, 1218.07	67.38, 96.29	75.88, 138.92
	Median	84.18	99.40	400.40	1031.03	73.18	92.90
	Q25, Q75	64.85, 111.82	74.40, 118.18	245.12, 884.06	233.85, 1615.82	64.96, 88.65	78.49, 177.94
	Min, Max	39.4, 161.3	36.2, 211.1	46.3, 2344.6	147.0, 4273.4	50.0, 211.9	33.3, 390.0
	Mean (SD)	88.95 (30.842)	100.02 (39.454)	662.93 (602.632)	1167.65 (1091.230)	87.42 (43.671)	124.06 (85.700)
	95% CI of Mean	78.95, 98.96	86.86, 113.18	402.33, 923.53	641.69, 1693.61	66.98, 107.86	82.74, 165.37

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 2							
	n	39	37	23	19	20	19
	Median	-81.22	-90.72	-25.94	-19.04	-82.68	-84.24
	Q25, Q75	-89.56, -69.19	-93.86, -86.70	-36.53, -7.98	-35.34, -12.82	-93.60, -70.15	-93.41, -64.51
	Min, Max	-95.5, 18.4	-97.7, -56.1	-72.0, 19.9	-52.2, 44.6	-97.1, -13.1	-96.1, -36.8
	Mean (SD)	-75.94 (20.038)	-87.68 (10.280)	-25.61 (24.165)	-17.39 (23.178)	-77.28 (21.865)	-78.68 (17.844)
	95% CI of Mean	-82.44, -69.44	-91.12, -84.25	-36.07, -15.16	-28.57, -6.22	-87.51, -67.04	-87.28, -70.07

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 3	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	79.37 (32.60)	90.34 (42.38)	486.70 (115.27)	773.80 (161.60)	76.42 (49.60)	111.27 (50.46)
	95% CI of Geometric Mean	71.60, 87.99	78.89, 103.45	327.03, 724.31	448.15, 1336.06	61.35, 95.18	88.44, 139.98
	Median	83.19	88.81	393.04	915.83	75.97	97.85
	Q25, Q75	61.88, 99.21	71.63, 120.89	302.52, 1164.08	295.56, 2427.39	61.62, 91.24	78.00, 142.06
	Min, Max	40.7, 128.8	42.7, 194.8	64.2, 2677.8	145.5, 4277.4	30.7, 227.5	62.3, 370.7
	Mean (SD)	83.19 (24.923)	97.76 (39.544)	702.88 (621.089)	1327.64 (1323.160)	85.35 (45.794)	125.92 (76.249)
	95% CI of Mean	75.11, 91.27	84.57, 110.95	434.29, 971.46	689.89, 1965.39	63.91, 106.79	89.16, 162.67

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 3							
	n	39	37	23	19	20	19
	Median	-80.61	-90.54	-17.23	-26.09	-82.96	-87.04
	Q25, Q75	-89.97, -67.22	-94.41, -87.52	-37.49, 5.10	-33.39, 7.61	-94.75, -62.82	-93.45, -59.16
	Min, Max	-96.0, 51.0	-97.6, -58.7	-68.5, 44.0	-50.7, 105.6	-97.2, -2.2	-95.4, -7.8
	Mean (SD)	-75.49 (24.568)	-87.37 (10.641)	-16.86 (28.376)	-8.85 (37.136)	-75.91 (25.110)	-74.60 (24.720)
	95% CI of Mean	-83.46, -67.52	-90.93, -83.82	-29.14, -4.59	-26.75, 9.06	-87.67, -64.16	-86.52, -62.68

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 4	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	71.08 (39.73)	76.86 (46.28)	464.12 (108.15)	752.24 (157.78)	73.99 (47.85)	79.38 (55.62)
	95% CI of Geometric Mean	62.78, 80.48	66.36, 89.03	317.21, 679.07	438.88, 1289.31	59.82, 91.51	61.80, 101.95
	Median	79.37	72.67	420.94	1192.31	73.42	78.13
	Q25, Q75	57.08, 88.34	51.71, 112.61	311.36, 982.35	277.78, 1979.75	52.76, 92.56	52.63, 105.04
	Min, Max	31.3, 173.8	34.0, 165.1	96.6, 2816.9	119.4, 3256.8	33.8, 242.7	30.5, 221.2
	Mean (SD)	76.18 (28.960)	84.29 (36.346)	664.89 (627.670)	1211.71 (1008.164)	82.43 (45.990)	90.29 (49.698)
	95% CI of Mean	66.78, 85.57	72.17, 96.42	393.46, 936.32	725.79, 1697.64	60.90, 103.96	66.33, 114.25

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 4							
	n	39	37	23	19	20	19
	Median	-82.12	-92.26	-24.78	-12.13	-82.05	-89.85
	Q25, Q75	-92.06, -71.68	-95.99, -87.61	-41.64, -4.52	-32.32, 0.00	-94.52, -65.94	-95.40, -67.83
	Min, Max	-96.0, 43.0	-97.9, -51.1	-59.2, 33.9	-47.3, 13.8	-97.9, -36.8	-97.1, -47.7
	Mean (SD)	-77.78 (23.386)	-87.79 (12.604)	-21.57 (25.498)	-14.96 (18.576)	-79.46 (17.141)	-82.14 (16.472)
	95% CI of Mean	-85.37, -70.20	-92.00, -83.59	-32.60, -10.54	-23.92, -6.00	-87.49, -71.44	-90.09, -74.20

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 5	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	80.32 (36.19)	83.20 (35.19)	517.51 (105.88)	778.70 (163.83)	80.87 (45.77)	80.56 (38.14)
	95% CI of Geometric Mean	71.68, 90.00	74.24, 93.24	355.69, 752.95	449.10, 1350.20	65.94, 99.19	67.45, 96.23
	Median	83.47	80.00	467.39	1193.69	83.99	76.34
	Q25, Q75	61.80, 106.48	66.93, 104.62	248.98, 900.15	246.01, 1777.43	66.15, 103.10	65.45, 93.63
	Min, Max	27.3, 140.4	39.1, 150.6	109.2, 2793.7	134.1, 3901.1	30.7, 202.4	35.0, 177.3
	Mean (SD)	84.88 (26.914)	88.07 (30.678)	735.08 (668.183)	1303.50 (1192.740)	88.27 (38.696)	86.07 (34.351)
	95% CI of Mean	76.15, 93.61	77.84, 98.31	446.13, 1024.02	728.61, 1878.39	70.15, 106.38	69.51, 102.64

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 5							
	n	39	37	23	19	20	19
	Median	-79.98	-92.38	-16.47	-18.37	-81.22	-88.55
	Q25, Q75	-88.95, -65.13	-95.26, -86.73	-25.11, -4.58	-30.27, 0.00	-94.63, -60.84	-95.12, -69.46
	Min, Max	-97.2, 37.3	-98.3, -39.8	-53.6, 43.8	-41.1, 113.6	-98.1, -35.9	-97.5, -48.0
	Mean (SD)	-74.52 (24.208)	-86.88 (14.423)	-13.94 (23.313)	-9.62 (34.811)	-75.43 (21.468)	-82.09 (15.808)
	95% CI of Mean	-82.38, -66.67	-91.69, -82.06	-24.02, -3.85	-26.40, 7.17	-85.48, -65.38	-89.71, -74.46

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Baseline	n	38	36	23	18	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	452.95 (109.93)	964.91 (96.14)	621.64 (97.11)	964.15 (129.89)	545.03 (117.44)	698.08 (129.03)
	95% CI of Geometric Mean	338.05, 606.88	733.84, 1268.73	436.99, 884.30	588.07, 1580.75	352.52, 842.65	433.18, 1124.95
	Median	375.68	1234.87	674.05	1376.68	542.07	562.84
	Q25, Q75	231.54, 994.44	614.66, 1724.89	334.25, 950.64	307.86, 1884.62	231.25, 1379.44	258.71, 2059.93
	Min, Max	80.8, 2071.4	172.3, 4067.8	145.8, 2547.8	217.8, 3506.2	139.2, 2258.1	196.9, 2896.8
	Mean (SD)	666.68 (610.565)	1258.73 (858.013)	839.92 (669.136)	1412.37 (1073.291)	796.68 (653.523)	1077.29 (959.201)
	95% CI of Mean	465.99, 867.38	968.41, 1549.04	550.56, 1129.28	878.63, 1946.11	490.82, 1102.54	614.97, 1539.62

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 30	n	38	36	23	18	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	124.05 (52.57)	157.19 (67.42)	612.91 (109.93)	1094.57 (128.29)	135.81 (70.74)	185.65 (63.26)
	95% CI of Geometric Mean	105.45, 145.92	127.79, 193.37	417.09, 900.66	670.22, 1787.59	100.80, 182.98	140.36, 245.54
	Median	128.41	169.79	641.55	1571.12	135.92	185.57
	Q25, Q75	93.11, 184.12	106.76, 216.26	261.32, 1235.00	382.11, 2397.87	88.97, 238.17	116.82, 299.11
	Min, Max	39.1, 335.2	53.5, 708.2	135.5, 3108.9	186.0, 4058.8	46.3, 385.0	64.6, 492.2
	Mean (SD)	138.46 (63.948)	190.73 (139.616)	877.43 (756.785)	1591.22 (1201.620)	162.58 (95.549)	215.88 (118.902)
	95% CI of Mean	117.44, 159.48	143.48, 237.97	550.17, 1204.70	993.66, 2188.78	117.85, 207.30	158.57, 273.20

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 2

		THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 30							
	n	38	36	23	18	20	19
	Median	-68.62	-84.08	5.53	12.10	-71.42	-65.11
	Q25, Q75	-85.86, -46.08	-92.37, -65.68	-22.65, 23.29	-3.67, 29.78	-89.04, -45.21	-87.34, -55.21
	Min, Max	-94.5, 37.5	-96.9, 1.1	-68.2, 151.5	-36.6, 135.0	-97.9, 28.5	-96.1, 24.2
	Mean (SD)	-61.04 (32.862)	-75.19 (25.207)	10.14 (53.411)	18.30 (37.611)	-58.22 (40.338)	-62.42 (31.222)
	95% CI of Mean	-71.84, -50.23	-83.73, -66.66	-12.96, 33.24	-0.41, 37.01	-77.10, -39.33	-77.47, -47.36

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Baseline	n	36	35	23	18	20	18
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	451.38 (110.56)	988.44 (91.08)	621.64 (97.11)	964.15 (129.89)	545.03 (117.44)	745.95 (125.85)
	95% CI of Geometric Mean	333.60, 610.73	756.85, 1290.91	436.99, 884.30	588.07, 1580.75	352.52, 842.65	459.50, 1210.95
	Median	375.68	1189.05	674.05	1376.68	542.07	695.60
	Q25, Q75	234.25, 908.61	627.77, 1692.87	334.25, 950.64	307.86, 1884.62	231.25, 1379.44	302.88, 2059.93
	Min, Max	80.8, 2071.4	172.3, 4067.8	145.8, 2547.8	217.8, 3506.2	139.2, 2258.1	196.9, 2896.8
	Mean (SD)	667.34 (618.754)	1266.15 (849.359)	839.92 (669.136)	1412.37 (1073.291)	796.68 (653.523)	1125.39 (963.145)
	95% CI of Mean	457.98, 876.70	974.38, 1557.92	550.56, 1129.28	878.63, 1946.11	490.82, 1102.54	646.42, 1604.36

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Day 60	n	36	35	23	18	20	18
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	115.32 (57.37)	177.15 (52.05)	631.89 (86.61)	1078.54 (126.11)	132.89 (79.45)	168.56 (52.49)
	95% CI of Geometric Mean	96.28, 138.13	149.72, 209.60	457.24, 873.25	663.96, 1751.99	95.79, 184.37	131.89, 215.42
	Median	111.30	156.12	551.57	1356.20	132.13	151.70
	Q25, Q75	78.43, 173.90	126.56, 222.22	426.71, 1223.94	392.33, 2830.69	82.72, 182.27	127.88, 255.47
	Min, Max	41.7, 483.9	95.6, 759.7	182.8, 2688.0	188.4, 3539.7	39.4, 905.4	76.2, 376.6
	Mean (SD)	133.67 (83.991)	204.69 (145.446)	819.87 (621.811)	1553.67 (1133.905)	176.60 (187.671)	189.19 (95.579)
	95% CI of Mean	105.24, 162.09	154.72, 254.65	550.98, 1088.77	989.79, 2117.55	88.76, 264.44	141.65, 236.72

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 3

		THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Timepoint	Statistic						
% Change from baseline to Day 60							
	n	36	35	23	18	20	18
	Median	-76.26	-83.70	3.54	3.49	-74.92	-72.64
	Q25, Q75	-86.58, -45.39	-90.54, -60.49	-30.01, 28.75	-8.75, 30.51	-93.18, -28.31	-87.56, -61.29
	Min, Max	-95.9, 29.7	-95.2, -28.3	-74.4, 171.5	-24.3, 146.2	-95.9, 61.1	-94.9, 45.6
	Mean (SD)	-62.68 (32.611)	-75.77 (19.816)	13.64 (55.924)	16.93 (40.443)	-54.25 (46.460)	-66.58 (33.999)
	95% CI of Mean	-73.72, -51.64	-82.58, -68.96	-10.54, 37.83	-3.18, 37.05	-76.00, -32.50	-83.49, -49.67

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Baseline	n	36	34	23	18	20	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	447.66 (111.60)	952.39 (99.11)	621.64 (97.11)	964.15 (129.89)	545.03 (117.44)	700.35 (124.13)
	95% CI of Geometric Mean	330.21, 606.88	713.62, 1271.05	436.99, 884.30	588.07, 1580.75	352.52, 842.65	426.28, 1150.64
	Median	375.68	1234.87	674.05	1376.68	542.07	562.84
	Q25, Q75	221.61, 908.61	601.55, 1756.91	334.25, 950.64	307.86, 1884.62	231.25, 1379.44	302.88, 1876.08
	Min, Max	80.8, 2071.4	172.3, 4067.8	145.8, 2547.8	217.8, 3506.2	139.2, 2258.1	196.9, 2896.8
	Mean (SD)	665.30 (620.168)	1257.91 (877.834)	839.92 (669.136)	1412.37 (1073.291)	796.68 (653.523)	1063.38 (955.031)
	95% CI of Mean	455.46, 875.14	951.61, 1564.20	550.56, 1129.28	878.63, 1946.11	490.82, 1102.54	572.34, 1554.42

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Day 90	n	36	34	23	18	20	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	126.31 (45.21)	160.14 (103.76)	616.93 (113.25)	1068.82 (131.11)	128.46 (49.03)	147.38 (68.19)
	95% CI of Geometric Mean	109.16, 146.16	118.84, 215.80	416.51, 913.79	650.00, 1757.49	103.38, 159.63	107.26, 202.50
	Median	119.81	136.58	516.62	1288.21	130.20	137.08
	Q25, Q75	100.40, 173.87	93.46, 234.94	315.46, 1329.91	376.64, 2824.00	92.34, 171.99	93.63, 231.14
	Min, Max	46.3, 390.0	30.7, 3645.2	77.9, 3061.6	224.0, 3942.3	59.2, 473.8	58.6, 470.5
	Mean (SD)	138.67 (65.985)	282.19 (607.021)	906.15 (853.625)	1577.78 (1221.083)	144.38 (87.925)	176.40 (112.553)
	95% CI of Mean	116.34, 161.00	70.39, 493.99	537.01, 1275.29	970.55, 2185.02	103.23, 185.54	118.53, 234.28

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

		THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
% Change from baseline to Day 90	n	36	34	23	18	20	17
	Median	-63.31	-84.55	-4.47	-0.99	-72.91	-74.59
	Q25, Q75	-87.57, -38.18	-91.45, -67.95	-27.54, 37.74	-11.34, 42.09	-90.52, -45.66	-91.50, -54.61
	Min, Max	-95.3, 26.1	-96.9, 179.1	-53.0, 278.8	-33.4, 194.6	-93.6, -14.8	-96.8, 21.2
	Mean (SD)	-58.45 (32.540)	-70.50 (48.849)	13.80 (72.264)	18.07 (51.340)	-66.23 (27.056)	-65.99 (32.404)
	95% CI of Mean	-69.47, -47.44	-87.55, -53.45	-17.45, 45.05	-7.46, 43.61	-78.89, -53.56	-82.66, -49.33

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	662.33 (116.62)		737.29 (114.14)		628.35 (121.71)	
	95% CI of Geometric Mean	537.45, 816.23		554.67, 980.04		463.23, 852.33	
	Median	708.14		756.44		658.34	
	Q25, Q75	272.73, 1519.32		307.86, 1826.20		245.36, 1434.67	
	Min, Max	80.8, 4067.8		145.8, 3506.2		139.2, 2896.8	
	Mean (SD)	969.93 (821.132)		1072.36 (901.976)		946.66 (812.055)	
	95% CI of Mean	784.79, 1155.07		791.28, 1353.44		686.95, 1206.37	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	245.89 (76.72)		627.24 (131.96)		226.26 (93.24)	
	95% CI of Geometric Mean	210.92, 286.66		458.70, 857.71		175.69, 291.39	
	Median	282.31	-64.51	584.28	-9.79	237.45	-66.83
	Q25, Q75	139.72, 403.15	-75.73, -45.64	273.90, 1462.96	-18.05, -3.34	143.36, 356.18	-75.68, -50.46
	Min, Max	64.9, 1279.8	-89.8, 358.2	77.2, 4339.6	-62.2, 43.1	31.3, 928.1	-85.7, 9.1
	Mean (SD)	306.24 (213.766)	-53.78 (51.626)	991.54 (982.046)	-12.50 (19.733)	298.92 (226.333)	-59.66 (21.302)
	95% CI of Mean	258.04, 354.44	-65.43, -42.14	685.51, 1297.57	-18.65, -6.34	226.53, 371.31	-66.47, -52.84

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	90.53 (43.70)		548.51 (143.67)		93.58 (59.99)	
	95% CI of Geometric Mean	82.38, 99.48		394.43, 762.77		78.37, 111.74	
	Median	92.34	-87.24	606.21	-25.66	87.64	-83.87
	Q25, Q75	67.48, 115.74	-92.04, -74.98	245.12, 1320.00	-35.34, -12.82	66.40, 115.45	-93.49, -68.09
	Min, Max	36.2, 363.4	-97.7, 18.4	46.3, 4273.4	-72.0, 44.6	33.3, 390.0	-97.1, -13.1
	Mean (SD)	99.10 (47.748)	-80.77 (19.217)	891.26 (884.476)	-21.90 (23.798)	110.70 (76.374)	-77.96 (19.503)
	95% CI of Mean	88.33, 109.87	-85.11, -76.43	615.63, 1166.88	-29.32, -14.47	86.27, 135.13	-84.20, -71.72

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	87.02 (42.54)		600.28 (138.60)		94.70 (57.61)	
	95% CI of Geometric Mean	79.37, 95.41		434.75, 828.84		79.79, 112.38	
	Median	87.34	-88.23	590.79	-17.61	86.36	-86.14
	Q25, Q75	63.53, 116.28	-93.75, -70.04	298.50, 1291.05	-33.43, 5.88	67.28, 131.43	-94.26, -62.38
	Min, Max	40.7, 363.4	-97.6, 51.0	64.2, 4277.4	-68.5, 105.6	30.7, 370.7	-97.2, -2.2
	Mean (SD)	95.04 (46.489)	-80.40 (21.744)	985.51 (1036.662)	-13.24 (32.462)	110.55 (72.779)	-75.34 (24.286)
	95% CI of Mean	84.56, 105.53	-85.30, -75.49	662.46, 1308.56	-23.36, -3.11	87.27, 133.83	-83.11, -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 / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	76.14 (47.68)		577.44 (133.52)		79.37 (56.58)	
	95% CI of Geometric Mean	68.75, 84.32		421.30, 791.44		67.05, 93.95	
	Median	79.04	-88.84	533.59	-20.43	77.11	-86.14
	Q25, Q75	56.82, 97.09	-94.89, -76.16	287.13, 1433.82	-37.55, -3.62	53.20, 98.08	-94.62, -66.77
	Min, Max	31.3, 363.4	-97.9, 43.0	96.6, 3256.8	-59.2, 33.9	30.5, 322.4	-97.9, -36.8
	Mean (SD)	84.83 (46.455)	-81.76 (21.419)	912.26 (856.448)	-18.58 (22.615)	92.17 (59.834)	-80.70 (16.442)
	95% CI of Mean	74.35, 95.31	-86.59, -76.92	645.37, 1179.15	-25.63, -11.53	73.03, 111.31	-85.96, -75.44

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	84.05 (40.28)		622.58 (132.98)		83.56 (47.48)	
	95% CI of Geometric Mean	77.01, 91.74		454.60, 852.64		72.34, 96.53	
	Median	83.13	-86.85	607.12	-17.42	81.90	-86.09
	Q25, Q75	66.93, 110.38	-94.50, -73.97	248.98, 1504.67	-28.70, -3.45	66.19, 99.56	-94.63, -66.35
	Min, Max	27.3, 363.4	-98.3, 37.3	109.2, 3901.1	-53.6, 113.6	30.7, 322.4	-98.1, -35.9
	Mean (SD)	91.02 (43.122)	-79.69 (22.589)	992.22 (972.694)	-11.98 (28.782)	93.08 (51.561)	-78.66 (18.734)
	95% CI of Mean	81.29, 100.74	-84.79, -74.59	689.10, 1295.34	-20.96, -3.01	76.58, 109.57	-84.65, -72.66

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	141.40 (60.74)		772.49 (124.28)		160.99 (69.07)	
	95% CI of Geometric Mean	124.62, 160.45		571.61, 1043.95		131.84, 196.59	
	Median	144.52	-80.99	861.84	8.16	176.43	-71.06
	Q25, Q75	100.63, 196.92	-88.83, -51.79	290.57, 1815.13	-5.69, 29.22	100.61, 274.18	-87.64, -53.90
	Min, Max	39.1, 708.2	-96.9, 37.5	135.5, 4058.8	-68.2, 151.5	46.3, 492.2	-97.9, 28.5
	Mean (SD)	166.08 (109.648)	-67.62 (30.472)	1169.56 (1024.909)	13.39 (46.241)	191.89 (110.140)	-60.71 (35.424)
	95% CI of Mean	141.35, 190.80	-74.49, -60.74	850.17, 1488.95	-1.02, 27.81	156.66, 227.12	-72.04, -49.37

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	146.64 (60.06)		780.55 (109.54)		148.51 (69.21)	
	95% CI of Geometric Mean	129.39, 166.19		591.87, 1029.36		121.58, 181.41	
	Median	141.87	-80.43	759.44	2.37	143.62	-72.82
	Q25, Q75	103.10, 203.90	-89.37, -49.45	392.33, 1574.64	-11.66, 28.75	89.65, 208.27	-92.25, -45.67
	Min, Max	41.7, 759.7	-95.9, 29.7	182.8, 3539.7	-74.4, 171.5	39.4, 905.4	-95.9, 61.1
	Mean (SD)	173.45 (122.887)	-68.15 (27.989)	1121.94 (943.471)	14.73 (48.626)	183.11 (148.450)	-60.77 (40.030)
	95% CI of Mean	145.74, 201.16	-74.46, -61.83	827.93, 1415.95	-0.43, 29.89	135.63, 230.59	-73.58, -47.97

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	144.37 (77.44)		767.39 (126.36)		138.70 (59.61)	
	95% CI of Geometric Mean	123.69, 168.50		566.00, 1040.44		116.27, 165.45	
	Median	127.38	-80.50	776.25	-1.27	134.68	-74.68
	Q25, Q75	98.81, 202.23	-88.82, -53.89	324.56, 1655.48	-15.60, 37.74	91.54, 196.22	-90.68, -51.49
	Min, Max	30.7, 3645.2	-96.9, 179.1	77.9, 3942.3	-53.0, 278.8	58.6, 473.8	-96.8, 21.2
	Mean (SD)	209.52 (408.985)	-64.99 (40.299)	1179.52 (1067.578)	15.30 (62.492)	162.13 (100.892)	-67.10 (28.378)
	95% CI of Mean	117.30, 301.74	-74.08, -55.90	846.84, 1512.21	-4.18, 34.78	129.85, 194.40	-76.18, -58.02

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	794.11 (133.92)	874.37 (122.19)	747.66 (114.37)
	95% CI of Geometric Mean	631.88, 997.99	649.15, 1177.73	558.06, 1001.68
	Median	976.10	798.21	707.25
	Q25, Q75	313.35, 1932.54	397.35, 2193.53	322.97, 1788.55
	Min, Max	86.4, 5905.7	142.6, 4025.8	161.7, 3676.8
	Mean (SD)	1234.33 (1100.220)	1314.24 (1129.190)	1093.75 (919.186)
	95% CI of Mean	986.26, 1482.40	962.36, 1666.13	799.77, 1387.72

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	285.65 (81.92)	752.14 (150.10)	244.34 (99.61)
	95% CI of Geometric Mean	243.03, 335.74	536.18, 1055.07	187.36, 318.64
	Median	333.18	668.06	245.40
	Q25, Q75	172.59, 484.53	308.90, 1838.22	163.76, 451.76
	Min, Max	73.5, 1758.6	78.9, 5857.6	26.1, 1598.5
	Mean (SD)	365.84 (282.483)	1281.11 (1371.360)	330.66 (279.435)
	95% CI of Mean	302.14, 429.53	853.76, 1708.46	241.29, 420.03

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	106.88 (46.40)	683.62 (156.99)	107.92 (51.37)
	95% CI of Geometric Mean	96.74, 118.07	483.01, 967.56	92.44, 125.98
	Median	106.52	739.17	111.31
	Q25, Q75	81.80, 133.84	273.56, 1750.32	82.05, 139.50
	Min, Max	33.6, 395.1	86.1, 5620.5	36.6, 344.4
	Mean (SD)	118.22 (59.440)	1203.26 (1340.439)	121.41 (65.276)
	95% CI of Mean	104.82, 131.63	785.54, 1620.97	100.53, 142.29

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	105.93 (44.73)	733.20 (152.75)	113.08 (48.31)
	95% CI of Geometric Mean	96.20, 116.64	520.86, 1032.08	97.67, 130.92
	Median	103.15	764.95	108.74
	Q25, Q75	84.90, 132.20	277.51, 1932.56	86.88, 154.50
	Min, Max	38.9, 395.1	95.6, 5341.4	44.9, 327.5
	Mean (SD)	116.70 (59.386)	1265.53 (1331.557)	125.78 (63.992)
	95% CI of Mean	103.31, 130.10	850.58, 1680.47	105.31, 146.25

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	92.91 (46.16)	659.65 (141.07)	91.24 (45.89)
	95% CI of Geometric Mean	84.14, 102.59	476.07, 914.00	79.33, 104.94
	Median	90.71	750.84	87.43
	Q25, Q75	68.95, 122.45	245.58, 1744.90	66.65, 125.95
	Min, Max	32.9, 395.1	84.5, 4586.4	36.1, 259.1
	Mean (SD)	102.72 (52.426)	1068.52 (1033.857)	100.37 (46.937)
	95% CI of Mean	90.90, 114.55	746.35, 1390.70	85.36, 115.39

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	98.30 (41.50)	771.53 (140.36)	100.96 (42.31)
	95% CI of Geometric Mean	89.84, 107.55	557.37, 1067.96	88.66, 114.95
	Median	103.13	730.95	100.48
	Q25, Q75	82.20, 128.35	268.15, 1973.40	81.13, 139.08
	Min, Max	34.3, 395.1	140.1, 5152.3	47.8, 259.1
	Mean (SD)	106.39 (47.505)	1277.63 (1310.796)	109.39 (45.718)
	95% CI of Mean	95.68, 117.11	869.16, 1686.11	94.77, 124.02

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	167.33 (64.98)	900.92 (139.85)	170.98 (70.18)
	95% CI of Geometric Mean	146.37, 191.29	651.32, 1246.15	139.65, 209.34
	Median	179.06	839.29	186.41
	Q25, Q75	108.72, 243.54	395.56, 1941.84	97.87, 257.10
	Min, Max	47.6, 977.1	86.7, 7449.7	46.9, 606.4
	Mean (SD)	201.59 (147.450)	1472.01 (1541.240)	205.49 (124.368)
	95% CI of Mean	168.34, 234.84	991.72, 1952.29	165.71, 245.27

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	168.16 (67.46)	898.76 (115.23)	167.85 (87.29)
	95% CI of Geometric Mean	146.47, 193.06	674.91, 1196.85	131.94, 213.53
	Median	165.02	880.82	178.65
	Q25, Q75	110.70, 245.88	387.59, 2058.86	125.28, 255.81
	Min, Max	52.3, 1130.2	162.7, 4793.5	16.4, 1451.2
	Mean (SD)	205.86 (160.531)	1333.40 (1196.932)	221.70 (225.028)
	95% CI of Mean	169.66, 242.06	960.40, 1706.39	149.73, 293.67

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	163.92 (83.02)	841.79 (129.37)	155.96 (70.87)
	95% CI of Geometric Mean	139.23, 193.00	618.01, 1146.60	127.18, 191.27
	Median	139.44	870.57	162.32
	Q25, Q75	103.75, 238.56	380.13, 1955.49	97.78, 244.88
	Min, Max	33.8, 3357.2	138.3, 5107.9	41.7, 700.7
	Mean (SD)	236.49 (388.493)	1314.42 (1246.500)	190.72 (134.045)
	95% CI of Mean	148.90, 324.09	925.98, 1702.86	147.84, 233.59

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	653.78 (115.03)		737.29 (114.14)		614.87 (122.18)	
	95% CI of Geometric Mean	530.04, 806.39		554.67, 980.04		451.06, 838.16	
	Median	708.14		756.44		562.84	
	Q25, Q75	267.73, 1473.25		307.86, 1826.20		234.01, 1405.14	
	Min, Max	80.8, 4067.8		145.8, 3506.2		139.2, 2896.8	
	Mean (SD)	948.00 (786.107)		1072.36 (901.976)		933.39 (818.265)	
	95% CI of Mean	768.36, 1127.64		791.28, 1353.44		668.13, 1198.64	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	242.57 (77.20)		627.24 (131.96)		223.52 (94.27)	
	95% CI of Geometric Mean	207.48, 283.59		458.70, 857.71		172.60, 289.45	
	Median	278.15	-64.51	584.28	-9.79	223.05	-66.27
	Q25, Q75	138.57, 393.53	-75.52, -46.15	273.90, 1462.96	-18.05, -3.34	143.31, 348.04	-75.70, -49.06
	Min, Max	64.9, 1279.8	-89.8, 358.2	77.2, 4339.6	-62.2, 43.1	31.3, 928.1	-85.7, 9.1
	Mean (SD)	303.36 (215.669)	-54.07 (51.809)	991.54 (982.046)	-12.50 (19.733)	297.24 (229.040)	-59.26 (21.430)
	95% CI of Mean	254.07, 352.65	-65.91, -42.23	685.51, 1297.57	-18.65, -6.34	222.99, 371.49	-66.21, -52.31

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	87.99 (39.48)		548.51 (143.67)		90.66 (56.16)	
	95% CI of Geometric Mean	80.66, 95.99		394.43, 762.77		76.50, 107.43	
	Median	91.49	-87.24	606.21	-25.66	87.10	-84.24
	Q25, Q75	67.39, 114.55	-92.02, -75.31	245.12, 1320.00	-35.34, -12.82	66.23, 110.13	-93.57, -66.07
	Min, Max	36.2, 211.1	-97.7, 18.4	46.3, 4273.4	-72.0, 44.6	33.3, 390.0	-97.1, -13.1
	Mean (SD)	94.34 (35.498)	-81.66 (17.001)	891.26 (884.476)	-21.90 (23.798)	105.27 (69.114)	-77.96 (19.758)
	95% CI of Mean	86.23, 102.46	-85.55, -77.77	615.63, 1166.88	-29.32, -14.47	82.86, 127.68	-84.37, -71.55

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	84.53 (37.97)		600.28 (138.60)		91.77 (53.73)	
	95% CI of Geometric Mean	77.73, 91.93		434.75, 828.84		77.94, 108.04	
	Median	86.06	-88.23	590.79	-17.61	86.21	-87.04
	Q25, Q75	63.17, 111.30	-93.65, -70.98	298.50, 1291.05	-33.43, 5.88	65.96, 125.49	-94.30, -61.57
	Min, Max	40.7, 194.8	-97.6, 51.0	64.2, 4277.4	-68.5, 105.6	30.7, 370.7	-97.2, -2.2
	Mean (SD)	90.28 (33.452)	-81.27 (19.898)	985.51 (1036.662)	-13.24 (32.462)	105.11 (64.996)	-75.27 (24.600)
	95% CI of Mean	82.63, 97.93	-85.83, -76.72	662.46, 1308.56	-23.36, -3.11	84.04, 126.19	-83.25, -67.30

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	73.84 (42.90)		577.44 (133.52)		76.57 (51.10)	
	95% CI of Geometric Mean	67.21, 81.11		421.30, 791.44		65.49, 89.51	
	Median	77.00	-88.84	533.59	-20.43	76.10	-86.57
	Q25, Q75	56.50, 94.44	-94.86, -76.36	287.13, 1433.82	-37.55, -3.62	52.63, 96.15	-94.64, -66.46
	Min, Max	31.3, 173.8	-97.9, 43.0	96.6, 3256.8	-59.2, 33.9	30.5, 242.7	-97.9, -36.8
	Mean (SD)	80.13 (32.798)	-82.66 (19.461)	912.26 (856.448)	-18.58 (22.615)	86.26 (47.364)	-80.77 (16.651)
	95% CI of Mean	72.63, 87.63	-87.11, -78.21	645.37, 1179.15	-25.63, -11.53	70.90, 101.62	-86.17, -75.37

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	81.71 (35.50)		622.58 (132.98)		80.72 (41.57)	
	95% CI of Geometric Mean	75.52, 88.41		454.60, 852.64		70.92, 91.88	
	Median	81.39	-86.85	607.12	-17.42	81.43	-86.78
	Q25, Q75	66.49, 105.55	-94.47, -74.50	248.98, 1504.67	-28.70, -3.45	65.45, 97.09	-94.98, -65.48
	Min, Max	27.3, 150.6	-98.3, 37.3	109.2, 3901.1	-53.6, 113.6	30.7, 202.4	-98.1, -35.9
	Mean (SD)	86.43 (28.659)	-80.54 (20.866)	992.22 (972.694)	-11.98 (28.782)	87.20 (36.178)	-78.67 (18.978)
	95% CI of Mean	79.88, 92.99	-85.31, -75.76	689.10, 1295.34	-20.96, -3.01	75.47, 98.93	-84.83, -72.52

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 10 AM on Day 1 in the SA arm.

**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=63)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	63		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	684.51 (117.80)		753.74 (114.14)		632.38 (121.47)	
	95% CI of Geometric Mean	541.18, 865.81		564.97, 1005.56		462.45, 864.74	
	Median	822.77		780.53		658.34	
	Q25, Q75	285.03, 1519.32		334.25, 1826.20		256.72, 1405.14	
	Min, Max	80.8, 4067.8		145.8, 3506.2		139.2, 2896.8	
	Mean (SD)	991.05 (806.114)		1091.24 (904.744)		952.38 (820.488)	
	95% CI of Mean	788.02, 1194.07		805.66, 1376.82		682.69, 1222.08	

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 10 AM on Day 1 in the SA arm.

**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=63)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	63	63	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	138.55 (60.11)		790.61 (124.30)		161.92 (67.51)	
	95% CI of Geometric Mean	120.46, 159.35		582.74, 1072.64		132.38, 198.06	
	Median	143.70	-82.61	875.78	8.43	176.43	-71.06
	Q25, Q75	96.06, 199.20	-90.11, -54.82	290.57, 1815.13	-5.69, 29.22	101.21, 262.65	-87.94, -52.59
	Min, Max	39.1, 708.2	-96.9, 37.5	135.5, 4058.8	-68.2, 151.5	46.3, 492.2	-97.9, 28.5
	Mean (SD)	161.65 (103.102)	-69.23 (30.058)	1190.80 (1028.235)	13.72 (46.766)	191.81 (109.033)	-60.02 (36.223)
	95% CI of Mean	135.68, 187.62	-76.80, -61.65	866.25, 1515.36	-1.05, 28.49	155.97, 227.65	-71.93, -48.11

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	685.41 (117.05)		753.74 (114.14)		632.38 (121.47)	
	95% CI of Geometric Mean	544.49, 862.81		564.97, 1005.56		462.45, 864.74	
	Median	806.30		780.53		658.34	
	Q25, Q75	293.43, 1519.32		334.25, 1826.20		256.72, 1405.14	
	Min, Max	80.8, 4067.8		145.8, 3506.2		139.2, 2896.8	
	Mean (SD)	991.90 (808.991)		1091.24 (904.744)		952.38 (820.488)	
	95% CI of Mean	791.44, 1192.36		805.66, 1376.82		682.69, 1222.08	

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	65	65	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	141.14 (56.56)		799.06 (109.15)		148.73 (67.73)	
	95% CI of Geometric Mean	123.87, 160.83		604.18, 1056.80		121.53, 182.03	
	Median	139.64	-83.48	820.51	3.54	143.62	-72.82
	Q25, Q75	103.10, 202.07	-89.98, -52.36	426.71, 1574.64	-11.66, 28.75	90.42, 207.92	-92.95, -39.23
	Min, Max	41.7, 691.2	-95.9, 29.7	182.8, 3539.7	-74.4, 171.5	39.4, 905.4	-95.9, 61.1
	Mean (SD)	163.13 (103.419)	-70.05 (27.967)	1142.03 (946.058)	15.09 (49.173)	182.56 (149.413)	-60.09 (40.969)
	95% CI of Mean	137.50, 188.76	-76.99, -63.12	843.41, 1440.65	-0.44, 30.61	133.45, 231.68	-73.56, -46.62

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	648.93 (119.94)		753.74 (114.14)		611.58 (119.59)	
	95% CI of Geometric Mean	513.56, 819.97		564.97, 1005.56		446.69, 837.33	
	Median	690.56		780.53		562.84	
	Q25, Q75	262.73, 1427.18		334.25, 1826.20		256.72, 1386.83	
	Min, Max	80.8, 4067.8		145.8, 3506.2		139.2, 2896.8	
	Mean (SD)	958.88 (815.589)		1091.24 (904.744)		919.22 (805.566)	
	95% CI of Mean	756.79, 1160.98		805.66, 1376.82		650.62, 1187.81	

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	65	65	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	137.03 (75.20)		785.27 (126.46)		136.83 (57.80)	
	95% CI of Geometric Mean	116.08, 161.75		576.82, 1069.04		114.40, 163.66	
	Median	122.07	-83.25	936.64	-1.47	132.28	-74.59
	Q25, Q75	97.47, 182.05	-90.49, -53.62	376.12, 1655.48	-15.60, 37.74	93.63, 175.36	-91.06, -48.38
	Min, Max	30.7, 3645.2	-96.9, 179.1	77.9, 3942.3	-53.0, 278.8	58.6, 473.8	-96.8, 21.2
	Mean (SD)	204.21 (442.822)	-64.83 (42.291)	1201.01 (1071.605)	15.68 (63.221)	159.09 (99.861)	-66.12 (29.207)
	95% CI of Mean	94.48, 313.94	-75.32, -54.35	862.77, 1539.26	-4.28, 35.64	125.79, 192.39	-75.86, -56.38

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	786.75 (133.34)	874.37 (122.19)	738.62 (115.98)
	95% CI of Geometric Mean	624.48, 991.17	649.15, 1177.73	547.58, 996.31
	Median	976.10	798.21	592.90
	Q25, Q75	311.78, 1906.81	397.35, 2193.53	321.98, 1813.53
	Min, Max	86.4, 5905.7	142.6, 4025.8	161.7, 3676.8
	Mean (SD)	1218.98 (1086.046)	1314.24 (1129.190)	1090.99 (931.034)
	95% CI of Mean	970.80, 1467.16	962.36, 1666.13	789.18, 1392.80

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	281.92 (82.54)	752.14 (150.10)	244.39 (101.42)
	95% CI of Geometric Mean	239.11, 332.41	536.18, 1055.07	186.07, 320.98
	Median	315.55	668.06	248.35
	Q25, Q75	167.24, 479.46	308.90, 1838.22	156.33, 454.20
	Min, Max	73.5, 1758.6	78.9, 5857.6	26.1, 1598.5
	Mean (SD)	362.90 (285.312)	1281.11 (1371.360)	332.92 (282.717)
	95% CI of Mean	297.70, 428.10	853.76, 1708.46	241.27, 424.57

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	104.18 (43.23)	683.62 (156.99)	105.52 (49.56)
	95% CI of Geometric Mean	94.77, 114.51	483.01, 967.56	90.64, 122.83
	Median	104.89	739.17	109.62
	Q25, Q75	81.20, 130.40	273.56, 1750.32	80.75, 139.45
	Min, Max	33.6, 278.5	86.1, 5620.5	36.6, 344.4
	Mean (SD)	113.48 (49.884)	1203.26 (1340.439)	117.88 (62.142)
	95% CI of Mean	102.07, 124.88	785.54, 1620.97	97.73, 138.03

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	102.60 (39.75)	733.20 (152.75)	110.70 (46.63)
	95% CI of Geometric Mean	94.00, 111.99	520.86, 1032.08	95.87, 127.82
	Median	100.78	764.95	108.60
	Q25, Q75	84.88, 127.08	277.51, 1932.56	86.10, 153.00
	Min, Max	38.9, 279.1	95.6, 5341.4	44.9, 327.5
	Mean (SD)	110.35 (44.585)	1265.53 (1331.557)	122.36 (61.018)
	95% CI of Mean	100.16, 120.54	850.58, 1680.47	102.58, 142.15

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	90.15 (41.66)	659.65 (141.07)	88.84 (42.60)
	95% CI of Geometric Mean	82.27, 98.79	476.07, 914.00	77.82, 101.41
	Median	88.78	750.84	83.15
	Q25, Q75	67.98, 121.02	245.58, 1744.90	65.70, 123.90
	Min, Max	32.9, 197.6	84.5, 4586.4	36.1, 207.5
	Mean (SD)	97.40 (38.522)	1068.52 (1033.857)	96.30 (39.765)
	95% CI of Mean	88.59, 106.20	746.35, 1390.70	83.41, 109.20

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	95.54 (37.04)	771.53 (140.36)	98.54 (39.51)
	95% CI of Geometric Mean	88.02, 103.70	557.37, 1067.96	87.10, 111.50
	Median	102.43	730.95	99.35
	Q25, Q75	81.65, 126.15	268.15, 1973.40	79.25, 135.50
	Min, Max	34.3, 181.1	140.1, 5152.3	47.8, 202.3
	Mean (SD)	101.19 (32.025)	1277.63 (1310.796)	105.56 (39.248)
	95% CI of Mean	93.87, 108.51	869.16, 1686.11	92.83, 118.28

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 10 AM on Day 1 in the SA arm.

**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=63)	mCC (N=41)	SA (N=38)
Baseline	n	63	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	832.69 (136.61)	886.46 (123.70)	757.27 (115.79)
	95% CI of Geometric Mean	643.06, 1078.25	654.02, 1201.52	559.25, 1025.40
	Median	1041.78	839.38	707.25
	Q25, Q75	313.35, 1932.54	397.35, 2193.53	323.96, 1813.53
	Min, Max	86.4, 5905.7	142.6, 4025.8	161.7, 3676.8
	Mean (SD)	1284.36 (1118.189)	1334.16 (1135.728)	1112.16 (933.968)
	95% CI of Mean	1002.74, 1565.97	975.67, 1692.64	805.17, 1419.15

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 10 AM on Day 1 in the SA arm.

**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=63)	mCC (N=41)	SA (N=38)
Day 30	n	63	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	164.36 (61.11)	914.04 (141.76)	172.29 (70.56)
	95% CI of Geometric Mean	142.62, 189.42	656.26, 1273.08	139.80, 212.32
	Median	176.21	863.55	186.41
	Q25, Q75	99.15, 247.94	395.56, 1941.84	101.23, 255.14
	Min, Max	59.2, 693.8	86.7, 7449.7	46.9, 606.4
	Mean (SD)	193.34 (123.908)	1495.77 (1552.580)	207.27 (125.806)
	95% CI of Mean	162.13, 224.55	1005.71, 1985.83	165.91, 248.62

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=38)
Baseline	n	65	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	832.25 (127.05)	886.46 (123.70)	757.27 (115.79)
	95% CI of Geometric Mean	652.77, 1061.08	654.02, 1201.52	559.25, 1025.40
	Median	1005.48	839.38	707.25
	Q25, Q75	348.13, 1871.01	397.35, 2193.53	323.96, 1813.53
	Min, Max	86.4, 5905.7	142.6, 4025.8	161.7, 3676.8
	Mean (SD)	1254.25 (1098.560)	1334.16 (1135.728)	1112.16 (933.968)
	95% CI of Mean	982.03, 1526.46	975.67, 1692.64	805.17, 1419.15

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=38)
Day 60	n	65	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	162.73 (65.22)	911.80 (116.46)	168.96 (88.58)
	95% CI of Geometric Mean	140.40, 188.59	680.76, 1221.25	131.56, 216.99
	Median	163.62	883.41	178.65
	Q25, Q75	110.70, 240.30	387.59, 2058.86	140.35, 253.67
	Min, Max	52.3, 1130.2	162.7, 4793.5	16.4, 1451.2
	Mean (SD)	197.39 (156.647)	1353.78 (1204.401)	224.33 (229.830)
	95% CI of Mean	158.57, 236.21	973.61, 1733.94	148.78, 299.88

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=37)
Baseline	n	65	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	768.93 (137.04)	886.46 (123.70)	739.22 (115.88)
	95% CI of Geometric Mean	596.00, 992.04	654.02, 1201.52	543.46, 1005.50
	Median	969.41	839.38	592.90
	Q25, Q75	310.21, 1871.01	397.35, 2193.53	323.96, 1763.57
	Min, Max	86.4, 5905.7	142.6, 4025.8	161.7, 3676.8
	Mean (SD)	1210.10 (1115.377)	1334.16 (1135.728)	1092.26 (938.651)
	95% CI of Mean	933.72, 1486.48	975.67, 1692.64	779.30, 1405.23

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=37)
Day 90	n	65	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	154.24 (81.59)	852.65 (131.18)	154.94 (72.24)
	95% CI of Geometric Mean	129.21, 184.11	621.76, 1169.27	124.83, 192.30
	Median	138.20	912.38	158.24
	Q25, Q75	102.70, 219.48	380.13, 1955.49	100.50, 240.98
	Min, Max	33.8, 3357.2	138.3, 5107.9	41.7, 700.7
	Mean (SD)	228.08 (417.947)	1334.33 (1255.201)	190.92 (137.828)
	95% CI of Mean	124.51, 331.65	938.14, 1730.53	144.96, 236.88

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	667.53 (49.95)		642.20 (51.11)		691.14 (53.57)	
	95% CI of Geometric Mean	599.28, 743.54		552.68, 746.21		587.29, 813.34	
	Median	681.14		617.49		660.55	
	Q25, Q75	471.90, 915.89		489.29, 848.79		476.07, 1096.71	
	Min, Max	264.9, 2669.4		253.0, 2075.8		273.3, 1873.9	
	Mean (SD)	746.87 (386.899)		719.99 (368.454)		783.19 (411.072)	
	95% CI of Mean	658.46, 835.29		605.17, 834.82		649.93, 916.45	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	298.65 (37.22)		550.49 (50.35)		224.60 (34.41)	
	95% CI of Geometric Mean	275.06, 324.28		474.70, 638.38		201.51, 250.32	
	Median	284.04	-56.67	561.64	-13.14	208.44	-65.20
	Q25, Q75	237.63, 367.76	-63.48, -41.83	378.13, 727.70	-27.35, 4.68	181.88, 259.95	-77.17, -55.99
	Min, Max	128.6, 976.7	-80.4, -6.0	220.8, 1684.5	-47.6, 41.4	121.2, 494.7	-89.2, -25.5
	Mean (SD)	319.71 (132.496)	-52.86 (15.454)	618.72 (331.345)	-11.99 (20.433)	238.08 (89.616)	-64.72 (14.033)
	95% CI of Mean	289.42, 349.99	-56.40, -49.32	515.46, 721.98	-18.36, -5.62	209.02, 267.13	-69.27, -60.17

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	245.31 (33.96)		522.67 (57.68)		150.03 (37.11)	
	95% CI of Geometric Mean	227.47, 264.55		442.28, 617.67		133.53, 168.55	
	Median	238.75	-63.23	526.22	-19.00	146.27	-76.29
	Q25, Q75	198.76, 306.25	-71.24, -52.87	325.45, 762.71	-30.39, 0.00	112.56, 190.03	-84.86, -68.24
	Min, Max	111.6, 693.1	-81.3, -14.1	176.1, 1620.9	-54.0, 25.5	74.1, 369.9	-93.1, -48.3
	Mean (SD)	259.55 (95.757)	-61.22 (13.078)	601.82 (336.068)	-16.49 (18.863)	160.20 (63.105)	-75.87 (10.871)
	95% CI of Mean	237.67, 281.44	-64.21, -58.22	497.09, 706.56	-22.38, -10.61	139.74, 180.66	-79.40, -72.34

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	257.30 (33.83)		531.35 (56.52)		156.10 (35.35)	
	95% CI of Geometric Mean	238.65, 277.40		450.95, 626.10		139.67, 174.47	
	Median	260.35	-62.65	461.47	-17.76	157.66	-77.80
	Q25, Q75	204.44, 304.69	-70.39, -50.93	383.21, 756.55	-30.64, -2.14	118.73, 189.17	-84.61, -68.25
	Min, Max	121.5, 560.6	-80.6, -0.3	176.4, 1917.1	-58.0, 35.3	86.7, 363.3	-91.5, -44.0
	Mean (SD)	271.66 (93.620)	-58.86 (15.850)	612.96 (365.426)	-14.57 (21.622)	165.89 (63.540)	-74.61 (12.520)
	95% CI of Mean	250.27, 293.06	-62.49, -55.23	499.08, 726.84	-21.32, -7.83	145.29, 186.49	-78.68, -70.55

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	257.01 (30.09)		533.66 (54.34)		159.32 (38.10)	
	95% CI of Geometric Mean	240.29, 274.89		455.43, 625.32		141.39, 179.52	
	Median	269.23	-60.90	471.41	-14.07	163.89	-75.19
	Q25, Q75	211.08, 306.55	-70.24, -50.86	364.72, 850.48	-28.47, 0.00	128.65, 200.42	-85.57, -64.73
	Min, Max	128.1, 485.3	-83.6, 15.9	165.4, 1658.7	-61.5, 32.8	57.5, 385.9	-89.9, -21.9
	Mean (SD)	267.95 (77.268)	-58.46 (17.569)	607.19 (329.857)	-14.48 (19.969)	169.85 (62.303)	-73.78 (13.853)
	95% CI of Mean	250.29, 285.61	-62.48, -54.44	504.40, 709.99	-20.71, -8.25	149.65, 190.05	-78.27, -69.28

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	304.68 (30.46)		591.33 (51.99)		186.71 (42.96)	
	95% CI of Geometric Mean	284.63, 326.14		507.72, 688.69		163.39, 213.36	
	Median	300.59	-54.84	587.31	-5.10	195.57	-71.37
	Q25, Q75	237.26, 381.92	-64.68, -40.07	388.59, 836.69	-24.17, 11.44	150.55, 246.94	-81.96, -56.37
	Min, Max	163.3, 631.0	-80.1, 15.5	261.3, 1548.8	-47.2, 48.3	48.9, 366.7	-92.1, 1.0
	Mean (SD)	318.34 (96.286)	-50.90 (19.081)	664.98 (334.031)	-5.48 (21.382)	200.69 (71.092)	-68.42 (18.422)
	95% CI of Mean	296.33, 340.35	-55.27, -46.54	560.88, 769.07	-12.15, 1.19	177.64, 223.75	-74.39, -62.44

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	676.86 (49.67)		631.06 (50.19)		691.14 (53.57)	
	95% CI of Geometric Mean	607.09, 754.65		543.36, 732.90		587.29, 813.34	
	Median	693.18		602.09		660.55	
	Q25, Q75	475.05, 919.43		489.29, 840.19		476.07, 1096.71	
	Min, Max	264.9, 2669.4		253.0, 2075.8		273.3, 1873.9	
	Mean (SD)	756.08 (387.782)		705.46 (360.640)		783.19 (411.072)	
	95% CI of Mean	666.23, 845.92		591.62, 819.30		649.93, 916.45	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	330.44 (32.51)		659.07 (45.57)		271.96 (45.07)	
	95% CI of Geometric Mean	307.04, 355.62		574.63, 755.91		236.57, 312.64	
	Median	331.06	-51.02	664.95	5.87	278.06	-64.96
	Q25, Q75	265.73, 405.78	-64.22, -33.97	479.44, 928.57	-17.97, 34.87	201.77, 366.27	-75.35, -36.74
	Min, Max	162.5, 676.2	-86.3, 40.9	300.9, 1637.1	-68.8, 159.9	105.8, 812.1	-87.5, 34.0
	Mean (SD)	347.29 (112.200)	-46.34 (24.601)	722.49 (318.513)	11.91 (42.610)	297.69 (135.183)	-52.26 (31.645)
	95% CI of Mean	321.29, 373.29	-52.04, -40.63	621.95, 823.03	-1.54, 25.37	253.87, 341.52	-62.53, -42.00

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	689.35 (48.88)		631.06 (50.19)		677.97 (52.60)	
	95% CI of Geometric Mean	617.81, 769.16		543.36, 732.90		576.32, 797.56	
	Median	704.75		602.09		639.80	
	Q25, Q75	486.49, 953.80		489.29, 840.19		476.07, 1082.67	
	Min, Max	264.9, 2669.4		253.0, 2075.8		273.3, 1873.9	
	Mean (SD)	767.83 (389.519)		705.46 (360.640)		766.03 (402.183)	
	95% CI of Mean	675.62, 860.03		591.62, 819.30		633.83, 898.23	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	334.96 (34.76)		684.81 (51.65)		255.75 (42.47)	
	95% CI of Geometric Mean	309.23, 362.84		587.37, 798.41		223.71, 292.38	
	Median	322.93	-53.98	648.99	8.49	257.79	-59.12
	Q25, Q75	273.38, 422.19	-65.43, -33.70	518.69, 961.24	-14.96, 37.75	187.07, 311.49	-75.94, -44.79
	Min, Max	164.6, 970.0	-81.6, 32.8	215.1, 1795.3	-57.4, 122.4	94.7, 689.9	-88.8, 13.6
	Mean (SD)	355.32 (133.419)	-46.39 (25.240)	766.66 (376.702)	16.05 (42.736)	278.43 (128.123)	-55.85 (25.284)
	95% CI of Mean	323.74, 386.91	-52.37, -40.42	647.75, 885.57	2.56, 29.55	236.31, 320.54	-64.17, -47.54

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	683.85 (49.24)		631.06 (50.19)		664.22 (51.43)	
	95% CI of Geometric Mean	611.94, 764.20		543.36, 732.90		565.16, 780.64	
	Median	706.88		602.09		619.05	
	Q25, Q75	486.49, 919.43		489.29, 840.19		476.07, 804.55	
	Min, Max	264.9, 2669.4		253.0, 2075.8		273.3, 1873.9	
	Mean (SD)	762.73 (390.139)		705.46 (360.640)		747.62 (391.162)	
	95% CI of Mean	669.70, 855.76		591.62, 819.30		617.19, 878.04	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	386.37 (34.98)		695.58 (48.02)		276.13 (41.02)	
	95% CI of Geometric Mean	356.30, 418.97		602.43, 803.13		242.11, 314.93	
	Median	392.90	-45.15	717.97	12.10	267.33	-58.99
	Q25, Q75	294.48, 452.87	-59.73, -23.62	493.61, 869.68	-9.26, 33.93	201.18, 349.87	-75.31, -34.92
	Min, Max	225.1, 945.4	-76.5, 108.3	271.5, 1945.2	-50.4, 169.2	121.9, 678.1	-88.4, 148.1
	Mean (SD)	410.86 (160.638)	-37.09 (32.660)	770.42 (370.957)	18.63 (48.990)	298.59 (126.847)	-48.38 (41.475)
	95% CI of Mean	372.55, 449.16	-44.88, -29.30	653.33, 887.51	3.16, 34.10	256.29, 340.89	-62.21, -34.55

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	803.29 (52.57)	761.59 (60.42)	830.24 (53.41)
	95% CI of Geometric Mean	717.56, 899.28	640.07, 906.18	705.80, 976.62
	Median	829.76	756.26	846.35
	Q25, Q75	576.00, 1120.42	562.07, 1266.37	634.70, 1115.28
	Min, Max	250.6, 2317.9	272.6, 2194.5	249.6, 2022.8
	Mean (SD)	901.13 (434.586)	881.72 (483.334)	931.17 (444.158)
	95% CI of Mean	801.81, 1000.44	731.10, 1032.34	787.19, 1075.16

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	347.11 (40.00)	660.10 (69.30)	245.57 (38.90)
	95% CI of Geometric Mean	317.86, 379.05	543.07, 802.36	217.43, 277.34
	Median	348.36	730.62	240.03
	Q25, Q75	272.89, 470.94	438.63, 972.93	186.22, 307.91
	Min, Max	158.0, 743.9	154.5, 2400.5	121.4, 878.7
	Mean (SD)	373.03 (143.023)	793.34 (500.496)	265.26 (126.935)
	95% CI of Mean	340.34, 405.72	637.37, 949.32	224.11, 306.41

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	290.44 (36.99)	651.42 (70.92)	174.62 (38.79)
	95% CI of Geometric Mean	267.62, 315.21	533.92, 794.78	154.66, 197.15
	Median	299.68	710.27	171.58
	Q25, Q75	215.66, 373.19	407.45, 1050.16	137.00, 213.56
	Min, Max	140.2, 665.0	158.4, 2194.5	90.9, 561.0
	Mean (SD)	309.18 (110.730)	787.27 (488.694)	188.06 (84.020)
	95% CI of Mean	283.87, 334.48	634.98, 939.56	160.82, 215.30

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	312.29 (34.59)	649.01 (64.17)	188.31 (39.37)
	95% CI of Geometric Mean	289.20, 337.23	540.48, 779.32	166.50, 212.97
	Median	326.84	656.12	183.16
	Q25, Q75	232.87, 397.35	416.05, 956.56	147.49, 259.23
	Min, Max	159.5, 746.0	205.7, 2194.5	71.8, 450.0
	Mean (SD)	330.27 (114.051)	769.36 (480.201)	201.80 (77.345)
	95% CI of Mean	304.21, 356.34	619.71, 919.00	176.72, 226.88

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	313.79 (33.80)	609.63 (65.34)	184.85 (44.18)
	95% CI of Geometric Mean	291.07, 338.29	506.25, 734.11	161.20, 211.97
	Median	325.11	594.98	204.76
	Q25, Q75	243.86, 397.58	441.78, 880.80	138.94, 231.90
	Min, Max	162.9, 678.7	142.8, 2194.5	59.1, 411.3
	Mean (SD)	330.65 (107.167)	720.96 (439.291)	200.30 (77.794)
	95% CI of Mean	306.15, 355.14	584.06, 857.86	175.08, 225.52

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	356.24 (38.07)	732.79 (58.38)	227.94 (45.29)
	95% CI of Geometric Mean	327.52, 387.48	618.99, 867.51	198.15, 262.20
	Median	363.02	707.63	235.05
	Q25, Q75	272.97, 482.04	467.93, 1054.52	183.22, 302.87
	Min, Max	126.1, 723.5	297.7, 2194.5	68.1, 497.6
	Mean (SD)	379.70 (133.245)	846.26 (473.307)	248.00 (100.299)
	95% CI of Mean	349.25, 410.16	698.76, 993.75	215.49, 280.52

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	810.26 (52.09)	742.18 (58.03)	830.24 (53.41)
	95% CI of Geometric Mean	723.31, 907.65	626.12, 879.76	705.80, 976.62
	Median	829.76	753.40	846.35
	Q25, Q75	576.11, 1139.14	562.07, 1192.29	634.70, 1115.28
	Min, Max	250.6, 2317.9	272.6, 1954.5	249.6, 2022.8
	Mean (SD)	907.43 (435.451)	849.70 (441.946)	931.17 (444.158)
	95% CI of Mean	806.54, 1008.32	710.20, 989.20	787.19, 1075.16

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	390.89 (38.76)	761.96 (60.32)	290.91 (59.12)
	95% CI of Geometric Mean	358.43, 426.28	639.11, 908.43	243.61, 347.40
	Median	390.63	801.75	303.29
	Q25, Q75	310.25, 501.97	532.12, 1143.42	229.70, 379.18
	Min, Max	130.5, 858.8	165.3, 2330.4	71.4, 1171.1
	Mean (SD)	418.10 (156.017)	878.40 (471.378)	335.31 (197.979)
	95% CI of Mean	381.94, 454.25	729.61, 1027.19	271.13, 399.49

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	826.03 (50.63)	742.18 (58.03)	811.86 (51.80)
	95% CI of Geometric Mean	737.71, 924.91	626.12, 879.76	691.66, 952.96
	Median	840.43	753.40	832.31
	Q25, Q75	616.45, 1144.43	562.07, 1192.29	634.70, 1073.90
	Min, Max	272.7, 2317.9	272.6, 1954.5	249.6, 2022.8
	Mean (SD)	920.86 (435.542)	849.70 (441.946)	904.54 (417.364)
	95% CI of Mean	817.76, 1023.95	710.20, 989.20	767.35, 1041.73

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	386.19 (42.35)	781.43 (59.76)	290.53 (62.70)
	95% CI of Geometric Mean	350.79, 425.16	656.35, 930.33	240.43, 351.07
	Median	407.53	728.08	302.83
	Q25, Q75	287.80, 514.70	584.82, 1096.36	205.34, 415.83
	Min, Max	149.7, 1060.4	209.4, 2609.6	48.9, 912.5
	Mean (SD)	418.61 (174.493)	902.66 (508.548)	335.96 (181.818)
	95% CI of Mean	377.30, 459.91	742.13, 1063.18	276.19, 395.73

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	808.88 (52.08)	742.18 (58.03)	802.85 (52.01)
	95% CI of Geometric Mean	719.71, 909.10	626.12, 879.76	682.00, 945.10
	Median	829.76	753.40	818.27
	Q25, Q75	576.11, 1139.14	562.07, 1192.29	634.70, 1071.30
	Min, Max	250.6, 2317.9	272.6, 1954.5	249.6, 2022.8
	Mean (SD)	905.14 (431.201)	849.70 (441.946)	895.81 (419.595)
	95% CI of Mean	802.32, 1007.96	710.20, 989.20	755.91, 1035.72

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	436.04 (44.48)	755.26 (59.98)	312.67 (52.52)
	95% CI of Geometric Mean	394.03, 482.53	634.03, 899.68	265.22, 368.60
	Median	439.75	824.52	323.32
	Q25, Q75	351.55, 570.68	537.66, 1088.68	245.31, 431.53
	Min, Max	107.2, 1223.2	201.3, 2537.6	114.9, 952.6
	Mean (SD)	474.63 (201.614)	866.59 (454.761)	350.11 (170.646)
	95% CI of Mean	426.55, 522.71	723.04, 1010.13	293.21, 407.01

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Baseline	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	635.78 (41.05)	711.27 (60.33)	646.33 (47.86)	636.16 (57.44)	675.94 (48.97)	711.32 (60.90)
	95% CI of Geometric Mean	563.08, 717.87	583.77, 866.62	535.85, 779.59	483.43, 837.14	550.35, 830.18	532.91, 949.45
	Median	661.64	769.49	602.09	632.88	639.80	743.55
	Q25, Q75	468.75, 830.94	486.49, 998.09	489.29, 905.43	542.82, 824.43	491.04, 802.43	463.33, 1096.71
	Min, Max	297.0, 1443.8	264.9, 2669.4	267.0, 1346.8	253.0, 2075.8	306.1, 1607.7	273.3, 1873.9
	Mean (SD)	685.95 (275.172)	826.26 (489.866)	711.59 (315.379)	732.35 (445.434)	751.85 (374.294)	823.74 (462.985)
	95% CI of Mean	601.26, 770.64	652.56, 999.96	581.40, 841.78	503.32, 961.37	585.90, 917.81	585.69, 1061.79

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 1	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	285.45 (34.88)	316.78 (39.79)	557.50 (50.21)	540.33 (52.23)	225.51 (32.53)	223.41 (37.82)
	95% CI of Geometric Mean	257.18, 316.83	276.51, 362.91	458.41, 678.01	419.76, 695.53	195.93, 259.56	185.12, 269.62
	Median	269.15	310.42	564.10	500.00	209.99	195.94
	Q25, Q75	233.11, 364.46	252.38, 374.72	378.13, 691.82	380.00, 750.95	187.71, 252.82	175.68, 260.27
	Min, Max	128.6, 544.8	162.4, 976.7	279.5, 1684.5	220.8, 1508.1	128.8, 494.5	121.2, 494.7
	Mean (SD)	301.69 (102.303)	343.19 (162.491)	626.87 (345.827)	606.74 (318.882)	237.45 (85.409)	238.89 (97.458)
	95% CI of Mean	270.20, 333.18	285.56, 400.81	484.11, 769.62	442.78, 770.70	199.58, 275.32	188.78, 289.00

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 1							
	n	43	33	25	17	22	17
	Median	-56.71	-56.63	-10.15	-18.05	-63.59	-67.65
	Q25, Q75	-63.25, -44.37	-64.29, -39.89	-24.10, 4.68	-27.35, -9.70	-75.77, -54.19	-77.17, -57.53
	Min, Max	-76.9, -6.0	-80.4, -20.6	-47.6, 41.4	-35.1, 26.2	-89.2, -25.5	-84.7, -32.1
	Mean (SD)	-53.24 (14.054)	-52.37 (17.323)	-11.06 (21.986)	-13.37 (18.478)	-63.54 (14.706)	-66.25 (13.397)
	95% CI of Mean	-57.57, -48.91	-58.51, -46.22	-20.14, -1.98	-22.87, -3.86	-70.07, -57.02	-73.14, -59.35

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 2	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	228.60 (30.66)	268.93 (36.10)	537.74 (55.26)	501.27 (62.88)	149.80 (36.55)	150.32 (39.04)
	95% CI of Geometric Mean	208.45, 250.70	237.54, 304.47	434.55, 665.45	372.55, 674.45	128.03, 175.26	123.86, 182.44
	Median	230.23	268.39	546.09	429.57	152.99	139.37
	Q25, Q75	193.07, 288.41	215.17, 315.07	344.44, 700.79	315.68, 811.07	110.81, 187.75	120.61, 190.73
	Min, Max	111.6, 519.3	149.6, 693.1	219.8, 1315.8	176.1, 1620.9	74.1, 318.0	78.6, 369.9
	Mean (SD)	238.81 (73.468)	286.58 (114.348)	611.81 (326.953)	587.14 (358.720)	159.16 (58.909)	161.55 (69.999)
	95% CI of Mean	216.20, 261.43	246.03, 327.13	476.85, 746.78	402.70, 771.58	133.03, 185.28	125.55, 197.54

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 2							
	n	43	33	25	17	22	17
	Median	-64.52	-62.17	-18.61	-19.44	-74.04	-78.38
	Q25, Q75	-70.88, -55.06	-74.04, -50.43	-28.53, 0.00	-38.50, -0.23	-85.44, -67.55	-84.43, -71.57
	Min, Max	-81.3, -39.0	-80.7, -14.1	-44.0, 22.4	-54.0, 25.5	-93.1, -50.5	-90.6, -48.3
	Mean (SD)	-62.60 (10.498)	-59.41 (15.820)	-15.14 (17.237)	-18.48 (21.424)	-75.19 (11.249)	-76.75 (10.635)
	95% CI of Mean	-65.84, -59.37	-65.03, -53.80	-22.26, -8.02	-29.50, -7.46	-80.18, -70.20	-82.23, -71.28

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 3	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	240.66 (32.06)	280.72 (34.39)	544.12 (52.08)	513.12 (64.54)	160.28 (35.07)	150.86 (36.52)
	95% CI of Geometric Mean	218.58, 264.98	249.33, 316.05	444.50, 666.06	378.83, 695.00	137.81, 186.41	125.77, 180.96
	Median	247.22	275.99	469.44	446.85	162.28	132.80
	Q25, Q75	184.54, 296.75	235.56, 323.73	384.69, 689.35	374.72, 756.55	118.73, 189.17	122.00, 178.59
	Min, Max	121.5, 520.6	154.7, 560.6	218.8, 1397.1	176.4, 1917.1	86.7, 334.4	95.2, 363.3
	Mean (SD)	252.37 (80.176)	296.80 (104.658)	614.06 (331.095)	611.35 (421.599)	169.73 (62.239)	160.93 (66.767)
	95% CI of Mean	227.69, 277.05	259.69, 333.92	477.39, 750.74	394.57, 828.12	142.13, 197.33	126.59, 195.26

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 3							
	n	43	33	25	17	22	17
	Median	-62.91	-61.04	-14.29	-22.27	-73.87	-78.36
	Q25, Q75	-70.30, -52.40	-71.04, -48.54	-26.51, -2.14	-37.47, -7.65	-83.92, -68.09	-84.61, -68.80
	Min, Max	-80.6, -22.1	-79.6, -0.3	-58.0, 19.5	-49.7, 35.3	-90.3, -45.5	-91.5, -44.0
	Mean (SD)	-60.29 (12.823)	-57.00 (19.149)	-13.74 (18.320)	-15.80 (26.302)	-73.40 (12.850)	-76.18 (12.286)
	95% CI of Mean	-64.24, -56.33	-63.80, -50.21	-21.30, -6.17	-29.33, -2.28	-79.10, -67.70	-82.50, -69.86

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 4	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	241.56 (30.65)	278.63 (27.59)	531.09 (49.47)	537.45 (63.03)	161.07 (31.69)	157.09 (46.53)
	95% CI of Geometric Mean	220.28, 264.90	253.12, 306.72	437.81, 644.24	399.19, 723.58	140.42, 184.75	125.11, 197.25
	Median	255.84	283.78	453.53	496.66	164.55	156.20
	Q25, Q75	187.50, 300.00	227.11, 307.34	375.77, 773.97	358.25, 860.52	132.32, 200.42	123.02, 196.67
	Min, Max	128.1, 385.1	176.9, 485.3	262.4, 1360.5	165.4, 1658.7	81.3, 277.6	57.5, 385.9
	Mean (SD)	251.84 (70.590)	288.94 (81.546)	593.93 (308.720)	626.70 (367.658)	168.37 (50.746)	171.77 (76.369)
	95% CI of Mean	230.11, 273.57	260.02, 317.86	466.49, 721.36	437.66, 815.74	145.87, 190.88	132.50, 211.04

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 4							
	n	43	33	25	17	22	17
	Median	-61.60	-60.20	-11.98	-14.76	-73.70	-77.52
	Q25, Q75	-69.50, -52.40	-70.52, -48.08	-25.62, -5.09	-28.51, 4.06	-83.83, -62.28	-85.84, -66.86
	Min, Max	-79.0, -32.0	-83.6, 15.9	-61.5, 32.8	-43.5, 22.0	-89.7, -54.9	-89.9, -21.9
	Mean (SD)	-60.28 (11.796)	-56.10 (23.034)	-15.27 (20.386)	-13.31 (19.900)	-73.51 (11.556)	-74.12 (16.741)
	95% CI of Mean	-63.92, -56.65	-64.27, -47.92	-23.69, -6.85	-23.55, -3.07	-78.64, -68.38	-82.74, -65.51

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 5	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	283.27 (28.92)	335.02 (29.98)	593.37 (52.05)	588.34 (53.71)	196.58 (32.76)	174.67 (54.50)
	95% CI of Geometric Mean	259.61, 309.09	301.92, 371.74	484.78, 726.28	454.17, 762.13	170.63, 226.48	134.38, 227.03
	Median	277.13	341.37	590.91	525.25	193.37	197.89
	Q25, Q75	228.28, 375.81	272.73, 427.71	409.70, 795.96	388.59, 836.69	152.61, 264.88	150.55, 246.10
	Min, Max	163.3, 456.3	205.2, 631.0	261.3, 1404.0	266.8, 1548.8	101.1, 366.7	48.9, 343.3
	Mean (SD)	294.50 (82.673)	349.41 (104.874)	665.55 (331.243)	664.13 (348.327)	206.30 (65.971)	193.45 (78.691)
	95% CI of Mean	269.05, 319.95	312.22, 386.60	528.82, 802.29	485.03, 843.22	177.04, 235.55	152.98, 233.91

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 5							
	n	43	33	25	17	22	17
	Median	-55.73	-53.88	-6.23	-4.58	-66.96	-76.78
	Q25, Q75	-64.41, -45.09	-65.03, -37.10	-20.23, 8.83	-25.39, 14.96	-80.91, -54.99	-82.99, -62.53
	Min, Max	-78.8, -11.2	-80.1, 15.5	-38.8, 19.6	-47.2, 48.3	-88.2, -33.4	-92.1, 1.0
	Mean (SD)	-53.06 (15.375)	-48.09 (22.992)	-6.60 (17.309)	-3.83 (26.782)	-67.30 (15.146)	-69.85 (22.385)
	95% CI of Mean	-57.80, -48.33	-56.25, -39.94	-13.75, 0.55	-17.60, 9.94	-74.02, -60.58	-81.37, -58.34

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Baseline	n	42	32	24	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	640.01 (41.31)	728.46 (59.27)	627.47 (46.05)	636.16 (57.44)	675.94 (48.97)	711.32 (60.90)
	95% CI of Geometric Mean	565.55, 724.28	597.72, 887.78	521.40, 755.11	483.43, 837.14	550.35, 830.18	532.91, 949.45
	Median	667.24	770.46	600.15	632.88	639.80	743.55
	Q25, Q75	468.75, 830.94	502.13, 999.04	457.92, 877.11	542.82, 824.43	491.04, 802.43	463.33, 1096.71
	Min, Max	297.0, 1443.8	264.9, 2669.4	267.0, 1346.8	253.0, 2075.8	306.1, 1607.7	273.3, 1873.9
	Mean (SD)	690.82 (276.623)	841.73 (489.451)	686.41 (295.390)	732.35 (445.434)	751.85 (374.294)	823.74 (462.985)
	95% CI of Mean	604.62, 777.03	665.25, 1018.20	561.68, 811.15	503.32, 961.37	585.90, 917.81	585.69, 1061.79

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Day 30	n	42	32	24	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	315.50 (32.51)	351.12 (31.92)	630.55 (48.56)	701.53 (41.69)	252.46 (49.33)	299.45 (38.13)
	95% CI of Geometric Mean	285.82, 348.26	313.82, 392.84	519.21, 765.78	571.03, 861.84	205.26, 310.49	247.77, 361.91
	Median	313.16	360.46	555.43	797.89	241.51	340.72
	Q25, Q75	238.41, 396.96	284.52, 434.65	472.72, 903.74	485.60, 928.57	179.59, 326.79	247.66, 391.80
	Min, Max	180.3, 603.5	162.5, 676.2	300.9, 1637.1	324.9, 1226.9	105.8, 812.1	118.3, 519.3
	Mean (SD)	331.59 (108.184)	367.90 (115.727)	700.63 (347.630)	753.35 (279.610)	282.52 (156.024)	317.32 (103.560)
	95% CI of Mean	297.87, 365.30	326.17, 409.63	553.84, 847.43	609.58, 897.11	213.34, 351.70	264.07, 370.57

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 30							
	n	42	32	24	17	22	17
	Median	-49.92	-54.89	-0.02	11.78	-68.85	-58.46
	Q25, Q75	-63.27, -30.91	-66.28, -34.42	-19.36, 27.68	-17.97, 40.99	-76.85, -33.58	-67.84, -42.97
	Min, Max	-80.4, 8.4	-86.3, 40.9	-68.8, 86.9	-40.9, 159.9	-87.5, 31.2	-82.9, 34.0
	Mean (SD)	-47.24 (19.351)	-45.16 (30.453)	6.89 (36.309)	19.00 (50.524)	-53.26 (33.086)	-50.97 (30.634)
	95% CI of Mean	-53.27, -41.20	-56.14, -34.17	-8.44, 22.23	-6.99, 44.98	-67.93, -38.59	-66.73, -35.22

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Baseline	n	41	30	24	17	21	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	638.14 (41.73)	766.04 (56.35)	627.47 (46.05)	636.16 (57.44)	652.13 (46.53)	711.32 (60.90)
	95% CI of Geometric Mean	562.33, 724.17	629.64, 931.98	521.40, 755.11	483.43, 837.14	533.11, 797.71	532.91, 949.45
	Median	661.64	782.08	600.15	632.88	619.05	743.55
	Q25, Q75	475.05, 830.94	557.20, 1000.00	457.92, 877.11	542.82, 824.43	491.04, 799.53	463.33, 1096.71
	Min, Max	297.0, 1443.8	264.9, 2669.4	267.0, 1346.8	253.0, 2075.8	306.1, 1607.7	273.3, 1873.9
	Mean (SD)	689.91 (279.705)	874.32 (487.859)	686.41 (295.390)	732.35 (445.434)	719.31 (350.189)	823.74 (462.985)
	95% CI of Mean	601.61, 778.20	692.15, 1056.49	561.68, 811.15	503.32, 961.37	559.90, 878.72	585.69, 1061.79

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Day 60	n	41	30	24	17	21	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	323.13 (37.08)	351.84 (31.27)	657.50 (45.87)	725.29 (60.37)	271.73 (45.84)	237.30 (37.91)
	95% CI of Geometric Mean	288.52, 361.89	313.92, 394.34	546.72, 790.73	544.56, 966.00	222.74, 331.49	196.54, 286.50
	Median	299.60	357.49	640.71	750.96	291.78	247.63
	Q25, Q75	270.91, 401.09	281.10, 441.07	506.63, 885.59	576.27, 1097.50	186.45, 316.83	188.13, 286.79
	Min, Max	164.6, 970.0	193.5, 610.2	242.0, 1795.3	215.1, 1785.7	132.1, 689.9	94.7, 529.3
	Mean (SD)	346.22 (148.667)	367.76 (110.475)	722.29 (343.143)	829.30 (422.347)	299.52 (149.218)	252.37 (93.932)
	95% CI of Mean	299.29, 393.15	326.51, 409.02	577.39, 867.19	612.14, 1046.45	231.59, 367.45	204.07, 300.67

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
% Change from baseline to Day 60							
	n	41	30	24	17	21	17
	Median	-51.45	-55.06	8.14	13.54	-51.13	-65.27
	Q25, Q75	-62.11, -33.91	-66.60, -30.08	-25.45, 35.53	-10.59, 40.04	-69.62, -39.20	-75.94, -54.55
	Min, Max	-77.2, 32.8	-81.6, 32.8	-57.4, 104.3	-39.4, 122.4	-88.1, 13.6	-88.8, 5.0
	Mean (SD)	-44.15 (26.290)	-49.46 (23.823)	12.67 (42.854)	20.82 (43.411)	-51.26 (27.036)	-61.52 (22.422)
	95% CI of Mean	-52.45, -35.85	-58.36, -40.56	-5.43, 30.78	-1.50, 43.15	-63.57, -38.95	-73.06, -49.99

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Baseline	n	39	31	24	17	21	16
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	648.01 (39.13)	731.77 (60.33)	627.47 (46.05)	636.16 (57.44)	652.13 (46.53)	680.43 (59.24)
	95% CI of Geometric Mean	573.39, 732.34	596.53, 897.67	521.40, 755.11	483.43, 837.14	533.11, 797.71	508.01, 911.37
	Median	672.84	771.43	600.15	632.88	619.05	681.06
	Q25, Q75	475.05, 830.94	486.49, 1000.00	457.92, 877.11	542.82, 824.43	491.04, 799.53	430.40, 1089.69
	Min, Max	302.6, 1443.8	264.9, 2669.4	267.0, 1346.8	253.0, 2075.8	306.1, 1607.7	273.3, 1873.9
	Mean (SD)	694.58 (267.148)	848.46 (496.030)	686.41 (295.390)	732.35 (445.434)	719.31 (350.189)	784.78 (448.457)
	95% CI of Mean	607.97, 781.18	666.51, 1030.41	561.68, 811.15	503.32, 961.37	559.90, 878.72	545.81, 1023.75

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Day 90	n	39	31	24	17	21	16
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	367.48 (33.75)	411.53 (35.93)	640.33 (40.24)	781.79 (56.63)	280.36 (37.74)	270.68 (46.39)
	95% CI of Geometric Mean	330.36, 408.76	362.15, 467.63	543.70, 754.12	596.11, 1025.31	237.45, 331.01	213.94, 342.47
	Median	362.73	409.36	649.93	783.30	273.57	265.72
	Q25, Q75	290.74, 424.30	325.71, 491.65	469.82, 782.39	602.22, 1148.73	201.18, 366.02	195.80, 338.16
	Min, Max	230.0, 945.4	225.1, 901.6	315.3, 1771.7	271.5, 1945.2	167.4, 620.1	121.9, 678.1
	Mean (SD)	389.37 (151.806)	437.89 (169.722)	690.96 (304.962)	882.60 (433.000)	299.62 (118.720)	297.24 (140.784)
	95% CI of Mean	340.16, 438.59	375.63, 500.15	562.18, 819.74	659.97, 1105.23	245.58, 353.67	222.22, 372.26

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
% Change from baseline to Day 90							
	n	39	31	24	17	21	16
	Median	-42.44	-48.54	12.23	8.20	-53.35	-64.63
	Q25, Q75	-58.30, -23.62	-60.95, -5.05	-13.94, 28.31	-6.30, 61.94	-67.91, -38.76	-76.25, -30.10
	Min, Max	-75.5, 24.4	-76.5, 108.3	-50.4, 65.7	-44.2, 169.2	-85.2, 0.2	-88.4, 148.1
	Mean (SD)	-39.21 (23.837)	-34.43 (41.479)	6.34 (28.904)	35.99 (65.210)	-51.36 (23.829)	-44.47 (57.815)
	95% CI of Mean	-46.94, -31.48	-49.65, -19.21	-5.87, 18.55	2.45, 69.52	-62.21, -40.51	-75.28, -13.65

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Baseline	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	551.93 (47.71)	815.68 (42.66)	602.59 (48.30)	693.64 (54.60)	633.30 (52.40)	757.73 (54.38)
	95% CI of Geometric Mean	476.57, 639.19	711.73, 934.80	494.34, 734.54	542.28, 887.24	502.92, 797.48	592.90, 968.39
	Median	505.88	803.63	602.09	658.42	639.56	700.00
	Q25, Q75	402.10, 709.01	681.61, 1009.77	426.56, 848.79	489.29, 1104.70	413.09, 941.10	529.61, 1350.19
	Min, Max	264.9, 1579.6	270.1, 2669.4	253.0, 1358.1	325.2, 2075.8	273.3, 1607.7	306.1, 1873.9
	Mean (SD)	614.80 (321.786)	886.09 (404.646)	661.78 (281.183)	790.46 (450.580)	712.22 (366.798)	857.90 (450.813)
	95% CI of Mean	510.48, 719.11	751.17, 1021.01	540.18, 783.38	573.28, 1007.63	540.55, 883.89	640.61, 1075.19

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 1	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	270.97 (39.80)	330.91 (31.39)	511.94 (42.24)	601.05 (59.05)	227.65 (35.42)	221.43 (34.27)
	95% CI of Geometric Mean	239.30, 306.83	298.75, 366.52	429.67, 609.97	461.77, 782.33	193.82, 267.39	188.57, 260.00
	Median	259.51	342.57	500.00	564.84	203.17	211.54
	Q25, Q75	210.38, 324.71	266.97, 393.70	375.00, 689.92	378.13, 836.16	182.36, 258.26	175.68, 260.27
	Min, Max	128.6, 976.7	162.4, 655.6	220.8, 978.9	292.8, 1684.5	128.8, 494.7	121.2, 494.5
	Mean (SD)	294.36 (148.810)	346.42 (108.486)	552.82 (221.023)	698.50 (422.022)	241.78 (93.449)	234.19 (87.780)
	95% CI of Mean	246.12, 342.60	310.25, 382.60	457.24, 648.40	495.08, 901.91	198.04, 285.52	191.87, 276.50

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 1							
	n	39	37	23	19	20	19
	Median	-52.67	-61.88	-13.58	-12.28	-58.84	-67.72
	Q25, Q75	-60.20, -35.13	-66.74, -48.16	-25.04, 7.66	-28.57, 0.00	-75.12, -53.42	-80.09, -61.47
	Min, Max	-77.7, -6.0	-80.4, -28.0	-47.6, 26.2	-43.5, 41.4	-80.6, -32.1	-89.2, -25.5
	Mean (SD)	-48.43 (16.400)	-57.52 (13.042)	-12.85 (19.576)	-10.95 (21.922)	-61.78 (13.231)	-67.82 (14.534)
	95% CI of Mean	-53.76, -43.11	-61.88, -53.17	-21.32, -4.38	-21.52, -0.38	-67.98, -55.58	-74.83, -60.81

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19	>19	10-19	>19	10-19	>19
		cig/day (N=39)	cig/day (N=37)	cig/day (N=23)	cig/day (N=19)	cig/day (N=20)	cig/day (N=19)
Day 2	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	221.76 (31.53)	272.85 (33.22)	485.10 (51.06)	572.06 (65.32)	163.61 (36.30)	136.94 (36.42)
	95% CI of Geometric Mean	200.69, 245.03	244.95, 303.94	393.95, 597.35	429.21, 762.46	138.77, 192.89	115.52, 162.34
	Median	224.53	268.39	571.71	506.35	160.25	139.37
	Q25, Q75	185.19, 276.98	220.53, 312.12	315.68, 700.79	325.45, 889.96	125.22, 195.45	103.00, 178.91
	Min, Max	111.6, 401.0	163.8, 693.1	176.1, 1108.1	219.8, 1620.9	101.1, 369.9	74.1, 281.7
	Mean (SD)	232.05 (70.613)	288.55 (110.255)	538.85 (243.988)	678.06 (416.287)	174.28 (69.610)	145.37 (53.290)
	95% CI of Mean	209.15, 254.94	251.78, 325.31	433.34, 644.36	477.41, 878.71	141.70, 206.87	119.68, 171.06

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19	>19	10-19	>19	10-19	>19
		cig/day (N=39)	cig/day (N=37)	cig/day (N=23)	cig/day (N=19)	cig/day (N=20)	cig/day (N=19)
% Change from baseline to Day 2							
	n	39	37	23	19	20	19
	Median	-60.64	-66.28	-19.25	-18.61	-73.66	-84.43
	Q25, Q75	-66.51, -48.99	-73.42, -58.86	-30.39, -0.23	-32.42, 0.64	-80.36, -67.67	-87.45, -70.53
	Min, Max	-80.7, -14.1	-81.3, -30.4	-54.0, 22.4	-45.3, 25.5	-85.4, -48.3	-93.1, -50.5
	Mean (SD)	-57.69 (13.757)	-64.94 (11.352)	-17.40 (18.804)	-15.39 (19.390)	-72.72 (9.307)	-79.19 (11.636)
	95% CI of Mean	-62.15, -53.22	-68.73, -61.15	-25.54, -9.27	-24.74, -6.04	-77.08, -68.36	-84.80, -73.58

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19	>19	10-19	>19	10-19	>19
		cig/day (N=39)	cig/day (N=37)	cig/day (N=23)	cig/day (N=19)	cig/day (N=20)	cig/day (N=19)
Day 3	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	238.35 (33.94)	278.91 (32.03)	492.92 (47.77)	581.91 (66.30)	161.20 (36.36)	150.91 (34.93)
	95% CI of Geometric Mean	214.15, 265.27	251.31, 309.54	405.16, 599.68	435.03, 778.39	136.69, 190.10	128.14, 177.73
	Median	255.89	262.77	446.85	469.44	158.94	143.39
	Q25, Q75	181.82, 289.43	235.56, 331.94	374.72, 689.35	383.21, 952.28	120.38, 186.56	114.89, 189.17
	Min, Max	121.5, 500.0	154.7, 560.6	176.4, 1071.4	218.8, 1917.1	95.2, 363.3	86.7, 334.4
	Mean (SD)	251.45 (85.818)	292.96 (97.862)	542.21 (240.535)	698.61 (468.307)	171.71 (68.424)	159.77 (59.194)
	95% CI of Mean	223.63, 279.28	260.33, 325.60	438.19, 646.23	472.89, 924.33	139.68, 203.74	131.23, 188.30

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 3							
	n	39	37	23	19	20	19
	Median	-58.11	-65.69	-16.73	-19.74	-71.15	-80.85
	Q25, Q75	-66.23, -44.17	-72.68, -60.13	-30.64, 1.88	-30.66, -2.85	-83.29, -65.63	-86.60, -70.51
	Min, Max	-79.6, -0.3	-80.6, -35.8	-58.0, 30.0	-38.0, 35.3	-88.1, -44.0	-91.5, -45.5
	Mean (SD)	-53.72 (18.115)	-64.28 (10.870)	-14.89 (23.808)	-14.19 (19.282)	-72.00 (12.323)	-77.36 (12.452)
	95% CI of Mean	-59.60, -47.84	-67.91, -60.65	-25.19, -4.59	-23.49, -4.89	-77.77, -66.23	-83.37, -71.36

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19	>19	10-19	>19	10-19	>19
		cig/day (N=39)	cig/day (N=37)	cig/day (N=23)	cig/day (N=19)	cig/day (N=20)	cig/day (N=19)
Day 4	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	229.91 (30.37)	289.03 (24.82)	502.41 (50.65)	574.08 (59.15)	174.07 (34.28)	145.15 (40.38)
	95% CI of Geometric Mean	208.81, 253.15	266.40, 313.59	408.62, 617.74	440.89, 747.52	148.93, 203.46	120.35, 175.05
	Median	228.29	293.01	496.66	466.09	166.83	156.03
	Q25, Q75	180.23, 286.90	251.61, 312.39	331.37, 773.97	376.17, 872.34	146.43, 207.71	112.94, 184.96
	Min, Max	128.1, 416.7	152.6, 485.3	165.4, 1021.7	262.4, 1658.7	87.6, 385.9	57.5, 268.9
	Mean (SD)	239.96 (71.717)	297.46 (72.565)	557.06 (249.485)	667.88 (405.784)	183.80 (66.170)	155.17 (55.940)
	95% CI of Mean	216.71, 263.21	273.26, 321.66	449.17, 664.95	472.29, 863.46	152.83, 214.77	128.20, 182.14

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 4							
	n	39	37	23	19	20	19
	Median	-56.39	-65.40	-11.98	-20.10	-73.73	-84.66
	Q25, Q75	-67.34, -50.23	-72.54, -54.39	-28.51, 0.10	-28.47, 0.00	-79.21, -62.28	-88.61, -66.35
	Min, Max	-83.6, 15.9	-83.0, 8.8	-61.5, 32.8	-42.9, 22.0	-85.8, -21.9	-89.9, -56.8
	Mean (SD)	-55.26 (17.801)	-61.84 (16.901)	-13.59 (22.292)	-15.55 (17.282)	-69.82 (14.724)	-77.94 (11.856)
	95% CI of Mean	-61.03, -49.48	-67.48, -56.20	-23.24, -3.95	-23.89, -7.22	-76.71, -62.92	-83.66, -72.22

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 5	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	279.34 (29.29)	333.88 (29.08)	568.30 (42.92)	620.46 (62.96)	201.14 (44.41)	172.64 (40.94)
	95% CI of Geometric Mean	254.54, 306.57	303.62, 367.15	475.73, 678.88	469.63, 819.71	164.91, 245.31	142.81, 208.72
	Median	275.00	344.62	590.91	570.54	211.39	179.26
	Q25, Q75	223.21, 353.20	267.77, 405.14	388.59, 756.07	386.96, 1050.16	177.63, 258.56	140.56, 246.10
	Min, Max	163.3, 488.4	208.9, 631.0	266.8, 1083.2	261.3, 1548.8	48.9, 366.7	66.6, 302.4
	Mean (SD)	290.77 (84.032)	347.40 (100.842)	614.50 (242.696)	726.08 (418.282)	215.60 (72.184)	185.00 (68.286)
	95% CI of Mean	263.53, 318.01	313.78, 381.03	509.55, 719.46	524.47, 927.69	181.81, 249.39	152.09, 217.92

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 5							
	n	39	37	23	19	20	19
	Median	-48.91	-58.56	5.45	-6.97	-68.97	-79.75
	Q25, Q75	-58.92, -32.84	-68.17, -45.51	-20.23, 14.96	-25.37, 0.00	-77.19, -53.40	-86.81, -61.07
	Min, Max	-76.0, 15.5	-80.1, -13.1	-47.2, 28.3	-39.6, 48.3	-92.1, 1.0	-89.7, -54.1
	Mean (SD)	-46.06 (19.856)	-56.01 (17.035)	-3.06 (21.754)	-8.41 (21.129)	-63.14 (21.223)	-73.97 (13.322)
	95% CI of Mean	-52.51, -39.62	-61.69, -50.32	-12.47, 6.35	-18.60, 1.78	-73.07, -53.20	-80.40, -67.55

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Baseline	n	38	36	23	18	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	559.39 (47.49)	827.72 (42.18)	602.59 (48.30)	669.40 (53.39)	633.30 (52.40)	757.73 (54.38)
	95% CI of Geometric Mean	482.32, 648.77	721.81, 949.17	494.34, 734.54	521.84, 858.67	502.92, 797.48	592.90, 968.39
	Median	511.83	808.97	602.09	611.90	639.56	700.00
	Q25, Q75	407.28, 709.01	693.18, 1020.98	426.56, 848.79	489.29, 840.19	413.09, 941.10	529.61, 1350.19
	Min, Max	264.9, 1579.6	270.1, 2669.4	253.0, 1358.1	325.2, 2075.8	273.3, 1607.7	306.1, 1873.9
	Mean (SD)	622.25 (322.671)	897.34 (404.481)	661.78 (281.183)	761.27 (444.780)	712.22 (366.798)	857.90 (450.813)
	95% CI of Mean	516.19, 728.32	760.48, 1034.20	540.18, 783.38	540.08, 982.46	540.55, 883.89	640.61, 1075.19

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19	>19	10-19	>19	10-19	>19
		cig/day (N=38)	cig/day (N=36)	cig/day (N=23)	cig/day (N=18)	cig/day (N=20)	cig/day (N=19)
Day 30	n	38	36	23	18	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	305.47 (30.53)	359.01 (32.71)	631.19 (44.21)	696.49 (47.98)	289.41 (34.95)	254.72 (54.48)
	95% CI of Geometric Mean	276.93, 336.96	322.30, 399.90	525.80, 757.71	555.41, 873.40	246.89, 339.24	199.23, 325.67
	Median	298.50	368.35	664.95	654.70	307.20	247.66
	Q25, Q75	239.45, 383.39	295.23, 463.89	459.76, 846.65	479.44, 1004.75	204.40, 379.03	179.59, 344.16
	Min, Max	180.3, 598.3	162.5, 676.2	300.9, 1237.6	329.3, 1637.1	161.4, 544.5	105.8, 812.1
	Mean (SD)	319.40 (100.463)	376.72 (117.693)	686.15 (284.176)	768.92 (360.737)	305.32 (101.313)	289.66 (166.168)
	95% CI of Mean	286.38, 352.43	336.90, 416.55	563.26, 809.04	589.53, 948.32	257.90, 352.74	209.57, 369.76

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 30							
	n	38	36	23	18	20	19
	Median	-43.46	-58.93	16.26	-3.88	-51.95	-65.62
	Q25, Q75	-60.10, -27.07	-66.28, -41.08	-21.62, 34.87	-17.97, 35.27	-72.25, -30.83	-80.03, -53.32
	Min, Max	-74.2, 40.6	-86.3, 40.9	-68.8, 159.9	-40.9, 89.6	-82.6, 34.0	-87.5, 31.2
	Mean (SD)	-40.91 (24.621)	-52.07 (23.573)	13.73 (46.805)	9.59 (37.773)	-46.43 (31.328)	-58.40 (31.632)
	95% CI of Mean	-49.01, -32.81	-60.05, -44.09	-6.52, 33.97	-9.20, 28.38	-61.10, -31.76	-73.65, -43.15

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Baseline	n	36	35	23	18	20	18
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	573.73 (46.80)	832.61 (42.34)	602.59 (48.30)	669.40 (53.39)	633.30 (52.40)	731.31 (53.17)
	95% CI of Geometric Mean	493.54, 666.96	724.22, 957.22	494.34, 734.54	521.84, 858.67	502.92, 797.48	570.62, 937.25
	Median	537.48	814.31	602.09	611.90	639.56	659.52
	Q25, Q75	412.20, 727.62	681.61, 1032.19	426.56, 848.79	489.29, 840.19	413.09, 941.10	529.61, 1111.94
	Min, Max	264.9, 1579.6	270.1, 2669.4	253.0, 1358.1	325.2, 2075.8	273.3, 1607.7	306.1, 1873.9
	Mean (SD)	636.35 (324.973)	903.06 (408.084)	661.78 (281.183)	761.27 (444.780)	712.22 (366.798)	825.82 (441.005)
	95% CI of Mean	526.39, 746.31	762.87, 1043.25	540.18, 783.38	540.08, 982.46	540.55, 883.89	606.51, 1045.13

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Day 60	n	36	35	23	18	20	18
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	306.30 (26.95)	367.24 (39.57)	638.40 (54.39)	749.04 (47.81)	269.05 (28.59)	241.74 (55.29)
	95% CI of Geometric Mean	280.05, 335.02	322.15, 418.64	512.26, 795.59	597.74, 938.64	235.97, 306.77	186.98, 312.52
	Median	294.09	374.72	648.99	652.09	260.57	215.40
	Q25, Q75	263.41, 362.95	281.07, 490.30	448.92, 893.59	566.10, 1064.34	224.66, 304.15	169.00, 329.92
	Min, Max	164.6, 511.0	185.4, 970.0	215.1, 1300.9	386.8, 1795.3	179.5, 529.3	94.7, 689.9
	Mean (SD)	316.88 (84.313)	394.86 (161.731)	715.40 (329.884)	832.17 (430.073)	280.13 (89.629)	276.54 (163.531)
	95% CI of Mean	288.35, 345.41	339.30, 450.42	572.74, 858.05	618.29, 1046.04	238.17, 322.08	195.21, 357.86

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 3

		THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Timepoint	Statistic						
% Change from baseline to Day 60							
	n	36	35	23	18	20	18
	Median	-46.21	-58.48	8.49	10.45	-54.29	-65.53
	Q25, Q75	-59.76, -28.51	-69.81, -36.55	-14.96, 37.75	-20.29, 52.03	-68.13, -41.84	-79.23, -49.44
	Min, Max	-77.4, 32.8	-81.6, 32.8	-57.4, 122.4	-32.6, 104.3	-82.8, 5.0	-88.8, 13.6
	Mean (SD)	-42.34 (23.945)	-50.57 (26.191)	14.00 (43.875)	18.67 (42.344)	-53.21 (21.299)	-58.79 (29.444)
	95% CI of Mean	-50.44, -34.23	-59.57, -41.57	-4.98, 32.98	-2.39, 39.74	-63.18, -43.24	-73.44, -44.14

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Baseline	n	36	34	23	18	20	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	572.11 (47.33)	826.03 (42.78)	602.59 (48.30)	669.40 (53.39)	633.30 (52.40)	702.53 (51.31)
	95% CI of Geometric Mean	491.38, 666.11	715.95, 953.04	494.34, 734.54	521.84, 858.67	502.92, 797.48	547.93, 900.74
	Median	537.48	808.97	602.09	611.90	639.56	619.05
	Q25, Q75	412.20, 727.62	704.75, 1009.77	426.56, 848.79	489.29, 840.19	413.09, 941.10	529.61, 804.55
	Min, Max	264.9, 1579.6	270.1, 2669.4	253.0, 1358.1	325.2, 2075.8	273.3, 1607.7	306.1, 1873.9
	Mean (SD)	635.55 (325.865)	897.38 (411.466)	661.78 (281.183)	761.27 (444.780)	712.22 (366.798)	789.27 (425.548)
	95% CI of Mean	525.29, 745.81	753.81, 1040.96	540.18, 783.38	540.08, 982.46	540.55, 883.89	570.47, 1008.07

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Day 90	n	36	34	23	18	20	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	345.14 (26.76)	435.40 (38.67)	633.41 (47.25)	783.98 (47.10)	311.53 (35.46)	239.60 (42.99)
	95% CI of Geometric Mean	315.75, 377.27	382.23, 495.97	521.65, 769.11	627.54, 979.42	265.18, 365.97	193.88, 296.11
	Median	325.53	413.54	691.82	724.85	300.00	211.45
	Q25, Q75	279.14, 420.56	343.57, 498.41	422.03, 849.47	580.00, 1113.70	253.00, 395.77	187.83, 300.72
	Min, Max	230.0, 595.8	225.1, 945.4	271.5, 1374.3	408.1, 1945.2	167.4, 678.1	121.9, 620.1
	Mean (SD)	357.13 (96.550)	467.75 (193.866)	693.83 (292.411)	868.28 (441.654)	330.17 (121.842)	261.44 (125.939)
	95% CI of Mean	324.45, 389.80	400.10, 535.40	567.38, 820.29	648.64, 1087.91	273.14, 387.20	196.68, 326.20

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 4

		THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Timepoint	Statistic						
% Change from baseline to Day 90							
	n	36	34	23	18	20	17
	Median	-38.64	-51.13	7.33	15.47	-46.76	-65.91
	Q25, Q75	-57.08, -20.52	-60.63, -37.22	-22.05, 37.04	-6.30, 33.78	-69.63, -32.41	-79.21, -40.62
	Min, Max	-76.5, 108.3	-75.5, 24.4	-50.4, 169.2	-43.0, 164.6	-77.3, 148.1	-88.4, 0.2
	Mean (SD)	-32.35 (36.684)	-42.11 (27.433)	14.91 (52.974)	23.39 (44.416)	-40.03 (49.616)	-58.20 (27.522)
	95% CI of Mean	-44.76, -19.93	-51.69, -32.53	-8.01, 37.82	1.30, 45.48	-63.26, -16.80	-72.36, -44.05

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	663.30 (50.15)		642.20 (51.11)		697.93 (53.25)	
	95% CI of Geometric Mean	596.11, 738.06		552.68, 746.21		594.86, 818.86	
	Median	681.14		617.49		680.28	
	Q25, Q75	468.75, 912.36		489.29, 848.79		483.56, 1089.69	
	Min, Max	264.9, 2669.4		253.0, 2075.8		273.3, 1873.9	
	Mean (SD)	742.61 (384.978)		719.99 (368.454)		789.17 (407.524)	
	95% CI of Mean	655.81, 829.42		605.17, 834.82		658.83, 919.50	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	300.12 (36.89)		550.49 (50.35)		226.11 (34.23)	
	95% CI of Geometric Mean	276.90, 325.29		474.70, 638.38		203.27, 251.51	
	Median	288.53	-56.56	561.64	-13.14	209.99	-65.42
	Q25, Q75	240.81, 370.51	-63.25, -41.70	378.13, 727.70	-27.35, 4.68	182.36, 260.11	-76.47, -56.76
	Min, Max	128.6, 976.7	-80.4, 0.0	220.8, 1684.5	-47.6, 41.4	121.2, 494.7	-89.2, -25.5
	Mean (SD)	320.83 (131.105)	-52.17 (16.384)	618.72 (331.345)	-11.99 (20.433)	239.47 (88.895)	-64.88 (13.891)
	95% CI of Mean	291.27, 350.40	-55.87, -48.47	515.46, 721.98	-18.36, -5.62	211.03, 267.90	-69.33, -60.44

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	248.07 (34.39)		522.67 (57.68)		152.74 (38.55)	
	95% CI of Geometric Mean	230.05, 267.49		442.28, 617.67		135.59, 172.05	
	Median	239.65	-62.36	526.22	-19.00	148.58	-75.22
	Q25, Q75	198.76, 312.12	-70.99, -52.29	325.45, 762.71	-30.39, 0.00	116.58, 190.38	-84.78, -69.09
	Min, Max	111.6, 693.1	-81.3, 0.0	176.1, 1620.9	-54.0, 25.5	74.1, 369.9	-93.1, -48.3
	Mean (SD)	262.74 (97.024)	-60.25 (14.729)	601.82 (336.068)	-16.49 (18.863)	163.88 (66.492)	-75.72 (10.771)
	95% CI of Mean	240.86, 284.62	-63.58, -56.92	497.09, 706.56	-22.38, -10.61	142.61, 185.15	-79.17, -72.27

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	259.31 (33.78)		531.35 (56.52)		158.77 (36.67)	
	95% CI of Geometric Mean	240.79, 279.26		450.95, 626.10		141.72, 177.87	
	Median	261.82	-61.72	461.47	-17.76	158.94	-77.11
	Q25, Q75	208.59, 306.82	-70.30, -50.90	383.21, 756.55	-30.64, -2.14	120.37, 190.29	-84.29, -68.29
	Min, Max	121.5, 560.6	-80.6, 0.0	176.4, 1917.1	-58.0, 35.3	86.7, 363.3	-91.5, -44.0
	Mean (SD)	273.66 (93.313)	-58.06 (17.006)	612.96 (365.426)	-14.57 (21.622)	169.43 (66.586)	-74.50 (12.381)
	95% CI of Mean	252.62, 294.71	-61.90, -54.22	499.08, 726.84	-21.32, -7.83	148.13, 190.73	-78.46, -70.53

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	259.30 (30.29)		533.66 (54.34)		161.96 (39.19)	
	95% CI of Geometric Mean	242.54, 277.21		455.43, 625.32		143.52, 182.77	
	Median	271.15	-60.19	471.41	-14.07	164.55	-74.60
	Q25, Q75	213.16, 307.34	-69.95, -50.46	364.72, 850.48	-28.47, 0.00	130.49, 201.17	-85.19, -64.85
	Min, Max	128.1, 485.3	-83.6, 15.9	165.4, 1658.7	-61.5, 32.8	57.5, 385.9	-89.9, -21.9
	Mean (SD)	270.45 (78.101)	-57.62 (18.573)	607.19 (329.857)	-14.48 (19.969)	173.29 (65.226)	-73.68 (13.687)
	95% CI of Mean	252.84, 288.07	-61.82, -53.43	504.40, 709.99	-20.71, -8.25	152.42, 194.15	-78.06, -69.30

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	306.74 (30.54)		591.33 (51.99)		189.05 (43.22)	
	95% CI of Geometric Mean	286.76, 328.10		507.72, 688.69		165.61, 215.81	
	Median	303.88	-54.18	587.31	-5.10	196.73	-70.95
	Q25, Q75	237.70, 386.36	-64.41, -40.05	388.59, 836.69	-24.17, 11.44	150.76, 255.91	-81.69, -56.59
	Min, Max	163.3, 631.0	-80.1, 15.5	261.3, 1548.8	-47.2, 48.3	48.9, 366.7	-92.1, 1.0
	Mean (SD)	320.54 (96.854)	-50.14 (19.715)	664.98 (334.031)	-5.48 (21.382)	203.36 (72.171)	-68.45 (18.186)
	95% CI of Mean	298.70, 342.38	-54.59, -45.69	560.88, 769.07	-12.15, 1.19	180.27, 226.45	-74.27, -62.63

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	330.00 (32.29)		670.01 (46.46)		272.79 (44.48)	
	95% CI of Geometric Mean	307.37, 354.28		583.78, 768.97		238.13, 312.50	
	Median	331.06	-50.33	681.15	5.04	289.58	-65.29
	Q25, Q75	265.73, 405.78	-63.46, -30.91	479.44, 960.83	-17.97, 34.87	202.05, 359.49	-75.10, -38.15
	Min, Max	162.5, 676.2	-86.3, 40.9	300.9, 1637.1	-68.8, 159.9	105.8, 812.1	-87.5, 34.0
	Mean (SD)	346.57 (110.834)	-45.14 (25.521)	736.61 (327.655)	11.63 (42.127)	297.93 (133.447)	-52.70 (31.362)
	95% CI of Mean	321.57, 371.56	-50.90, -39.38	634.51, 838.72	-1.51, 24.76	255.25, 340.61	-62.74, -42.67

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	333.81 (34.15)		695.54 (52.19)		254.67 (41.85)	
	95% CI of Geometric Mean	309.72, 359.76		596.90, 810.47		223.96, 289.58	
	Median	323.66	-53.89	656.69	8.14	257.79	-61.41
	Q25, Q75	273.38, 418.96	-63.24, -29.25	518.69, 1064.34	-14.96, 37.75	186.76, 309.40	-76.27, -47.11
	Min, Max	164.6, 970.0	-81.6, 49.3	215.1, 1795.3	-57.4, 122.4	94.7, 689.9	-88.8, 13.6
	Mean (SD)	353.39 (130.050)	-43.96 (27.812)	779.73 (381.605)	15.67 (42.284)	276.68 (125.867)	-57.00 (25.217)
	95% CI of Mean	324.06, 382.71	-50.23, -37.68	660.81, 898.66	2.49, 28.85	236.42, 316.94	-65.07, -48.93

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	379.88 (34.73)		706.22 (48.61)		274.24 (40.02)	
	95% CI of Geometric Mean	352.05, 409.92		611.80, 815.20		242.43, 310.23	
	Median	391.43	-44.03	724.85	11.18	270.45	-60.85
	Q25, Q75	291.87, 452.87	-59.73, -20.84	493.61, 941.88	-9.26, 33.93	200.81, 338.21	-76.25, -36.84
	Min, Max	200.3, 945.4	-76.5, 108.3	271.5, 1945.2	-50.4, 169.2	121.9, 678.1	-88.4, 148.1
	Mean (SD)	403.58 (156.305)	-36.24 (32.794)	783.40 (375.944)	18.19 (48.474)	295.62 (123.330)	-50.69 (40.732)
	95% CI of Mean	368.33, 438.82	-43.64, -28.84	666.25, 900.56	3.08, 33.30	256.17, 335.07	-63.72, -37.65

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	795.27 (52.86)	761.59 (60.42)	830.45 (52.63)
	95% CI of Geometric Mean	711.08, 889.44	640.07, 906.18	708.98, 972.73
	Median	827.73	756.26	842.56
	Q25, Q75	575.89, 1101.70	562.07, 1266.37	662.33, 1094.59
	Min, Max	250.6, 2317.9	272.6, 2194.5	249.6, 2022.8
	Mean (SD)	893.27 (433.425)	881.72 (483.334)	928.86 (438.670)
	95% CI of Mean	795.54, 990.99	731.10, 1032.34	788.56, 1069.16

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	348.65 (39.64)	660.10 (69.30)	244.17 (38.55)
	95% CI of Geometric Mean	319.87, 380.01	543.07, 802.36	216.76, 275.04
	Median	350.85	730.62	237.19
	Q25, Q75	275.06, 474.86	438.63, 972.93	190.68, 299.29
	Min, Max	158.0, 743.9	154.5, 2400.5	121.4, 878.7
	Mean (SD)	374.17 (141.713)	793.34 (500.496)	263.51 (125.782)
	95% CI of Mean	342.21, 406.12	637.37, 949.32	223.28, 303.75

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	292.85 (36.95)	651.42 (70.92)	176.14 (38.70)
	95% CI of Geometric Mean	270.16, 317.45	533.92, 794.78	156.30, 198.49
	Median	301.20	710.27	172.29
	Q25, Q75	220.28, 374.30	407.45, 1050.16	137.42, 213.73
	Min, Max	140.2, 665.0	158.4, 2194.5	90.9, 561.0
	Mean (SD)	311.62 (110.640)	787.27 (488.694)	189.53 (83.457)
	95% CI of Mean	286.67, 336.57	634.98, 939.56	162.84, 216.23

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	315.66 (35.20)	649.01 (64.17)	189.59 (39.10)
	95% CI of Geometric Mean	292.25, 340.95	540.48, 779.32	168.04, 213.90
	Median	328.27	656.12	183.29
	Q25, Q75	233.81, 399.31	416.05, 956.56	149.95, 258.20
	Min, Max	159.5, 746.0	205.7, 2194.5	71.8, 450.0
	Mean (SD)	334.52 (117.876)	769.36 (480.201)	202.93 (76.680)
	95% CI of Mean	307.93, 361.10	619.71, 919.00	178.40, 227.46

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	316.42 (33.97)	609.63 (65.34)	186.19 (43.84)
	95% CI of Geometric Mean	293.70, 340.89	506.25, 734.11	162.82, 212.91
	Median	329.74	594.98	206.87
	Q25, Q75	246.51, 398.25	441.78, 880.80	149.48, 233.23
	Min, Max	162.9, 678.7	142.8, 2194.5	59.1, 411.3
	Mean (SD)	333.55 (108.291)	720.96 (439.291)	201.46 (77.144)
	95% CI of Mean	309.13, 357.97	584.06, 857.86	176.79, 226.14

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	358.71 (38.12)	732.79 (58.38)	228.40 (44.68)
	95% CI of Geometric Mean	330.12, 389.78	618.99, 867.51	199.26, 261.78
	Median	363.02	707.63	235.30
	Q25, Q75	273.27, 487.71	467.93, 1054.52	184.52, 302.21
	Min, Max	126.1, 723.5	297.7, 2194.5	68.1, 497.6
	Mean (SD)	382.40 (134.269)	846.26 (473.307)	247.98 (99.005)
	95% CI of Mean	352.13, 412.68	698.76, 993.75	216.31, 279.65

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	390.51 (37.94)	781.40 (62.46)	289.72 (58.31)
	95% CI of Geometric Mean	359.51, 424.17	653.43, 934.42	243.69, 344.45
	Median	388.75	803.41	300.12
	Q25, Q75	311.35, 501.97	532.12, 1159.54	230.66, 377.41
	Min, Max	130.5, 858.8	165.3, 2330.4	71.4, 1171.1
	Mean (SD)	416.68 (153.101)	909.74 (507.955)	333.10 (195.924)
	95% CI of Mean	382.16, 451.21	751.44, 1068.03	270.44, 395.77

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	382.79 (42.13)	800.88 (61.78)	287.83 (61.00)
	95% CI of Geometric Mean	349.44, 419.31	670.83, 956.13	240.44, 344.55
	Median	404.07	781.29	300.70
	Q25, Q75	287.80, 505.79	584.82, 1130.98	213.63, 406.48
	Min, Max	149.7, 1060.4	209.4, 2609.6	48.9, 912.5
	Mean (SD)	414.54 (171.111)	933.41 (540.414)	331.21 (178.336)
	95% CI of Mean	375.95, 453.12	765.00, 1101.82	274.17, 388.25

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	431.34 (42.64)	774.69 (62.18)	308.38 (50.63)
	95% CI of Geometric Mean	393.37, 472.99	648.26, 925.78	264.69, 359.29
	Median	438.37	851.74	319.95
	Q25, Q75	349.20, 559.13	537.66, 1094.45	243.47, 425.69
	Min, Max	107.2, 1223.2	201.3, 2537.6	114.9, 952.6
	Mean (SD)	467.03 (194.026)	898.21 (493.708)	343.48 (165.843)
	95% CI of Mean	423.28, 510.78	744.35, 1052.06	290.44, 396.53

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	667.53 (49.95)		642.20 (51.11)		691.14 (53.57)	
	95% CI of Geometric Mean	599.28, 743.54		552.68, 746.21		587.29, 813.34	
	Median	681.14		617.49		660.55	
	Q25, Q75	471.90, 915.89		489.29, 848.79		476.07, 1096.71	
	Min, Max	264.9, 2669.4		253.0, 2075.8		273.3, 1873.9	
	Mean (SD)	746.87 (386.899)		719.99 (368.454)		783.19 (411.072)	
	95% CI of Mean	658.46, 835.29		605.17, 834.82		649.93, 916.45	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	298.65 (37.22)		550.49 (50.35)		224.60 (34.41)	
	95% CI of Geometric Mean	275.06, 324.28		474.70, 638.38		201.51, 250.32	
	Median	284.04	-56.67	561.64	-13.14	208.44	-65.20
	Q25, Q75	237.63, 367.76	-63.48, -41.83	378.13, 727.70	-27.35, 4.68	181.88, 259.95	-77.17, -55.99
	Min, Max	128.6, 976.7	-80.4, -6.0	220.8, 1684.5	-47.6, 41.4	121.2, 494.7	-89.2, -25.5
	Mean (SD)	319.71 (132.496)	-52.86 (15.454)	618.72 (331.345)	-11.99 (20.433)	238.08 (89.616)	-64.72 (14.033)
	95% CI of Mean	289.42, 349.99	-56.40, -49.32	515.46, 721.98	-18.36, -5.62	209.02, 267.13	-69.27, -60.17

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	245.31 (33.96)		522.67 (57.68)		150.03 (37.11)	
	95% CI of Geometric Mean	227.47, 264.55		442.28, 617.67		133.53, 168.55	
	Median	238.75	-63.23	526.22	-19.00	146.27	-76.29
	Q25, Q75	198.76, 306.25	-71.24, -52.87	325.45, 762.71	-30.39, 0.00	112.56, 190.03	-84.86, -68.24
	Min, Max	111.6, 693.1	-81.3, -14.1	176.1, 1620.9	-54.0, 25.5	74.1, 369.9	-93.1, -48.3
	Mean (SD)	259.55 (95.757)	-61.22 (13.078)	601.82 (336.068)	-16.49 (18.863)	160.20 (63.105)	-75.87 (10.871)
	95% CI of Mean	237.67, 281.44	-64.21, -58.22	497.09, 706.56	-22.38, -10.61	139.74, 180.66	-79.40, -72.34

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	257.30 (33.83)		531.35 (56.52)		156.10 (35.35)	
	95% CI of Geometric Mean	238.65, 277.40		450.95, 626.10		139.67, 174.47	
	Median	260.35	-62.65	461.47	-17.76	157.66	-77.80
	Q25, Q75	204.44, 304.69	-70.39, -50.93	383.21, 756.55	-30.64, -2.14	118.73, 189.17	-84.61, -68.25
	Min, Max	121.5, 560.6	-80.6, -0.3	176.4, 1917.1	-58.0, 35.3	86.7, 363.3	-91.5, -44.0
	Mean (SD)	271.66 (93.620)	-58.86 (15.850)	612.96 (365.426)	-14.57 (21.622)	165.89 (63.540)	-74.61 (12.520)
	95% CI of Mean	250.27, 293.06	-62.49, -55.23	499.08, 726.84	-21.32, -7.83	145.29, 186.49	-78.68, -70.55

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	257.01 (30.09)		533.66 (54.34)		159.32 (38.10)	
	95% CI of Geometric Mean	240.29, 274.89		455.43, 625.32		141.39, 179.52	
	Median	269.23	-60.90	471.41	-14.07	163.89	-75.19
	Q25, Q75	211.08, 306.55	-70.24, -50.86	364.72, 850.48	-28.47, 0.00	128.65, 200.42	-85.57, -64.73
	Min, Max	128.1, 485.3	-83.6, 15.9	165.4, 1658.7	-61.5, 32.8	57.5, 385.9	-89.9, -21.9
	Mean (SD)	267.95 (77.268)	-58.46 (17.569)	607.19 (329.857)	-14.48 (19.969)	169.85 (62.303)	-73.78 (13.853)
	95% CI of Mean	250.29, 285.61	-62.48, -54.44	504.40, 709.99	-20.71, -8.25	149.65, 190.05	-78.27, -69.28

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	304.68 (30.46)		591.33 (51.99)		186.71 (42.96)	
	95% CI of Geometric Mean	284.63, 326.14		507.72, 688.69		163.39, 213.36	
	Median	300.59	-54.84	587.31	-5.10	195.57	-71.37
	Q25, Q75	237.26, 381.92	-64.68, -40.07	388.59, 836.69	-24.17, 11.44	150.55, 246.94	-81.96, -56.37
	Min, Max	163.3, 631.0	-80.1, 15.5	261.3, 1548.8	-47.2, 48.3	48.9, 366.7	-92.1, 1.0
	Mean (SD)	318.34 (96.286)	-50.90 (19.081)	664.98 (334.031)	-5.48 (21.382)	200.69 (71.092)	-68.42 (18.422)
	95% CI of Mean	296.33, 340.35	-55.27, -46.54	560.88, 769.07	-12.15, 1.19	177.64, 223.75	-74.39, -62.44

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 10 AM on Day 1 in the SA arm.

**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=63)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	63		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	684.41 (49.66)		631.06 (50.19)		677.97 (52.60)	
	95% CI of Geometric Mean	608.09, 770.31		543.36, 732.90		576.32, 797.56	
	Median	704.75		602.09		639.80	
	Q25, Q75	486.49, 919.43		489.29, 840.19		476.07, 1082.67	
	Min, Max	264.9, 2669.4		253.0, 2075.8		273.3, 1873.9	
	Mean (SD)	764.01 (392.373)		705.46 (360.640)		766.03 (402.183)	
	95% CI of Mean	665.18, 862.83		591.62, 819.30		633.83, 898.23	

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 10 AM on Day 1 in the SA arm.

**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=63)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	63	63	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	329.26 (31.80)		659.07 (45.57)		274.94 (45.10)	
	95% CI of Geometric Mean	304.51, 356.03		574.63, 755.91		238.68, 316.71	
	Median	336.65	-52.58	664.95	5.87	289.58	-61.98
	Q25, Q75	245.08, 405.56	-64.22, -33.97	479.44, 928.57	-17.97, 34.87	202.33, 366.27	-74.86, -36.74
	Min, Max	162.5, 676.2	-86.3, 40.9	300.9, 1637.1	-68.8, 159.9	105.8, 812.1	-86.1, 34.0
	Mean (SD)	345.22 (108.676)	-47.08 (24.863)	722.49 (318.513)	11.91 (42.610)	300.80 (135.578)	-51.34 (31.529)
	95% CI of Mean	317.85, 372.60	-53.34, -40.81	621.95, 823.03	-1.54, 25.37	256.23, 345.37	-61.70, -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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	694.78 (47.78)		631.06 (50.19)		677.97 (52.60)	
	95% CI of Geometric Mean	620.94, 777.40		543.36, 732.90		576.32, 797.56	
	Median	704.75		602.09		639.80	
	Q25, Q75	498.25, 953.80		489.29, 840.19		476.07, 1082.67	
	Min, Max	264.9, 2669.4		253.0, 2075.8		273.3, 1873.9	
	Mean (SD)	770.54 (385.586)		705.46 (360.640)		766.03 (402.183)	
	95% CI of Mean	675.00, 866.09		591.62, 819.30		633.83, 898.23	

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	65	65	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	331.96 (32.31)		684.81 (51.65)		255.75 (42.47)	
	95% CI of Geometric Mean	307.02, 358.91		587.37, 798.41		223.71, 292.38	
	Median	322.93	-54.20	648.99	8.49	257.79	-59.12
	Q25, Q75	277.08, 418.96	-64.82, -33.91	518.69, 961.24	-14.96, 37.75	187.07, 311.49	-75.94, -44.79
	Min, Max	164.6, 695.0	-81.6, 32.8	215.1, 1795.3	-57.4, 122.4	94.7, 689.9	-88.8, 13.6
	Mean (SD)	348.64 (112.101)	-47.78 (22.960)	766.66 (376.702)	16.05 (42.736)	278.43 (128.123)	-55.85 (25.284)
	95% CI of Mean	320.86, 376.42	-53.47, -42.08	647.75, 885.57	2.56, 29.55	236.31, 320.54	-64.17, -47.54

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	687.30 (48.17)		631.06 (50.19)		664.22 (51.43)	
	95% CI of Geometric Mean	613.74, 769.67		543.36, 732.90		565.16, 780.64	
	Median	704.75		602.09		619.05	
	Q25, Q75	493.43, 919.43		489.29, 840.19		476.07, 804.55	
	Min, Max	264.9, 2669.4		253.0, 2075.8		273.3, 1873.9	
	Mean (SD)	763.39 (385.323)		705.46 (360.640)		747.62 (391.162)	
	95% CI of Mean	667.91, 858.87		591.62, 819.30		617.19, 878.04	

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	65	65	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	388.73 (34.84)		695.58 (48.02)		276.13 (41.02)	
	95% CI of Geometric Mean	357.46, 422.74		602.43, 803.13		242.11, 314.93	
	Median	394.12	-45.62	717.97	12.10	267.33	-58.99
	Q25, Q75	295.69, 452.87	-59.73, -32.89	493.61, 869.68	-9.26, 33.93	201.18, 349.87	-75.31, -34.92
	Min, Max	225.1, 945.4	-75.5, 108.3	271.5, 1945.2	-50.4, 169.2	121.9, 678.1	-88.4, 148.1
	Mean (SD)	413.25 (161.989)	-36.94 (33.353)	770.42 (370.957)	18.63 (48.990)	298.59 (126.847)	-48.38 (41.475)
	95% CI of Mean	373.11, 453.39	-45.21, -28.67	653.33, 887.51	3.16, 34.10	256.29, 340.89	-62.21, -34.55

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	803.29 (52.57)	761.59 (60.42)	830.24 (53.41)
	95% CI of Geometric Mean	717.56, 899.28	640.07, 906.18	705.80, 976.62
	Median	829.76	756.26	846.35
	Q25, Q75	576.00, 1120.42	562.07, 1266.37	634.70, 1115.28
	Min, Max	250.6, 2317.9	272.6, 2194.5	249.6, 2022.8
	Mean (SD)	901.13 (434.586)	881.72 (483.334)	931.17 (444.158)
	95% CI of Mean	801.81, 1000.44	731.10, 1032.34	787.19, 1075.16

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	347.11 (40.00)	660.10 (69.30)	245.57 (38.90)
	95% CI of Geometric Mean	317.86, 379.05	543.07, 802.36	217.43, 277.34
	Median	348.36	730.62	240.03
	Q25, Q75	272.89, 470.94	438.63, 972.93	186.22, 307.91
	Min, Max	158.0, 743.9	154.5, 2400.5	121.4, 878.7
	Mean (SD)	373.03 (143.023)	793.34 (500.496)	265.26 (126.935)
	95% CI of Mean	340.34, 405.72	637.37, 949.32	224.11, 306.41

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	290.44 (36.99)	651.42 (70.92)	174.62 (38.79)
	95% CI of Geometric Mean	267.62, 315.21	533.92, 794.78	154.66, 197.15
	Median	299.68	710.27	171.58
	Q25, Q75	215.66, 373.19	407.45, 1050.16	137.00, 213.56
	Min, Max	140.2, 665.0	158.4, 2194.5	90.9, 561.0
	Mean (SD)	309.18 (110.730)	787.27 (488.694)	188.06 (84.020)
	95% CI of Mean	283.87, 334.48	634.98, 939.56	160.82, 215.30

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	312.29 (34.59)	649.01 (64.17)	188.31 (39.37)
	95% CI of Geometric Mean	289.20, 337.23	540.48, 779.32	166.50, 212.97
	Median	326.84	656.12	183.16
	Q25, Q75	232.87, 397.35	416.05, 956.56	147.49, 259.23
	Min, Max	159.5, 746.0	205.7, 2194.5	71.8, 450.0
	Mean (SD)	330.27 (114.051)	769.36 (480.201)	201.80 (77.345)
	95% CI of Mean	304.21, 356.34	619.71, 919.00	176.72, 226.88

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	313.79 (33.80)	609.63 (65.34)	184.85 (44.18)
	95% CI of Geometric Mean	291.07, 338.29	506.25, 734.11	161.20, 211.97
	Median	325.11	594.98	204.76
	Q25, Q75	243.86, 397.58	441.78, 880.80	138.94, 231.90
	Min, Max	162.9, 678.7	142.8, 2194.5	59.1, 411.3
	Mean (SD)	330.65 (107.167)	720.96 (439.291)	200.30 (77.794)
	95% CI of Mean	306.15, 355.14	584.06, 857.86	175.08, 225.52

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	356.24 (38.07)	732.79 (58.38)	227.94 (45.29)
	95% CI of Geometric Mean	327.52, 387.48	618.99, 867.51	198.15, 262.20
	Median	363.02	707.63	235.05
	Q25, Q75	272.97, 482.04	467.93, 1054.52	183.22, 302.87
	Min, Max	126.1, 723.5	297.7, 2194.5	68.1, 497.6
	Mean (SD)	379.70 (133.245)	846.26 (473.307)	248.00 (100.299)
	95% CI of Mean	349.25, 410.16	698.76, 993.75	215.49, 280.52

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 10 AM on Day 1 in the SA arm.

**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=63)	mCC (N=41)	SA (N=38)
Baseline	n	63	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	832.57 (52.62)	742.18 (58.03)	811.86 (51.80)
	95% CI of Geometric Mean	735.11, 942.95	626.12, 879.76	691.66, 952.96
	Median	880.78	753.40	832.31
	Q25, Q75	636.17, 1144.43	562.07, 1192.29	634.70, 1073.90
	Min, Max	250.6, 2317.9	272.6, 1954.5	249.6, 2022.8
	Mean (SD)	933.15 (447.793)	849.70 (441.946)	904.54 (417.364)
	95% CI of Mean	820.37, 1045.93	710.20, 989.20	767.35, 1041.73

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 10 AM on Day 1 in the SA arm.

**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=63)	mCC (N=41)	SA (N=38)
Day 30	n	63	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	390.62 (39.27)	761.96 (60.32)	292.55 (59.89)
	95% CI of Geometric Mean	355.09, 429.71	639.11, 908.43	243.87, 350.94
	Median	391.04	801.75	305.16
	Q25, Q75	306.29, 526.79	532.12, 1143.42	229.70, 379.18
	Min, Max	130.5, 858.8	165.3, 2330.4	71.4, 1171.1
	Mean (SD)	418.10 (155.230)	878.40 (471.378)	337.95 (199.941)
	95% CI of Mean	379.00, 457.20	729.61, 1027.19	272.23, 403.67

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=38)
Baseline	n	65	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	843.62 (49.24)	742.18 (58.03)	811.86 (51.80)
	95% CI of Geometric Mean	751.65, 946.86	626.12, 879.76	691.66, 952.96
	Median	840.43	753.40	832.31
	Q25, Q75	636.17, 1144.43	562.07, 1192.29	634.70, 1073.90
	Min, Max	272.7, 2317.9	272.6, 1954.5	249.6, 2022.8
	Mean (SD)	936.24 (437.949)	849.70 (441.946)	904.54 (417.364)
	95% CI of Mean	827.72, 1044.76	710.20, 989.20	767.35, 1041.73

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=38)
Day 60	n	65	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	382.71 (42.22)	781.43 (59.76)	290.53 (62.70)
	95% CI of Geometric Mean	346.16, 423.12	656.35, 930.33	240.43, 351.07
	Median	407.53	728.08	302.83
	Q25, Q75	287.80, 497.95	584.82, 1096.36	205.34, 415.83
	Min, Max	149.7, 1060.4	209.4, 2609.6	48.9, 912.5
	Mean (SD)	414.64 (173.063)	902.66 (508.548)	335.96 (181.818)
	95% CI of Mean	371.75, 457.53	742.13, 1063.18	276.19, 395.73

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=37)
Baseline	n	65	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	814.40 (51.61)	742.18 (58.03)	802.85 (52.01)
	95% CI of Geometric Mean	722.00, 918.61	626.12, 879.76	682.00, 945.10
	Median	819.08	753.40	818.27
	Q25, Q75	616.45, 1139.14	562.07, 1192.29	634.70, 1071.30
	Min, Max	250.6, 2317.9	272.6, 1954.5	249.6, 2022.8
	Mean (SD)	910.30 (435.487)	849.70 (441.946)	895.81 (419.595)
	95% CI of Mean	802.39, 1018.22	710.20, 989.20	755.91, 1035.72

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=37)
Day 90	n	65	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	437.56 (44.31)	755.26 (59.98)	312.67 (52.52)
	95% CI of Geometric Mean	393.98, 485.96	634.03, 899.68	265.22, 368.60
	Median	440.01	824.52	323.32
	Q25, Q75	354.43, 570.68	537.66, 1088.68	245.31, 431.53
	Min, Max	107.2, 1223.2	201.3, 2537.6	114.9, 952.6
	Mean (SD)	475.68 (200.488)	866.59 (454.761)	350.11 (170.646)
	95% CI of Mean	425.99, 525.36	723.04, 1010.13	293.21, 407.01

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1058.84 (115.52)		1096.79 (115.64)		1027.37 (123.71)	
	95% CI of Geometric Mean	857.94, 1306.79		823.05, 1461.57		751.76, 1404.03	
	Median	1274.20		1041.05		902.99	
	Q25, Q75	458.38, 2165.87		568.40, 2251.82		395.95, 2415.73	
	Min, Max	167.6, 6057.5		206.8, 6078.8		190.4, 5315.9	
	Mean (SD)	1532.81 (1280.008)		1610.43 (1405.371)		1555.74 (1369.913)	
	95% CI of Mean	1240.31, 1825.31		1172.48, 2048.38		1111.66, 1999.82	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	415.85 (112.05)		998.20 (119.69)		392.60 (127.59)	
	95% CI of Geometric Mean	338.40, 511.02		744.08, 1339.11		285.47, 539.93	
	Median	475.21	-61.48	852.83	-8.64	438.24	-60.17
	Q25, Q75	182.68, 905.69	-67.57, -50.94	458.59, 2338.40	-20.32, 5.23	152.95, 834.37	-68.71, -51.47
	Min, Max	85.5, 1929.6	-86.3, 5.9	191.4, 6271.2	-43.5, 36.0	78.8, 2127.0	-84.1, -36.1
	Mean (SD)	595.48 (472.802)	-58.31 (15.368)	1506.13 (1404.918)	-7.39 (17.447)	603.51 (546.177)	-60.17 (11.141)
	95% CI of Mean	487.43, 703.52	-61.83, -54.80	1068.32, 1943.94	-12.83, -1.95	426.46, 780.57	-63.78, -56.55

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	191.02 (80.08)		986.94 (115.74)		181.50 (88.35)	
	95% CI of Geometric Mean	162.63, 224.36		740.50, 1315.40		141.88, 232.17	
	Median	199.67	-83.08	912.34	-5.63	159.82	-82.69
	Q25, Q75	110.11, 320.43	-85.77, -74.58	421.95, 2203.39	-20.76, 7.13	93.50, 350.97	-87.65, -75.09
	Min, Max	22.9, 1151.6	-98.2, -55.1	237.4, 7352.9	-60.2, 41.9	44.7, 832.8	-92.6, -58.5
	Mean (SD)	242.34 (181.911)	-79.70 (9.675)	1481.46 (1462.241)	-7.27 (21.626)	239.34 (185.864)	-80.53 (9.044)
	95% CI of Mean	200.77, 283.92	-81.92, -77.49	1025.78, 1937.13	-14.02, -0.53	179.09, 299.60	-83.46, -77.59

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	143.55 (59.90)		994.67 (132.30)		108.40 (97.62)	
	95% CI of Geometric Mean	126.48, 162.91		727.03, 1360.83		83.15, 141.33	
	Median	149.34	-87.61	888.01	-5.15	113.53	-89.98
	Q25, Q75	96.04, 218.62	-90.53, -80.43	524.92, 2468.97	-27.59, 14.43	62.19, 194.69	-92.35, -84.70
	Min, Max	47.5, 538.3	-95.5, -40.5	158.0, 7116.2	-56.1, 54.4	17.1, 455.9	-97.3, -53.2
	Mean (SD)	167.14 (98.187)	-84.17 (9.905)	1579.75 (1602.965)	-5.46 (26.804)	144.75 (107.150)	-87.72 (7.860)
	95% CI of Mean	144.70, 189.58	-86.43, -81.90	1080.22, 2079.27	-13.82, 2.90	110.01, 179.48	-90.27, -85.17

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	122.57 (45.94)		1095.90 (122.17)		118.06 (67.55)	
	95% CI of Geometric Mean	110.90, 135.46		813.64, 1476.07		96.78, 144.02	
	Median	121.18	-89.45	1035.81	-2.09	105.74	-89.89
	Q25, Q75	85.95, 160.20	-92.88, -81.14	498.96, 2363.34	-18.29, 13.11	78.41, 202.97	-93.04, -78.49
	Min, Max	55.9, 359.2	-96.4, -46.0	151.5, 7710.4	-45.0, 247.8	18.3, 325.7	-95.5, -63.0
	Mean (SD)	135.38 (65.788)	-85.76 (10.105)	1699.39 (1745.384)	6.63 (47.495)	139.14 (76.808)	-86.28 (8.620)
	95% CI of Mean	120.34, 150.42	-88.07, -83.45	1155.49, 2243.30	-8.18, 21.43	114.24, 164.05	-89.08, -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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	118.36 (44.66)		1096.47 (129.25)		102.51 (62.05)	
	95% CI of Geometric Mean	107.37, 130.48		805.13, 1493.22		85.19, 123.34	
	Median	119.32	-89.85	1103.64	1.42	106.75	-90.78
	Q25, Q75	87.74, 152.75	-93.07, -82.35	503.79, 2354.23	-19.55, 18.10	74.07, 160.31	-93.85, -82.70
	Min, Max	51.5, 280.7	-97.5, -41.6	174.4, 7234.4	-47.8, 100.9	21.4, 279.9	-98.1, -45.0
	Mean (SD)	129.53 (56.858)	-85.88 (10.628)	1730.83 (1722.313)	5.44 (35.808)	117.57 (57.635)	-86.80 (10.811)
	95% CI of Mean	116.53, 142.53	-88.31, -83.45	1194.12, 2267.55	-5.72, 16.60	98.88, 136.26	-90.31, -83.29

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1066.20 (117.31)		1124.11 (115.15)		1027.37 (123.71)	
	95% CI of Geometric Mean	859.47, 1322.66		841.13, 1502.28		751.76, 1404.03	
	Median	1322.13		1091.90		902.99	
	Q25, Q75	446.29, 2190.48		584.82, 2251.82		395.95, 2415.73	
	Min, Max	167.6, 6057.5		206.8, 6078.8		190.4, 5315.9	
	Mean (SD)	1550.60 (1291.727)		1639.95 (1409.582)		1555.74 (1369.913)	
	95% CI of Mean	1251.32, 1849.87		1195.02, 2084.87		1111.66, 1999.82	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	115.39 (70.47)		1067.05 (132.92)		97.51 (76.46)	
	95% CI of Geometric Mean	99.60, 133.68		776.07, 1467.13		78.25, 121.50	
	Median	117.73	-89.98	1157.78	-2.80	94.44	-88.62
	Q25, Q75	85.67, 150.00	-94.54, -81.20	439.78, 2445.00	-36.29, 37.54	62.56, 137.43	-94.44, -81.40
	Min, Max	20.2, 1013.6	-98.4, -23.5	162.7, 6287.7	-63.6, 176.7	29.2, 516.7	-98.7, -66.8
	Mean (SD)	146.50 (149.768)	-84.93 (13.698)	1664.53 (1528.788)	6.60 (53.718)	124.98 (106.756)	-87.52 (8.667)
	95% CI of Mean	111.80, 181.21	-88.11, -81.75	1181.98, 2147.08	-10.36, 23.56	90.37, 159.59	-90.33, -84.70

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1099.73 (113.30)		1124.11 (115.15)		1041.88 (125.48)	
	95% CI of Geometric Mean	886.90, 1363.63		841.13, 1502.28		756.84, 1434.26	
	Median	1367.48		1091.90		1083.72	
	Q25, Q75	470.47, 2190.48		584.82, 2251.82		395.95, 2415.73	
	Min, Max	167.6, 6057.5		206.8, 6078.8		190.4, 5315.9	
	Mean (SD)	1575.51 (1296.984)		1639.95 (1409.582)		1580.81 (1379.207)	
	95% CI of Mean	1268.51, 1882.50		1195.02, 2084.87		1127.47, 2034.15	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	115.00 (88.10)		995.50 (115.48)		111.24 (93.93)	
	95% CI of Geometric Mean	96.11, 137.60		744.48, 1331.16		85.65, 144.48	
	Median	110.36	-90.34	910.26	-4.65	106.36	-89.75
	Q25, Q75	82.49, 150.45	-94.55, -81.09	541.95, 1779.92	-35.50, 41.10	66.86, 167.33	-95.48, -80.57
	Min, Max	16.8, 1489.3	-98.4, -36.5	200.0, 7724.9	-78.3, 113.3	23.6, 1223.0	-98.1, -6.7
	Mean (SD)	164.83 (226.118)	-85.50 (13.211)	1484.15 (1460.975)	-1.25 (44.903)	161.38 (203.309)	-82.67 (20.597)
	95% CI of Mean	111.31, 218.36	-88.63, -82.37	1023.01, 1945.30	-15.43, 12.93	94.55, 228.21	-89.44, -75.89

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1053.22 (119.13)		1124.11 (115.15)		1019.78 (126.33)	
	95% CI of Geometric Mean	841.76, 1317.80		841.13, 1502.28		736.34, 1412.32	
	Median	1319.54		1091.90		902.99	
	Q25, Q75	446.29, 2190.48		584.82, 2251.82		395.95, 2415.73	
	Min, Max	167.6, 6057.5		206.8, 6078.8		190.4, 5315.9	
	Mean (SD)	1545.97 (1310.615)		1639.95 (1409.582)		1561.29 (1392.904)	
	95% CI of Mean	1233.46, 1858.48		1195.02, 2084.87		1096.87, 2025.71	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	145.58 (87.23)		1157.25 (127.57)		144.07 (96.75)	
	95% CI of Geometric Mean	121.67, 174.18		848.59, 1578.17		109.87, 188.92	
	Median	128.33	-88.05	1102.30	2.76	146.89	-88.03
	Q25, Q75	91.86, 207.36	-91.68, -74.13	562.91, 2501.32	-24.24, 36.47	104.00, 178.95	-94.30, -67.38
	Min, Max	19.8, 1165.8	-97.5, -25.7	168.7, 8096.2	-54.5, 190.3	19.3, 1378.4	-98.6, 52.7
	Mean (SD)	198.74 (195.600)	-81.21 (15.516)	1838.55 (1934.326)	14.28 (57.385)	207.87 (249.305)	-75.57 (29.054)
	95% CI of Mean	152.09, 245.38	-84.91, -77.50	1228.00, 2449.11	-3.83, 32.40	124.75, 291.00	-85.26, -65.88

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1274.20 (126.02)	1300.70 (119.99)	1234.15 (115.88)
	95% CI of Geometric Mean	1019.69, 1592.25	969.09, 1745.78	915.10, 1664.44
	Median	1399.81	1081.45	1308.96
	Q25, Q75	592.69, 2935.40	633.18, 3162.11	546.00, 2794.62
	Min, Max	198.6, 6129.4	293.7, 6642.3	204.4, 5392.4
	Mean (SD)	1897.27 (1527.543)	1931.31 (1625.253)	1786.52 (1449.100)
	95% CI of Mean	1548.21, 2246.33	1424.84, 2437.78	1316.77, 2256.27

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	483.32 (119.21)	1196.96 (134.62)	429.26 (130.81)
	95% CI of Geometric Mean	389.87, 599.18	871.90, 1643.22	310.54, 593.35
	Median	626.04	1009.37	472.03
	Q25, Q75	214.24, 1031.39	510.00, 2858.24	169.34, 995.65
	Min, Max	82.1, 2549.6	225.8, 6977.4	65.8, 2741.5
	Mean (SD)	709.10 (578.736)	1910.12 (1808.673)	661.37 (599.289)
	95% CI of Mean	576.85, 841.35	1346.49, 2473.75	467.10, 855.64

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	226.16 (84.15)	1227.31 (128.21)	211.25 (80.61)
	95% CI of Geometric Mean	191.33, 267.32	902.63, 1668.78	167.95, 265.72
	Median	230.42	1098.89	206.75
	Q25, Q75	147.14, 415.46	603.09, 3114.71	129.00, 446.24
	Min, Max	18.9, 795.8	230.4, 9558.3	49.0, 683.3
	Mean (SD)	286.09 (189.592)	1932.16 (1925.747)	265.75 (175.470)
	95% CI of Mean	242.76, 329.42	1332.05, 2532.27	208.86, 322.63

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	174.23 (61.86)	1214.91 (146.54)	130.77 (97.15)
	95% CI of Geometric Mean	152.97, 198.43	870.22, 1696.12	100.39, 170.33
	Median	190.79	1239.64	134.63
	Q25, Q75	111.69, 264.32	504.95, 3070.00	67.94, 261.07
	Min, Max	52.9, 445.5	163.8, 8458.7	25.5, 431.3
	Mean (SD)	202.06 (105.540)	2013.79 (1999.123)	173.06 (118.772)
	95% CI of Mean	177.94, 226.18	1390.82, 2636.77	134.55, 211.57

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	149.64 (52.43)	1251.92 (133.17)	136.97 (66.11)
	95% CI of Geometric Mean	133.70, 167.48	913.88, 1715.00	112.68, 166.50
	Median	157.68	1428.20	130.01
	Q25, Q75	103.50, 209.37	584.35, 2530.22	98.38, 236.35
	Min, Max	50.7, 377.1	160.9, 13089.2	22.9, 350.7
	Mean (SD)	167.88 (79.561)	2051.99 (2385.913)	160.62 (87.582)
	95% CI of Mean	149.69, 186.06	1308.48, 2795.49	132.23, 189.02

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	138.39 (49.07)	1358.78 (136.77)	125.14 (62.07)
	95% CI of Geometric Mean	124.45, 153.89	986.68, 1871.21	104.00, 150.59
	Median	133.20	1413.67	129.60
	Q25, Q75	104.06, 196.38	610.20, 3031.60	93.19, 189.72
	Min, Max	44.2, 371.5	245.7, 9333.0	30.7, 298.0
	Mean (SD)	153.51 (70.867)	2205.46 (2219.201)	143.73 (70.273)
	95% CI of Mean	137.31, 169.71	1513.90, 2897.01	120.94, 166.51

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1276.34 (127.26)	1322.06 (121.10)	1234.15 (115.88)
	95% CI of Geometric Mean	1016.78, 1602.16	979.50, 1784.42	915.10, 1664.44
	Median	1399.81	1185.72	1308.96
	Q25, Q75	596.39, 2952.56	633.18, 3162.11	546.00, 2794.62
	Min, Max	198.6, 6129.4	293.7, 6642.3	204.4, 5392.4
	Mean (SD)	1907.67 (1539.412)	1962.14 (1632.959)	1786.52 (1449.100)
	95% CI of Mean	1551.01, 2264.33	1446.71, 2477.57	1316.77, 2256.27

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	136.50 (78.31)	1233.64 (151.07)	104.31 (83.32)
	95% CI of Geometric Mean	116.28, 160.22	874.47, 1740.33	82.43, 131.99
	Median	141.37	1473.08	120.11
	Q25, Q75	86.13, 197.10	567.15, 3267.20	72.60, 156.23
	Min, Max	21.7, 1322.5	133.8, 7871.5	15.6, 565.2
	Mean (SD)	180.97 (202.639)	2045.28 (1997.031)	131.87 (99.568)
	95% CI of Mean	134.01, 227.92	1414.93, 2675.63	99.59, 164.15

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1317.77 (122.55)	1322.06 (121.10)	1247.64 (117.73)
	95% CI of Geometric Mean	1050.51, 1653.03	979.50, 1784.42	918.26, 1695.15
	Median	1404.10	1185.72	1410.85
	Q25, Q75	610.30, 2952.56	633.18, 3162.11	546.00, 2794.62
	Min, Max	198.6, 6129.4	293.7, 6642.3	204.4, 5392.4
	Mean (SD)	1935.12 (1538.498)	1962.14 (1632.959)	1812.04 (1459.641)
	95% CI of Mean	1570.96, 2299.28	1446.71, 2477.57	1332.27, 2291.82

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	132.58 (91.74)	1135.95 (119.90)	126.37 (105.39)
	95% CI of Geometric Mean	110.19, 159.53	843.26, 1530.23	95.11, 167.90
	Median	128.90	1160.29	105.63
	Q25, Q75	91.34, 182.74	524.16, 2464.20	79.53, 178.85
	Min, Max	19.9, 1932.8	193.8, 6228.4	15.9, 1960.2
	Mean (SD)	194.12 (274.827)	1716.10 (1584.182)	199.32 (316.054)
	95% CI of Mean	129.07, 259.18	1216.06, 2216.13	95.43, 303.21

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1245.78 (129.68)	1322.06 (121.10)	1232.62 (119.60)
	95% CI of Geometric Mean	983.09, 1578.66	979.50, 1784.42	900.27, 1687.67
	Median	1391.42	1185.72	1308.96
	Q25, Q75	573.18, 2960.58	633.18, 3162.11	546.00, 2794.62
	Min, Max	198.6, 6129.4	293.7, 6642.3	204.4, 5392.4
	Mean (SD)	1888.04 (1565.342)	1962.14 (1632.959)	1808.24 (1479.583)
	95% CI of Mean	1514.79, 2261.29	1446.71, 2477.57	1314.92, 2301.56

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	164.29 (95.12)	1256.55 (128.06)	163.13 (83.74)
	95% CI of Geometric Mean	135.67, 198.95	920.70, 1714.90	127.93, 208.02
	Median	145.73	1331.25	140.45
	Q25, Q75	98.33, 238.27	583.74, 3147.76	115.88, 188.94
	Min, Max	21.4, 1554.8	254.3, 7091.4	30.5, 1482.0
	Mean (SD)	238.57 (274.113)	1991.65 (1966.781)	225.77 (263.843)
	95% CI of Mean	173.21, 303.93	1370.86, 2612.45	137.79, 313.74

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Baseline	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	1094.90 (97.80)	1013.64 (141.86)	1012.49 (122.73)	1233.67 (107.96)	729.42 (82.29)	1600.39 (147.58)
	95% CI of Geometric Mean	850.91, 1408.84	698.51, 1470.93	681.65, 1503.90	785.10, 1938.53	530.29, 1003.33	920.72, 2781.80
	Median	1276.79	1256.96	1091.90	952.57	763.78	2302.82
	Q25, Q75	629.71, 2141.26	416.97, 2562.14	545.34, 2217.09	701.37, 2798.26	391.79, 1357.14	889.02, 3546.67
	Min, Max	167.6, 4221.9	187.2, 6057.5	206.8, 6078.8	300.3, 4609.6	254.2, 3006.5	190.4, 5315.9
	Mean (SD)	1447.46 (991.057)	1644.03 (1590.085)	1508.89 (1356.967)	1759.75 (1503.087)	939.67 (729.687)	2353.00 (1600.322)
	95% CI of Mean	1142.45, 1752.46	1080.20, 2207.85	948.75, 2069.02	986.93, 2532.57	616.14, 1263.20	1530.18, 3175.81

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 1	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	420.17 (101.84)	410.28 (128.19)	932.18 (119.64)	1103.88 (123.58)	270.99 (100.74)	634.32 (125.08)
	95% CI of Geometric Mean	324.10, 544.72	289.24, 581.98	631.72, 1375.53	672.85, 1811.02	186.97, 392.75	385.14, 1044.71
	Median	513.27	368.10	821.19	881.38	266.94	791.44
	Q25, Q75	185.16, 817.31	171.75, 1014.37	458.59, 2124.14	541.98, 2416.67	123.09, 515.38	467.90, 1281.75
	Min, Max	89.1, 1929.6	85.5, 1646.1	191.4, 5500.7	247.5, 6271.2	78.8, 1542.7	79.9, 2127.0
	Mean (SD)	572.02 (428.386)	626.05 (530.433)	1384.88 (1253.937)	1684.43 (1625.596)	382.25 (355.818)	889.85 (622.806)
	95% CI of Mean	440.17, 703.86	437.96, 814.14	867.28, 1902.49	848.62, 2520.24	224.48, 540.02	569.62, 1210.07

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 1							
	n	43	33	25	17	22	17
	Median	-63.58	-60.43	-7.49	-13.15	-61.68	-59.99
	Q25, Q75	-68.64, -50.89	-66.69, -50.99	-19.99, 3.72	-21.08, 5.23	-68.71, -53.11	-67.40, -47.53
	Min, Max	-78.1, -12.8	-86.3, 5.9	-43.5, 21.4	-36.5, 36.0	-84.1, -36.1	-72.6, -44.3
	Mean (SD)	-59.65 (13.615)	-56.58 (17.456)	-6.49 (16.395)	-8.72 (19.330)	-60.93 (12.005)	-59.18 (10.187)
	95% CI of Mean	-63.84, -55.45	-62.77, -50.38	-13.26, 0.29	-18.66, 1.22	-66.25, -55.60	-64.42, -53.94

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 2	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	188.60 (61.44)	194.21 (104.73)	981.77 (113.76)	994.60 (124.11)	137.70 (63.02)	259.47 (99.75)
	95% CI of Geometric Mean	158.45, 224.49	143.14, 263.51	673.99, 1430.10	605.41, 1633.97	106.56, 177.95	169.24, 397.79
	Median	215.15	173.85	921.88	902.81	130.06	350.97
	Q25, Q75	110.38, 301.62	106.45, 372.21	460.36, 2128.57	421.95, 2248.59	91.36, 220.15	159.82, 449.02
	Min, Max	66.9, 540.0	22.9, 1151.6	237.4, 7352.9	247.5, 5503.4	44.7, 457.9	57.1, 832.8
	Mean (SD)	219.34 (120.561)	272.32 (238.419)	1458.79 (1502.007)	1514.78 (1446.716)	162.20 (101.421)	339.17 (223.101)
	95% CI of Mean	182.23, 256.45	187.77, 356.86	838.79, 2078.80	770.94, 2258.62	117.23, 207.18	224.46, 453.89

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 2							
	n	43	33	25	17	22	17
	Median	-83.87	-80.48	0.00	-9.17	-80.64	-83.27
	Q25, Q75	-86.97, -76.64	-85.36, -70.00	-15.58, 10.41	-39.62, -1.83	-87.32, -75.07	-87.79, -81.69
	Min, Max	-94.4, -57.7	-98.2, -55.1	-31.3, 41.9	-60.2, 19.4	-92.6, -59.3	-91.4, -58.5
	Mean (SD)	-81.16 (8.381)	-77.80 (10.983)	-1.29 (19.024)	-16.07 (22.746)	-79.20 (9.222)	-82.25 (8.779)
	95% CI of Mean	-83.74, -78.57	-81.70, -73.90	-9.15, 6.57	-27.77, -4.37	-83.29, -75.10	-86.77, -77.73

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 3	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	135.48 (46.31)	154.78 (75.73)	980.35 (127.60)	1016.11 (146.08)	85.18 (83.60)	148.10 (101.75)
	95% CI of Geometric Mean	118.29, 155.17	121.91, 196.52	653.37, 1470.95	586.52, 1760.33	61.68, 117.63	96.01, 228.46
	Median	148.67	150.87	912.10	863.92	86.40	181.16
	Q25, Q75	95.54, 181.34	96.55, 252.56	550.39, 1966.53	524.92, 2738.69	60.92, 143.56	66.45, 253.21
	Min, Max	51.5, 285.5	47.5, 538.3	181.7, 6773.7	158.0, 7116.2	17.1, 279.9	29.1, 455.9
	Mean (SD)	148.07 (60.779)	191.99 (128.925)	1508.80 (1498.515)	1684.08 (1787.899)	106.09 (67.673)	194.77 (128.622)
	95% CI of Mean	129.36, 166.78	146.27, 237.71	890.24, 2127.36	764.82, 2603.34	76.08, 136.10	128.63, 260.90

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 3							
	n	43	33	25	17	22	17
	Median	-88.23	-83.74	0.93	-25.42	-88.74	-90.98
	Q25, Q75	-90.82, -81.83	-89.74, -79.66	-20.91, 11.43	-34.85, 18.35	-92.13, -83.68	-93.07, -85.92
	Min, Max	-95.5, -56.9	-93.6, -40.5	-34.1, 52.5	-56.1, 54.4	-95.4, -53.2	-97.3, -76.4
	Mean (SD)	-85.67 (8.556)	-82.21 (11.265)	-0.79 (22.162)	-12.33 (31.938)	-86.39 (9.128)	-89.44 (5.640)
	95% CI of Mean	-88.31, -83.03	-86.21, -78.21	-9.94, 8.36	-28.76, 4.09	-90.44, -82.34	-92.34, -86.53

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 4	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	115.32 (36.02)	132.70 (56.52)	1052.96 (125.74)	1162.25 (122.04)	91.21 (59.59)	164.87 (57.28)
	95% CI of Geometric Mean	103.56, 128.41	110.09, 159.94	704.45, 1573.87	711.31, 1899.06	71.43, 116.46	125.36, 216.81
	Median	120.86	123.78	1075.38	996.24	89.87	187.50
	Q25, Q75	84.44, 142.55	90.45, 208.80	450.00, 2000.00	500.00, 3031.58	77.96, 105.83	136.84, 253.65
	Min, Max	63.4, 236.2	55.9, 359.2	151.5, 7710.4	245.4, 6850.6	18.3, 223.3	54.0, 325.7
	Mean (SD)	122.52 (44.524)	152.13 (83.848)	1645.30 (1771.768)	1778.94 (1756.781)	103.70 (51.849)	185.01 (80.745)
	95% CI of Mean	108.81, 136.23	122.40, 181.87	913.95, 2376.65	875.68, 2682.19	80.71, 126.69	143.49, 226.53

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 4							
	n	43	33	25	17	22	17
	Median	-89.66	-87.23	-1.02	-10.38	-89.40	-92.00
	Q25, Q75	-93.11, -83.86	-91.35, -80.86	-18.83, 28.61	-17.85, 8.34	-91.76, -77.99	-93.12, -84.52
	Min, Max	-96.3, -57.4	-96.4, -46.0	-45.0, 247.8	-41.5, 48.6	-94.5, -69.1	-95.5, -63.0
	Mean (SD)	-87.21 (8.766)	-83.87 (11.488)	13.45 (58.153)	-3.40 (22.980)	-85.42 (8.292)	-87.40 (9.158)
	95% CI of Mean	-89.91, -84.51	-87.95, -79.79	-10.56, 37.46	-15.22, 8.42	-89.10, -81.74	-92.11, -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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 5	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	108.30 (36.77)	132.88 (51.52)	1085.84 (126.61)	1112.29 (139.63)	86.84 (63.32)	127.06 (52.58)
	95% CI of Geometric Mean	97.06, 120.85	111.87, 157.83	725.15, 1625.94	651.61, 1898.64	67.12, 112.34	98.55, 163.80
	Median	116.15	121.14	1181.82	951.18	96.72	134.62
	Q25, Q75	81.59, 135.16	89.31, 207.58	503.79, 2194.57	510.17, 2836.19	63.09, 133.85	104.75, 176.71
	Min, Max	51.5, 229.7	53.9, 280.7	174.4, 6447.0	191.5, 7234.4	21.4, 187.8	44.3, 279.9
	Mean (SD)	114.99 (39.845)	148.47 (69.564)	1669.10 (1619.102)	1821.62 (1911.637)	99.47 (47.235)	141.00 (62.667)
	95% CI of Mean	102.72, 127.26	123.80, 173.14	1000.76, 2337.44	838.74, 2804.50	78.52, 120.41	108.77, 173.22

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 5							
	n	43	33	25	17	22	17
	Median	-91.21	-88.45	3.35	-10.83	-88.30	-93.24
	Q25, Q75	-93.75, -83.09	-92.09, -79.18	-12.19, 18.10	-26.32, 15.03	-92.50, -81.60	-95.23, -84.86
	Min, Max	-97.5, -41.6	-96.2, -59.8	-37.2, 100.9	-47.8, 56.9	-96.8, -68.1	-98.1, -45.0
	Mean (SD)	-87.42 (10.463)	-83.87 (10.663)	12.81 (37.896)	-5.40 (30.361)	-85.84 (8.488)	-88.03 (13.423)
	95% CI of Mean	-90.64, -84.19	-87.66, -80.09	-2.84, 28.46	-21.02, 10.21	-89.61, -82.07	-94.94, -81.13

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Baseline	n	42	32	24	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	1092.94 (99.42)	1032.10 (144.46)	1052.44 (122.82)	1233.67 (107.96)	729.42 (82.29)	1600.39 (147.58)
	95% CI of Geometric Mean	844.10, 1415.12	703.85, 1513.42	702.00, 1577.82	785.10, 1938.53	530.29, 1003.33	920.72, 2781.80
	Median	1334.30	1312.22	1128.25	952.57	763.78	2302.82
	Q25, Q75	629.71, 2141.26	399.36, 2577.37	556.87, 2234.45	701.37, 2798.26	391.79, 1357.14	889.02, 3546.67
	Min, Max	167.6, 4221.9	187.2, 6057.5	206.8, 6078.8	300.3, 4609.6	254.2, 3006.5	190.4, 5315.9
	Mean (SD)	1453.81 (1002.183)	1677.63 (1603.583)	1555.09 (1365.917)	1759.75 (1503.087)	939.67 (729.687)	2353.00 (1600.322)
	95% CI of Mean	1141.51, 1766.12	1099.47, 2255.78	978.31, 2131.87	986.93, 2532.57	616.14, 1263.20	1530.18, 3175.81

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Day 30	n	42	32	24	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	125.92 (71.37)	102.89 (68.11)	1084.92 (124.54)	1042.33 (151.99)	84.18 (59.08)	117.93 (93.91)
	95% CI of Geometric Mean	103.09, 153.79	82.36, 128.54	720.99, 1632.53	593.89, 1829.35	66.04, 107.30	78.36, 177.50
	Median	116.03	118.76	1239.49	1032.26	87.08	128.52
	Q25, Q75	86.86, 153.42	69.79, 147.56	435.91, 2411.07	439.78, 2890.76	58.39, 108.54	68.13, 171.82
	Min, Max	23.3, 1013.6	20.2, 583.7	162.7, 5756.3	171.2, 6287.7	31.3, 387.6	29.2, 516.7
	Mean (SD)	163.39 (179.660)	124.34 (96.110)	1610.57 (1385.929)	1740.71 (1752.512)	99.53 (75.272)	157.92 (132.618)
	95% CI of Mean	107.40, 219.38	89.69, 159.00	1025.34, 2195.80	839.65, 2641.78	66.15, 132.91	89.73, 226.11

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 30							
	n	42	32	24	17	22	17
	Median	-88.76	-90.41	1.37	-29.71	-87.28	-93.41
	Q25, Q75	-94.54, -78.57	-94.63, -83.85	-10.30, 42.79	-40.81, 36.41	-93.59, -79.13	-96.77, -83.97
	Min, Max	-96.8, -52.7	-98.4, -23.5	-63.6, 122.9	-58.9, 176.7	-96.9, -66.8	-98.7, -72.2
	Mean (SD)	-84.95 (11.132)	-84.91 (16.673)	12.50 (47.725)	-1.73 (61.758)	-85.86 (8.855)	-89.66 (8.174)
	95% CI of Mean	-88.42, -81.47	-90.93, -78.89	-7.66, 32.65	-33.49, 30.03	-89.79, -81.93	-93.87, -85.46

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Baseline	n	41	30	24	17	21	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	1070.98 (99.63)	1140.26 (135.24)	1052.44 (122.82)	1233.67 (107.96)	736.06 (84.73)	1600.39 (147.58)
	95% CI of Geometric Mean	824.07, 1391.88	779.17, 1668.70	702.00, 1577.82	785.10, 1938.53	526.62, 1028.78	920.72, 2781.80
	Median	1271.60	1385.40	1128.25	952.57	770.27	2302.82
	Q25, Q75	629.71, 2073.34	441.88, 2592.59	556.87, 2234.45	701.37, 2798.26	391.79, 1357.14	889.02, 3546.67
	Min, Max	167.6, 4221.9	187.2, 6057.5	206.8, 6078.8	300.3, 4609.6	254.2, 3006.5	190.4, 5315.9
	Mean (SD)	1430.29 (1005.561)	1773.97 (1610.947)	1555.09 (1365.917)	1759.75 (1503.087)	955.70 (743.729)	2353.00 (1600.322)
	95% CI of Mean	1112.89, 1747.69	1172.43, 2375.51	978.31, 2131.87	986.93, 2532.57	617.15, 1294.25	1530.18, 3175.81

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Day 60	n	41	30	24	17	21	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	110.70 (106.84)	121.15 (62.67)	936.10 (108.38)	1085.84 (129.86)	104.28 (104.08)	120.49 (83.89)
	95% CI of Geometric Mean	84.04, 145.81	97.71, 150.19	645.19, 1358.16	651.32, 1810.22	70.60, 154.02	82.78, 175.36
	Median	100.87	120.64	907.41	989.65	97.40	130.90
	Q25, Q75	74.87, 148.38	85.47, 152.83	487.87, 1685.49	566.87, 1991.53	65.36, 131.78	76.94, 171.39
	Min, Max	16.8, 1489.3	19.4, 656.5	200.0, 3821.7	217.7, 7724.9	33.0, 1223.0	23.6, 370.1
	Mean (SD)	180.23 (282.821)	143.78 (110.876)	1300.68 (1003.997)	1743.17 (1940.446)	169.71 (260.600)	151.09 (102.431)
	95% CI of Mean	90.96, 269.51	102.38, 185.19	876.73, 1724.64	745.48, 2740.86	51.08, 288.34	98.42, 203.76

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
% Change from baseline to Day 60							
	n	41	30	24	17	21	17
	Median	-90.35	-89.78	-10.36	-2.57	-86.23	-92.51
	Q25, Q75	-93.66, -83.22	-94.55, -81.09	-33.88, 19.92	-47.97, 44.05	-93.45, -65.19	-96.10, -84.97
	Min, Max	-96.8, -44.8	-98.4, -36.5	-78.3, 113.3	-57.1, 67.6	-97.1, -6.7	-98.1, -79.8
	Mean (SD)	-86.46 (11.610)	-84.20 (15.242)	-1.35 (44.487)	-1.11 (46.858)	-76.52 (25.690)	-90.26 (6.724)
	95% CI of Mean	-90.12, -82.79	-89.90, -78.50	-20.14, 17.44	-25.20, 22.99	-88.22, -64.82	-93.72, -86.80

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Baseline	n	39	31	24	17	21	16
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	1098.98 (101.61)	998.35 (144.57)	1052.44 (122.82)	1233.67 (107.96)	736.06 (84.73)	1564.41 (154.94)
	95% CI of Geometric Mean	836.43, 1443.94	676.21, 1473.96	702.00, 1577.82	785.10, 1938.53	526.62, 1028.78	867.62, 2820.77
	Median	1391.82	1256.96	1128.25	952.57	770.27	2321.79
	Q25, Q75	629.71, 2190.48	381.74, 2562.14	556.87, 2234.45	701.37, 2798.26	391.79, 1357.14	642.49, 3561.21
	Min, Max	167.6, 4221.9	187.2, 6057.5	206.8, 6078.8	300.3, 4609.6	254.2, 3006.5	190.4, 5315.9
	Mean (SD)	1472.48 (1024.119)	1638.42 (1614.428)	1555.09 (1365.917)	1759.75 (1503.087)	955.70 (743.729)	2356.13 (1652.752)
	95% CI of Mean	1140.50, 1804.47	1046.24, 2230.61	978.31, 2131.87	986.93, 2532.57	617.15, 1294.25	1475.44, 3236.83

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Day 90	n	39	31	24	17	21	16
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	134.55 (108.42)	160.74 (59.00)	974.37 (121.26)	1475.33 (131.90)	110.97 (110.32)	202.93 (59.54)
	95% CI of Geometric Mean	101.10, 179.07	131.54, 196.43	652.11, 1455.87	880.48, 2472.06	73.93, 166.58	151.31, 272.15
	Median	118.76	147.86	1078.51	1102.30	104.35	177.40
	Q25, Q75	76.18, 171.66	116.03, 215.50	541.99, 2063.62	605.26, 3472.75	72.32, 146.89	158.36, 205.00
	Min, Max	19.8, 1165.8	63.4, 633.9	168.7, 5269.2	445.7, 8096.2	19.3, 1378.4	106.4, 805.6
	Mean (SD)	206.33 (237.024)	189.19 (129.094)	1449.59 (1334.221)	2387.68 (2499.550)	181.48 (288.682)	242.51 (189.197)
	95% CI of Mean	129.49, 283.17	141.83, 236.55	886.19, 2012.98	1102.52, 3672.83	50.07, 312.89	141.69, 343.33

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
% Change from baseline to Day 90							
	n	39	31	24	17	21	16
	Median	-88.89	-82.29	-7.41	12.56	-81.82	-91.03
	Q25, Q75	-91.28, -78.40	-92.00, -63.90	-36.32, 23.70	-11.44, 39.56	-92.47, -67.38	-94.82, -62.80
	Min, Max	-97.5, -56.0	-97.5, -25.7	-54.5, 190.3	-29.4, 189.0	-98.6, 52.7	-96.4, -19.2
	Mean (SD)	-84.84 (10.304)	-76.64 (19.508)	4.36 (58.122)	28.29 (54.960)	-73.70 (33.267)	-78.03 (23.217)
	95% CI of Mean	-88.18, -81.49	-83.80, -69.48	-20.19, 28.91	0.03, 56.55	-88.85, -58.55	-90.40, -65.65

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Baseline	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	753.53 (110.69)	1515.48 (97.13)	929.52 (95.77)	1340.03 (137.44)	930.37 (127.24)	1140.44 (122.98)
	95% CI of Geometric Mean	563.89, 1006.95	1154.83, 1988.75	655.76, 1317.57	815.67, 2201.47	587.78, 1472.61	718.06, 1811.27
	Median	700.60	1689.54	929.89	2139.13	1032.74	902.99
	Q25, Q75	360.76, 1551.93	1180.48, 2660.19	584.82, 2002.01	545.34, 3053.85	344.13, 2321.79	396.77, 2415.73
	Min, Max	167.6, 4581.3	196.7, 6057.5	206.8, 3880.1	215.0, 6078.8	190.4, 3546.7	310.9, 5315.9
	Mean (SD)	1112.73 (1050.296)	1975.60 (1362.456)	1252.49 (1006.590)	2043.72 (1702.496)	1384.31 (1123.651)	1736.19 (1600.651)
	95% CI of Mean	772.26, 1453.20	1521.33, 2429.87	817.20, 1687.77	1223.14, 2864.30	858.42, 1910.20	964.69, 2507.68

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 1	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	309.41 (108.38)	567.91 (98.68)	831.11 (97.05)	1246.02 (143.58)	343.39 (121.07)	452.04 (135.90)
	95% CI of Geometric Mean	232.52, 411.74	431.39, 747.62	584.34, 1182.09	748.35, 2074.62	220.14, 535.65	276.10, 740.08
	Median	261.32	681.59	808.82	1698.41	369.69	467.90
	Q25, Q75	145.63, 549.12	352.62, 1054.19	451.47, 1601.85	458.59, 3040.54	150.85, 775.79	185.27, 1281.75
	Min, Max	85.5, 1486.4	103.0, 1929.6	191.4, 3091.8	219.8, 6271.2	78.8, 1910.8	95.9, 2127.0
	Mean (SD)	451.73 (408.340)	747.00 (493.685)	1125.84 (891.369)	1966.48 (1765.295)	508.70 (455.225)	703.31 (624.915)
	95% CI of Mean	319.36, 584.10	582.39, 911.61	740.38, 1511.30	1115.63, 2817.33	295.64, 721.75	402.11, 1004.52

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 1							
	n	39	37	23	19	20	19
	Median	-59.63	-62.82	-10.42	-7.76	-62.76	-59.99
	Q25, Q75	-66.84, -48.46	-69.96, -54.30	-25.87, 6.87	-20.30, 0.04	-69.28, -53.77	-67.66, -47.53
	Min, Max	-86.3, 5.9	-76.8, -31.4	-43.5, 19.1	-27.0, 36.0	-78.7, -44.5	-84.1, -36.1
	Mean (SD)	-55.87 (17.869)	-60.89 (11.902)	-8.72 (18.614)	-5.78 (16.274)	-61.72 (10.393)	-58.53 (11.936)
	95% CI of Mean	-61.67, -50.07	-64.87, -56.92	-16.77, -0.67	-13.63, 2.07	-66.59, -56.86	-64.28, -52.77

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 2	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	156.75 (68.15)	235.28 (84.88)	806.17 (91.25)	1260.83 (139.44)	170.40 (80.45)	193.96 (98.88)
	95% CI of Geometric Mean	128.31, 191.50	184.04, 300.78	575.78, 1128.75	764.07, 2080.55	122.42, 237.18	130.27, 288.78
	Median	133.75	270.23	815.23	1680.20	167.79	159.82
	Q25, Q75	98.45, 223.91	157.14, 372.21	413.66, 1376.07	460.36, 2496.47	92.43, 314.05	110.20, 436.72
	Min, Max	58.6, 636.9	22.9, 1151.6	240.9, 3153.2	237.4, 7352.9	57.1, 525.3	44.7, 832.8
	Mean (SD)	191.54 (136.886)	295.90 (208.369)	1069.44 (831.370)	1980.21 (1883.073)	213.97 (144.429)	266.05 (222.357)
	95% CI of Mean	147.16, 235.91	226.42, 365.38	709.92, 1428.95	1072.60, 2887.83	146.37, 281.57	158.88, 373.23

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 2							
	n	39	37	23	19	20	19
	Median	-79.51	-84.46	-10.72	-1.83	-82.98	-82.33
	Q25, Q75	-84.91, -69.44	-87.76, -79.17	-28.47, 3.41	-15.58, 10.41	-87.52, -74.46	-87.79, -75.62
	Min, Max	-94.4, -55.9	-98.2, -55.1	-60.2, 41.9	-46.5, 21.0	-91.4, -58.5	-92.6, -59.3
	Mean (SD)	-77.18 (9.786)	-82.36 (8.932)	-10.09 (23.673)	-3.87 (18.921)	-79.48 (10.217)	-81.62 (7.748)
	95% CI of Mean	-80.36, -74.00	-85.34, -79.38	-20.33, 0.16	-12.99, 5.26	-84.27, -74.70	-85.36, -77.88

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 3	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	124.80 (60.40)	166.36 (55.32)	818.60 (110.90)	1259.21 (154.20)	96.68 (97.38)	122.28 (98.59)
	95% CI of Geometric Mean	104.16, 149.53	140.03, 197.64	555.77, 1205.72	739.88, 2143.05	65.97, 141.70	82.19, 181.91
	Median	116.41	165.88	807.57	1638.89	105.49	113.53
	Q25, Q75	83.39, 176.35	120.87, 246.51	414.15, 1904.76	550.39, 2738.69	59.65, 193.51	69.83, 224.37
	Min, Max	51.5, 538.3	47.5, 465.6	158.0, 4300.0	181.7, 7116.2	17.1, 287.3	24.5, 455.9
	Mean (SD)	146.89 (96.580)	188.48 (96.574)	1177.65 (1044.218)	2066.50 (2015.776)	125.68 (81.440)	164.82 (128.093)
	95% CI of Mean	115.58, 178.20	156.28, 220.68	726.09, 1629.21	1094.92, 3038.08	87.56, 163.80	103.07, 226.56

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 3							
	n	39	37	23	19	20	19
	Median	-83.74	-89.58	-7.89	0.00	-89.90	-89.98
	Q25, Q75	-88.25, -76.27	-91.91, -83.57	-30.66, 19.07	-23.39, 11.43	-93.41, -84.19	-92.13, -85.26
	Min, Max	-95.5, -40.5	-95.3, -68.3	-56.1, 52.5	-35.2, 54.4	-95.4, -76.0	-97.3, -53.2
	Mean (SD)	-80.69 (11.618)	-87.83 (5.925)	-7.21 (29.534)	-3.34 (23.700)	-88.29 (5.882)	-87.12 (9.653)
	95% CI of Mean	-84.46, -76.92	-89.81, -85.85	-19.99, 5.56	-14.77, 8.09	-91.04, -85.53	-91.78, -82.47

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 4	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	106.79 (45.81)	141.72 (41.04)	886.92 (85.23)	1415.80 (161.87)	112.13 (76.69)	124.64 (59.06)
	95% CI of Geometric Mean	92.70, 123.02	124.25, 161.65	644.34, 1220.83	819.55, 2445.84	81.56, 154.16	95.75, 162.24
	Median	96.96	137.54	956.86	1764.71	104.98	105.74
	Q25, Q75	77.54, 136.48	114.04, 192.98	498.96, 1268.13	436.27, 3241.85	76.68, 195.24	78.41, 223.30
	Min, Max	59.1, 359.2	55.9, 348.3	245.4, 3629.5	151.5, 7710.4	18.3, 278.5	50.3, 325.7
	Mean (SD)	118.85 (66.264)	152.80 (61.435)	1151.94 (910.135)	2362.10 (2253.882)	134.64 (74.312)	143.89 (81.110)
	95% CI of Mean	97.37, 140.34	132.31, 173.29	758.36, 1545.51	1275.76, 3448.44	99.85, 169.42	104.79, 182.99

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 4							
	n	39	37	23	19	20	19
	Median	-86.26	-91.15	-2.68	-0.23	-89.87	-90.18
	Q25, Q75	-90.81, -77.78	-93.73, -85.30	-18.83, 11.56	-17.50, 28.61	-93.04, -78.24	-92.91, -81.67
	Min, Max	-96.2, -46.0	-96.4, -54.0	-43.7, 66.2	-45.0, 247.8	-95.2, -63.0	-95.5, -72.2
	Mean (SD)	-82.99 (10.975)	-88.69 (8.273)	-0.33 (30.734)	15.06 (62.022)	-85.31 (9.682)	-87.30 (7.467)
	95% CI of Mean	-86.55, -79.42	-91.45, -85.92	-13.63, 12.96	-14.84, 44.95	-89.85, -80.77	-90.91, -83.70

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 1**

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 5	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	106.43 (45.63)	132.39 (40.82)	951.41 (109.29)	1301.96 (154.49)	92.85 (66.37)	113.76 (56.84)
	95% CI of Geometric Mean	92.43, 122.54	116.15, 150.90	648.45, 1395.92	764.55, 2217.10	69.98, 123.20	88.15, 146.80
	Median	97.90	128.38	1048.08	1452.70	106.97	106.75
	Q25, Q75	76.76, 125.76	111.60, 177.68	503.79, 1528.42	438.72, 3054.02	72.87, 142.74	89.66, 180.14
	Min, Max	51.5, 272.0	57.5, 280.7	191.5, 6447.0	174.4, 7234.4	21.4, 187.8	44.3, 279.9
	Mean (SD)	117.37 (57.189)	142.34 (54.350)	1403.25 (1441.682)	2127.38 (1978.202)	106.59 (47.993)	129.13 (65.623)
	95% CI of Mean	98.83, 135.91	124.22, 160.47	779.82, 2026.69	1173.91, 3080.85	84.12, 129.05	97.50, 160.76

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 1

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 5							
	n	39	37	23	19	20	19
	Median	-85.03	-91.96	3.35	0.00	-92.17	-90.00
	Q25, Q75	-92.20, -77.38	-93.75, -89.04	-17.25, 31.80	-23.49, 17.90	-94.66, -82.85	-93.24, -82.70
	Min, Max	-97.0, -41.6	-97.5, -59.8	-47.8, 100.9	-36.7, 79.7	-96.9, -45.0	-98.1, -68.1
	Mean (SD)	-82.63 (11.597)	-89.30 (8.360)	9.29 (40.495)	0.78 (29.571)	-86.19 (12.917)	-87.44 (8.354)
	95% CI of Mean	-86.39, -78.87	-92.10, -86.51	-8.23, 26.81	-13.48, 15.03	-92.24, -80.14	-91.47, -83.41

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Baseline	n	38	36	23	18	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	759.12 (112.65)	1526.03 (98.85)	929.52 (95.77)	1433.13 (134.47)	930.37 (127.24)	1140.44 (122.98)
	95% CI of Geometric Mean	563.77, 1022.16	1154.12, 2017.79	655.76, 1317.57	864.63, 2375.39	587.78, 1472.61	718.06, 1811.27
	Median	708.06	1809.31	929.89	2178.11	1032.74	902.99
	Q25, Q75	360.76, 1551.93	1125.58, 2720.39	584.82, 2002.01	568.40, 3053.85	344.13, 2321.79	396.77, 2415.73
	Min, Max	167.6, 4581.3	196.7, 6057.5	206.8, 3880.1	215.0, 6078.8	190.4, 3546.7	310.9, 5315.9
	Mean (SD)	1127.04 (1060.534)	1997.69 (1375.048)	1252.49 (1006.590)	2135.04 (1703.301)	1384.31 (1123.651)	1736.19 (1600.651)
	95% CI of Mean	778.45, 1475.63	1532.43, 2462.94	817.20, 1687.77	1288.00, 2982.08	858.42, 1910.20	964.69, 2507.68

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 30	n	38	36	23	18	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	103.51 (56.38)	129.41 (82.88)	840.49 (115.24)	1447.53 (144.28)	88.59 (61.74)	107.87 (91.68)
	95% CI of Geometric Mean	87.09, 123.02	101.32, 165.28	564.81, 1250.74	854.10, 2453.25	67.90, 115.59	74.03, 157.18
	Median	110.99	119.11	1032.26	1881.82	89.47	108.54
	Q25, Q75	71.10, 149.63	93.47, 157.59	415.89, 1800.64	520.97, 2942.64	57.77, 120.75	64.88, 171.82
	Min, Max	23.3, 294.4	20.2, 1013.6	162.7, 3502.5	267.9, 6287.7	34.5, 387.6	29.2, 516.7
	Mean (SD)	117.25 (58.700)	177.39 (203.053)	1206.74 (980.578)	2249.49 (1899.761)	105.08 (76.648)	145.93 (130.212)
	95% CI of Mean	97.95, 136.55	108.68, 246.10	782.70, 1630.78	1304.75, 3194.22	69.20, 140.95	83.17, 208.70

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 2

		THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 30							
	n	38	36	23	18	20	19
	Median	-85.31	-91.81	-2.80	-2.61	-91.14	-87.86
	Q25, Q75	-92.89, -72.04	-94.62, -88.40	-44.46, 47.18	-24.88, 36.41	-94.46, -80.06	-94.44, -82.79
	Min, Max	-96.8, -23.5	-98.4, -52.7	-63.6, 176.7	-37.0, 81.8	-97.4, -66.8	-98.7, -71.3
	Mean (SD)	-80.95 (16.173)	-89.13 (8.915)	6.72 (64.989)	6.45 (36.384)	-87.52 (9.117)	-87.51 (8.417)
	95% CI of Mean	-86.27, -75.63	-92.15, -86.11	-21.39, 34.83	-11.65, 24.54	-91.79, -83.25	-91.57, -83.45

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Baseline	n	36	35	23	18	20	18
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	771.37 (113.10)	1583.83 (88.86)	929.52 (95.77)	1433.13 (134.47)	930.37 (127.24)	1181.52 (125.95)
	95% CI of Geometric Mean	567.40, 1048.65	1218.72, 2058.31	655.76, 1317.57	864.63, 2375.39	587.78, 1472.61	727.63, 1918.53
	Median	708.06	1689.54	929.89	2178.11	1032.74	1130.06
	Q25, Q75	362.80, 1559.10	1180.48, 2780.59	584.82, 2002.01	568.40, 3053.85	344.13, 2321.79	396.77, 2415.73
	Min, Max	167.6, 4581.3	196.7, 6057.5	206.8, 3880.1	215.0, 6078.8	190.4, 3546.7	310.9, 5315.9
	Mean (SD)	1147.14 (1079.886)	2016.11 (1367.004)	1252.49 (1006.590)	2135.04 (1703.301)	1384.31 (1123.651)	1799.13 (1622.678)
	95% CI of Mean	781.76, 1512.53	1546.53, 2485.70	817.20, 1687.77	1288.00, 2982.08	858.42, 1910.20	992.19, 2606.08

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Day 60	n	36	35	23	18	20	18
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	90.13 (82.22)	147.76 (82.94)	787.29 (93.98)	1343.56 (131.62)	108.44 (99.92)	114.44 (90.78)
	95% CI of Geometric Mean	70.67, 114.94	115.24, 189.45	558.11, 1110.56	816.08, 2211.98	73.46, 160.08	77.82, 168.27
	Median	95.45	137.70	857.76	1462.71	108.16	104.20
	Q25, Q75	73.48, 124.53	90.09, 164.67	367.25, 1662.84	617.28, 3025.11	66.11, 149.77	70.33, 171.39
	Min, Max	16.8, 656.5	55.3, 1489.3	200.0, 2664.5	231.5, 7724.9	23.6, 1223.0	33.0, 413.9
	Mean (SD)	115.15 (105.201)	215.93 (297.610)	1038.80 (746.825)	2053.22 (1920.731)	169.66 (258.637)	152.19 (122.598)
	95% CI of Mean	79.55, 150.75	113.69, 318.17	715.84, 1361.75	1098.06, 3008.38	48.61, 290.71	91.22, 213.16

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 3

		THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Timepoint	Statistic						
% Change from baseline to Day 60							
	n	36	35	23	18	20	18
	Median	-89.09	-91.40	-21.71	7.49	-89.49	-89.85
	Q25, Q75	-94.28, -80.98	-95.02, -83.61	-42.87, 53.41	-35.20, 23.27	-94.08, -80.32	-96.23, -80.57
	Min, Max	-96.8, -36.5	-98.4, -44.8	-78.3, 113.3	-51.9, 67.6	-96.6, -13.5	-98.1, -6.7
	Mean (SD)	-84.35 (13.414)	-86.69 (13.086)	-2.54 (51.308)	0.40 (36.500)	-82.61 (19.386)	-82.73 (22.435)
	95% CI of Mean	-88.89, -79.80	-91.19, -82.19	-24.73, 19.65	-17.76, 18.56	-91.69, -73.53	-93.89, -71.57

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Baseline	n	36	34	23	18	20	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	760.26 (115.64)	1487.30 (101.50)	929.52 (95.77)	1433.13 (134.47)	930.37 (127.24)	1136.04 (129.03)
	95% CI of Geometric Mean	556.64, 1038.38	1108.88, 1994.87	655.76, 1317.57	864.63, 2375.39	587.78, 1472.61	682.85, 1889.99
	Median	708.06	1613.38	929.89	2178.11	1032.74	902.99
	Q25, Q75	354.47, 1559.10	994.20, 2660.19	584.82, 2002.01	568.40, 3053.85	344.13, 2321.79	396.77, 2415.73
	Min, Max	167.6, 4581.3	196.7, 6057.5	206.8, 3880.1	215.0, 6078.8	190.4, 3546.7	310.9, 5315.9
	Mean (SD)	1142.31 (1083.579)	1973.37 (1407.235)	1252.49 (1006.590)	2135.04 (1703.301)	1384.31 (1123.651)	1769.51 (1667.592)
	95% CI of Mean	775.68, 1508.95	1482.36, 2464.39	817.20, 1687.77	1288.00, 2982.08	858.42, 1910.20	912.11, 2626.91

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 10 AM on Day 1 in the SA arm.



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

Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Day 90	n	36	34	23	18	20	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	112.33 (74.37)	191.56 (87.17)	940.70 (99.06)	1507.97 (158.46)	145.25 (62.50)	142.69 (141.00)
	95% CI of Geometric Mean	89.74, 140.61	147.36, 249.02	657.91, 1345.05	863.71, 2632.80	111.02, 190.04	83.32, 244.35
	Median	113.36	152.68	791.60	1721.24	158.36	146.11
	Q25, Q75	77.71, 157.83	116.03, 287.94	562.91, 1544.44	548.55, 3472.75	94.03, 178.71	104.00, 188.89
	Min, Max	19.8, 516.6	65.6, 1165.8	168.7, 4499.3	176.6, 8096.2	67.1, 580.6	19.3, 1378.4
	Mean (SD)	139.53 (105.786)	261.43 (245.467)	1303.33 (1154.688)	2522.45 (2489.088)	173.49 (128.108)	248.33 (342.254)
	95% CI of Mean	103.73, 175.33	175.78, 347.08	804.00, 1802.66	1284.65, 3760.25	113.53, 233.45	72.35, 424.30

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 10 AM on Day 1 in the SA arm.

**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****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19	>19	10-19	>19	10-19	>19
		cig/day (N=36)	cig/day (N=34)	cig/day (N=23)	cig/day (N=18)	cig/day (N=20)	cig/day (N=17)
% Change from baseline to Day 90							
	n	36	34	23	18	20	17
	Median	-86.17	-89.03	4.17	-2.65	-86.15	-88.03
	Q25, Q75	-90.06, -73.25	-92.16, -76.22	-29.44, 39.56	-17.39, 35.03	-93.14, -64.37	-95.34, -69.14
	Min, Max	-97.5, -25.7	-97.5, -38.9	-54.5, 117.6	-52.3, 190.3	-95.8, -19.2	-98.6, 52.7
	Mean (SD)	-80.33 (16.052)	-82.14 (15.113)	10.18 (46.705)	19.53 (69.812)	-75.94 (22.563)	-75.14 (35.978)
	95% CI of Mean	-85.76, -74.89	-87.42, -76.86	-10.02, 30.38	-15.19, 54.25	-86.50, -65.37	-93.65, -56.64

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1067.39 (116.27)		1096.79 (115.64)		1066.13 (126.90)	
	95% CI of Geometric Mean	866.50, 1314.85		823.05, 1461.57		779.40, 1458.34	
	Median	1274.20		1041.05		1083.72	
	Q25, Q75	470.47, 2190.48		568.40, 2251.82		396.36, 2487.36	
	Min, Max	167.6, 6057.5		206.8, 6078.8		190.4, 5315.9	
	Mean (SD)	1551.65 (1299.450)		1610.43 (1405.371)		1629.81 (1431.082)	
	95% CI of Mean	1258.67, 1844.64		1172.48, 2048.38		1172.12, 2087.49	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	421.03 (110.68)		998.20 (119.69)		410.03 (132.84)	
	95% CI of Geometric Mean	344.15, 515.10		744.08, 1339.11		296.99, 566.08	
	Median	510.00	-61.48	852.83	-8.64	453.07	-60.08
	Q25, Q75	184.75, 868.94	-67.93, -50.89	458.59, 2338.40	-20.32, 5.23	154.52, 908.04	-68.19, -51.28
	Min, Max	85.5, 1929.6	-86.3, 5.9	191.4, 6271.2	-43.5, 36.0	78.8, 2230.5	-84.1, -36.1
	Mean (SD)	598.06 (467.726)	-57.82 (16.708)	1506.13 (1404.918)	-7.39 (17.447)	644.18 (597.358)	-59.93 (11.100)
	95% CI of Mean	492.60, 703.52	-61.60, -54.05	1068.32, 1943.94	-12.83, -1.95	453.14, 835.23	-63.48, -56.37

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	195.15 (80.65)		986.94 (115.74)		189.18 (93.76)	
	95% CI of Geometric Mean	166.36, 228.92		740.50, 1315.40		146.74, 243.89	
	Median	214.24	-83.08	912.34	-5.63	177.91	-82.51
	Q25, Q75	110.33, 342.64	-85.95, -74.38	421.95, 2203.39	-20.76, 7.13	96.04, 369.44	-87.52, -75.31
	Min, Max	22.9, 1151.6	-98.2, 0.0	237.4, 7352.9	-60.2, 41.9	44.7, 952.1	-92.6, -58.5
	Mean (SD)	247.58 (182.869)	-78.82 (13.209)	1481.46 (1462.241)	-7.27 (21.626)	257.16 (215.318)	-80.49 (8.931)
	95% CI of Mean	206.35, 288.82	-81.80, -75.84	1025.78, 1937.13	-14.02, -0.53	188.30, 326.03	-83.35, -77.62

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	146.96 (61.81)		994.67 (132.30)		114.46 (107.71)	
	95% CI of Geometric Mean	129.26, 167.07		727.03, 1360.83		86.44, 151.55	
	Median	150.09	-87.61	888.01	-5.15	118.78	-89.79
	Q25, Q75	96.55, 230.17	-90.60, -80.24	524.92, 2468.97	-27.59, 14.43	64.32, 199.39	-92.31, -84.19
	Min, Max	47.5, 538.3	-95.5, 0.0	158.0, 7116.2	-56.1, 54.4	17.1, 952.1	-97.3, -53.2
	Mean (SD)	172.71 (105.288)	-83.21 (13.707)	1579.75 (1602.965)	-5.46 (26.804)	164.93 (165.783)	-87.50 (7.883)
	95% CI of Mean	148.97, 196.46	-86.31, -80.12	1080.22, 2079.27	-13.82, 2.90	111.91, 217.96	-90.03, -84.97

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	125.46 (48.99)		1095.90 (122.17)		124.38 (77.99)	
	95% CI of Geometric Mean	113.00, 139.30		813.64, 1476.07		99.77, 155.07	
	Median	122.63	-89.45	1035.81	-2.09	105.79	-89.87
	Q25, Q75	87.46, 165.85	-92.91, -81.11	498.96, 2363.34	-18.29, 13.11	78.45, 204.88	-92.97, -78.71
	Min, Max	55.9, 523.2	-96.4, 0.0	151.5, 7710.4	-45.0, 247.8	18.3, 952.1	-95.5, -63.0
	Mean (SD)	140.89 (78.492)	-84.79 (13.974)	1699.39 (1745.384)	6.63 (47.495)	159.47 (149.239)	-86.10 (8.588)
	95% CI of Mean	123.19, 158.59	-87.94, -81.63	1155.49, 2243.30	-8.18, 21.43	111.74, 207.20	-88.85, -83.35

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	121.16 (47.93)		1096.47 (129.25)		108.38 (74.50)	
	95% CI of Geometric Mean	109.35, 134.24		805.13, 1493.22		87.63, 134.05	
	Median	120.68	-89.85	1103.64	1.42	107.97	-90.71
	Q25, Q75	87.95, 165.89	-93.19, -81.75	503.79, 2354.23	-19.55, 18.10	78.81, 163.16	-93.54, -82.15
	Min, Max	51.5, 523.2	-97.5, 0.0	174.4, 7234.4	-47.8, 100.9	21.4, 952.1	-98.1, -45.0
	Mean (SD)	135.04 (71.747)	-84.91 (14.358)	1730.83 (1722.313)	5.44 (35.808)	138.43 (143.699)	-86.60 (10.744)
	95% CI of Mean	118.86, 151.22	-88.15, -81.66	1194.12, 2267.55	-5.72, 16.60	92.47, 184.40	-90.04, -83.16

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	120.22 (72.58)		1042.41 (132.72)		103.23 (88.50)	
	95% CI of Geometric Mean	103.81, 139.21		761.45, 1427.04		80.94, 131.65	
	Median	119.11	-89.80	1134.86	-2.15	98.77	-88.24
	Q25, Q75	86.15, 159.44	-94.41, -80.02	423.89, 2445.00	-36.29, 37.54	63.72, 139.83	-94.44, -80.27
	Min, Max	20.2, 1013.6	-98.4, 0.0	162.7, 6287.7	-63.6, 176.7	29.2, 952.1	-98.7, -66.8
	Mean (SD)	153.54 (152.346)	-83.69 (16.644)	1634.42 (1522.583)	6.44 (53.068)	145.66 (167.957)	-87.30 (8.663)
	95% CI of Mean	119.19, 187.90	-87.45, -79.94	1159.95, 2108.90	-10.10, 22.98	91.94, 199.38	-90.08, -84.53

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	121.16 (94.58)		974.12 (115.40)		116.74 (102.39)	
	95% CI of Geometric Mean	101.17, 145.09		731.30, 1297.57		89.04, 153.06	
	Median	112.52	-90.11	908.13	-3.61	106.36	-87.87
	Q25, Q75	83.68, 159.38	-94.27, -80.66	474.23, 1779.92	-35.50, 41.10	67.98, 167.49	-95.47, -80.33
	Min, Max	16.8, 1489.3	-98.4, 0.0	200.0, 7724.9	-78.3, 113.3	23.6, 1223.0	-98.1, -6.7
	Mean (SD)	176.65 (228.395)	-83.35 (17.146)	1458.34 (1452.712)	-1.22 (44.352)	179.36 (234.624)	-82.64 (20.075)
	95% CI of Mean	125.15, 228.15	-87.22, -79.48	1005.64, 1911.04	-15.05, 12.61	104.32, 254.40	-89.06, -76.21

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	154.25 (90.70)		1128.34 (127.91)		148.73 (101.33)	
	95% CI of Geometric Mean	129.52, 183.69		830.23, 1533.50		113.67, 194.60	
	Median	135.31	-87.25	1004.66	1.38	146.69	-87.24
	Q25, Q75	95.77, 220.00	-91.68, -73.74	548.55, 2501.32	-24.24, 36.47	96.83, 182.33	-94.43, -67.55
	Min, Max	19.8, 1165.8	-97.5, 0.0	168.7, 8096.2	-54.5, 190.3	19.3, 1378.4	-98.6, 52.7
	Mean (SD)	214.22 (211.527)	-79.57 (18.684)	1804.30 (1923.442)	13.94 (56.724)	221.46 (268.179)	-76.37 (28.115)
	95% CI of Mean	166.52, 261.91	-83.79, -75.36	1204.91, 2403.69	-3.74, 31.62	135.68, 307.23	-85.37, -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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1279.77 (126.10)	1300.70 (119.99)	1268.56 (116.74)
	95% CI of Geometric Mean	1027.09, 1594.60	969.09, 1745.78	943.02, 1706.48
	Median	1399.81	1081.45	1410.85
	Q25, Q75	588.98, 2952.56	633.18, 3162.11	587.07, 2919.17
	Min, Max	198.6, 6129.4	293.7, 6642.3	204.4, 5392.4
	Mean (SD)	1907.31 (1534.109)	1931.31 (1625.253)	1834.55 (1462.296)
	95% CI of Mean	1561.41, 2253.20	1424.84, 2437.78	1366.88, 2302.22

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	489.11 (117.67)	1196.96 (134.62)	442.78 (132.15)
	95% CI of Geometric Mean	396.39, 603.51	871.90, 1643.22	321.05, 610.65
	Median	626.04	1009.37	492.47
	Q25, Q75	218.55, 1032.70	510.00, 2858.24	171.54, 1019.15
	Min, Max	82.1, 2549.6	225.8, 6977.4	65.8, 2741.5
	Mean (SD)	711.53 (572.625)	1910.12 (1808.673)	681.95 (605.700)
	95% CI of Mean	582.42, 840.65	1346.49, 2473.75	488.23, 875.66

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	230.38 (84.18)	1227.31 (128.21)	218.16 (83.52)
	95% CI of Geometric Mean	195.33, 271.72	902.63, 1668.78	172.87, 275.31
	Median	238.44	1098.89	207.39
	Q25, Q75	148.13, 422.78	603.09, 3114.71	130.23, 446.83
	Min, Max	18.9, 795.8	230.4, 9558.3	49.0, 765.1
	Mean (SD)	290.93 (190.113)	1932.16 (1925.747)	278.23 (190.350)
	95% CI of Mean	248.06, 333.80	1332.05, 2532.27	217.35, 339.11

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	178.89 (63.98)	1214.91 (146.54)	136.67 (103.25)
	95% CI of Geometric Mean	156.76, 204.15	870.22, 1696.12	104.07, 179.48
	Median	198.08	1239.64	141.18
	Q25, Q75	113.41, 280.44	504.95, 3070.00	69.20, 273.83
	Min, Max	52.9, 568.9	163.8, 8458.7	25.5, 765.1
	Mean (SD)	209.54 (114.679)	2013.79 (1999.123)	187.86 (150.023)
	95% CI of Mean	183.68, 235.40	1390.82, 2636.77	139.88, 235.85

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	153.10 (54.70)	1251.92 (133.17)	142.99 (73.01)
	95% CI of Geometric Mean	136.42, 171.82	913.88, 1715.00	116.01, 176.24
	Median	159.71	1428.20	132.70
	Q25, Q75	105.86, 225.63	584.35, 2530.22	98.79, 237.33
	Min, Max	50.7, 568.9	160.9, 13089.2	22.9, 765.1
	Mean (SD)	173.86 (90.959)	2051.99 (2385.913)	175.74 (128.872)
	95% CI of Mean	153.35, 194.37	1308.48, 2795.49	134.52, 216.96

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	141.69 (51.82)	1358.78 (136.77)	130.94 (70.08)
	95% CI of Geometric Mean	126.93, 158.16	986.68, 1871.21	106.97, 160.27
	Median	134.05	1413.67	141.52
	Q25, Q75	105.32, 202.35	610.20, 3031.60	93.21, 194.96
	Min, Max	44.2, 568.9	245.7, 9333.0	30.7, 765.1
	Mean (SD)	159.58 (84.492)	2205.46 (2219.201)	159.26 (120.264)
	95% CI of Mean	140.53, 178.64	1513.90, 2897.01	120.79, 197.73

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	142.26 (79.91)	1215.72 (148.91)	109.63 (91.97)
	95% CI of Geometric Mean	121.41, 166.69	868.03, 1702.66	85.35, 140.83
	Median	148.08	1411.53	120.76
	Q25, Q75	88.97, 208.58	567.15, 3267.20	73.06, 156.38
	Min, Max	21.7, 1322.5	133.8, 7871.5	15.6, 765.1
	Mean (SD)	188.74 (202.785)	2012.47 (1983.956)	147.70 (140.298)
	95% CI of Mean	143.02, 234.47	1394.22, 2630.72	102.82, 192.57

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	138.93 (99.20)	1121.65 (118.38)	131.95 (109.71)
	95% CI of Geometric Mean	115.28, 167.44	837.89, 1501.51	99.29, 175.33
	Median	131.33	1114.78	112.17
	Q25, Q75	91.34, 186.64	524.16, 2464.20	80.46, 186.48
	Min, Max	19.9, 1932.8	193.8, 6228.4	15.9, 1960.2
	Mean (SD)	208.48 (280.362)	1691.12 (1573.092)	211.41 (320.931)
	95% CI of Mean	145.26, 271.70	1200.91, 2181.34	108.77, 314.06

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	175.14 (96.44)	1237.75 (126.61)	167.24 (86.15)
	95% CI of Geometric Mean	145.87, 210.28	912.56, 1678.80	131.78, 212.25
	Median	161.46	1136.07	139.89
	Q25, Q75	104.38, 251.34	583.74, 3147.76	116.62, 209.02
	Min, Max	21.4, 1554.8	254.3, 7091.4	30.5, 1482.0
	Mean (SD)	253.31 (277.561)	1960.12 (1953.369)	234.17 (268.656)
	95% CI of Mean	190.73, 315.90	1351.40, 2568.84	148.24, 320.09

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1058.84 (115.52)		1096.79 (115.64)		1027.37 (123.71)	
	95% CI of Geometric Mean	857.94, 1306.79		823.05, 1461.57		751.76, 1404.03	
	Median	1274.20		1041.05		902.99	
	Q25, Q75	458.38, 2165.87		568.40, 2251.82		395.95, 2415.73	
	Min, Max	167.6, 6057.5		206.8, 6078.8		190.4, 5315.9	
	Mean (SD)	1532.81 (1280.008)		1610.43 (1405.371)		1555.74 (1369.913)	
	95% CI of Mean	1240.31, 1825.31		1172.48, 2048.38		1111.66, 1999.82	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	415.85 (112.05)		998.20 (119.69)		392.60 (127.59)	
	95% CI of Geometric Mean	338.40, 511.02		744.08, 1339.11		285.47, 539.93	
	Median	475.21	-61.48	852.83	-8.64	438.24	-60.17
	Q25, Q75	182.68, 905.69	-67.57, -50.94	458.59, 2338.40	-20.32, 5.23	152.95, 834.37	-68.71, -51.47
	Min, Max	85.5, 1929.6	-86.3, 5.9	191.4, 6271.2	-43.5, 36.0	78.8, 2127.0	-84.1, -36.1
	Mean (SD)	595.48 (472.802)	-58.31 (15.368)	1506.13 (1404.918)	-7.39 (17.447)	603.51 (546.177)	-60.17 (11.141)
	95% CI of Mean	487.43, 703.52	-61.83, -54.80	1068.32, 1943.94	-12.83, -1.95	426.46, 780.57	-63.78, -56.55

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	191.02 (80.08)		986.94 (115.74)		181.50 (88.35)	
	95% CI of Geometric Mean	162.63, 224.36		740.50, 1315.40		141.88, 232.17	
	Median	199.67	-83.08	912.34	-5.63	159.82	-82.69
	Q25, Q75	110.11, 320.43	-85.77, -74.58	421.95, 2203.39	-20.76, 7.13	93.50, 350.97	-87.65, -75.09
	Min, Max	22.9, 1151.6	-98.2, -55.1	237.4, 7352.9	-60.2, 41.9	44.7, 832.8	-92.6, -58.5
	Mean (SD)	242.34 (181.911)	-79.70 (9.675)	1481.46 (1462.241)	-7.27 (21.626)	239.34 (185.864)	-80.53 (9.044)
	95% CI of Mean	200.77, 283.92	-81.92, -77.49	1025.78, 1937.13	-14.02, -0.53	179.09, 299.60	-83.46, -77.59

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	143.55 (59.90)		994.67 (132.30)		108.40 (97.62)	
	95% CI of Geometric Mean	126.48, 162.91		727.03, 1360.83		83.15, 141.33	
	Median	149.34	-87.61	888.01	-5.15	113.53	-89.98
	Q25, Q75	96.04, 218.62	-90.53, -80.43	524.92, 2468.97	-27.59, 14.43	62.19, 194.69	-92.35, -84.70
	Min, Max	47.5, 538.3	-95.5, -40.5	158.0, 7116.2	-56.1, 54.4	17.1, 455.9	-97.3, -53.2
	Mean (SD)	167.14 (98.187)	-84.17 (9.905)	1579.75 (1602.965)	-5.46 (26.804)	144.75 (107.150)	-87.72 (7.860)
	95% CI of Mean	144.70, 189.58	-86.43, -81.90	1080.22, 2079.27	-13.82, 2.90	110.01, 179.48	-90.27, -85.17

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	122.57 (45.94)		1095.90 (122.17)		118.06 (67.55)	
	95% CI of Geometric Mean	110.90, 135.46		813.64, 1476.07		96.78, 144.02	
	Median	121.18	-89.45	1035.81	-2.09	105.74	-89.89
	Q25, Q75	85.95, 160.20	-92.88, -81.14	498.96, 2363.34	-18.29, 13.11	78.41, 202.97	-93.04, -78.49
	Min, Max	55.9, 359.2	-96.4, -46.0	151.5, 7710.4	-45.0, 247.8	18.3, 325.7	-95.5, -63.0
	Mean (SD)	135.38 (65.788)	-85.76 (10.105)	1699.39 (1745.384)	6.63 (47.495)	139.14 (76.808)	-86.28 (8.620)
	95% CI of Mean	120.34, 150.42	-88.07, -83.45	1155.49, 2243.30	-8.18, 21.43	114.24, 164.05	-89.08, -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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	118.36 (44.66)		1096.47 (129.25)		102.51 (62.05)	
	95% CI of Geometric Mean	107.37, 130.48		805.13, 1493.22		85.19, 123.34	
	Median	119.32	-89.85	1103.64	1.42	106.75	-90.78
	Q25, Q75	87.74, 152.75	-93.07, -82.35	503.79, 2354.23	-19.55, 18.10	74.07, 160.31	-93.85, -82.70
	Min, Max	51.5, 280.7	-97.5, -41.6	174.4, 7234.4	-47.8, 100.9	21.4, 279.9	-98.1, -45.0
	Mean (SD)	129.53 (56.858)	-85.88 (10.628)	1730.83 (1722.313)	5.44 (35.808)	117.57 (57.635)	-86.80 (10.811)
	95% CI of Mean	116.53, 142.53	-88.31, -83.45	1194.12, 2267.55	-5.72, 16.60	98.88, 136.26	-90.31, -83.29

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 10 AM on Day 1 in the SA arm.

**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=63)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	63		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1115.76 (112.23)		1124.11 (115.15)		1041.88 (125.48)	
	95% CI of Geometric Mean	888.83, 1400.63		841.13, 1502.28		756.84, 1434.26	
	Median	1391.82		1091.90		1083.72	
	Q25, Q75	545.45, 2190.48		584.82, 2251.82		395.95, 2415.73	
	Min, Max	167.6, 6057.5		206.8, 6078.8		190.4, 5315.9	
	Mean (SD)	1582.99 (1277.945)		1639.95 (1409.582)		1580.81 (1379.207)	
	95% CI of Mean	1261.14, 1904.84		1195.02, 2084.87		1127.47, 2034.15	

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 10 AM on Day 1 in the SA arm.

**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=63)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	63	63	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	115.45 (67.16)		1067.05 (132.92)		97.73 (77.73)	
	95% CI of Geometric Mean	99.00, 134.63		776.07, 1467.13		77.96, 122.51	
	Median	118.78	-90.12	1157.78	-2.80	98.77	-89.36
	Q25, Q75	92.42, 149.63	-94.58, -83.37	439.78, 2445.00	-36.29, 37.54	62.56, 137.43	-94.44, -81.40
	Min, Max	20.2, 1013.6	-98.4, -23.5	162.7, 6287.7	-63.6, 176.7	29.2, 516.7	-98.7, -66.8
	Mean (SD)	142.35 (135.939)	-85.56 (13.776)	1664.53 (1528.788)	6.60 (53.718)	125.91 (108.029)	-87.58 (8.775)
	95% CI of Mean	108.11, 176.59	-89.04, -82.09	1181.98, 2147.08	-10.36, 23.56	90.40, 161.42	-90.47, -84.69

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1141.56 (112.42)		1124.11 (115.15)		1041.88 (125.48)	
	95% CI of Geometric Mean	912.48, 1428.14		841.13, 1502.28		756.84, 1434.26	
	Median	1403.31		1091.90		1083.72	
	Q25, Q75	545.45, 2190.48		584.82, 2251.82		395.95, 2415.73	
	Min, Max	167.6, 6057.5		206.8, 6078.8		190.4, 5315.9	
	Mean (SD)	1623.33 (1313.987)		1639.95 (1409.582)		1580.81 (1379.207)	
	95% CI of Mean	1297.73, 1948.92		1195.02, 2084.87		1127.47, 2034.15	

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	65	65	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	112.40 (82.45)		995.50 (115.48)		111.24 (93.93)	
	95% CI of Geometric Mean	94.02, 134.36		744.48, 1331.16		85.65, 144.48	
	Median	110.36	-90.40	910.26	-4.65	106.36	-89.75
	Q25, Q75	83.68, 150.45	-94.63, -83.61	541.95, 1779.92	-35.50, 41.10	66.86, 167.33	-95.48, -80.57
	Min, Max	16.8, 1182.0	-98.4, -44.8	200.0, 7724.9	-78.3, 113.3	23.6, 1223.0	-98.1, -6.7
	Mean (SD)	149.86 (166.955)	-86.69 (11.516)	1484.15 (1460.975)	-1.25 (44.903)	161.38 (203.309)	-82.67 (20.597)
	95% CI of Mean	108.49, 191.23	-89.55, -83.83	1023.01, 1945.30	-15.43, 12.93	94.55, 228.21	-89.44, -75.89

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1069.05 (117.29)		1124.11 (115.15)		1019.78 (126.33)	
	95% CI of Geometric Mean	848.97, 1346.17		841.13, 1502.28		736.34, 1412.32	
	Median	1367.48		1091.90		902.99	
	Q25, Q75	470.47, 2141.26		584.82, 2251.82		395.95, 2415.73	
	Min, Max	167.6, 6057.5		206.8, 6078.8		190.4, 5315.9	
	Mean (SD)	1559.34 (1322.664)		1639.95 (1409.582)		1561.29 (1392.904)	
	95% CI of Mean	1231.60, 1887.09		1195.02, 2084.87		1096.87, 2025.71	

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	65	65	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	140.20 (81.20)		1157.25 (127.57)		144.07 (96.75)	
	95% CI of Geometric Mean	117.53, 167.24		848.59, 1578.17		109.87, 188.92	
	Median	127.93	-88.89	1102.30	2.76	146.89	-88.03
	Q25, Q75	91.86, 177.56	-92.00, -76.22	562.91, 2501.32	-24.24, 36.47	104.00, 178.95	-94.30, -67.38
	Min, Max	19.8, 743.2	-97.5, -36.1	168.7, 8096.2	-54.5, 190.3	19.3, 1378.4	-98.6, 52.7
	Mean (SD)	183.01 (156.741)	-82.31 (14.286)	1838.55 (1934.326)	14.28 (57.385)	207.87 (249.305)	-75.57 (29.054)
	95% CI of Mean	144.17, 221.85	-85.86, -78.77	1228.00, 2449.11	-3.83, 32.40	124.75, 291.00	-85.26, -65.88

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1274.20 (126.02)	1300.70 (119.99)	1234.15 (115.88)
	95% CI of Geometric Mean	1019.69, 1592.25	969.09, 1745.78	915.10, 1664.44
	Median	1399.81	1081.45	1308.96
	Q25, Q75	592.69, 2935.40	633.18, 3162.11	546.00, 2794.62
	Min, Max	198.6, 6129.4	293.7, 6642.3	204.4, 5392.4
	Mean (SD)	1897.27 (1527.543)	1931.31 (1625.253)	1786.52 (1449.100)
	95% CI of Mean	1548.21, 2246.33	1424.84, 2437.78	1316.77, 2256.27

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	483.32 (119.21)	1196.96 (134.62)	429.26 (130.81)
	95% CI of Geometric Mean	389.87, 599.18	871.90, 1643.22	310.54, 593.35
	Median	626.04	1009.37	472.03
	Q25, Q75	214.24, 1031.39	510.00, 2858.24	169.34, 995.65
	Min, Max	82.1, 2549.6	225.8, 6977.4	65.8, 2741.5
	Mean (SD)	709.10 (578.736)	1910.12 (1808.673)	661.37 (599.289)
	95% CI of Mean	576.85, 841.35	1346.49, 2473.75	467.10, 855.64

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	226.16 (84.15)	1227.31 (128.21)	211.25 (80.61)
	95% CI of Geometric Mean	191.33, 267.32	902.63, 1668.78	167.95, 265.72
	Median	230.42	1098.89	206.75
	Q25, Q75	147.14, 415.46	603.09, 3114.71	129.00, 446.24
	Min, Max	18.9, 795.8	230.4, 9558.3	49.0, 683.3
	Mean (SD)	286.09 (189.592)	1932.16 (1925.747)	265.75 (175.470)
	95% CI of Mean	242.76, 329.42	1332.05, 2532.27	208.86, 322.63

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	174.23 (61.86)	1214.91 (146.54)	130.77 (97.15)
	95% CI of Geometric Mean	152.97, 198.43	870.22, 1696.12	100.39, 170.33
	Median	190.79	1239.64	134.63
	Q25, Q75	111.69, 264.32	504.95, 3070.00	67.94, 261.07
	Min, Max	52.9, 445.5	163.8, 8458.7	25.5, 431.3
	Mean (SD)	202.06 (105.540)	2013.79 (1999.123)	173.06 (118.772)
	95% CI of Mean	177.94, 226.18	1390.82, 2636.77	134.55, 211.57

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	149.64 (52.43)	1251.92 (133.17)	136.97 (66.11)
	95% CI of Geometric Mean	133.70, 167.48	913.88, 1715.00	112.68, 166.50
	Median	157.68	1428.20	130.01
	Q25, Q75	103.50, 209.37	584.35, 2530.22	98.38, 236.35
	Min, Max	50.7, 377.1	160.9, 13089.2	22.9, 350.7
	Mean (SD)	167.88 (79.561)	2051.99 (2385.913)	160.62 (87.582)
	95% CI of Mean	149.69, 186.06	1308.48, 2795.49	132.23, 189.02

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	138.39 (49.07)	1358.78 (136.77)	125.14 (62.07)
	95% CI of Geometric Mean	124.45, 153.89	986.68, 1871.21	104.00, 150.59
	Median	133.20	1413.67	129.60
	Q25, Q75	104.06, 196.38	610.20, 3031.60	93.19, 189.72
	Min, Max	44.2, 371.5	245.7, 9333.0	30.7, 298.0
	Mean (SD)	153.51 (70.867)	2205.46 (2219.201)	143.73 (70.273)
	95% CI of Mean	137.31, 169.71	1513.90, 2897.01	120.94, 166.51

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 10 AM on Day 1 in the SA arm.

**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=63)	mCC (N=41)	SA (N=38)
Baseline	n	63	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1357.29 (123.43)	1322.06 (121.10)	1247.64 (117.73)
	95% CI of Geometric Mean	1065.23, 1729.42	979.50, 1784.42	918.26, 1695.15
	Median	1523.52	1185.72	1410.85
	Q25, Q75	612.01, 2960.58	633.18, 3162.11	546.00, 2794.62
	Min, Max	198.6, 6129.4	293.7, 6642.3	204.4, 5392.4
	Mean (SD)	1984.09 (1547.572)	1962.14 (1632.959)	1812.04 (1459.641)
	95% CI of Mean	1594.33, 2373.84	1446.71, 2477.57	1332.27, 2291.82

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 10 AM on Day 1 in the SA arm.

**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=63)	mCC (N=41)	SA (N=38)
Day 30	n	63	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	136.97 (74.13)	1233.64 (151.07)	103.98 (84.72)
	95% CI of Geometric Mean	115.93, 161.81	874.47, 1740.33	81.65, 132.43
	Median	150.63	1473.08	120.76
	Q25, Q75	100.49, 197.10	567.15, 3267.20	72.60, 156.23
	Min, Max	21.7, 1206.7	133.8, 7871.5	15.6, 565.2
	Mean (SD)	172.81 (161.532)	2045.28 (1997.031)	132.25 (100.876)
	95% CI of Mean	132.12, 213.49	1414.93, 2675.63	99.09, 165.41

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=38)
Baseline	n	65	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1386.12 (116.03)	1322.06 (121.10)	1247.64 (117.73)
	95% CI of Geometric Mean	1102.61, 1742.52	979.50, 1784.42	918.26, 1695.15
	Median	1523.52	1185.72	1410.85
	Q25, Q75	626.71, 2952.56	633.18, 3162.11	546.00, 2794.62
	Min, Max	198.6, 6129.4	293.7, 6642.3	204.4, 5392.4
	Mean (SD)	1980.04 (1522.699)	1962.14 (1632.959)	1812.04 (1459.641)
	95% CI of Mean	1602.73, 2357.35	1446.71, 2477.57	1332.27, 2291.82

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=38)
Day 60	n	65	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	129.58 (89.39)	1135.95 (119.90)	126.37 (105.39)
	95% CI of Geometric Mean	107.17, 156.68	843.26, 1530.23	95.11, 167.90
	Median	131.00	1160.29	105.63
	Q25, Q75	91.17, 182.74	524.16, 2464.20	79.53, 178.85
	Min, Max	19.9, 1932.8	193.8, 6228.4	15.9, 1960.2
	Mean (SD)	184.33 (255.757)	1716.10 (1584.182)	199.32 (316.054)
	95% CI of Mean	120.95, 247.71	1216.06, 2216.13	95.43, 303.21

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=37)
Baseline	n	65	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1266.75 (126.19)	1322.06 (121.10)	1232.62 (119.60)
	95% CI of Geometric Mean	994.63, 1613.32	979.50, 1784.42	900.27, 1687.67
	Median	1395.51	1185.72	1308.96
	Q25, Q75	596.39, 2904.72	633.18, 3162.11	546.00, 2794.62
	Min, Max	198.6, 6129.4	293.7, 6642.3	204.4, 5392.4
	Mean (SD)	1891.05 (1547.569)	1962.14 (1632.959)	1808.24 (1479.583)
	95% CI of Mean	1507.58, 2274.52	1446.71, 2477.57	1314.92, 2301.56

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=37)
Day 90	n	65	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	157.81 (88.10)	1256.55 (128.06)	163.13 (83.74)
	95% CI of Geometric Mean	130.78, 190.41	920.70, 1714.90	127.93, 208.02
	Median	148.29	1331.25	140.45
	Q25, Q75	98.33, 228.24	583.74, 3147.76	115.88, 188.94
	Min, Max	21.4, 1326.7	254.3, 7091.4	30.5, 1482.0
	Mean (SD)	216.93 (222.418)	1991.65 (1966.781)	225.77 (263.843)
	95% CI of Mean	161.81, 272.04	1370.86, 2612.45	137.79, 313.74

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	85.64 (79.61)		84.77 (74.73)		79.54 (91.50)	
	95% CI of Geometric Mean	72.96, 100.51		68.88, 104.33		61.76, 102.42	
	Median	99.62		88.37		84.24	
	Q25, Q75	55.00, 135.10		47.56, 141.06		65.92, 130.60	
	Min, Max	11.9, 342.9		17.0, 318.8		11.0, 376.4	
	Mean (SD)	105.68 (64.932)		103.82 (66.603)		102.55 (73.037)	
	95% CI of Mean	90.83, 120.52		83.06, 124.58		78.87, 126.23	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	60.37 (77.02)		82.96 (69.85)		55.66 (100.34)	
	95% CI of Geometric Mean	51.64, 70.56		68.16, 100.98		42.47, 72.96	
	Median	71.30	-27.88	84.39	-0.03	57.84	-27.96
	Q25, Q75	38.12, 93.30	-37.50, -22.29	53.74, 141.08	-8.89, 5.84	38.95, 99.02	-38.56, -19.30
	Min, Max	9.1, 245.5	-66.3, 40.4	17.6, 321.4	-37.5, 32.3	4.6, 262.8	-57.6, 26.8
	Mean (SD)	74.02 (45.788)	-28.02 (15.315)	99.36 (59.947)	-1.08 (14.233)	73.77 (54.375)	-28.29 (16.292)
	95% CI of Mean	63.55, 84.49	-31.52, -24.51	80.67, 118.04	-5.52, 3.36	56.14, 91.40	-33.57, -23.00

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	47.69 (75.20)		83.00 (70.61)		43.33 (103.35)	
	95% CI of Geometric Mean	40.92, 55.58		68.07, 101.20		32.86, 57.12	
	Median	53.67	-42.78	83.76	-1.69	47.14	-42.51
	Q25, Q75	29.65, 75.34	-53.27, -35.90	53.08, 137.21	-9.16, 5.03	27.48, 75.05	-51.20, -35.44
	Min, Max	7.5, 181.7	-69.2, 40.2	17.1, 276.5	-35.7, 54.9	3.5, 216.5	-68.1, -23.8
	Mean (SD)	57.85 (33.956)	-42.63 (15.129)	99.43 (58.020)	-0.87 (16.206)	57.98 (43.275)	-44.15 (11.870)
	95% CI of Mean	50.09, 65.61	-46.10, -39.17	81.35, 117.52	-5.92, 4.19	43.95, 72.01	-48.00, -40.30

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	42.72 (76.38)		83.59 (70.82)		38.27 (99.44)	
	95% CI of Geometric Mean	36.58, 49.88		68.52, 101.97		29.25, 50.08	
	Median	49.33	-49.26	84.73	-1.56	39.22	-49.19
	Q25, Q75	25.40, 66.01	-58.54, -41.41	49.59, 139.27	-11.15, 6.40	24.09, 66.77	-59.64, -44.88
	Min, Max	6.9, 175.8	-70.7, -8.6	17.4, 294.5	-34.0, 51.9	5.8, 186.6	-77.1, -16.2
	Mean (SD)	52.32 (32.231)	-48.66 (12.564)	100.19 (59.009)	0.20 (18.645)	51.13 (38.585)	-50.56 (11.242)
	95% CI of Mean	44.95, 59.69	-51.54, -45.79	81.79, 118.58	-5.62, 6.01	38.62, 63.64	-54.21, -46.91

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	39.00 (73.28)		83.85 (71.21)		32.65 (111.57)	
	95% CI of Geometric Mean	33.57, 45.31		68.67, 102.37		24.39, 43.71	
	Median	43.45	-53.46	84.57	-0.83	36.31	-55.02
	Q25, Q75	23.99, 61.33	-61.60, -45.26	50.52, 150.60	-11.98, 6.46	18.75, 63.52	-61.46, -48.51
	Min, Max	6.3, 121.4	-78.7, -8.9	16.9, 281.2	-37.4, 64.6	3.5, 155.3	-86.8, -41.1
	Mean (SD)	47.09 (27.256)	-52.93 (12.173)	100.95 (60.628)	0.54 (19.179)	45.19 (35.035)	-57.07 (11.073)
	95% CI of Mean	40.85, 53.32	-55.72, -50.15	82.05, 119.85	-5.44, 6.53	33.83, 56.56	-60.67, -53.48

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	37.90 (79.54)		85.94 (67.94)		29.58 (108.10)	
	95% CI of Geometric Mean	32.29, 44.48		70.93, 104.13		22.24, 39.35	
	Median	41.35	-55.63	82.26	-2.48	34.17	-59.61
	Q25, Q75	23.47, 62.10	-63.44, -45.18	54.23, 153.30	-11.06, 11.11	17.41, 54.52	-67.77, -54.52
	Min, Max	5.0, 123.8	-72.7, -21.0	15.1, 273.8	-32.4, 75.3	3.3, 139.7	-89.0, -41.2
	Mean (SD)	46.60 (27.761)	-54.39 (11.417)	102.11 (59.624)	3.91 (24.832)	40.54 (31.208)	-61.03 (10.580)
	95% CI of Mean	40.25, 52.95	-57.01, -51.78	83.52, 120.69	-3.83, 11.65	30.42, 50.66	-64.46, -57.59

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	85.79 (80.56)		85.55 (75.52)		79.54 (91.50)	
	95% CI of Geometric Mean	72.82, 101.07		69.20, 105.75		61.76, 102.42	
	Median	99.62		88.74		84.24	
	Q25, Q75	55.46, 136.79		47.56, 141.06		65.92, 130.60	
	Min, Max	11.9, 342.9		17.0, 318.8		11.0, 376.4	
	Mean (SD)	106.20 (65.524)		104.93 (67.038)		102.55 (73.037)	
	95% CI of Mean	91.02, 121.39		83.77, 126.09		78.87, 126.23	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	26.82 (76.42)		86.16 (80.20)		20.43 (131.00)	
	95% CI of Geometric Mean	22.92, 31.39		68.97, 107.62		14.77, 28.25	
	Median	28.87	-68.82	104.05	6.42	25.62	-72.52
	Q25, Q75	17.74, 40.73	-77.89, -60.62	51.71, 145.66	-10.86, 21.58	10.70, 43.15	-84.00, -60.15
	Min, Max	4.7, 127.5	-88.4, 3.2	17.4, 282.8	-69.1, 82.6	1.6, 109.9	-89.1, -19.2
	Mean (SD)	33.03 (22.183)	-64.62 (19.513)	106.48 (64.195)	5.25 (28.832)	31.22 (28.604)	-69.93 (18.124)
	95% CI of Mean	27.89, 38.17	-69.15, -60.10	86.21, 126.75	-3.86, 14.35	21.94, 40.50	-75.81, -64.05

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	91.92 (71.59)		85.55 (75.52)		78.72 (92.73)	
	95% CI of Geometric Mean	78.93, 107.04		69.20, 105.75		60.76, 101.99	
	Median	108.01		88.74		82.58	
	Q25, Q75	59.38, 142.24		47.56, 141.06		65.92, 130.60	
	Min, Max	11.9, 342.9		17.0, 318.8		11.0, 376.4	
	Mean (SD)	110.26 (64.255)		104.93 (67.038)		102.15 (73.975)	
	95% CI of Mean	95.05, 125.47		83.77, 126.09		77.83, 126.47	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	23.79 (84.98)		88.67 (80.00)		14.44 (183.63)	
	95% CI of Geometric Mean	19.97, 28.33		71.01, 110.71		9.68, 21.53	
	Median	25.87	-75.33	88.98	9.75	14.21	-84.79
	Q25, Q75	16.80, 37.70	-84.36, -62.26	55.30, 150.20	-10.42, 26.74	6.94, 36.05	-90.42, -54.31
	Min, Max	3.8, 176.8	-92.8, 88.2	17.4, 340.4	-69.1, 141.3	1.4, 137.3	-97.8, 7.9
	Mean (SD)	30.80 (25.713)	-68.42 (26.266)	109.99 (71.025)	11.61 (41.229)	28.00 (34.502)	-70.96 (28.179)
	95% CI of Mean	24.71, 36.89	-74.64, -62.20	87.56, 132.41	-1.40, 24.63	16.65, 39.34	-80.23, -61.70

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	90.66 (74.30)		85.55 (75.52)		78.79 (94.45)	
	95% CI of Geometric Mean	77.39, 106.19		69.20, 105.75		60.37, 102.84	
	Median	107.17		88.74		84.24	
	Q25, Q75	58.71, 142.24		47.56, 141.06		65.92, 130.60	
	Min, Max	15.9, 342.9		17.0, 318.8		11.0, 376.4	
	Mean (SD)	109.88 (65.198)		104.93 (67.038)		102.86 (74.866)	
	95% CI of Mean	94.33, 125.43		83.77, 126.09		77.89, 127.82	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	23.23 (89.70)		95.03 (73.04)		13.95 (214.03)	
	95% CI of Geometric Mean	19.34, 27.91		77.31, 116.82		9.00, 21.60	
	Median	25.28	-73.80	111.87	21.57	12.93	-79.34
	Q25, Q75	13.65, 38.74	-84.10, -59.95	60.41, 138.52	-8.98, 44.91	5.26, 39.21	-95.01, -56.23
	Min, Max	3.5, 158.0	-93.3, 6.2	22.4, 284.5	-60.3, 117.4	1.0, 166.1	-97.6, 10.5
	Mean (SD)	30.73 (25.606)	-68.58 (21.270)	114.57 (67.411)	18.79 (41.869)	30.00 (38.678)	-66.54 (35.413)
	95% CI of Mean	24.62, 36.84	-73.66, -63.50	93.29, 135.86	5.57, 32.01	17.10, 42.90	-78.36, -54.73

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	103.06 (80.04)	100.53 (83.33)	95.54 (87.57)
	95% CI of Geometric Mean	87.75, 121.04	80.17, 126.07	74.81, 122.02
	Median	112.44	110.16	98.08
	Q25, Q75	66.29, 178.25	63.77, 186.13	64.50, 168.39
	Min, Max	14.9, 342.4	20.3, 298.6	11.8, 384.3
	Mean (SD)	126.99 (75.901)	124.88 (73.743)	120.85 (79.507)
	95% CI of Mean	109.64, 144.33	101.89, 147.86	95.07, 146.63

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	70.16 (76.58)	99.48 (89.87)	60.86 (106.49)
	95% CI of Geometric Mean	60.07, 81.95	78.27, 126.44	45.89, 80.71
	Median	85.78	119.55	73.89
	Q25, Q75	46.38, 112.99	55.23, 182.14	42.71, 102.16
	Min, Max	10.3, 243.1	13.1, 274.7	5.2, 467.0
	Mean (SD)	84.78 (47.040)	125.72 (74.279)	85.24 (80.487)
	95% CI of Mean	74.03, 95.54	102.57, 148.87	59.15, 111.34

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	56.47 (81.91)	103.44 (88.05)	50.43 (101.89)
	95% CI of Geometric Mean	47.93, 66.52	81.69, 130.99	38.36, 66.30
	Median	65.82	120.86	60.23
	Q25, Q75	34.90, 90.85	69.01, 197.67	36.11, 86.56
	Min, Max	10.2, 203.0	20.5, 275.7	3.8, 194.7
	Mean (SD)	70.46 (44.454)	130.70 (78.537)	66.38 (45.035)
	95% CI of Mean	60.30, 80.63	106.22, 155.18	51.78, 80.99

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	51.85 (78.22)	102.10 (81.36)	46.17 (97.30)
	95% CI of Geometric Mean	44.27, 60.72	81.76, 127.50	35.43, 60.15
	Median	62.81	113.17	49.19
	Q25, Q75	32.62, 79.87	65.11, 176.09	32.05, 75.00
	Min, Max	5.9, 205.9	20.3, 291.9	6.4, 220.0
	Mean (SD)	63.29 (37.323)	126.19 (74.444)	61.39 (46.120)
	95% CI of Mean	54.76, 71.83	102.99, 149.40	46.43, 76.35

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	47.62 (79.50)	95.78 (84.75)	37.89 (123.26)
	95% CI of Geometric Mean	40.58, 55.88	76.15, 120.47	27.74, 51.74
	Median	54.36	114.09	48.37
	Q25, Q75	29.13, 74.34	70.41, 176.00	21.27, 71.07
	Min, Max	9.0, 144.1	16.9, 245.2	4.0, 218.6
	Mean (SD)	58.59 (34.746)	118.95 (68.405)	54.39 (43.856)
	95% CI of Mean	50.64, 66.53	97.63, 140.28	40.17, 68.61

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	44.31 (82.74)	106.50 (76.86)	36.11 (106.81)
	95% CI of Geometric Mean	37.57, 52.27	86.12, 131.70	27.21, 47.92
	Median	52.05	118.85	42.31
	Q25, Q75	26.90, 70.24	68.09, 192.94	24.25, 62.26
	Min, Max	6.7, 140.8	17.6, 265.4	4.3, 207.0
	Mean (SD)	55.21 (33.882)	128.98 (71.105)	49.40 (39.457)
	95% CI of Mean	47.46, 62.95	106.82, 151.14	36.61, 62.20

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	102.70 (79.88)	100.61 (84.67)	95.54 (87.57)
	95% CI of Geometric Mean	87.27, 120.86	79.77, 126.89	74.81, 122.02
	Median	112.44	112.82	98.08
	Q25, Q75	68.75, 178.22	63.77, 186.13	64.50, 168.39
	Min, Max	14.9, 342.4	20.3, 298.6	11.8, 384.3
	Mean (SD)	126.36 (75.260)	125.55 (74.530)	120.85 (79.507)
	95% CI of Mean	108.92, 143.80	102.02, 149.08	95.07, 146.63

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	31.73 (85.76)	99.61 (89.28)	21.85 (130.64)
	95% CI of Geometric Mean	26.71, 37.69	78.22, 126.84	15.81, 30.21
	Median	35.74	130.51	24.66
	Q25, Q75	19.10, 47.33	46.32, 178.29	11.32, 42.07
	Min, Max	4.4, 207.0	26.1, 281.3	2.7, 152.0
	Mean (SD)	40.89 (32.421)	127.64 (80.414)	33.80 (32.546)
	95% CI of Mean	33.37, 48.41	102.26, 153.03	23.25, 44.36

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	110.14 (72.47)	100.61 (84.67)	94.27 (88.39)
	95% CI of Geometric Mean	94.44, 128.45	79.77, 126.89	73.43, 121.01
	Median	114.42	112.82	97.29
	Q25, Q75	77.02, 182.72	63.77, 186.13	64.50, 168.39
	Min, Max	19.0, 342.4	20.3, 298.6	11.8, 384.3
	Mean (SD)	132.18 (75.061)	125.55 (74.530)	119.84 (80.319)
	95% CI of Mean	114.40, 149.95	102.02, 149.08	93.43, 146.24

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	27.43 (92.98)	101.18 (89.70)	16.41 (188.69)
	95% CI of Geometric Mean	22.75, 33.07	79.39, 128.95	10.94, 24.60
	Median	30.59	115.15	15.88
	Q25, Q75	14.39, 46.44	64.47, 182.98	6.60, 41.62
	Min, Max	4.0, 145.4	24.8, 360.5	1.8, 193.0
	Mean (SD)	36.26 (27.691)	130.45 (87.155)	33.41 (43.034)
	95% CI of Mean	29.70, 42.82	102.94, 157.97	19.26, 47.56

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	107.23 (76.80)	100.61 (84.67)	95.24 (89.59)
	95% CI of Geometric Mean	91.16, 126.13	79.77, 126.89	73.73, 123.02
	Median	117.64	112.82	98.08
	Q25, Q75	77.02, 178.27	63.77, 186.13	65.57, 168.39
	Min, Max	14.9, 342.4	20.3, 298.6	11.8, 384.3
	Mean (SD)	130.26 (75.123)	125.55 (74.530)	121.33 (80.889)
	95% CI of Mean	112.35, 148.18	102.02, 149.08	94.36, 148.31

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	26.22 (105.43)	103.19 (87.34)	15.80 (219.40)
	95% CI of Geometric Mean	21.33, 32.22	81.36, 130.87	10.14, 24.59
	Median	30.85	107.70	13.01
	Q25, Q75	15.05, 48.97	64.77, 177.87	5.27, 44.80
	Min, Max	3.6, 210.8	16.2, 407.5	1.4, 179.8
	Mean (SD)	37.13 (35.044)	132.28 (92.460)	34.81 (44.422)
	95% CI of Mean	28.77, 45.49	103.09, 161.47	19.99, 49.62

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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Baseline							
	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	90.45 (65.54)	79.76 (97.92)	92.78 (56.02)	74.23 (100.30)	83.40 (83.60)	74.80 (104.89)
	95% CI of Geometric Mean	75.24, 108.72	59.63, 106.67	74.78, 115.11	48.33, 114.00	60.39, 115.18	48.03, 116.48
	Median	99.66	93.23	100.00	47.56	79.25	90.48
	Q25, Q75	62.96, 133.40	43.36, 136.79	60.97, 132.17	42.04, 152.23	65.92, 127.23	67.89, 143.61
	Min, Max	11.9, 221.0	15.9, 342.9	24.0, 264.2	17.0, 318.8	14.7, 376.4	11.0, 201.8
	Mean (SD)	104.65 (52.073)	107.01 (79.494)	104.82 (52.227)	102.36 (85.275)	106.34 (82.755)	97.64 (60.295)
	95% CI of Mean	88.62, 120.68	78.82, 135.21	83.25, 126.38	58.51, 146.21	69.64, 143.04	66.64, 128.65

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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 1							
	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	63.94 (63.87)	56.01 (93.93)	90.07 (51.78)	73.53 (94.27)	61.03 (80.09)	49.41 (128.70)
	95% CI of Geometric Mean	53.40, 76.56	42.24, 74.26	73.65, 110.14	48.79, 110.79	44.66, 83.39	29.72, 82.15
	Median	70.97	73.81	94.59	62.91	61.89	57.84
	Q25, Q75	43.66, 93.37	29.34, 93.22	62.50, 135.24	42.02, 143.12	43.86, 90.32	36.99, 104.43
	Min, Max	9.1, 156.0	13.2, 245.5	23.7, 173.8	17.6, 321.4	9.9, 262.8	4.6, 176.0
	Mean (SD)	73.77 (36.876)	74.35 (55.936)	99.75 (42.614)	98.78 (80.525)	76.49 (57.569)	70.25 (51.467)
	95% CI of Mean	62.42, 85.12	54.51, 94.18	82.15, 117.34	57.37, 140.19	50.96, 102.02	43.78, 96.72

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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 1							
	n	43	33	25	17	22	17
	Median	-27.63	-28.42	-0.50	0.81	-27.94	-28.53
	Q25, Q75	-36.75, -22.15	-38.25, -22.42	-8.89, 5.29	-3.57, 6.09	-33.04, -21.22	-42.63, -18.87
	Min, Max	-50.8, 11.5	-66.3, 40.4	-37.5, 17.6	-33.0, 32.3	-44.2, 26.8	-57.6, 7.7
	Mean (SD)	-28.41 (11.667)	-27.51 (19.251)	-2.25 (11.144)	0.64 (18.097)	-25.59 (15.092)	-31.78 (17.563)
	95% CI of Mean	-32.01, -24.82	-34.34, -20.68	-6.85, 2.36	-8.67, 9.95	-32.28, -18.89	-40.81, -22.74

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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 2							
	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	49.80 (63.46)	45.09 (90.72)	91.48 (53.74)	71.93 (92.62)	49.60 (81.34)	36.37 (131.24)
	95% CI of Geometric Mean	41.63, 59.56	34.25, 59.35	74.31, 112.63	47.99, 107.81	36.16, 68.04	21.74, 60.85
	Median	53.05	56.88	88.28	56.34	49.38	43.14
	Q25, Q75	38.19, 73.31	24.97, 75.93	63.83, 130.43	40.03, 137.21	33.19, 71.61	26.62, 75.05
	Min, Max	7.5, 122.2	10.3, 181.7	23.7, 184.7	17.1, 276.5	8.5, 216.5	3.5, 121.0
	Mean (SD)	57.42 (28.713)	58.42 (40.246)	102.07 (45.527)	95.54 (74.096)	62.54 (47.310)	52.08 (38.007)
	95% CI of Mean	48.57, 66.26	44.14, 72.69	83.28, 120.87	57.44, 133.64	41.56, 83.52	32.54, 71.63

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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 2							
	n	43	33	25	17	22	17
	Median	-44.66	-42.70	-1.11	-4.59	-41.62	-47.89
	Q25, Q75	-53.69, -37.16	-48.75, -35.21	-6.81, 1.53	-9.16, 5.03	-42.88, -35.43	-63.14, -42.01
	Min, Max	-63.4, -19.5	-69.2, 40.2	-30.1, 54.9	-35.7, 40.4	-59.4, -23.8	-68.1, -25.8
	Mean (SD)	-43.79 (11.668)	-41.13 (18.805)	-0.37 (15.408)	-1.60 (17.774)	-39.88 (8.824)	-49.68 (13.222)
	95% CI of Mean	-47.39, -40.20	-47.80, -34.45	-6.73, 6.00	-10.74, 7.54	-43.79, -35.96	-56.48, -42.88

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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 3							
	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	44.73 (64.82)	40.23 (91.70)	90.70 (54.74)	74.13 (92.97)	43.69 (85.71)	32.25 (116.23)
	95% CI of Geometric Mean	37.28, 53.68	30.49, 53.07	73.42, 112.05	49.40, 111.24	31.43, 60.72	20.04, 51.87
	Median	49.15	51.05	108.33	72.26	40.02	39.15
	Q25, Q75	32.04, 65.19	20.99, 67.75	58.48, 130.44	43.95, 141.01	30.53, 77.59	21.10, 64.01
	Min, Max	6.9, 110.6	9.7, 175.8	21.9, 186.2	17.4, 294.5	7.1, 186.6	5.8, 123.7
	Mean (SD)	51.98 (27.100)	52.76 (38.347)	101.36 (44.783)	98.46 (76.872)	55.87 (42.051)	44.99 (33.825)
	95% CI of Mean	43.64, 60.33	39.16, 66.36	82.87, 119.85	58.93, 137.99	37.22, 74.52	27.60, 62.39

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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 3							
	n	43	33	25	17	22	17
	Median	-49.47	-48.47	-2.23	2.40	-47.44	-52.68
	Q25, Q75	-58.68, -41.39	-57.40, -41.73	-9.11, 3.17	-11.81, 6.72	-51.48, -42.26	-64.51, -46.83
	Min, Max	-66.5, -20.7	-70.7, -8.6	-31.1, 34.1	-34.0, 51.9	-67.0, -16.2	-77.1, -31.8
	Mean (SD)	-49.25 (11.897)	-47.90 (13.534)	-0.99 (16.207)	1.95 (22.167)	-46.82 (9.676)	-55.40 (11.541)
	95% CI of Mean	-52.91, -45.58	-52.71, -43.10	-7.69, 5.70	-9.46, 13.35	-51.11, -42.52	-61.33, -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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 4	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	41.54 (64.18)	35.93 (84.86)	88.80 (52.88)	77.06 (97.54)	37.82 (90.74)	27.00 (137.76)
	95% CI of Geometric Mean	34.67, 49.78	27.67, 46.65	72.34, 109.00	50.61, 117.33	26.82, 53.34	15.88, 45.89
	Median	43.16	44.11	93.97	61.99	36.72	35.33
	Q25, Q75	29.75, 61.90	19.88, 61.14	61.47, 134.38	41.70, 163.10	23.91, 63.52	12.14, 56.09
	Min, Max	6.3, 98.6	9.8, 121.4	24.5, 180.3	16.9, 281.2	6.6, 155.3	3.5, 96.9
	Mean (SD)	48.19 (25.106)	45.65 (30.168)	98.86 (43.813)	104.03 (80.764)	49.55 (38.917)	39.55 (29.450)
	95% CI of Mean	40.46, 55.92	34.94, 56.35	80.77, 116.95	62.50, 145.56	32.29, 66.81	24.41, 54.70

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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 4							
	n	43	33	25	17	22	17
	Median	-53.76	-53.29	-1.61	-0.20	-51.43	-60.48
	Q25, Q75	-61.81, -45.99	-61.58, -44.96	-13.32, 3.45	-9.87, 16.37	-55.87, -47.20	-69.90, -51.99
	Min, Max	-71.1, -8.9	-78.7, -21.7	-37.4, 46.3	-22.1, 64.6	-83.1, -41.1	-86.8, -46.6
	Mean (SD)	-52.72 (12.010)	-53.21 (12.563)	-3.11 (15.633)	5.92 (22.902)	-53.38 (9.389)	-61.85 (11.510)
	95% CI of Mean	-56.42, -49.02	-57.67, -48.75	-9.57, 3.35	-5.86, 17.70	-57.55, -49.21	-67.77, -55.93

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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
Day 5	n	43	33	25	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	40.57 (65.32)	34.68 (97.49)	92.63 (45.96)	76.97 (97.02)	36.64 (84.77)	22.42 (129.33)
	95% CI of Geometric Mean	33.77, 48.75	25.95, 46.34	77.31, 110.98	50.63, 117.01	26.44, 50.78	13.46, 37.34
	Median	40.23	45.24	84.75	68.06	34.64	29.17
	Q25, Q75	29.13, 60.94	19.96, 62.37	67.45, 123.31	44.84, 161.45	23.52, 55.71	10.12, 52.67
	Min, Max	6.8, 102.2	5.0, 123.8	39.3, 178.5	15.1, 273.8	6.0, 139.7	3.3, 88.9
	Mean (SD)	47.45 (25.855)	45.49 (30.440)	101.25 (42.730)	103.36 (79.800)	46.56 (33.898)	32.76 (26.284)
	95% CI of Mean	39.49, 55.41	34.69, 56.29	83.61, 118.89	62.33, 144.40	31.52, 61.59	19.24, 46.27

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 10 AM on Day 1 in the SA arm.

**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=43)	Females (N=33)	Males (N=25)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 5							
	n	43	33	25	17	22	17
	Median	-54.83	-55.97	-2.76	-2.00	-55.16	-67.77
	Q25, Q75	-62.89, -43.60	-64.39, -50.14	-9.09, 8.58	-14.12, 18.77	-60.22, -50.48	-73.48, -61.54
	Min, Max	-72.7, -24.2	-72.2, -21.0	-32.4, 63.5	-28.2, 75.3	-70.6, -41.2	-89.0, -51.0
	Mean (SD)	-53.75 (11.682)	-55.23 (11.185)	1.68 (21.246)	7.20 (29.728)	-55.50 (7.116)	-68.17 (10.155)
	95% CI of Mean	-57.35, -50.15	-59.20, -51.26	-7.10, 10.45	-8.09, 22.49	-58.66, -52.34	-73.40, -62.95

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 10 AM on Day 1 in the SA arm.

**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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Baseline	n	42	32	24	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	89.88 (66.29)	80.71 (99.61)	94.59 (56.28)	74.23 (100.30)	83.40 (83.60)	74.80 (104.89)
	95% CI of Geometric Mean	74.46, 108.48	59.83, 108.88	75.79, 118.04	48.33, 114.00	60.39, 115.18	48.03, 116.48
	Median	99.62	100.82	102.50	47.56	79.25	90.48
	Q25, Q75	62.96, 133.40	40.78, 147.96	65.99, 132.48	42.04, 152.23	65.92, 127.23	67.89, 143.61
	Min, Max	11.9, 221.0	15.9, 342.9	24.0, 264.2	17.0, 318.8	14.7, 376.4	11.0, 201.8
	Mean (SD)	104.33 (52.661)	108.65 (80.197)	106.75 (52.428)	102.36 (85.275)	106.34 (82.755)	97.64 (60.295)
	95% CI of Mean	87.92, 120.75	79.74, 137.57	84.61, 128.89	58.51, 146.21	69.64, 143.04	66.64, 128.65

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 10 AM on Day 1 in the SA arm.

**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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
Day 30	n	42	32	24	17	22	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	30.33 (64.24)	22.82 (88.53)	89.45 (76.32)	81.71 (88.32)	22.18 (143.25)	18.37 (119.52)
	95% CI of Geometric Mean	25.25, 36.44	17.34, 30.03	67.19, 119.07	55.30, 120.75	13.88, 35.43	11.31, 29.82
	Median	29.43	28.48	114.06	68.89	24.29	26.52
	Q25, Q75	22.28, 44.23	13.16, 38.10	55.71, 139.34	47.09, 145.66	11.55, 54.52	10.70, 30.61
	Min, Max	10.8, 127.5	4.7, 76.2	17.4, 197.6	22.0, 282.8	1.6, 109.9	3.0, 106.9
	Mean (SD)	36.11 (24.241)	28.99 (18.761)	106.75 (54.410)	106.10 (77.759)	34.50 (30.919)	26.97 (25.584)
	95% CI of Mean	28.55, 43.66	22.22, 35.76	83.77, 129.73	66.12, 146.09	20.79, 48.21	13.81, 40.13

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 10 AM on Day 1 in the SA arm.

**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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=42)	Females (N=32)	Males (N=24)	Females (N=17)	Males (N=22)	Females (N=17)
% Change from baseline to Day 30							
	n	42	32	24	17	22	17
	Median	-67.75	-69.55	6.12	14.04	-72.35	-72.52
	Q25, Q75	-77.15, -55.81	-80.95, -61.96	-8.41, 15.86	-11.31, 30.16	-82.84, -56.44	-84.14, -63.15
	Min, Max	-84.2, -8.7	-88.4, 3.2	-69.1, 25.5	-37.5, 82.6	-89.1, -19.2	-88.2, -41.1
	Mean (SD)	-62.21 (20.111)	-67.80 (18.529)	-1.19 (24.840)	14.34 (32.269)	-68.31 (20.364)	-72.03 (15.086)
	95% CI of Mean	-68.48, -55.93	-74.48, -61.11	-11.68, 9.30	-2.26, 30.93	-77.34, -59.28	-79.79, -64.27

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 10 AM on Day 1 in the SA arm.

**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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Baseline	n	41	30	24	17	21	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	93.60 (61.65)	89.67 (85.97)	94.59 (56.28)	74.23 (100.30)	82.05 (85.66)	74.80 (104.89)
	95% CI of Geometric Mean	78.24, 111.97	67.91, 118.38	75.79, 118.04	48.33, 114.00	58.53, 115.01	48.03, 116.48
	Median	106.33	111.68	102.50	47.56	78.10	90.48
	Q25, Q75	66.04, 133.40	45.06, 159.13	65.99, 132.48	42.04, 152.23	65.92, 127.23	67.89, 143.61
	Min, Max	11.9, 221.0	26.4, 342.9	24.0, 264.2	17.0, 318.8	14.7, 376.4	11.0, 201.8
	Mean (SD)	106.95 (51.629)	114.79 (79.073)	106.75 (52.428)	102.36 (85.275)	105.80 (84.759)	97.64 (60.295)
	95% CI of Mean	90.65, 123.25	85.26, 144.32	84.61, 128.89	58.51, 146.21	67.22, 144.39	66.64, 128.65

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 10 AM on Day 1 in the SA arm.

**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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
Day 60	n	41	30	24	17	21	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	25.49 (82.08)	21.64 (89.23)	94.40 (80.31)	81.16 (81.27)	16.51 (208.72)	12.24 (159.02)
	95% CI of Geometric Mean	20.32, 31.98	16.26, 28.80	70.08, 127.17	56.27, 117.05	9.15, 29.78	6.87, 21.81
	Median	25.87	25.85	103.79	82.48	14.22	11.60
	Q25, Q75	19.17, 40.74	14.44, 35.18	73.88, 150.28	46.14, 134.67	9.84, 42.12	4.72, 22.40
	Min, Max	4.9, 176.8	3.8, 98.6	17.4, 297.0	23.9, 340.4	1.4, 136.0	2.0, 137.3
	Mean (SD)	33.05 (29.405)	27.74 (19.657)	114.80 (65.935)	103.20 (79.236)	32.14 (36.223)	22.88 (32.593)
	95% CI of Mean	23.76, 42.33	20.39, 35.08	86.95, 142.64	62.45, 143.94	15.64, 48.63	6.12, 39.64

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 10 AM on Day 1 in the SA arm.

**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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=41)	Females (N=30)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=17)
% Change from baseline to Day 60							
	n	41	30	24	17	21	17
	Median	-76.07	-75.05	9.72	9.75	-82.35	-86.30
	Q25, Q75	-80.45, -64.65	-85.63, -62.26	-8.04, 24.71	-16.73, 40.84	-90.42, -51.42	-89.73, -65.59
	Min, Max	-89.6, 88.2	-92.8, -24.5	-69.1, 83.5	-46.7, 141.3	-96.9, 7.9	-97.8, -24.3
	Mean (SD)	-65.90 (31.730)	-71.86 (15.982)	7.33 (36.595)	17.66 (47.518)	-66.57 (32.900)	-76.39 (20.654)
	95% CI of Mean	-75.92, -55.88	-77.83, -65.88	-8.13, 22.79	-6.77, 42.10	-81.55, -51.59	-87.01, -65.76

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 10 AM on Day 1 in the SA arm.

**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=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Baseline	n	39	31	24	17	21	16
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	98.81 (49.64)	81.35 (101.71)	94.59 (56.28)	74.23 (100.30)	82.05 (85.66)	74.72 (109.85)
	95% CI of Geometric Mean	84.86, 115.05	59.71, 110.81	75.79, 118.04	48.33, 114.00	58.53, 115.01	46.51, 120.04
	Median	106.33	108.40	102.50	47.56	78.10	91.33
	Q25, Q75	66.04, 142.24	38.21, 159.13	65.99, 132.48	42.04, 152.23	65.92, 127.23	49.55, 153.54
	Min, Max	43.6, 221.0	15.9, 342.9	24.0, 264.2	17.0, 318.8	14.7, 376.4	11.0, 201.8
	Mean (SD)	109.69 (50.274)	110.12 (81.087)	106.75 (52.428)	102.36 (85.275)	105.80 (84.759)	98.99 (62.006)
	95% CI of Mean	93.38, 125.99	80.37, 139.87	84.61, 128.89	58.51, 146.21	67.22, 144.39	65.95, 132.04

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 10 AM on Day 1 in the SA arm.

**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=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
Day 90	n	39	31	24	17	21	16
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	25.13 (90.17)	21.04 (89.26)	95.40 (70.12)	94.52 (79.92)	16.96 (256.24)	10.79 (163.89)
	95% CI of Geometric Mean	19.57, 32.28	15.89, 27.87	73.04, 124.60	65.86, 135.67	8.87, 32.41	5.87, 19.84
	Median	29.02	22.71	115.79	94.32	19.43	6.89
	Q25, Q75	15.47, 38.74	12.46, 41.29	61.89, 137.97	57.26, 192.26	6.14, 58.80	4.87, 27.85
	Min, Max	3.5, 158.0	5.1, 96.5	22.4, 284.5	22.7, 249.3	1.0, 123.2	2.9, 166.1
	Mean (SD)	33.29 (28.771)	27.51 (20.985)	113.08 (64.194)	116.68 (73.680)	35.16 (37.391)	23.22 (40.497)
	95% CI of Mean	23.96, 42.62	19.81, 35.21	85.97, 140.20	78.79, 154.56	18.13, 52.18	1.64, 44.81

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 10 AM on Day 1 in the SA arm.

**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=39)	Females (N=31)	Males (N=24)	Females (N=17)	Males (N=21)	Females (N=16)
% Change from baseline to Day 90							
	n	39	31	24	17	21	16
	Median	-77.20	-72.34	9.17	35.71	-79.34	-81.05
	Q25, Q75	-84.17, -62.62	-83.40, -55.95	-21.82, 30.11	5.70, 75.23	-92.90, -9.44	-95.56, -64.44
	Min, Max	-93.2, 6.2	-93.3, -26.1	-60.3, 82.6	-42.6, 117.4	-97.6, 10.5	-96.8, -8.4
	Mean (SD)	-68.42 (23.313)	-68.78 (18.763)	7.29 (36.301)	35.02 (44.831)	-59.47 (41.310)	-75.83 (23.922)
	95% CI of Mean	-75.98, -60.86	-75.67, -61.90	-8.05, 22.62	11.96, 58.07	-78.28, -40.66	-88.58, -63.08

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 10 AM on Day 1 in the SA arm.

**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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Baseline							
	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	72.17 (88.01)	102.56 (64.98)	71.05 (81.17)	104.98 (59.61)	57.79 (106.46)	111.32 (53.50)
	95% CI of Geometric Mean	56.46, 92.26	84.14, 125.01	52.23, 96.65	80.47, 136.93	38.45, 86.86	87.40, 141.77
	Median	68.39	114.56	71.01	108.72	68.91	105.37
	Q25, Q75	43.57, 132.68	70.92, 142.24	43.92, 131.31	58.42, 152.23	31.17, 109.44	78.10, 159.57
	Min, Max	11.9, 259.6	17.4, 342.9	17.0, 264.2	41.2, 318.8	11.0, 279.3	42.3, 376.4
	Mean (SD)	92.67 (62.910)	119.38 (65.036)	89.81 (63.946)	120.79 (67.463)	79.69 (64.526)	126.61 (75.333)
	95% CI of Mean	72.27, 113.07	97.70, 141.07	62.15, 117.46	88.27, 153.31	49.49, 109.89	90.30, 162.92

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 10 AM on Day 1 in the SA arm.

**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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 1							
	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	50.58 (87.62)	72.73 (59.09)	68.20 (70.12)	105.18 (60.03)	39.93 (120.78)	78.96 (55.57)
	95% CI of Geometric Mean	39.60, 64.61	60.60, 87.30	51.88, 89.65	80.50, 137.42	25.61, 62.25	61.49, 101.40
	Median	52.45	81.76	66.81	106.67	46.38	84.21
	Q25, Q75	28.70, 90.70	53.41, 94.03	43.84, 123.65	58.42, 156.58	20.77, 72.84	53.05, 106.85
	Min, Max	9.1, 245.5	14.4, 192.6	17.6, 165.7	41.8, 321.4	4.6, 201.3	34.5, 262.8
	Mean (SD)	65.80 (49.614)	82.69 (40.238)	81.29 (46.585)	121.23 (67.904)	58.11 (51.982)	90.25 (53.201)
	95% CI of Mean	49.71, 81.89	69.26, 96.11	61.14, 101.44	88.50, 153.96	33.78, 82.45	64.61, 115.90

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 10 AM on Day 1 in the SA arm.

**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**

	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 1							
	n	39	37	23	19	20	19
	Median	-29.31	-27.48	0.27	-0.07	-29.11	-26.76
	Q25, Q75	-38.26, -22.42	-36.75, -19.62	-12.76, 6.09	-5.41, 3.74	-42.30, -21.36	-35.52, -18.41
	Min, Max	-66.3, 40.4	-51.3, 16.9	-37.5, 32.3	-25.9, 28.2	-57.6, 26.8	-54.3, -9.0
	Mean (SD)	-28.03 (17.519)	-28.01 (12.834)	-2.70 (15.831)	0.88 (12.153)	-28.49 (20.010)	-28.07 (11.729)
	95% CI of Mean	-33.71, -22.34	-32.29, -23.73	-9.55, 4.15	-4.98, 6.74	-37.86, -19.12	-33.73, -22.41

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 10 AM on Day 1 in the SA arm.

**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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 2	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	40.08 (84.22)	57.29 (59.21)	67.63 (72.28)	106.35 (57.90)	30.50 (122.68)	62.70 (57.25)
	95% CI of Geometric Mean	31.61, 50.82	47.71, 68.78	51.09, 89.52	82.07, 137.82	19.47, 47.76	48.51, 81.05
	Median	45.68	59.74	63.83	106.09	36.02	65.80
	Q25, Q75	22.24, 74.75	46.01, 78.90	40.58, 120.94	80.74, 167.66	16.82, 53.59	42.70, 84.33
	Min, Max	7.5, 122.2	12.0, 181.7	17.1, 184.7	38.4, 276.5	3.5, 159.7	24.5, 216.5
	Mean (SD)	50.63 (32.714)	65.46 (34.007)	81.64 (49.593)	120.97 (61.382)	44.50 (39.050)	72.17 (43.928)
	95% CI of Mean	40.02, 61.24	54.12, 76.80	60.19, 103.09	91.38, 150.56	26.22, 62.78	50.99, 93.35

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 10 AM on Day 1 in the SA arm.

**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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 2							
	n	39	37	23	19	20	19
	Median	-42.76	-42.80	-3.51	0.00	-42.61	-42.51
	Q25, Q75	-53.34, -35.21	-51.17, -37.16	-12.94, 8.47	-6.81, 2.62	-57.62, -35.23	-45.32, -35.90
	Min, Max	-69.2, -19.5	-68.1, 40.2	-35.7, 18.5	-22.6, 54.9	-68.1, -25.8	-64.6, -23.8
	Mean (SD)	-43.14 (12.233)	-42.10 (17.841)	-3.75 (14.174)	2.62 (18.144)	-45.49 (13.418)	-42.74 (10.164)
	95% CI of Mean	-47.11, -39.17	-48.05, -36.15	-9.89, 2.38	-6.13, 11.37	-51.78, -39.21	-47.64, -37.83

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 10 AM on Day 1 in the SA arm.

**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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 3	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	36.21 (86.50)	50.85 (59.94)	67.94 (74.12)	107.43 (55.61)	25.84 (106.35)	57.86 (59.31)
	95% CI of Geometric Mean	28.41, 46.14	42.27, 61.18	51.03, 90.46	83.65, 137.97	17.20, 38.83	44.40, 75.39
	Median	37.10	54.29	70.05	110.08	28.67	64.01
	Q25, Q75	20.99, 66.02	40.97, 65.66	43.95, 125.77	69.93, 160.00	14.23, 45.08	39.16, 79.55
	Min, Max	6.9, 110.6	10.1, 175.8	17.4, 186.2	45.2, 294.5	5.8, 140.0	20.5, 186.6
	Mean (SD)	46.60 (32.265)	58.34 (31.506)	82.45 (50.047)	121.65 (63.102)	36.21 (32.000)	66.83 (39.428)
	95% CI of Mean	36.14, 57.06	47.84, 68.85	60.80, 104.10	91.24, 152.07	21.23, 51.19	47.83, 85.84

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 10 AM on Day 1 in the SA arm.

**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	>19	10-19	>19	10-19	>19
		cig/day (N=39)	cig/day (N=37)	cig/day (N=23)	cig/day (N=19)	cig/day (N=20)	cig/day (N=19)
% Change from baseline to Day 3							
	n	39	37	23	19	20	19
	Median	-48.88	-49.92	-4.08	0.40	-51.22	-46.63
	Q25, Q75	-58.45, -39.48	-58.74, -41.43	-14.67, 6.72	-7.63, 6.40	-61.30, -46.88	-51.53, -44.49
	Min, Max	-70.7, -20.7	-66.5, -8.6	-34.0, 51.9	-20.8, 51.5	-77.1, -39.7	-68.3, -16.2
	Mean (SD)	-48.43 (12.187)	-48.92 (13.114)	-2.57 (19.716)	3.55 (17.180)	-54.07 (10.172)	-46.86 (11.381)
	95% CI of Mean	-52.38, -44.47	-53.29, -44.54	-11.10, 5.96	-4.74, 11.83	-58.83, -49.30	-52.35, -41.37

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 10 AM on Day 1 in the SA arm.

**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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 4	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	32.81 (82.22)	46.81 (57.27)	68.41 (75.57)	107.26 (55.11)	22.65 (128.65)	48.00 (67.02)
	95% CI of Geometric Mean	25.98, 41.42	39.19, 55.91	51.15, 91.49	83.68, 137.48	14.26, 35.97	35.78, 64.38
	Median	31.98	49.38	61.99	107.06	27.39	52.87
	Q25, Q75	20.13, 61.90	36.07, 60.09	41.70, 134.38	75.44, 163.10	11.43, 42.85	35.04, 72.91
	Min, Max	6.3, 98.6	10.5, 121.4	16.9, 192.4	45.7, 281.2	3.5, 147.5	12.4, 155.3
	Mean (SD)	41.43 (27.527)	53.05 (26.011)	83.98 (53.614)	121.49 (63.609)	34.40 (33.709)	56.56 (33.554)
	95% CI of Mean	32.50, 50.35	44.38, 61.73	60.79, 107.17	90.83, 152.15	18.62, 50.18	40.38, 72.74

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 10 AM on Day 1 in the SA arm.

**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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
% Change from baseline to Day 4							
	n	39	37	23	19	20	19
	Median	-53.63	-53.29	-1.87	2.06	-56.06	-51.06
	Q25, Q75	-61.63, -46.76	-61.58, -43.30	-14.28, 4.20	-11.81, 7.14	-66.32, -49.50	-58.73, -48.51
	Min, Max	-73.2, -8.9	-78.7, -21.7	-37.4, 37.2	-24.9, 64.6	-86.8, -41.1	-83.1, -42.9
	Mean (SD)	-53.20 (11.821)	-52.65 (12.690)	-2.24 (17.479)	3.92 (21.037)	-58.66 (12.014)	-55.41 (10.038)
	95% CI of Mean	-57.04, -49.36	-56.88, -48.41	-9.81, 5.32	-6.23, 14.06	-64.28, -53.03	-60.25, -50.56

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 10 AM on Day 1 in the SA arm.

**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=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 5	n	39	37	23	19	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	31.42 (85.50)	46.17 (66.25)	72.23 (70.88)	106.07 (57.02)	19.59 (121.92)	45.65 (57.43)
	95% CI of Geometric Mean	24.71, 39.95	37.76, 56.47	54.81, 95.18	82.13, 136.98	12.53, 30.62	35.29, 59.05
	Median	29.46	46.45	68.06	108.74	21.88	52.67
	Q25, Q75	19.68, 61.83	37.70, 62.95	45.19, 120.03	74.93, 161.50	9.60, 34.77	32.40, 69.56
	Min, Max	6.8, 102.2	5.0, 123.8	15.1, 178.5	42.1, 273.8	3.3, 126.4	16.8, 139.7
	Mean (SD)	40.21 (27.540)	53.33 (26.723)	86.58 (51.801)	120.89 (64.323)	29.36 (29.089)	52.31 (29.625)
	95% CI of Mean	31.28, 49.14	44.42, 62.25	64.18, 108.99	89.89, 151.90	15.74, 42.97	38.03, 66.60

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 10 AM on Day 1 in the SA arm.

**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**

		THSm2.2		mCC		SA	
		10-19 cig/day (N=39)	>19 cig/day (N=37)	10-19 cig/day (N=23)	>19 cig/day (N=19)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 5							
	n	39	37	23	19	20	19
	Median	-55.97	-55.37	0.97	-2.76	-64.18	-56.03
	Q25, Q75	-64.39, -45.11	-62.89, -46.38	-11.06, 11.11	-14.12, 11.48	-69.96, -54.69	-62.32, -53.66
	Min, Max	-72.7, -24.2	-71.4, -21.0	-32.4, 63.5	-23.6, 75.3	-89.0, -46.2	-73.9, -41.2
	Mean (SD)	-55.19 (10.923)	-53.55 (12.008)	4.40 (25.480)	3.32 (24.705)	-63.77 (11.929)	-58.14 (8.305)
	95% CI of Mean	-58.74, -51.65	-57.56, -49.54	-6.63, 15.42	-8.59, 15.23	-69.35, -58.18	-62.15, -54.14

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 10 AM on Day 1 in the SA arm.

**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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Baseline	n	38	36	23	18	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	72.71 (89.35)	102.16 (66.01)	71.05 (81.17)	108.45 (59.21)	57.79 (106.46)	111.32 (53.50)
	95% CI of Geometric Mean	56.52, 93.53	83.35, 125.22	52.23, 96.65	82.57, 142.44	38.45, 86.86	87.40, 141.77
	Median	69.02	111.48	71.01	110.27	68.91	105.37
	Q25, Q75	43.57, 132.68	70.55, 145.49	43.92, 131.31	87.99, 152.23	31.17, 109.44	78.10, 159.57
	Min, Max	11.9, 259.6	17.4, 342.9	17.0, 264.2	41.2, 318.8	11.0, 279.3	42.3, 376.4
	Mean (SD)	93.68 (63.438)	119.42 (65.958)	89.81 (63.946)	124.26 (67.657)	79.69 (64.526)	126.61 (75.333)
	95% CI of Mean	72.82, 114.53	97.10, 141.74	62.15, 117.46	90.61, 157.91	49.49, 109.89	90.30, 162.92

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 10 AM on Day 1 in the SA arm.

**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 2**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Day 30	n	38	36	23	18	20	19
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	22.00 (78.88)	33.07 (65.82)	65.52 (82.22)	122.25 (55.57)	14.16 (159.38)	30.06 (77.25)
	95% CI of Geometric Mean	17.50, 27.65	26.99, 40.52	48.01, 89.40	94.45, 158.23	8.36, 23.96	21.61, 41.81
	Median	24.99	33.89	66.21	131.63	12.78	29.92
	Q25, Q75	12.41, 36.23	26.50, 42.43	37.65, 124.75	86.19, 189.42	6.58, 26.79	22.24, 45.54
	Min, Max	4.7, 73.9	5.4, 127.5	17.4, 181.1	47.0, 282.8	1.6, 109.9	6.3, 106.9
	Mean (SD)	27.25 (17.372)	39.13 (25.154)	82.26 (53.405)	137.43 (64.784)	25.64 (30.874)	37.09 (25.498)
	95% CI of Mean	21.53, 32.96	30.62, 47.65	59.16, 105.35	105.21, 169.65	11.18, 40.09	24.80, 49.39

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 10 AM on Day 1 in the SA arm.

**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 2**

		THSm2.2		mCC		SA	
		10-19 cig/day (N=38)	>19 cig/day (N=36)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=19)
Timepoint	Statistic						
% Change from baseline to Day 30							
	n	38	36	23	18	20	19
	Median	-72.09	-65.97	-0.99	16.53	-76.50	-71.73
	Q25, Q75	-77.77, -62.76	-78.40, -58.87	-18.87, 15.65	2.42, 25.45	-84.38, -64.85	-82.84, -56.44
	Min, Max	-85.9, 3.2	-88.4, -14.3	-69.1, 82.6	-37.5, 58.8	-89.1, -19.2	-86.7, -39.5
	Mean (SD)	-65.38 (21.345)	-63.82 (17.640)	-2.54 (30.712)	15.20 (23.422)	-70.15 (21.075)	-69.70 (14.985)
	95% CI of Mean	-72.40, -58.36	-69.80, -57.85	-15.82, 10.75	3.54, 26.85	-80.02, -60.28	-76.93, -62.47

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 10 AM on Day 1 in the SA arm.

**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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Baseline	n	36	35	23	18	20	18
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	78.46 (81.16)	108.17 (56.51)	71.05 (81.17)	108.45 (59.21)	57.79 (106.46)	110.98 (55.24)
	95% CI of Geometric Mean	61.67, 99.81	90.28, 129.62	52.23, 96.65	82.57, 142.44	38.45, 86.86	85.85, 143.45
	Median	76.43	118.05	71.01	110.27	68.91	98.96
	Q25, Q75	47.16, 133.04	70.92, 148.73	43.92, 131.31	87.99, 152.23	31.17, 109.44	78.10, 159.57
	Min, Max	11.9, 259.6	29.3, 342.9	17.0, 264.2	41.2, 318.8	11.0, 279.3	42.3, 376.4
	Mean (SD)	97.84 (62.568)	123.03 (64.337)	89.81 (63.946)	124.26 (67.657)	79.69 (64.526)	127.11 (77.485)
	95% CI of Mean	76.67, 119.02	100.93, 145.14	62.15, 117.46	90.61, 157.91	49.49, 109.89	88.57, 165.64

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 10 AM on Day 1 in the SA arm.

**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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=35)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=18)
Day 60	n	36	35	23	18	20	18
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	18.33 (86.27)	31.10 (70.20)	69.61 (88.64)	120.79 (51.25)	10.12 (249.79)	21.44 (99.14)
	95% CI of Geometric Mean	14.24, 23.60	25.02, 38.66	50.08, 96.76	95.00, 153.58	5.23, 19.56	14.20, 32.35
	Median	21.41	29.91	83.93	125.22	9.06	17.36
	Q25, Q75	10.17, 29.15	21.56, 48.83	41.26, 134.67	80.84, 155.77	2.90, 29.70	11.60, 42.12
	Min, Max	3.8, 98.6	9.2, 176.8	17.4, 212.1	68.4, 340.4	1.4, 136.0	6.9, 137.3
	Mean (SD)	23.49 (17.626)	38.33 (30.438)	89.53 (60.767)	136.12 (76.169)	24.98 (35.533)	31.35 (34.016)
	95% CI of Mean	17.52, 29.46	27.87, 48.79	63.25, 115.82	98.24, 174.01	8.35, 41.62	14.43, 48.27

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 10 AM on Day 1 in the SA arm.

**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 3**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19	>19	10-19	>19	10-19	>19
		cig/day (N=36)	cig/day (N=35)	cig/day (N=23)	cig/day (N=18)	cig/day (N=20)	cig/day (N=18)
% Change from baseline to Day 60							
	n	36	35	23	18	20	18
	Median	-78.56	-71.36	7.13	12.71	-82.19	-84.79
	Q25, Q75	-85.37, -67.98	-79.27, -56.90	-16.73, 24.95	-5.67, 52.04	-90.66, -61.28	-89.73, -45.33
	Min, Max	-89.6, 88.2	-92.8, 18.9	-69.1, 83.5	-46.7, 141.3	-97.8, 7.9	-95.1, -14.5
	Mean (SD)	-70.84 (30.249)	-65.93 (21.584)	5.51 (36.607)	19.41 (46.376)	-71.46 (29.503)	-70.41 (27.472)
	95% CI of Mean	-81.08, -60.60	-73.35, -58.51	-10.32, 21.35	-3.66, 42.47	-85.27, -57.65	-84.08, -56.75

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 10 AM on Day 1 in the SA arm.

**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=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Baseline	n	36	34	23	18	20	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	79.11 (78.13)	104.73 (67.13)	71.05 (81.17)	108.45 (59.21)	57.79 (106.46)	113.47 (56.09)
	95% CI of Geometric Mean	62.62, 99.92	84.65, 129.57	52.23, 96.65	82.57, 142.44	38.45, 86.86	86.71, 148.48
	Median	76.43	116.46	71.01	110.27	68.91	105.37
	Q25, Q75	47.16, 133.04	72.63, 148.73	43.92, 131.31	87.99, 152.23	31.17, 109.44	80.41, 159.57
	Min, Max	15.9, 259.6	17.4, 342.9	17.0, 264.2	41.2, 318.8	11.0, 279.3	42.3, 376.4
	Mean (SD)	97.96 (62.410)	122.50 (66.615)	89.81 (63.946)	124.26 (67.657)	79.69 (64.526)	130.11 (78.783)
	95% CI of Mean	76.83, 119.08	99.25, 145.75	62.15, 117.46	90.61, 157.91	49.49, 109.89	89.60, 170.62

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 10 AM on Day 1 in the SA arm.

**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=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Day 90	n	36	34	23	18	20	17
	BLOQ, n (%)	0	0	0	0	0	0
	Geometric Mean (CV%)	17.40 (89.67)	31.55 (72.34)	72.09 (70.42)	135.27 (53.23)	11.27 (250.89)	17.92 (173.11)
	95% CI of Geometric Mean	13.41, 22.57	25.15, 39.57	54.79, 94.86	105.52, 173.41	5.82, 21.81	9.78, 32.83
	Median	18.34	32.48	83.33	137.71	8.87	16.10
	Q25, Q75	9.11, 31.54	22.71, 46.13	49.77, 122.14	94.32, 204.41	3.27, 37.02	6.91, 39.21
	Min, Max	3.5, 96.5	8.7, 158.0	22.4, 240.2	57.3, 284.5	1.0, 123.2	3.3, 166.1
	Mean (SD)	22.85 (18.011)	39.07 (29.791)	86.04 (50.905)	151.03 (69.495)	25.78 (32.530)	34.95 (45.398)
	95% CI of Mean	16.75, 28.95	28.67, 49.47	64.02, 108.06	116.47, 185.60	10.55, 41.01	11.61, 58.30

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 10 AM on Day 1 in the SA arm.

**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**

		THSm2.2		mCC		SA	
		10-19 cig/day (N=36)	>19 cig/day (N=34)	10-19 cig/day (N=23)	>19 cig/day (N=18)	10-19 cig/day (N=20)	>19 cig/day (N=17)
Timepoint	Statistic						
% Change from baseline to Day 90							
	n	36	34	23	18	20	17
	Median	-79.71	-71.22	16.17	30.11	-76.75	-89.12
	Q25, Q75	-85.16, -68.62	-79.09, -54.82	-28.56, 46.72	4.62, 44.91	-93.95, -61.26	-95.72, -13.54
	Min, Max	-93.2, -18.6	-93.3, 6.2	-60.3, 91.0	-21.8, 117.4	-96.8, 10.5	-97.6, -7.3
	Mean (SD)	-73.75 (17.135)	-63.11 (23.971)	10.60 (44.949)	29.25 (36.102)	-67.17 (33.610)	-65.80 (38.460)
	95% CI of Mean	-79.55, -67.94	-71.48, -54.74	-8.85, 30.04	11.29, 47.21	-82.91, -51.44	-85.58, -46.02

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	84.85 (78.88)		84.77 (74.73)		81.03 (91.32)	
	95% CI of Geometric Mean	72.53, 99.27		68.88, 104.33		63.16, 103.95	
	Median	96.64		88.37		87.36	
	Q25, Q75	54.55, 133.40		47.56, 141.06		66.90, 133.28	
	Min, Max	11.9, 342.9		17.0, 318.8		11.0, 376.4	
	Mean (SD)	104.57 (64.517)		103.82 (66.603)		104.16 (72.815)	
	95% CI of Mean	90.02, 119.12		83.06, 124.58		80.87, 127.46	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	60.03 (75.92)		82.96 (69.85)		56.61 (99.69)	
	95% CI of Geometric Mean	51.56, 69.90		68.16, 100.98		43.40, 73.84	
	Median	70.29	-27.88	84.39	-0.03	60.07	-28.19
	Q25, Q75	38.19, 93.22	-36.75, -22.15	53.74, 141.08	-8.89, 5.84	38.98, 101.57	-37.79, -20.26
	Min, Max	9.1, 245.5	-66.3, 40.4	17.6, 321.4	-37.5, 32.3	4.6, 262.8	-57.6, 26.8
	Mean (SD)	73.38 (45.372)	-27.73 (15.459)	99.36 (59.947)	-1.08 (14.233)	74.66 (53.967)	-28.44 (16.113)
	95% CI of Mean	63.14, 83.61	-31.22, -24.24	80.67, 118.04	-5.52, 3.36	57.39, 91.92	-33.60, -23.29

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	47.69 (74.00)		83.00 (70.61)		43.98 (102.38)	
	95% CI of Geometric Mean	41.09, 55.36		68.07, 101.20		33.54, 57.66	
	Median	53.47	-42.73	83.76	-1.69	47.46	-42.67
	Q25, Q75	29.73, 74.75	-53.21, -35.39	53.08, 137.21	-9.16, 5.03	28.08, 76.95	-51.69, -35.67
	Min, Max	7.5, 181.7	-69.2, 40.2	17.1, 276.5	-35.7, 54.9	3.5, 216.5	-68.1, -23.8
	Mean (SD)	57.59 (33.555)	-42.01 (15.705)	99.43 (58.020)	-0.87 (16.206)	58.50 (42.844)	-44.37 (11.797)
	95% CI of Mean	50.02, 65.16	-45.55, -38.46	81.35, 117.52	-5.92, 4.19	44.80, 72.21	-48.15, -40.59

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	42.79 (75.16)		83.59 (70.82)		38.97 (98.99)	
	95% CI of Geometric Mean	36.79, 49.77		68.52, 101.97		29.91, 50.76	
	Median	49.18	-48.96	84.73	-1.56	39.54	-49.53
	Q25, Q75	25.55, 66.00	-58.45, -41.39	49.59, 139.27	-11.15, 6.40	24.38, 72.18	-57.38, -45.17
	Min, Max	6.9, 175.8	-70.7, 0.0	17.4, 294.5	-34.0, 51.9	5.8, 186.6	-77.1, -16.2
	Mean (SD)	52.15 (31.828)	-47.95 (13.589)	100.19 (59.009)	0.20 (18.645)	51.82 (38.339)	-50.61 (11.103)
	95% CI of Mean	44.97, 59.33	-51.02, -44.88	81.79, 118.58	-5.62, 6.01	39.56, 64.09	-54.17, -47.06

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	39.16 (72.18)		83.85 (71.21)		33.38 (111.44)	
	95% CI of Geometric Mean	33.84, 45.32		68.67, 102.37		25.04, 44.50	
	Median	43.93	-53.18	84.57	-0.83	36.72	-54.82
	Q25, Q75	24.67, 61.14	-61.58, -44.96	50.52, 150.60	-11.98, 6.46	20.08, 63.72	-61.20, -48.87
	Min, Max	6.3, 121.4	-78.7, 0.0	16.9, 281.2	-37.4, 64.6	3.5, 155.3	-86.8, -41.1
	Mean (SD)	47.05 (26.902)	-52.11 (13.481)	100.95 (60.628)	0.54 (19.179)	46.04 (34.989)	-56.97 (10.950)
	95% CI of Mean	40.98, 53.12	-55.15, -49.06	82.05, 119.85	-5.44, 6.53	34.84, 57.23	-60.47, -53.46

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	38.10 (78.35)		85.94 (67.94)		30.31 (108.52)	
	95% CI of Geometric Mean	32.60, 44.54		70.93, 104.13		22.86, 40.20	
	Median	42.65	-55.54	82.26	-2.48	34.32	-59.41
	Q25, Q75	23.99, 61.83	-63.43, -44.29	54.23, 153.30	-11.06, 11.11	19.13, 55.11	-67.72, -54.09
	Min, Max	5.0, 123.8	-72.7, 0.0	15.1, 273.8	-32.4, 75.3	3.3, 139.7	-89.0, -41.2
	Mean (SD)	46.61 (27.401)	-53.49 (12.954)	102.11 (59.624)	3.91 (24.832)	41.50 (31.395)	-60.82 (10.523)
	95% CI of Mean	40.42, 52.79	-56.42, -50.57	83.52, 120.69	-3.83, 11.65	31.45, 51.54	-64.19, -57.45

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	27.33 (74.93)		85.36 (79.32)		21.13 (133.07)	
	95% CI of Geometric Mean	23.50, 31.77		68.66, 106.13		15.30, 29.19	
	Median	29.88	-67.77	100.28	6.12	25.89	-72.16
	Q25, Q75	17.74, 40.88	-77.77, -58.54	51.71, 145.66	-10.86, 21.58	11.13, 44.34	-83.94, -59.95
	Min, Max	4.7, 127.5	-88.4, 3.2	17.4, 282.8	-69.1, 82.6	1.6, 109.9	-89.1, -19.2
	Mean (SD)	33.37 (21.764)	-63.27 (20.768)	105.34 (63.839)	5.12 (28.490)	32.41 (29.222)	-69.50 (18.094)
	95% CI of Mean	28.46, 38.29	-67.96, -58.58	85.44, 125.23	-3.76, 14.01	23.06, 41.76	-75.30, -63.71

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	23.50 (84.58)		87.79 (79.19)		15.58 (188.13)	
	95% CI of Geometric Mean	19.91, 27.73		70.63, 109.12		10.51, 23.09	
	Median	26.28	-73.91	88.05	8.44	14.83	-83.56
	Q25, Q75	14.79, 37.70	-82.24, -57.38	55.30, 150.20	-10.42, 26.74	7.67, 44.09	-90.08, -53.25
	Min, Max	3.8, 176.8	-92.8, 88.2	17.4, 340.4	-69.1, 141.3	1.4, 137.3	-97.8, 7.9
	Mean (SD)	30.32 (24.923)	-66.06 (26.832)	108.76 (70.604)	11.34 (40.762)	29.93 (34.782)	-70.08 (27.724)
	95% CI of Mean	24.70, 35.95	-72.11, -60.00	86.75, 130.77	-1.37, 24.04	18.80, 41.06	-78.95, -61.21

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	23.42 (85.33)		93.94 (72.53)		15.00 (212.43)	
	95% CI of Geometric Mean	19.82, 27.68		76.71, 115.04		9.87, 22.79	
	Median	25.58	-72.87	106.19	20.21	14.52	-79.13
	Q25, Q75	14.26, 38.74	-83.40, -55.95	58.42, 138.52	-8.98, 44.91	5.70, 44.94	-94.31, -53.25
	Min, Max	3.5, 158.0	-93.3, 132.1	22.4, 284.5	-60.3, 117.4	1.0, 166.1	-97.6, 10.5
	Mean (SD)	30.38 (24.516)	-64.08 (32.191)	113.24 (67.145)	18.34 (41.456)	31.37 (38.264)	-66.33 (34.279)
	95% CI of Mean	24.85, 35.91	-71.34, -56.82	92.31, 134.17	5.41, 31.26	19.13, 43.61	-77.30, -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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	101.74 (79.56)	100.53 (83.33)	96.41 (86.42)
	95% CI of Geometric Mean	86.87, 119.14	80.17, 126.07	75.92, 122.43
	Median	111.63	110.16	99.96
	Q25, Q75	63.84, 178.22	63.77, 186.13	65.03, 164.76
	Min, Max	14.9, 342.4	20.3, 298.6	11.8, 384.3
	Mean (SD)	125.38 (75.613)	124.88 (73.743)	121.25 (78.523)
	95% CI of Mean	108.33, 142.43	101.89, 147.86	96.14, 146.37

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	69.74 (75.54)	99.48 (89.87)	61.13 (104.62)
	95% CI of Geometric Mean	59.93, 81.15	78.27, 126.44	46.43, 80.49
	Median	84.02	119.55	73.31
	Q25, Q75	46.77, 110.78	55.23, 182.14	43.33, 101.79
	Min, Max	10.3, 243.1	13.1, 274.7	5.2, 467.0
	Mean (SD)	84.05 (46.667)	125.72 (74.279)	84.93 (79.473)
	95% CI of Mean	73.52, 94.57	102.57, 148.87	59.51, 110.35

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	56.30 (80.58)	103.44 (88.05)	50.72 (100.19)
	95% CI of Geometric Mean	48.00, 66.04	81.69, 130.99	38.84, 66.22
	Median	64.71	120.86	60.98
	Q25, Q75	36.00, 90.73	69.01, 197.67	36.77, 85.43
	Min, Max	10.2, 203.0	20.5, 275.7	3.8, 194.7
	Mean (SD)	69.95 (43.990)	130.70 (78.537)	66.31 (44.456)
	95% CI of Mean	60.03, 79.87	106.22, 155.18	52.08, 80.53

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	52.09 (77.20)	102.10 (81.36)	46.53 (95.84)
	95% CI of Geometric Mean	44.64, 60.78	81.76, 127.50	35.94, 60.24
	Median	62.81	113.17	52.56
	Q25, Q75	33.07, 80.47	65.11, 176.09	32.16, 74.27
	Min, Max	5.9, 205.9	20.3, 291.9	6.4, 220.0
	Mean (SD)	63.32 (36.929)	126.19 (74.444)	61.44 (45.526)
	95% CI of Mean	54.99, 71.65	102.99, 149.40	46.87, 76.00

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	47.79 (78.28)	95.78 (84.75)	38.38 (121.51)
	95% CI of Geometric Mean	40.89, 55.86	76.15, 120.47	28.30, 52.04
	Median	54.36	114.09	49.82
	Q25, Q75	29.64, 74.26	70.41, 176.00	22.77, 69.32
	Min, Max	9.0, 144.1	16.9, 245.2	4.0, 218.6
	Mean (SD)	58.50 (34.315)	118.95 (68.405)	54.61 (43.313)
	95% CI of Mean	50.76, 66.24	97.63, 140.28	40.75, 68.47

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	44.56 (81.54)	106.50 (76.86)	36.62 (105.64)
	95% CI of Geometric Mean	37.93, 52.35	86.12, 131.70	27.76, 48.31
	Median	52.05	118.85	42.59
	Q25, Q75	27.14, 70.14	68.09, 192.94	24.57, 62.81
	Min, Max	6.7, 140.8	17.6, 265.4	4.3, 207.0
	Mean (SD)	55.22 (33.462)	128.98 (71.105)	49.75 (39.010)
	95% CI of Mean	47.67, 62.77	106.82, 151.14	37.27, 62.23

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	32.34 (84.16)	99.55 (87.84)	22.44 (130.93)
	95% CI of Geometric Mean	27.41, 38.14	78.65, 126.01	16.30, 30.90
	Median	36.91	129.61	24.71
	Q25, Q75	19.78, 48.45	46.32, 178.29	11.60, 48.34
	Min, Max	4.4, 207.0	26.1, 281.3	2.7, 152.0
	Mean (SD)	41.28 (31.785)	126.93 (79.564)	34.54 (32.464)
	95% CI of Mean	34.11, 48.45	102.13, 151.72	24.15, 44.93

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	26.95 (94.34)	101.09 (88.25)	17.61 (191.03)
	95% CI of Geometric Mean	22.50, 32.26	79.79, 128.06	11.84, 26.18
	Median	29.96	112.31	16.87
	Q25, Q75	14.39, 46.44	64.47, 182.98	6.81, 55.53
	Min, Max	4.0, 145.4	24.8, 360.5	1.8, 193.0
	Mean (SD)	35.68 (27.013)	129.67 (86.237)	35.11 (42.590)
	95% CI of Mean	29.59, 41.78	102.79, 156.54	21.48, 48.74

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	26.60 (100.45)	103.05 (85.95)	16.87 (215.40)
	95% CI of Geometric Mean	22.03, 32.11	81.73, 129.93	11.07, 25.70
	Median	30.85	105.60	14.68
	Q25, Q75	15.11, 48.14	64.77, 177.87	5.39, 54.73
	Min, Max	3.6, 210.8	16.2, 407.5	1.4, 179.8
	Mean (SD)	36.79 (33.552)	131.45 (91.484)	35.87 (43.458)
	95% CI of Mean	29.22, 44.36	102.94, 159.96	21.97, 49.77

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	85.64 (79.61)		84.77 (74.73)		79.54 (91.50)	
	95% CI of Geometric Mean	72.96, 100.51		68.88, 104.33		61.76, 102.42	
	Median	99.62		88.37		84.24	
	Q25, Q75	55.00, 135.10		47.56, 141.06		65.92, 130.60	
	Min, Max	11.9, 342.9		17.0, 318.8		11.0, 376.4	
	Mean (SD)	105.68 (64.932)		103.82 (66.603)		102.55 (73.037)	
	95% CI of Mean	90.83, 120.52		83.06, 124.58		78.87, 126.23	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	60.37 (77.02)		82.96 (69.85)		55.66 (100.34)	
	95% CI of Geometric Mean	51.64, 70.56		68.16, 100.98		42.47, 72.96	
	Median	71.30	-27.88	84.39	-0.03	57.84	-27.96
	Q25, Q75	38.12, 93.30	-37.50, -22.29	53.74, 141.08	-8.89, 5.84	38.95, 99.02	-38.56, -19.30
	Min, Max	9.1, 245.5	-66.3, 40.4	17.6, 321.4	-37.5, 32.3	4.6, 262.8	-57.6, 26.8
	Mean (SD)	74.02 (45.788)	-28.02 (15.315)	99.36 (59.947)	-1.08 (14.233)	73.77 (54.375)	-28.29 (16.292)
	95% CI of Mean	63.55, 84.49	-31.52, -24.51	80.67, 118.04	-5.52, 3.36	56.14, 91.40	-33.57, -23.00

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	47.69 (75.20)		83.00 (70.61)		43.33 (103.35)	
	95% CI of Geometric Mean	40.92, 55.58		68.07, 101.20		32.86, 57.12	
	Median	53.67	-42.78	83.76	-1.69	47.14	-42.51
	Q25, Q75	29.65, 75.34	-53.27, -35.90	53.08, 137.21	-9.16, 5.03	27.48, 75.05	-51.20, -35.44
	Min, Max	7.5, 181.7	-69.2, 40.2	17.1, 276.5	-35.7, 54.9	3.5, 216.5	-68.1, -23.8
	Mean (SD)	57.85 (33.956)	-42.63 (15.129)	99.43 (58.020)	-0.87 (16.206)	57.98 (43.275)	-44.15 (11.870)
	95% CI of Mean	50.09, 65.61	-46.10, -39.17	81.35, 117.52	-5.92, 4.19	43.95, 72.01	-48.00, -40.30

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	42.72 (76.38)		83.59 (70.82)		38.27 (99.44)	
	95% CI of Geometric Mean	36.58, 49.88		68.52, 101.97		29.25, 50.08	
	Median	49.33	-49.26	84.73	-1.56	39.22	-49.19
	Q25, Q75	25.40, 66.01	-58.54, -41.41	49.59, 139.27	-11.15, 6.40	24.09, 66.77	-59.64, -44.88
	Min, Max	6.9, 175.8	-70.7, -8.6	17.4, 294.5	-34.0, 51.9	5.8, 186.6	-77.1, -16.2
	Mean (SD)	52.32 (32.231)	-48.66 (12.564)	100.19 (59.009)	0.20 (18.645)	51.13 (38.585)	-50.56 (11.242)
	95% CI of Mean	44.95, 59.69	-51.54, -45.79	81.79, 118.58	-5.62, 6.01	38.62, 63.64	-54.21, -46.91

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	39.00 (73.28)		83.85 (71.21)		32.65 (111.57)	
	95% CI of Geometric Mean	33.57, 45.31		68.67, 102.37		24.39, 43.71	
	Median	43.45	-53.46	84.57	-0.83	36.31	-55.02
	Q25, Q75	23.99, 61.33	-61.60, -45.26	50.52, 150.60	-11.98, 6.46	18.75, 63.52	-61.46, -48.51
	Min, Max	6.3, 121.4	-78.7, -8.9	16.9, 281.2	-37.4, 64.6	3.5, 155.3	-86.8, -41.1
	Mean (SD)	47.09 (27.256)	-52.93 (12.173)	100.95 (60.628)	0.54 (19.179)	45.19 (35.035)	-57.07 (11.073)
	95% CI of Mean	40.85, 53.32	-55.72, -50.15	82.05, 119.85	-5.44, 6.53	33.83, 56.56	-60.67, -53.48

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	37.90 (79.54)		85.94 (67.94)		29.58 (108.10)	
	95% CI of Geometric Mean	32.29, 44.48		70.93, 104.13		22.24, 39.35	
	Median	41.35	-55.63	82.26	-2.48	34.17	-59.61
	Q25, Q75	23.47, 62.10	-63.44, -45.18	54.23, 153.30	-11.06, 11.11	17.41, 54.52	-67.77, -54.52
	Min, Max	5.0, 123.8	-72.7, -21.0	15.1, 273.8	-32.4, 75.3	3.3, 139.7	-89.0, -41.2
	Mean (SD)	46.60 (27.761)	-54.39 (11.417)	102.11 (59.624)	3.91 (24.832)	40.54 (31.208)	-61.03 (10.580)
	95% CI of Mean	40.25, 52.95	-57.01, -51.78	83.52, 120.69	-3.83, 11.65	30.42, 50.66	-64.46, -57.59

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 10 AM on Day 1 in the SA arm.

**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=63)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	63		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	87.07 (78.77)		85.55 (75.52)		78.72 (92.73)	
	95% CI of Geometric Mean	73.09, 103.72		69.20, 105.75		60.76, 101.99	
	Median	99.66		88.74		82.58	
	Q25, Q75	58.71, 136.79		47.56, 141.06		65.92, 130.60	
	Min, Max	11.9, 342.9		17.0, 318.8		11.0, 376.4	
	Mean (SD)	106.84 (64.628)		104.93 (67.038)		102.15 (73.975)	
	95% CI of Mean	90.56, 123.12		83.77, 126.09		77.83, 126.47	

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 10 AM on Day 1 in the SA arm.

**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=63)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	63	63	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	26.78 (68.68)		86.16 (80.20)		19.91 (131.03)	
	95% CI of Geometric Mean	22.90, 31.33		68.97, 107.62		14.33, 27.66	
	Median	28.72	-70.03	104.05	6.42	24.29	-72.74
	Q25, Q75	17.74, 40.65	-78.21, -61.46	51.71, 145.66	-10.86, 21.58	10.70, 33.18	-84.00, -63.15
	Min, Max	4.7, 114.6	-88.4, 3.2	17.4, 282.8	-69.1, 82.6	1.6, 109.9	-89.1, -19.2
	Mean (SD)	31.90 (19.304)	-65.40 (18.839)	106.48 (64.195)	5.25 (28.832)	30.61 (28.727)	-70.36 (18.167)
	95% CI of Mean	27.03, 36.76	-70.15, -60.65	86.21, 126.75	-3.86, 14.35	21.16, 40.05	-76.34, -64.38

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	90.62 (69.55)		85.55 (75.52)		78.72 (92.73)	
	95% CI of Geometric Mean	77.55, 105.88		69.20, 105.75		60.76, 101.99	
	Median	106.33		88.74		82.58	
	Q25, Q75	61.76, 133.40		47.56, 141.06		65.92, 130.60	
	Min, Max	11.9, 342.9		17.0, 318.8		11.0, 376.4	
	Mean (SD)	107.69 (61.435)		104.93 (67.038)		102.15 (73.975)	
	95% CI of Mean	92.47, 122.92		83.77, 126.09		77.83, 126.47	

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	65	65	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	23.22 (81.46)		88.67 (80.00)		14.44 (183.63)	
	95% CI of Geometric Mean	19.45, 27.71		71.01, 110.71		9.68, 21.53	
	Median	25.03	-74.78	88.98	9.75	14.21	-84.79
	Q25, Q75	16.80, 37.59	-83.80, -62.40	55.30, 150.20	-10.42, 26.74	6.94, 36.05	-90.42, -54.31
	Min, Max	3.8, 98.6	-92.8, 88.2	17.4, 340.4	-69.1, 141.3	1.4, 137.3	-97.8, 7.9
	Mean (SD)	29.04 (19.385)	-69.16 (24.918)	109.99 (71.025)	11.61 (41.229)	28.00 (34.502)	-70.96 (28.179)
	95% CI of Mean	24.23, 33.85	-75.34, -62.99	87.56, 132.41	-1.40, 24.63	16.65, 39.34	-80.23, -61.70

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	90.83 (73.25)		85.55 (75.52)		78.79 (94.45)	
	95% CI of Geometric Mean	77.21, 106.85		69.20, 105.75		60.37, 102.84	
	Median	108.01		88.74		84.24	
	Q25, Q75	59.38, 136.79		47.56, 141.06		65.92, 130.60	
	Min, Max	15.9, 342.9		17.0, 318.8		11.0, 376.4	
	Mean (SD)	109.41 (63.614)		104.93 (67.038)		102.86 (74.866)	
	95% CI of Mean	93.64, 125.18		83.77, 126.09		77.89, 127.82	

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 10 AM on Day 1 in the SA arm.

**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=65)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	65	65	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	22.66 (85.11)		95.03 (73.04)		13.95 (214.03)	
	95% CI of Geometric Mean	18.87, 27.22		77.31, 116.82		9.00, 21.60	
	Median	24.62	-74.05	111.87	21.57	12.93	-79.34
	Q25, Q75	13.65, 38.74	-84.10, -60.99	60.41, 138.52	-8.98, 44.91	5.26, 39.21	-95.01, -56.23
	Min, Max	3.5, 96.5	-93.3, -19.1	22.4, 284.5	-60.3, 117.4	1.0, 166.1	-97.6, 10.5
	Mean (SD)	29.05 (20.995)	-70.06 (18.689)	114.57 (67.411)	18.79 (41.869)	30.00 (38.678)	-66.54 (35.413)
	95% CI of Mean	23.85, 34.26	-74.69, -65.42	93.29, 135.86	5.57, 32.01	17.10, 42.90	-78.36, -54.73

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	103.06 (80.04)	100.53 (83.33)	95.54 (87.57)
	95% CI of Geometric Mean	87.75, 121.04	80.17, 126.07	74.81, 122.02
	Median	112.44	110.16	98.08
	Q25, Q75	66.29, 178.25	63.77, 186.13	64.50, 168.39
	Min, Max	14.9, 342.4	20.3, 298.6	11.8, 384.3
	Mean (SD)	126.99 (75.901)	124.88 (73.743)	120.85 (79.507)
	95% CI of Mean	109.64, 144.33	101.89, 147.86	95.07, 146.63

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	70.16 (76.58)	99.48 (89.87)	60.86 (106.49)
	95% CI of Geometric Mean	60.07, 81.95	78.27, 126.44	45.89, 80.71
	Median	85.78	119.55	73.89
	Q25, Q75	46.38, 112.99	55.23, 182.14	42.71, 102.16
	Min, Max	10.3, 243.1	13.1, 274.7	5.2, 467.0
	Mean (SD)	84.78 (47.040)	125.72 (74.279)	85.24 (80.487)
	95% CI of Mean	74.03, 95.54	102.57, 148.87	59.15, 111.34

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	56.47 (81.91)	103.44 (88.05)	50.43 (101.89)
	95% CI of Geometric Mean	47.93, 66.52	81.69, 130.99	38.36, 66.30
	Median	65.82	120.86	60.23
	Q25, Q75	34.90, 90.85	69.01, 197.67	36.11, 86.56
	Min, Max	10.2, 203.0	20.5, 275.7	3.8, 194.7
	Mean (SD)	70.46 (44.454)	130.70 (78.537)	66.38 (45.035)
	95% CI of Mean	60.30, 80.63	106.22, 155.18	51.78, 80.99

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	51.85 (78.22)	102.10 (81.36)	46.17 (97.30)
	95% CI of Geometric Mean	44.27, 60.72	81.76, 127.50	35.43, 60.15
	Median	62.81	113.17	49.19
	Q25, Q75	32.62, 79.87	65.11, 176.09	32.05, 75.00
	Min, Max	5.9, 205.9	20.3, 291.9	6.4, 220.0
	Mean (SD)	63.29 (37.323)	126.19 (74.444)	61.39 (46.120)
	95% CI of Mean	54.76, 71.83	102.99, 149.40	46.43, 76.35

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	47.62 (79.50)	95.78 (84.75)	37.89 (123.26)
	95% CI of Geometric Mean	40.58, 55.88	76.15, 120.47	27.74, 51.74
	Median	54.36	114.09	48.37
	Q25, Q75	29.13, 74.34	70.41, 176.00	21.27, 71.07
	Min, Max	9.0, 144.1	16.9, 245.2	4.0, 218.6
	Mean (SD)	58.59 (34.746)	118.95 (68.405)	54.39 (43.856)
	95% CI of Mean	50.64, 66.53	97.63, 140.28	40.17, 68.61

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	44.31 (82.74)	106.50 (76.86)	36.11 (106.81)
	95% CI of Geometric Mean	37.57, 52.27	86.12, 131.70	27.21, 47.92
	Median	52.05	118.85	42.31
	Q25, Q75	26.90, 70.24	68.09, 192.94	24.25, 62.26
	Min, Max	6.7, 140.8	17.6, 265.4	4.3, 207.0
	Mean (SD)	55.21 (33.882)	128.98 (71.105)	49.40 (39.457)
	95% CI of Mean	47.46, 62.95	106.82, 151.14	36.61, 62.20

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 10 AM on Day 1 in the SA arm.

**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=63)	mCC (N=41)	SA (N=38)
Baseline	n	63	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	105.92 (78.72)	100.61 (84.67)	94.27 (88.39)
	95% CI of Geometric Mean	88.92, 126.16	79.77, 126.89	73.43, 121.01
	Median	111.71	112.82	97.29
	Q25, Q75	77.02, 178.27	63.77, 186.13	64.50, 168.39
	Min, Max	14.9, 342.4	20.3, 298.6	11.8, 384.3
	Mean (SD)	129.49 (76.263)	125.55 (74.530)	119.84 (80.319)
	95% CI of Mean	110.28, 148.70	102.02, 149.08	93.43, 146.24

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 10 AM on Day 1 in the SA arm.

**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=63)	mCC (N=41)	SA (N=38)
Day 30	n	63	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	31.78 (79.34)	99.61 (89.28)	21.18 (129.41)
	95% CI of Geometric Mean	26.64, 37.89	78.22, 126.84	15.29, 29.35
	Median	36.61	130.51	24.30
	Q25, Q75	19.10, 46.76	46.32, 178.29	11.32, 39.72
	Min, Max	4.4, 160.0	26.1, 281.3	2.7, 152.0
	Mean (SD)	39.43 (26.743)	127.64 (80.414)	32.81 (32.384)
	95% CI of Mean	32.69, 46.17	102.26, 153.03	22.16, 43.46

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=38)
Baseline	n	65	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	110.03 (71.13)	100.61 (84.67)	94.27 (88.39)
	95% CI of Geometric Mean	93.89, 128.94	79.77, 126.89	73.43, 121.01
	Median	114.42	112.82	97.29
	Q25, Q75	81.20, 178.22	63.77, 186.13	64.50, 168.39
	Min, Max	19.0, 342.4	20.3, 298.6	11.8, 384.3
	Mean (SD)	131.28 (74.019)	125.55 (74.530)	119.84 (80.319)
	95% CI of Mean	112.93, 149.62	102.02, 149.08	93.43, 146.24

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=38)
Day 60	n	65	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	26.77 (91.37)	101.18 (89.70)	16.41 (188.69)
	95% CI of Geometric Mean	22.06, 32.47	79.39, 128.95	10.94, 24.60
	Median	28.98	115.15	15.88
	Q25, Q75	14.39, 44.15	64.47, 182.98	6.60, 41.62
	Min, Max	4.0, 120.1	24.8, 360.5	1.8, 193.0
	Mean (SD)	34.97 (25.214)	130.45 (87.155)	33.41 (43.034)
	95% CI of Mean	28.72, 41.22	102.94, 157.97	19.26, 47.56

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=37)
Baseline	n	65	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	107.63 (76.18)	100.61 (84.67)	95.24 (89.59)
	95% CI of Geometric Mean	91.01, 127.28	79.77, 126.89	73.73, 123.02
	Median	114.42	112.82	98.08
	Q25, Q75	81.20, 178.22	63.77, 186.13	65.57, 168.39
	Min, Max	14.9, 342.4	20.3, 298.6	11.8, 384.3
	Mean (SD)	130.33 (74.973)	125.55 (74.530)	121.33 (80.889)
	95% CI of Mean	111.75, 148.91	102.02, 149.08	94.36, 148.31

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 10 AM on Day 1 in the SA arm.

**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=65)	mCC (N=41)	SA (N=37)
Day 90	n	65	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	25.51 (99.55)	103.19 (87.34)	15.80 (219.40)
	95% CI of Geometric Mean	20.77, 31.34	81.36, 130.87	10.14, 24.59
	Median	29.52	107.70	13.01
	Q25, Q75	15.05, 47.01	64.77, 177.87	5.27, 44.80
	Min, Max	3.6, 170.8	16.2, 407.5	1.4, 179.8
	Mean (SD)	34.75 (28.709)	132.28 (92.460)	34.81 (44.422)
	95% CI of Mean	27.63, 41.87	103.09, 161.47	19.99, 49.62

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
15 Min < T0 - Baseline							
	n	76		41			
	Missing, n (%)	0		1 (2.4)			
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	4.87 (94.09)		NC			
	95% CI of Geometric Mean	4.06, 5.85		NC			
	Median	6.00		6.00			
	Q25, Q75	3.00, 9.00		3.00, 9.00			
	Min, Max	1.0, 23.0		0.0, 22.0			
	Mean (SD)	6.32 (4.196)		6.76 (4.620)			
	95% CI of Mean	5.35, 7.28		5.29, 8.22			

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
08:00 - 09:30							
- Baseline							
	n					39	
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					6.22 (60.80)	
	95% CI of Geometric Mean					5.18, 7.46	
	Median					6.00	
	Q25, Q75					5.00, 9.00	
	Min, Max					1.0, 15.0	
	Mean (SD)					7.08 (3.320)	
	95% CI of Mean					6.00, 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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
12:00 - 13:30							
- Baseline							
	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	10.36 (72.00)		10.47 (90.25)		11.21 (58.48)	
	95% CI of Geometric Mean	8.93, 12.01		8.23, 13.33		9.40, 13.37	
	Median	11.50		11.00		11.00	
	Q25, Q75	8.00, 16.00		7.00, 21.00		8.00, 17.00	
	Min, Max	2.0, 30.0		1.0, 38.0		4.0, 31.0	
	Mean (SD)	12.29 (6.450)		13.40 (8.852)		12.90 (7.030)	
	95% CI of Mean	10.81, 13.77		10.64, 16.17		10.61, 15.18	

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
16:00 - 17:30							
- Baseline							
	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	10.83 (80.04)		NC		11.62 (80.79)	
	95% CI of Geometric Mean	9.22, 12.72		NC		9.23, 14.63	
	Median	11.50		12.00		13.00	
	Q25, Q75	6.50, 19.00		6.00, 19.00		8.00, 19.00	
	Min, Max	2.0, 43.0		0.0, 41.0		1.0, 43.0	
	Mean (SD)	13.47 (8.696)		13.64 (9.181)		14.21 (8.542)	
	95% CI of Mean	11.48, 15.47		10.78, 16.51		11.43, 16.98	

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
20:00 - 21:30							
- Baseline							
	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		10.24 (101.31)		10.52 (87.29)	
	95% CI of Geometric Mean	NC		7.88, 13.32		8.24, 13.43	
	Median	14.00		11.50		12.00	
	Q25, Q75	9.00, 19.00		7.00, 18.00		7.00, 17.00	
	Min, Max	0.0, 43.0		1.0, 40.0		1.0, 35.0	
	Mean (SD)	14.89 (8.322)		13.36 (8.633)		13.10 (7.947)	
	95% CI of Mean	12.99, 16.80		10.66, 16.05		10.52, 15.68	

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1 -							
12:00 - 13:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.66 (75.04)		9.91 (83.53)		4.53 (54.33)	
	95% CI of Geometric Mean	3.14, 4.27		7.87, 12.47		3.84, 5.35	
	Median	4.00	-60.00	11.00	0.00	5.00	-60.00
	Q25, Q75	3.00, 6.00	-70.33, -50.00	7.00, 17.00	-36.36, 33.33	4.00, 6.00	-72.22, -40.00
	Min, Max	1.0, 13.0	-92.9, 50.0	2.0, 28.0	-71.4, 400.0	1.0, 11.0	-87.5, 25.0
	Mean (SD)	4.41 (2.435)	-58.42 (23.668)	12.34 (7.436)	14.06 (80.748)	5.08 (2.344)	-54.45 (22.990)
	95% CI of Mean	3.85, 4.97	-63.83, -53.00	9.99, 14.69	-11.43, 39.55	4.31, 5.84	-61.91, -46.99

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1 -							
16:00 - 17:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		NC		3.92 (59.66)	
	95% CI of Geometric Mean	NC		NC		3.27, 4.69	
	Median	4.00	-72.05	13.00	0.00	5.00	-69.23
	Q25, Q75	2.00, 5.00	-79.29, -50.00	7.00, 18.00	-27.59, 28.57	3.00, 6.00	-76.19, -53.33
	Min, Max	0.0, 12.0	-100.0, 150.0	0.0, 31.0	-70.0, 250.0	1.0, 8.0	-88.5, 200.0
	Mean (SD)	4.01 (2.194)	-59.25 (37.575)	13.02 (8.011)	12.13 (57.651)	4.46 (2.076)	-56.81 (46.466)
	95% CI of Mean	3.51, 4.52	-67.84, -50.66	10.49, 15.56	-6.07, 30.33	3.78, 5.14	-71.87, -41.74

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1 - 20:00 - 21:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		11.49 (78.54)		NC	
	95% CI of Geometric Mean	NC		9.23, 14.31		NC	
	Median	3.00	-76.83	12.00	14.29	3.00	-75.00
	Q25, Q75	2.00, 4.00	-82.84, -64.29	9.00, 18.00	-18.18, 50.00	2.00, 4.00	-81.25, -58.33
	Min, Max	0.0, 10.0	-100.0, 200.0	1.0, 36.0	-66.7, 900.0	0.0, 12.0	-100.0, 100.0
	Mean (SD)	3.41 (1.871)	-67.47 (38.514)	13.88 (7.866)	42.13 (148.201)	3.56 (2.125)	-60.53 (39.473)
	95% CI of Mean	2.98, 3.84	-76.27, -58.66	11.39, 16.37	-4.66, 88.91	2.87, 4.26	-73.33, -47.73

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2 - Within 15 Min Prior To Smoking	n	76	76	41	41		
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	NC		NC			
	95% CI of Geometric Mean	NC		NC			
	Median	2.00	-66.67	6.00	0.00		
	Q25, Q75	1.00, 3.00	-77.78, -33.33	3.00, 9.00	-28.57, 28.57		
	Min, Max	0.0, 9.0	-100.0, 200.0	0.0, 22.0	-66.7, 900.0		
	Mean (SD)	2.32 (1.426)	-44.84 (58.333)	6.90 (4.727)	35.56 (156.275)		
	95% CI of Mean	1.99, 2.65	-58.18, -31.51	5.41, 8.40	-13.77, 84.90		

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2 -							
08:00 - 09:30							
	n					39	39
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					NC	
	95% CI of Geometric Mean					NC	
	Median					3.00	-62.50
	Q25, Q75					1.00, 3.00	-80.00, -44.44
	Min, Max					0.0, 7.0	-100.0, 100.0
	Mean (SD)					2.64 (1.663)	-56.97 (35.414)
	95% CI of Mean					2.10, 3.18	-68.46, -45.49

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2 -							
12:00 - 13:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		8.60 (107.32)		2.53 (53.38)	
	95% CI of Geometric Mean	NC		6.52, 11.34		2.14, 2.98	
	Median	2.00	-80.00	10.00	0.00	3.00	-77.78
	Q25, Q75	2.00, 3.00	-88.24, -62.50	7.00, 15.00	-27.27, 20.00	2.00, 3.00	-85.71, -66.67
	Min, Max	0.0, 5.0	-100.0, 0.0	1.0, 37.0	-89.5, 116.7	1.0, 7.0	-92.0, 0.0
	Mean (SD)	2.39 (1.156)	-72.14 (23.900)	11.54 (7.954)	-3.91 (44.745)	2.85 (1.461)	-72.95 (18.994)
	95% CI of Mean	2.13, 2.66	-77.60, -66.67	9.02, 14.05	-18.04, 10.21	2.37, 3.32	-79.12, -66.79

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2 - 16:00 - 17:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	3.00	-79.47	13.00	3.45	3.00	-75.00
	Q25, Q75	2.00, 4.00	-85.88, -63.64	8.00, 21.00	-22.22, 33.33	2.00, 4.00	-87.50, -66.67
	Min, Max	0.0, 7.0	-100.0, 50.0	0.0, 33.0	-100.0, 500.0	0.0, 6.0	-100.0, 400.0
	Mean (SD)	2.76 (1.478)	-70.39 (26.829)	14.07 (9.018)	24.72 (97.529)	3.10 (1.652)	-61.41 (78.307)
	95% CI of Mean	2.42, 3.11	-76.52, -64.25	11.22, 16.92	-6.07, 55.51	2.56, 3.64	-86.80, -36.02

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2 - 20:00 - 21:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	3.00	-81.53	13.00	20.00	3.00	-81.25
	Q25, Q75	1.00, 4.00	-88.89, -72.73	9.00, 19.00	0.00, 42.86	1.00, 4.00	-88.89, -66.67
	Min, Max	0.0, 7.0	-100.0, 100.0	0.0, 29.0	-100.0, 700.0	0.0, 9.0	-100.0, 14.3
	Mean (SD)	2.59 (1.426)	-73.38 (31.244)	13.90 (7.899)	35.21 (119.330)	2.85 (1.994)	-69.22 (30.034)
	95% CI of Mean	2.26, 2.92	-80.52, -66.23	11.40, 16.40	-2.46, 72.88	2.19, 3.50	-78.96, -59.48

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3 - Within 15 Min Prior To Smoking	n	76	76	41	41		
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	NC		5.07 (79.76)			
	95% CI of Geometric Mean	NC		4.06, 6.33			
	Median	2.00	-66.67	6.00	0.00		
	Q25, Q75	1.00, 3.00	-78.36, -46.43	3.00, 8.00	-28.57, 42.86		
	Min, Max	0.0, 4.0	-100.0, 100.0	1.0, 13.0	-66.7, 200.0		
	Mean (SD)	1.95 (1.045)	-55.71 (39.053)	6.17 (3.435)	17.08 (73.852)		
	95% CI of Mean	1.70, 2.19	-64.63, -46.78	5.08, 7.26	-6.24, 40.39		

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3 -							
08:00 - 09:30							
	n					39	39
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					2.15 (51.26)	
	95% CI of Geometric Mean					1.83, 2.52	
	Median					2.00	-66.67
	Q25, Q75					2.00, 3.00	-75.00, -50.00
	Min, Max					1.0, 5.0	-87.5, 100.0
	Mean (SD)					2.38 (1.017)	-58.61 (32.605)
	95% CI of Mean					2.05, 2.72	-69.19, -48.04

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3 - 12:00 - 13:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		8.72 (90.94)		2.05 (52.92)	
	95% CI of Geometric Mean	NC		6.82, 11.14		1.74, 2.41	
	Median	2.00	-81.82	10.00	-24.14	2.00	-80.00
	Q25, Q75	2.00, 3.00	-87.50, -70.00	5.00, 16.00	-42.86, 22.22	1.00, 3.00	-89.29, -70.00
	Min, Max	0.0, 6.0	-100.0, 0.0	1.0, 34.0	-71.4, 400.0	1.0, 5.0	-95.0, -25.0
	Mean (SD)	2.14 (1.003)	-76.90 (17.702)	11.17 (7.311)	5.60 (86.410)	2.28 (0.999)	-77.16 (15.910)
	95% CI of Mean	1.91, 2.38	-80.95, -72.85	8.86, 13.48	-21.68, 32.88	1.95, 2.61	-82.32, -72.00

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3 - 16:00 - 17:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.02 (59.92)		NC		2.35 (55.57)	
	95% CI of Geometric Mean	1.78, 2.30		NC		1.98, 2.78	
	Median	2.00	-82.09	12.00	-11.11	3.00	-80.95
	Q25, Q75	1.00, 3.00	-90.24, -69.62	8.00, 16.00	-31.25, 33.33	2.00, 3.00	-87.50, -69.23
	Min, Max	1.0, 6.0	-95.2, 50.0	0.0, 29.0	-100.0, 900.0	1.0, 5.0	-97.7, 400.0
	Mean (SD)	2.34 (1.261)	-74.02 (25.191)	12.46 (7.481)	29.95 (161.088)	2.64 (1.203)	-63.88 (78.295)
	95% CI of Mean	2.05, 2.64	-79.78, -68.26	10.10, 14.83	-20.90, 80.80	2.25, 3.04	-89.27, -38.49

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3 - 20:00 - 21:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		10.98 (93.69)		NC	
	95% CI of Geometric Mean	NC		8.54, 14.11		NC	
	Median	2.00	-82.35	13.00	0.00	2.00	-81.25
	Q25, Q75	2.00, 3.00	-88.89, -73.21	7.00, 18.00	-30.00, 66.67	1.00, 3.00	-87.50, -70.59
	Min, Max	0.0, 6.0	-100.0, 66.7	1.0, 31.0	-85.7, 600.0	0.0, 10.0	-100.0, 14.3
	Mean (SD)	2.43 (1.204)	-75.05 (28.371)	13.78 (8.018)	39.71 (119.775)	2.67 (1.897)	-69.33 (30.676)
	95% CI of Mean	2.15, 2.71	-81.54, -68.57	11.24, 16.32	1.90, 77.52	2.05, 3.29	-79.28, -59.38

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4 - Within 15 Min Prior To Smoking	n	76	76	41	41		
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	NC		NC			
	95% CI of Geometric Mean	NC		NC			
	Median	2.00	-66.67	6.00	0.00		
	Q25, Q75	1.00, 3.00	-77.78, -50.00	4.00, 8.00	-28.57, 25.00		
	Min, Max	0.0, 4.0	-100.0, 200.0	0.0, 23.0	-80.0, 250.0		
	Mean (SD)	2.04 (0.945)	-49.54 (50.832)	6.41 (4.056)	13.70 (66.598)		
	95% CI of Mean	1.82, 2.26	-61.16, -37.92	5.13, 7.70	-7.33, 34.72		

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4 -							
08:00 - 09:30							
	n					39	39
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					NC	
	95% CI of Geometric Mean					NC	
	Median					2.00	-66.67
	Q25, Q75					1.00, 3.00	-80.00, -50.00
	Min, Max					0.0, 4.0	-100.0, 0.0
	Mean (SD)					2.21 (1.129)	-65.25 (19.885)
	95% CI of Mean					1.83, 2.58	-71.70, -58.79

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4 - 12:00 - 13:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	2.00	-80.63	11.00	0.00	2.00	-81.82
	Q25, Q75	1.00, 3.00	-90.00, -66.67	6.00, 16.00	-44.83, 50.00	1.00, 3.00	-91.67, -69.23
	Min, Max	0.0, 6.0	-100.0, 0.0	0.0, 30.0	-100.0, 333.3	0.0, 6.0	-100.0, -25.0
	Mean (SD)	2.17 (1.148)	-74.88 (22.621)	11.68 (6.810)	14.68 (86.875)	2.18 (1.190)	-77.24 (17.476)
	95% CI of Mean	1.90, 2.44	-80.05, -69.71	9.53, 13.84	-12.75, 42.11	1.79, 2.57	-82.91, -71.57

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4 - 16:00 - 17:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		10.08 (83.03)		NC	
	95% CI of Geometric Mean	NC		8.02, 12.68		NC	
	Median	2.00	-80.63	11.00	-18.75	3.00	-81.25
	Q25, Q75	1.50, 3.50	-86.88, -70.33	8.00, 16.00	-38.46, 50.00	1.00, 3.00	-90.48, -70.00
	Min, Max	0.0, 7.0	-100.0, 100.0	1.0, 35.0	-69.2, 750.0	0.0, 5.0	-100.0, 300.0
	Mean (SD)	2.54 (1.428)	-70.99 (32.504)	12.41 (7.430)	41.08 (165.144)	2.38 (1.228)	-69.12 (62.541)
	95% CI of Mean	2.21, 2.87	-78.42, -63.56	10.06, 14.76	-11.06, 93.21	1.98, 2.79	-89.40, -48.84

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4 - 20:00 - 21:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.95 (57.71)		11.53 (87.62)		2.34 (67.68)	
	95% CI of Geometric Mean	1.72, 2.21		9.08, 14.64		1.91, 2.86	
	Median	2.00	-83.77	14.00	7.14	2.00	-80.00
	Q25, Q75	1.00, 3.00	-90.91, -75.00	10.00, 18.00	-22.22, 64.00	2.00, 4.00	-87.50, -60.87
	Min, Max	1.0, 5.0	-97.3, 100.0	1.0, 41.0	-66.7, 500.0	1.0, 9.0	-96.3, 50.0
	Mean (SD)	2.24 (1.188)	-75.80 (29.785)	14.07 (7.542)	37.10 (100.294)	2.82 (1.862)	-67.44 (33.068)
	95% CI of Mean	1.96, 2.51	-82.61, -68.99	11.69, 16.46	5.44, 68.76	2.21, 3.43	-78.16, -56.72

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - Within 15 Min Prior To Smoking	n	76	76	41	41		
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	NC		NC			
	95% CI of Geometric Mean	NC		NC			
	Median	2.00	-66.67	6.00	-7.69		
	Q25, Q75	1.00, 3.00	-77.78, -50.00	3.00, 8.00	-35.71, 14.29		
	Min, Max	0.0, 4.0	-100.0, 200.0	0.0, 14.0	-85.7, 300.0		
	Mean (SD)	2.01 (0.872)	-46.20 (57.658)	5.93 (3.546)	11.88 (85.226)		
	95% CI of Mean	1.81, 2.22	-59.38, -33.02	4.80, 7.05	-15.02, 38.79		

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 -							
08:00 - 09:30							
	n					39	39
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					NC	
	95% CI of Geometric Mean					NC	
	Median					2.00	-66.67
	Q25, Q75					2.00, 3.00	-80.00, -60.00
	Min, Max					0.0, 5.0	-100.0, 100.0
	Mean (SD)					2.10 (1.021)	-61.13 (35.230)
	95% CI of Mean					1.77, 2.44	-72.55, -49.70

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 -							
12:00 - 13:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.03 (47.49)		NC		NC	
	95% CI of Geometric Mean	1.83, 2.26		NC		NC	
	Median	2.00	-80.00	11.00	0.00	2.00	-80.00
	Q25, Q75	2.00, 3.00	-88.68, -70.00	9.00, 15.00	-25.00, 37.50	2.00, 3.00	-90.48, -72.73
	Min, Max	1.0, 6.0	-95.7, 50.0	0.0, 34.0	-100.0, 800.0	0.0, 5.0	-100.0, -40.0
	Mean (SD)	2.24 (0.979)	-73.40 (24.945)	12.71 (7.847)	28.61 (137.838)	2.15 (1.015)	-78.99 (14.253)
	95% CI of Mean	2.01, 2.47	-79.11, -67.69	10.23, 15.19	-14.90, 72.12	1.82, 2.49	-83.61, -74.36

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 16:00 - 17:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		11.05 (95.33)		2.37 (62.32)	
	95% CI of Geometric Mean	NC		8.57, 14.25		1.96, 2.86	
	Median	2.00	-80.00	13.00	12.50	2.00	-78.95
	Q25, Q75	2.00, 3.00	-87.08, -63.33	8.00, 20.00	-25.00, 54.55	2.00, 4.00	-87.50, -70.00
	Min, Max	0.0, 6.0	-100.0, 100.0	1.0, 34.0	-90.0, 650.0	1.0, 7.0	-95.3, 400.0
	Mean (SD)	2.51 (1.228)	-71.30 (29.914)	13.93 (7.920)	44.97 (134.556)	2.77 (1.598)	-64.37 (78.100)
	95% CI of Mean	2.23, 2.80	-78.15, -64.46	11.42, 16.43	2.49, 87.44	2.25, 3.29	-89.70, -39.05

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 20:00 - 21:30							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		12.43 (78.45)		2.48 (69.37)	
	95% CI of Geometric Mean	NC		9.98, 15.47		2.02, 3.05	
	Median	2.00	-81.82	13.00	28.57	2.00	-80.00
	Q25, Q75	2.00, 3.00	-90.16, -68.99	9.00, 20.00	-13.64, 66.67	2.00, 4.00	-86.67, -62.50
	Min, Max	0.0, 8.0	-100.0, 50.0	2.0, 32.0	-66.7, 500.0	1.0, 8.0	-95.5, 33.3
	Mean (SD)	2.51 (1.410)	-74.76 (27.048)	15.10 (8.426)	43.75 (94.957)	3.00 (1.920)	-66.44 (31.213)
	95% CI of Mean	2.19, 2.84	-80.95, -68.58	12.43, 17.76	13.77, 73.73	2.37, 3.63	-76.56, -56.31

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day							
6/Discharge							
Confinement							
	n	76	76	41	41	39	39
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.10 (44.78)		8.22 (74.81)		NC	
	95% CI of Geometric Mean	1.90, 2.33		6.65, 10.15		NC	
	Median	2.00	-80.00	10.00	-14.29	2.00	-83.33
	Q25, Q75	2.00, 3.00	-87.23, -66.67	5.00, 12.00	-50.00, 30.00	1.00, 2.00	-91.67, -75.00
	Min, Max	1.0, 5.0	-95.7, 100.0	1.0, 27.0	-75.0, 300.0	0.0, 5.0	-100.0, 25.0
	Mean (SD)	2.29 (0.907)	-72.65 (27.637)	9.88 (5.689)	-3.52 (66.832)	1.90 (0.853)	-79.69 (20.405)
	95% CI of Mean	2.08, 2.50	-78.97, -66.33	8.08, 11.68	-24.62, 17.58	1.62, 2.18	-86.31, -73.07

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline							
	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	10.55 (69.11)		10.29 (90.33)		11.21 (58.48)	
	95% CI of Geometric Mean	9.12, 12.19		8.06, 13.13		9.40, 13.37	
	Median	11.50		11.00		11.00	
	Q25, Q75	8.00, 16.00		7.00, 19.00		8.00, 17.00	
	Min, Max	2.0, 30.0		1.0, 38.0		4.0, 31.0	
	Mean (SD)	12.41 (6.422)		13.20 (8.855)		12.90 (7.030)	
	95% CI of Mean	10.91, 13.90		10.40, 16.00		10.61, 15.18	

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30							
	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	2.00	-80.48	13.00	12.50	2.00	-81.82
	Q25, Q75	2.00, 3.00	-87.50, -75.00	9.00, 17.00	-46.88, 128.57	1.00, 3.00	-91.67, -70.00
	Min, Max	0.0, 7.0	-100.0, 150.0	0.0, 34.0	-100.0, 600.0	0.0, 8.0	-100.0, -25.0
	Mean (SD)	2.41 (1.344)	-73.92 (31.685)	13.83 (7.609)	50.52 (139.387)	2.38 (1.887)	-77.68 (17.612)
	95% CI of Mean	2.09, 2.72	-81.27, -66.58	11.42, 16.24	6.52, 94.52	1.77, 3.00	-83.39, -71.96

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	10.76 (69.86)		10.29 (90.33)		10.95 (56.71)	
	95% CI of Geometric Mean	9.27, 12.50		8.06, 13.13		9.20, 13.02	
	Median	12.00		11.00		11.00	
	Q25, Q75	8.00, 16.00		7.00, 19.00		8.00, 16.00	
	Min, Max	2.0, 30.0		1.0, 38.0		4.0, 31.0	
	Mean (SD)	12.66 (6.452)		13.20 (8.855)		12.50 (6.665)	
	95% CI of Mean	11.13, 14.19		10.40, 16.00		10.30, 14.70	

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60							
	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		9.46 (85.99)		NC	
	95% CI of Geometric Mean	NC		7.48, 11.97		NC	
	Median	2.00	-85.71	12.00	0.00	2.00	-80.00
	Q25, Q75	1.00, 3.00	-90.91, -75.00	7.00, 16.00	-27.27, 40.00	2.00, 3.00	-88.89, -66.67
	Min, Max	0.0, 10.0	-100.0, 400.0	1.0, 30.0	-85.7, 600.0	0.0, 7.0	-100.0, 25.0
	Mean (SD)	2.17 (1.674)	-71.17 (62.996)	11.71 (6.631)	28.20 (123.450)	2.55 (1.672)	-72.30 (25.510)
	95% CI of Mean	1.77, 2.57	-86.08, -56.25	9.61, 13.81	-10.77, 67.17	2.00, 3.11	-80.69, -63.91

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	10.59 (69.09)		10.29 (90.33)		10.97 (57.59)	
	95% CI of Geometric Mean	9.12, 12.29		8.06, 13.13		9.17, 13.12	
	Median	11.50		11.00		11.00	
	Q25, Q75	8.00, 16.00		7.00, 19.00		8.00, 16.00	
	Min, Max	2.0, 30.0		1.0, 38.0		4.0, 31.0	
	Mean (SD)	12.44 (6.420)		13.20 (8.855)		12.57 (6.744)	
	95% CI of Mean	10.91, 13.98		10.40, 16.00		10.31, 14.82	

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set****Parameter (units): Exhaled CO (ppm)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.04 (53.30)		9.27 (88.13)		NC	
	95% CI of Geometric Mean	1.80, 2.30		7.29, 11.78		NC	
	Median	2.00	-83.33	11.00	0.00	2.00	-83.33
	Q25, Q75	2.00, 3.00	-88.89, -70.00	7.00, 15.00	-43.48, 66.67	1.00, 3.00	-90.48, -66.67
	Min, Max	1.0, 7.0	-96.2, 50.0	1.0, 29.0	-95.8, 400.0	0.0, 9.0	-100.0, -10.0
	Mean (SD)	2.31 (1.292)	-72.63 (27.519)	11.56 (6.761)	24.54 (100.508)	2.51 (2.037)	-74.46 (24.019)
	95% CI of Mean	2.00, 2.63	-79.20, -66.07	9.42, 13.70	-7.19, 56.27	1.83, 3.20	-82.47, -66.45

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 10 AM on Day 1 in the SA arm.

Note: T0 = Time of first product use on the Day

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
15 Min < T0 - Baseline							
	n	78		41			
	Missing, n (%)	0		1 (2.4)			
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	4.85 (92.54)		NC			
	95% CI of Geometric Mean	4.05, 5.79		NC			
	Median	6.00		6.00			
	Q25, Q75	3.00, 9.00		3.00, 9.00			
	Min, Max	1.0, 23.0		0.0, 22.0			
	Mean (SD)	6.26 (4.158)		6.76 (4.620)			
	95% CI of Mean	5.31, 7.20		5.29, 8.22			

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
08:00 - 09:30							
- Baseline							
	n					40	
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					6.11 (61.39)	
	95% CI of Geometric Mean					5.09, 7.32	
	Median					6.00	
	Q25, Q75					5.00, 9.00	
	Min, Max					1.0, 15.0	
	Mean (SD)					6.98 (3.340)	
	95% CI of Mean					5.90, 8.05	

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
12:00 - 13:30							
- Baseline							
	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	10.34 (71.13)		10.47 (90.25)		11.29 (57.86)	
	95% CI of Geometric Mean	8.94, 11.94		8.23, 13.33		9.51, 13.42	
	Median	11.50		11.00		11.50	
	Q25, Q75	8.00, 16.00		7.00, 21.00		8.00, 16.50	
	Min, Max	2.0, 30.0		1.0, 38.0		4.0, 31.0	
	Mean (SD)	12.23 (6.394)		13.40 (8.852)		12.95 (6.947)	
	95% CI of Mean	10.78, 13.68		10.64, 16.17		10.72, 15.18	

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
16:00 - 17:30							
- Baseline							
	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	10.74 (79.01)		NC		11.63 (79.47)	
	95% CI of Geometric Mean	9.18, 12.58		NC		9.29, 14.55	
	Median	11.00		12.00		13.00	
	Q25, Q75	7.00, 19.00		6.00, 19.00		8.00, 18.50	
	Min, Max	2.0, 43.0		0.0, 41.0		1.0, 43.0	
	Mean (SD)	13.33 (8.628)		13.64 (9.181)		14.15 (8.439)	
	95% CI of Mean	11.38, 15.28		10.78, 16.51		11.45, 16.85	

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
20:00 - 21:30							
- Baseline							
	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		10.24 (101.31)		10.55 (85.87)	
	95% CI of Geometric Mean	NC		7.88, 13.32		8.31, 13.39	
	Median	14.00		11.50		12.00	
	Q25, Q75	9.00, 19.00		7.00, 18.00		7.50, 16.50	
	Min, Max	0.0, 43.0		1.0, 40.0		1.0, 35.0	
	Mean (SD)	14.74 (8.268)		13.36 (8.633)		13.08 (7.846)	
	95% CI of Mean	12.87, 16.61		10.66, 16.05		10.56, 15.59	

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1 -							
12:00 - 13:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.64 (74.33)		9.91 (83.53)		4.36 (60.19)	
	95% CI of Geometric Mean	3.13, 4.23		7.87, 12.47		3.65, 5.22	
	Median	4.00	-60.00	11.00	0.00	4.50	-60.36
	Q25, Q75	3.00, 6.00	-71.43, -50.00	7.00, 17.00	-36.36, 33.33	3.50, 6.00	-72.22, -40.00
	Min, Max	1.0, 13.0	-92.9, 50.0	2.0, 28.0	-71.4, 400.0	1.0, 11.0	-93.3, 25.0
	Mean (SD)	4.37 (2.419)	-58.55 (23.615)	12.34 (7.436)	14.06 (80.748)	4.98 (2.402)	-55.42 (23.511)
	95% CI of Mean	3.82, 4.92	-63.88, -53.22	9.99, 14.69	-11.43, 39.55	4.20, 5.75	-62.95, -47.90

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1 - 16:00 - 17:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		NC		3.92 (58.77)	
	95% CI of Geometric Mean	NC		NC		3.29, 4.67	
	Median	4.00	-72.05	13.00	0.00	4.50	-67.95
	Q25, Q75	2.00, 5.00	-80.00, -50.00	7.00, 18.00	-27.59, 28.57	3.00, 6.00	-75.60, -53.59
	Min, Max	0.0, 12.0	-100.0, 150.0	0.0, 31.0	-70.0, 250.0	1.0, 8.0	-88.5, 200.0
	Mean (SD)	3.99 (2.195)	-59.23 (37.401)	13.02 (8.011)	12.13 (57.651)	4.45 (2.051)	-57.05 (45.893)
	95% CI of Mean	3.49, 4.49	-67.67, -50.80	10.49, 15.56	-6.07, 30.33	3.79, 5.11	-71.73, -42.37

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1 -							
20:00 - 21:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		11.49 (78.54)		NC	
	95% CI of Geometric Mean	NC		9.23, 14.31		NC	
	Median	3.00	-76.83	12.00	14.29	3.00	-75.00
	Q25, Q75	2.00, 4.00	-82.35, -64.29	9.00, 18.00	-18.18, 50.00	2.00, 4.00	-81.25, -59.17
	Min, Max	0.0, 10.0	-100.0, 200.0	1.0, 36.0	-66.7, 900.0	0.0, 12.0	-100.0, 100.0
	Mean (SD)	3.44 (1.898)	-66.92 (38.546)	13.88 (7.866)	42.13 (148.201)	3.55 (2.100)	-60.89 (39.031)
	95% CI of Mean	3.00, 3.87	-75.62, -58.23	11.39, 16.37	-4.66, 88.91	2.87, 4.23	-73.38, -48.40

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2 - Within 15 Min Prior To Smoking	n	77	77	41	41		
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	NC		NC			
	95% CI of Geometric Mean	NC		NC			
	Median	2.00	-66.67	6.00	0.00		
	Q25, Q75	1.00, 3.00	-77.78, -33.33	3.00, 9.00	-28.57, 28.57		
	Min, Max	0.0, 9.0	-100.0, 200.0	0.0, 22.0	-66.7, 900.0		
	Mean (SD)	2.30 (1.425)	-45.24 (58.050)	6.90 (4.727)	35.56 (156.275)		
	95% CI of Mean	1.97, 2.63	-58.42, -32.06	5.41, 8.40	-13.77, 84.90		

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2 -							
08:00 - 09:30							
	n					40	40
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					NC	
	95% CI of Geometric Mean					NC	
	Median					3.00	-64.58
	Q25, Q75					1.00, 3.00	-80.00, -47.22
	Min, Max					0.0, 7.0	-100.0, 100.0
	Mean (SD)					2.60 (1.662)	-57.21 (34.991)
	95% CI of Mean					2.06, 3.14	-68.41, -46.02

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2 - 12:00 - 13:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		8.60 (107.32)		2.47 (55.17)	
	95% CI of Geometric Mean	NC		6.52, 11.34		2.09, 2.91	
	Median	2.00	-80.00	10.00	0.00	3.00	-78.17
	Q25, Q75	2.00, 3.00	-88.24, -62.50	7.00, 15.00	-27.27, 20.00	2.00, 3.00	-86.41, -68.63
	Min, Max	0.0, 5.0	-100.0, 0.0	1.0, 37.0	-89.5, 116.7	1.0, 7.0	-93.3, 0.0
	Mean (SD)	2.40 (1.166)	-72.02 (23.933)	11.54 (7.954)	-3.91 (44.745)	2.80 (1.472)	-73.46 (19.024)
	95% CI of Mean	2.13, 2.67	-77.42, -66.62	9.02, 14.05	-18.04, 10.21	2.32, 3.28	-79.55, -67.38

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2 - 16:00 - 17:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	3.00	-79.47	13.00	3.45	3.00	-75.96
	Q25, Q75	2.00, 4.00	-86.05, -63.64	8.00, 21.00	-22.22, 33.33	2.00, 4.00	-87.94, -67.95
	Min, Max	0.0, 7.0	-100.0, 50.0	0.0, 33.0	-100.0, 500.0	0.0, 6.0	-100.0, 400.0
	Mean (SD)	2.76 (1.514)	-70.23 (27.115)	14.07 (9.018)	24.72 (97.529)	3.05 (1.664)	-62.17 (77.445)
	95% CI of Mean	2.41, 3.10	-76.35, -64.11	11.22, 16.92	-6.07, 55.51	2.51, 3.59	-86.94, -37.40

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2 - 20:00 - 21:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	3.00	-81.53	13.00	20.00	3.00	-81.53
	Q25, Q75	1.00, 4.00	-88.89, -72.73	9.00, 19.00	0.00, 42.86	1.00, 4.00	-88.56, -67.71
	Min, Max	0.0, 7.0	-100.0, 100.0	0.0, 29.0	-100.0, 700.0	0.0, 9.0	-100.0, 14.3
	Mean (SD)	2.62 (1.523)	-72.94 (31.749)	13.90 (7.899)	35.21 (119.330)	2.83 (1.973)	-69.57 (29.730)
	95% CI of Mean	2.27, 2.96	-80.10, -65.77	11.40, 16.40	-2.46, 72.88	2.19, 3.46	-79.09, -60.06

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3 - Within 15 Min Prior To Smoking	n	77	77	41	41		
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	NC		5.07 (79.76)			
	95% CI of Geometric Mean	NC		4.06, 6.33			
	Median	2.00	-66.67	6.00	0.00		
	Q25, Q75	1.00, 3.00	-77.78, -50.00	3.00, 8.00	-28.57, 42.86		
	Min, Max	0.0, 4.0	-100.0, 100.0	1.0, 13.0	-66.7, 200.0		
	Mean (SD)	1.95 (1.038)	-55.63 (38.800)	6.17 (3.435)	17.08 (73.852)		
	95% CI of Mean	1.71, 2.19	-64.44, -46.82	5.08, 7.26	-6.24, 40.39		

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3 -							
08:00 - 09:30	n					40	40
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					NC	
	95% CI of Geometric Mean					NC	
	Median					2.00	-66.67
	Q25, Q75					1.50, 3.00	-76.39, -50.00
	Min, Max					0.0, 5.0	-100.0, 100.0
	Mean (SD)					2.33 (1.072)	-59.65 (32.843)
	95% CI of Mean					1.98, 2.67	-70.16, -49.14

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3 - 12:00 - 13:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		8.72 (90.94)		2.01 (53.70)	
	95% CI of Geometric Mean	NC		6.82, 11.14		1.71, 2.37	
	Median	2.00	-81.82	10.00	-24.14	2.00	-80.91
	Q25, Q75	2.00, 3.00	-87.50, -70.00	5.00, 16.00	-42.86, 22.22	1.00, 3.00	-89.64, -71.36
	Min, Max	0.0, 6.0	-100.0, 0.0	1.0, 34.0	-71.4, 400.0	1.0, 5.0	-95.0, -25.0
	Mean (SD)	2.15 (1.021)	-76.66 (17.981)	11.17 (7.311)	5.60 (86.410)	2.25 (1.007)	-77.56 (15.912)
	95% CI of Mean	1.92, 2.39	-80.72, -72.60	8.86, 13.48	-21.68, 32.88	1.92, 2.58	-82.66, -72.47

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3 - 16:00 - 17:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.06 (60.42)		NC		2.30 (56.89)	
	95% CI of Geometric Mean	1.81, 2.34		NC		1.93, 2.73	
	Median	2.00	-81.82	12.00	-11.11	3.00	-81.39
	Q25, Q75	1.00, 3.00	-90.00, -66.67	8.00, 16.00	-31.25, 33.33	2.00, 3.00	-87.50, -69.62
	Min, Max	1.0, 6.0	-95.2, 50.0	0.0, 29.0	-100.0, 900.0	1.0, 5.0	-97.7, 400.0
	Mean (SD)	2.38 (1.282)	-73.34 (25.400)	12.46 (7.481)	29.95 (161.088)	2.60 (1.216)	-64.57 (77.409)
	95% CI of Mean	2.09, 2.68	-79.08, -67.61	10.10, 14.83	-20.90, 80.80	2.21, 2.99	-89.34, -39.81

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3 - 20:00 - 21:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		10.98 (93.69)		NC	
	95% CI of Geometric Mean	NC		8.54, 14.11		NC	
	Median	2.00	-82.35	13.00	0.00	2.00	-82.29
	Q25, Q75	2.00, 3.00	-88.89, -71.43	7.00, 18.00	-30.00, 66.67	1.50, 3.00	-87.50, -71.66
	Min, Max	0.0, 7.0	-100.0, 66.7	1.0, 31.0	-85.7, 600.0	0.0, 10.0	-100.0, 14.3
	Mean (SD)	2.49 (1.297)	-74.31 (28.889)	13.78 (8.018)	39.71 (119.775)	2.65 (1.875)	-69.68 (30.361)
	95% CI of Mean	2.19, 2.78	-80.83, -67.80	11.24, 16.32	1.90, 77.52	2.05, 3.25	-79.39, -59.96

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4 - Within 15 Min Prior To Smoking	n	77	77	41	41		
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	NC		NC			
	95% CI of Geometric Mean	NC		NC			
	Median	2.00	-66.67	6.00	0.00		
	Q25, Q75	1.00, 3.00	-77.78, -50.00	4.00, 8.00	-28.57, 25.00		
	Min, Max	0.0, 4.0	-100.0, 200.0	0.0, 23.0	-80.0, 250.0		
	Mean (SD)	2.04 (0.939)	-49.54 (50.497)	6.41 (4.056)	13.70 (66.598)		
	95% CI of Mean	1.82, 2.26	-61.01, -38.08	5.13, 7.70	-7.33, 34.72		

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4 -							
08:00 - 09:30							
	n					40	40
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					NC	
	95% CI of Geometric Mean					NC	
	Median					2.00	-66.67
	Q25, Q75					1.00, 3.00	-80.00, -52.78
	Min, Max					0.0, 4.0	-100.0, 0.0
	Mean (SD)					2.15 (1.167)	-66.11 (20.383)
	95% CI of Mean					1.77, 2.53	-72.64, -59.59

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4 - 12:00 - 13:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	2.00	-80.63	11.00	0.00	2.00	-81.82
	Q25, Q75	1.00, 3.00	-90.00, -66.67	6.00, 16.00	-44.83, 50.00	1.00, 3.00	-91.67, -69.62
	Min, Max	0.0, 6.0	-100.0, 0.0	0.0, 30.0	-100.0, 333.3	0.0, 6.0	-100.0, -25.0
	Mean (SD)	2.19 (1.152)	-74.59 (22.647)	11.68 (6.810)	14.68 (86.875)	2.15 (1.189)	-77.64 (17.437)
	95% CI of Mean	1.93, 2.46	-79.71, -69.48	9.53, 13.84	-12.75, 42.11	1.76, 2.54	-83.22, -72.06

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4 - 16:00 - 17:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		10.08 (83.03)		NC	
	95% CI of Geometric Mean	NC		8.02, 12.68		NC	
	Median	2.00	-80.63	11.00	-18.75	2.50	-83.48
	Q25, Q75	1.00, 4.00	-87.10, -69.23	8.00, 16.00	-38.46, 50.00	1.00, 3.00	-90.69, -70.71
	Min, Max	0.0, 7.0	-100.0, 100.0	1.0, 35.0	-69.2, 750.0	0.0, 5.0	-100.0, 300.0
	Mean (SD)	2.55 (1.448)	-70.68 (32.504)	12.41 (7.430)	41.08 (165.144)	2.35 (1.232)	-69.68 (61.837)
	95% CI of Mean	2.22, 2.88	-78.01, -63.34	10.06, 14.76	-11.06, 93.21	1.95, 2.75	-89.46, -49.90

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4 - 20:00 - 21:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.98 (59.27)		11.53 (87.62)		2.33 (66.70)	
	95% CI of Geometric Mean	1.74, 2.25		9.08, 14.64		1.92, 2.84	
	Median	2.00	-83.33	14.00	7.14	2.00	-80.00
	Q25, Q75	1.00, 3.00	-90.91, -75.00	10.00, 18.00	-22.22, 64.00	2.00, 3.50	-87.50, -62.58
	Min, Max	1.0, 7.0	-97.3, 100.0	1.0, 41.0	-66.7, 500.0	1.0, 9.0	-96.3, 50.0
	Mean (SD)	2.29 (1.291)	-75.04 (30.262)	14.07 (7.542)	37.10 (100.294)	2.80 (1.843)	-67.84 (32.738)
	95% CI of Mean	2.00, 2.59	-81.87, -68.21	11.69, 16.46	5.44, 68.76	2.21, 3.39	-78.31, -57.36

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - Within 15 Min Prior To Smoking	n	77	77	41	41		
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)		
	BLOQ, n (%)	0		0			
	Geometric Mean (CV%)	NC		NC			
	95% CI of Geometric Mean	NC		NC			
	Median	2.00	-66.67	6.00	-7.69		
	Q25, Q75	1.00, 3.00	-77.78, -50.00	3.00, 8.00	-35.71, 14.29		
	Min, Max	0.0, 4.0	-100.0, 200.0	0.0, 14.0	-85.7, 300.0		
	Mean (SD)	2.01 (0.866)	-46.25 (57.279)	5.93 (3.546)	11.88 (85.226)		
	95% CI of Mean	1.81, 2.21	-59.26, -33.24	4.80, 7.05	-15.02, 38.79		

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 -							
08:00 - 09:30							
	n					40	40
	BLOQ, n (%)					0	
	Geometric Mean (CV%)					NC	
	95% CI of Geometric Mean					NC	
	Median					2.00	-66.67
	Q25, Q75					2.00, 3.00	-80.00, -60.00
	Min, Max					0.0, 5.0	-100.0, 100.0
	Mean (SD)					2.05 (1.061)	-62.10 (35.314)
	95% CI of Mean					1.71, 2.39	-73.40, -50.80

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 12:00 - 13:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.05 (47.57)		NC		NC	
	95% CI of Geometric Mean	1.85, 2.27		NC		NC	
	Median	2.00	-80.00	11.00	0.00	2.00	-80.63
	Q25, Q75	2.00, 3.00	-88.46, -70.00	9.00, 15.00	-25.00, 37.50	1.50, 3.00	-91.07, -72.73
	Min, Max	1.0, 6.0	-95.7, 50.0	0.0, 34.0	-100.0, 800.0	0.0, 5.0	-100.0, -40.0
	Mean (SD)	2.26 (0.987)	-73.15 (24.896)	12.71 (7.847)	28.61 (137.838)	2.13 (1.018)	-79.35 (14.251)
	95% CI of Mean	2.03, 2.48	-78.77, -67.53	10.23, 15.19	-14.90, 72.12	1.79, 2.46	-83.91, -74.79

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 16:00 - 17:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		11.05 (95.33)		2.32 (63.45)	
	95% CI of Geometric Mean	NC		8.57, 14.25		1.92, 2.80	
	Median	2.00	-80.00	13.00	12.50	2.00	-79.47
	Q25, Q75	2.00, 3.00	-87.50, -60.00	8.00, 20.00	-25.00, 54.55	2.00, 3.50	-87.98, -70.71
	Min, Max	0.0, 6.0	-100.0, 100.0	1.0, 34.0	-90.0, 650.0	1.0, 7.0	-95.3, 400.0
	Mean (SD)	2.53 (1.256)	-70.98 (29.987)	13.93 (7.920)	44.97 (134.556)	2.73 (1.602)	-65.06 (77.213)
	95% CI of Mean	2.24, 2.81	-77.75, -64.22	11.42, 16.43	2.49, 87.44	2.21, 3.24	-89.76, -40.36

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5 - 20:00 - 21:30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		12.43 (78.45)		2.47 (68.42)	
	95% CI of Geometric Mean	NC		9.98, 15.47		2.02, 3.02	
	Median	2.00	-81.82	13.00	28.57	2.00	-80.00
	Q25, Q75	2.00, 3.00	-90.00, -68.75	9.00, 20.00	-13.64, 66.67	2.00, 4.00	-86.19, -64.58
	Min, Max	0.0, 8.0	-100.0, 50.0	2.0, 32.0	-66.7, 500.0	1.0, 8.0	-95.5, 33.3
	Mean (SD)	2.55 (1.492)	-74.16 (27.669)	15.10 (8.426)	43.75 (94.957)	2.98 (1.902)	-66.86 (30.926)
	95% CI of Mean	2.21, 2.89	-80.40, -67.92	12.43, 17.76	13.77, 73.73	2.36, 3.59	-76.75, -56.96

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day							
6/Discharge							
Confinement							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.12 (44.86)		8.22 (74.81)		NC	
	95% CI of Geometric Mean	1.92, 2.34		6.65, 10.15		NC	
	Median	2.00	-80.00	10.00	-14.29	2.00	-83.33
	Q25, Q75	2.00, 3.00	-86.96, -66.67	5.00, 12.00	-50.00, 30.00	1.00, 2.00	-91.67, -76.39
	Min, Max	1.0, 5.0	-95.7, 100.0	1.0, 27.0	-75.0, 300.0	0.0, 5.0	-100.0, 25.0
	Mean (SD)	2.31 (0.917)	-72.42 (27.520)	9.88 (5.689)	-3.52 (66.832)	1.88 (0.853)	-80.03 (20.257)
	95% CI of Mean	2.10, 2.52	-78.63, -66.21	8.08, 11.68	-24.62, 17.58	1.60, 2.15	-86.52, -73.55

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	2.00	-80.48	13.00	12.50	2.00	-82.58
	Q25, Q75	2.00, 3.00	-86.96, -75.00	9.00, 17.00	-46.88, 128.57	1.00, 2.50	-91.99, -70.29
	Min, Max	0.0, 7.0	-100.0, 150.0	0.0, 34.0	-100.0, 600.0	0.0, 8.0	-100.0, -25.0
	Mean (SD)	2.41 (1.324)	-72.87 (32.209)	13.83 (7.609)	50.52 (139.387)	2.35 (1.875)	-78.07 (17.560)
	95% CI of Mean	2.11, 2.71	-80.13, -65.60	11.42, 16.24	6.52, 94.52	1.75, 2.95	-83.69, -72.45

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	NC		9.46 (85.99)		NC	
	95% CI of Geometric Mean	NC		7.48, 11.97		NC	
	Median	2.00	-84.62	12.00	0.00	2.00	-81.18
	Q25, Q75	1.00, 3.00	-90.91, -72.73	7.00, 16.00	-27.27, 40.00	2.00, 3.00	-89.88, -67.71
	Min, Max	0.0, 10.0	-100.0, 400.0	1.0, 30.0	-85.7, 600.0	0.0, 7.0	-100.0, 25.0
	Mean (SD)	2.21 (1.724)	-70.05 (61.204)	11.71 (6.631)	28.20 (123.450)	2.53 (1.649)	-73.25 (25.203)
	95% CI of Mean	1.81, 2.60	-83.85, -56.24	9.61, 13.81	-10.77, 67.17	1.99, 3.06	-81.32, -65.19

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 10 AM on Day 1 in the SA arm.

Note: NC=Not calculated

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS****Parameter (units): Exhaled CO (ppm)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90							
	n	78	78	41	41	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.07 (55.28)		9.27 (88.13)		NC	
	95% CI of Geometric Mean	1.84, 2.33		7.29, 11.78		NC	
	Median	2.00	-83.33	11.00	0.00	2.00	-83.97
	Q25, Q75	2.00, 3.00	-88.89, -66.67	7.00, 15.00	-43.48, 66.67	1.00, 3.00	-90.69, -70.83
	Min, Max	1.0, 7.0	-96.2, 50.0	1.0, 29.0	-95.8, 400.0	0.0, 9.0	-100.0, -10.0
	Mean (SD)	2.37 (1.369)	-71.56 (27.552)	11.56 (6.761)	24.54 (100.508)	2.48 (1.975)	-75.44 (23.391)
	95% CI of Mean	2.06, 2.69	-77.77, -65.34	9.42, 13.70	-7.19, 56.27	1.84, 3.11	-82.93, -67.95

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 10 AM on Day 1 in the SA arm.

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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	153.98 (47.66)		164.33 (46.40)		148.01 (49.23)	
	95% CI of Geometric Mean	138.85, 170.75		143.20, 188.58		127.26, 172.14	
	Median	148.89		147.85		159.09	
	Q25, Q75	106.42, 223.13		120.55, 218.60		104.52, 196.69	
	Min, Max	60.1, 409.2		76.4, 517.8		56.8, 416.0	
	Mean (SD)	170.21 (78.096)		182.00 (92.668)		163.92 (75.954)	
	95% CI of Mean	152.36, 188.06		153.12, 210.88		139.29, 188.55	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	102.11 (47.90)		156.27 (43.45)		102.29 (47.27)	
	95% CI of Geometric Mean	92.04, 113.29		137.27, 177.89		88.43, 118.32	
	Median	93.61	-34.21	143.89	-4.65	104.88	-29.73
	Q25, Q75	78.22, 133.91	-43.75, -22.16	105.97, 208.79	-13.91, 9.26	76.93, 135.68	-43.77, -20.07
	Min, Max	40.9, 435.8	-71.3, 59.9	89.4, 409.0	-35.5, 73.1	35.3, 288.9	-70.9, 80.1
	Mean (SD)	114.00 (62.277)	-30.92 (20.855)	171.19 (81.497)	-3.00 (20.152)	112.80 (52.733)	-26.89 (27.373)
	95% CI of Mean	99.77, 128.24	-35.69, -26.15	145.79, 196.59	-9.29, 3.28	95.70, 129.90	-35.76, -18.01

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	64.60 (47.22)		127.86 (44.01)		62.51 (54.73)	
	95% CI of Geometric Mean	58.30, 71.58		112.14, 145.77		52.95, 73.79	
	Median	64.74	-58.67	118.81	-19.48	66.12	-55.49
	Q25, Q75	44.38, 85.25	-65.64, -50.94	93.91, 184.18	-31.35, -12.22	50.90, 86.63	-68.18, -43.31
	Min, Max	28.9, 301.1	-78.7, 7.4	65.6, 304.9	-51.7, 41.2	10.6, 144.1	-86.6, 1.3
	Mean (SD)	72.06 (40.015)	-55.81 (15.871)	139.74 (61.965)	-20.46 (17.254)	69.74 (30.622)	-54.20 (18.489)
	95% CI of Mean	62.91, 81.20	-59.45, -52.18	120.42, 159.05	-25.84, -15.08	59.81, 79.67	-60.20, -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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	74.08 (53.98)		153.78 (47.80)		78.97 (57.95)	
	95% CI of Geometric Mean	65.99, 83.16		133.51, 177.13		66.32, 94.02	
	Median	69.45	-51.54	155.83	-8.74	76.48	-48.54
	Q25, Q75	51.98, 105.61	-62.19, -36.91	110.28, 226.28	-17.10, 3.80	54.14, 100.00	-58.50, -32.27
	Min, Max	26.9, 339.5	-84.5, 16.3	73.2, 376.8	-41.6, 110.9	28.0, 611.4	-76.8, 147.3
	Mean (SD)	84.75 (50.452)	-48.63 (18.364)	170.12 (79.087)	-3.56 (26.337)	95.05 (91.213)	-40.83 (35.738)
	95% CI of Mean	73.22, 96.29	-52.83, -44.43	145.47, 194.77	-11.77, 4.65	65.47, 124.62	-52.42, -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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	64.61 (49.91)		144.31 (47.47)		58.54 (52.33)	
	95% CI of Geometric Mean	58.01, 71.97		125.40, 166.08		49.90, 68.66	
	Median	64.63	-58.86	140.31	-13.32	57.41	-61.35
	Q25, Q75	47.18, 81.56	-67.42, -44.24	100.00, 205.85	-21.92, -0.28	42.66, 78.21	-68.14, -50.80
	Min, Max	21.7, 266.7	-80.1, 0.1	70.5, 392.4	-43.4, 60.0	18.8, 336.9	-83.4, 36.3
	Mean (SD)	72.84 (42.537)	-55.07 (17.442)	159.92 (77.672)	-10.62 (17.673)	67.24 (49.476)	-57.44 (19.520)
	95% CI of Mean	63.12, 82.57	-59.07, -51.08	135.71, 184.13	-16.13, -5.10	51.20, 83.28	-63.77, -51.11

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	46.36 (49.07)		122.90 (55.00)		41.14 (48.66)	
	95% CI of Geometric Mean	41.68, 51.55		104.71, 144.26		35.42, 47.78	
	Median	43.85	-68.36	110.33	-26.82	44.68	-72.53
	Q25, Q75	33.41, 62.10	-77.13, -60.44	84.16, 177.65	-34.33, -15.86	32.24, 56.68	-77.38, -62.33
	Min, Max	17.4, 196.7	-86.1, -32.6	50.9, 386.0	-53.5, 73.8	16.1, 111.8	-89.8, -48.4
	Mean (SD)	52.14 (29.755)	-68.08 (10.757)	140.77 (80.111)	-23.00 (21.008)	45.44 (20.670)	-70.04 (11.005)
	95% CI of Mean	45.34, 58.94	-70.54, -65.62	115.80, 165.74	-29.55, -16.44	38.74, 52.15	-73.62, -66.47

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	153.62 (48.34)		162.86 (46.59)		148.01 (49.23)	
	95% CI of Geometric Mean	138.14, 170.83		141.60, 187.31		127.26, 172.14	
	Median	146.84		145.51		159.09	
	Q25, Q75	103.64, 223.56		120.55, 209.46		104.52, 196.69	
	Min, Max	60.1, 409.2		76.4, 517.8		56.8, 416.0	
	Mean (SD)	170.27 (79.135)		180.64 (93.396)		163.92 (75.954)	
	95% CI of Mean	151.93, 188.61		151.16, 210.13		139.29, 188.55	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	99.69 (50.16)		183.50 (44.28)		94.02 (62.94)	
	95% CI of Geometric Mean	89.32, 111.26		160.55, 209.72		77.96, 113.38	
	Median	100.62	-33.90	189.57	15.27	95.14	-35.10
	Q25, Q75	75.96, 131.69	-54.12, -10.68	140.43, 235.77	-4.75, 36.46	62.39, 132.06	-54.34, -9.66
	Min, Max	33.2, 354.3	-78.9, 248.9	57.6, 460.8	-49.4, 96.4	26.2, 418.5	-87.7, 112.0
	Mean (SD)	111.27 (55.700)	-24.89 (49.571)	199.93 (85.504)	17.02 (31.853)	111.21 (73.904)	-27.36 (38.819)
	95% CI of Mean	98.36, 124.18	-36.38, -13.40	172.93, 226.92	6.96, 27.08	87.25, 135.17	-39.95, -14.78

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	156.48 (48.10)		162.86 (46.59)		146.59 (49.50)	
	95% CI of Geometric Mean	140.46, 174.33		141.60, 187.31		125.68, 170.98	
	Median	150.00		145.51		156.87	
	Q25, Q75	109.21, 228.04		120.55, 209.46		104.52, 191.36	
	Min, Max	60.1, 409.2		76.4, 517.8		56.8, 416.0	
	Mean (SD)	173.13 (79.285)		180.64 (93.396)		162.62 (76.533)	
	95% CI of Mean	154.36, 191.90		151.16, 210.13		137.46, 187.78	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	97.95 (69.59)		189.23 (55.83)		90.98 (66.64)	
	95% CI of Geometric Mean	84.41, 113.66		160.54, 223.04		74.54, 111.04	
	Median	89.93	-42.89	179.35	17.28	91.93	-41.09
	Q25, Q75	68.34, 134.17	-57.95, -14.32	136.99, 229.46	-15.50, 51.63	61.08, 139.16	-56.25, -11.34
	Min, Max	29.9, 2915.4	-76.1, 1953.9	57.1, 839.1	-49.9, 235.7	17.1, 420.3	-76.6, 64.5
	Mean (SD)	144.39 (338.253)	-3.79 (239.857)	218.93 (144.223)	27.17 (58.894)	108.58 (72.545)	-29.85 (36.796)
	95% CI of Mean	64.32, 224.46	-60.57, 52.99	173.41, 264.46	8.57, 45.76	84.73, 132.43	-41.95, -17.75

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	152.56 (48.99)		162.86 (46.59)		146.00 (50.18)	
	95% CI of Geometric Mean	136.59, 170.41		141.60, 187.31		124.66, 170.99	
	Median	144.88		145.51		154.65	
	Q25, Q75	103.64, 223.56		120.55, 209.46		104.52, 191.36	
	Min, Max	60.1, 409.2		76.4, 517.8		56.8, 416.0	
	Mean (SD)	169.60 (80.415)		180.64 (93.396)		162.41 (77.577)	
	95% CI of Mean	150.42, 188.78		151.16, 210.13		136.54, 188.28	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	85.47 (48.25)		167.38 (44.82)		88.21 (49.14)	
	95% CI of Geometric Mean	76.64, 95.33		146.23, 191.58		75.53, 103.01	
	Median	87.76	-46.84	163.54	11.72	88.63	-44.08
	Q25, Q75	62.39, 108.09	-60.07, -23.34	126.76, 227.70	-3.32, 30.30	66.85, 117.23	-57.13, -16.72
	Min, Max	31.6, 293.9	-87.1, 89.5	64.8, 478.5	-62.8, 67.3	30.0, 267.9	-74.6, 90.6
	Mean (SD)	95.08 (48.081)	-36.75 (34.327)	182.92 (80.928)	7.87 (30.733)	97.94 (47.722)	-31.39 (38.354)
	95% CI of Mean	83.61, 106.55	-44.94, -28.56	157.37, 208.47	-1.84, 17.57	82.02, 113.85	-44.18, -18.59

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	185.30 (45.70)	194.88 (56.81)	177.80 (51.35)
	95% CI of Geometric Mean	167.74, 204.69	165.27, 229.80	151.99, 207.99
	Median	192.83	194.52	178.30
	Q25, Q75	138.53, 256.95	130.44, 290.34	129.76, 247.05
	Min, Max	65.1, 420.7	73.7, 629.1	58.4, 422.0
	Mean (SD)	202.83 (86.168)	224.30 (129.352)	198.46 (94.146)
	95% CI of Mean	183.13, 222.52	183.98, 264.61	167.94, 228.98

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	118.68 (41.58)	187.38 (62.45)	111.84 (51.76)
	95% CI of Geometric Mean	108.33, 130.02	156.70, 224.08	95.49, 130.97
	Median	112.87	177.37	111.22
	Q25, Q75	92.55, 157.96	133.54, 285.29	71.57, 153.39
	Min, Max	49.8, 270.4	49.4, 594.3	38.4, 513.5
	Mean (SD)	128.40 (52.706)	218.72 (124.391)	126.99 (78.930)
	95% CI of Mean	116.35, 140.45	179.95, 257.49	101.40, 152.59

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	76.49 (44.05)	159.35 (58.19)	72.75 (54.63)
	95% CI of Geometric Mean	69.46, 84.22	134.67, 188.56	61.64, 85.87
	Median	72.60	139.06	71.14
	Q25, Q75	56.18, 102.62	117.26, 235.08	54.90, 104.30
	Min, Max	33.0, 215.2	44.7, 474.3	16.3, 213.4
	Mean (SD)	83.87 (39.298)	183.60 (102.665)	82.02 (40.835)
	95% CI of Mean	74.88, 92.85	151.61, 215.60	68.78, 95.26

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	89.91 (45.21)	187.83 (50.29)	95.26 (60.80)
	95% CI of Geometric Mean	81.47, 99.23	161.99, 217.79	79.42, 114.25
	Median	92.44	179.24	92.29
	Q25, Q75	64.79, 115.88	138.69, 253.23	72.89, 125.98
	Min, Max	37.6, 262.5	72.5, 568.8	25.9, 720.8
	Mean (SD)	98.76 (45.463)	210.47 (108.781)	115.09 (107.452)
	95% CI of Mean	88.36, 109.15	176.57, 244.38	80.25, 149.92

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	78.89 (46.75)	164.86 (57.20)	67.91 (57.40)
	95% CI of Geometric Mean	71.26, 87.33	139.67, 194.59	57.12, 80.74
	Median	76.75	164.82	63.08
	Q25, Q75	58.42, 104.78	121.28, 227.85	48.04, 89.84
	Min, Max	23.3, 214.0	36.5, 461.3	24.2, 474.0
	Mean (SD)	87.11 (41.097)	188.22 (99.609)	80.92 (71.206)
	95% CI of Mean	77.71, 96.51	157.18, 219.27	57.83, 104.00

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	54.20 (42.18)	152.31 (57.43)	50.22 (52.34)
	95% CI of Geometric Mean	49.41, 59.46	128.96, 179.88	42.81, 58.91
	Median	52.48	143.53	50.88
	Q25, Q75	44.42, 65.86	105.25, 213.17	37.51, 66.84
	Min, Max	16.2, 172.9	58.5, 545.6	13.2, 165.6
	Mean (SD)	58.98 (27.241)	176.91 (109.087)	56.40 (28.963)
	95% CI of Mean	52.75, 65.21	142.92, 210.91	47.01, 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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	183.90 (45.82)	191.54 (56.12)	177.80 (51.35)
	95% CI of Geometric Mean	166.21, 203.47	162.38, 225.93	151.99, 207.99
	Median	192.83	194.36	178.30
	Q25, Q75	136.86, 253.41	130.44, 264.39	129.76, 247.05
	Min, Max	65.1, 420.7	73.7, 629.1	58.4, 422.0
	Mean (SD)	201.43 (86.163)	220.10 (128.034)	198.46 (94.146)
	95% CI of Mean	181.46, 221.40	179.69, 260.52	167.94, 228.98

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	117.93 (51.67)	212.15 (53.64)	100.57 (61.73)
	95% CI of Geometric Mean	105.35, 132.00	181.01, 248.64	83.65, 120.91
	Median	116.94	211.01	95.05
	Q25, Q75	93.13, 157.86	151.35, 328.28	78.55, 134.46
	Min, Max	30.0, 517.2	49.6, 562.0	23.1, 705.6
	Mean (SD)	133.16 (75.945)	237.63 (110.493)	120.97 (106.180)
	95% CI of Mean	115.56, 150.76	202.75, 272.51	86.55, 155.39

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	187.51 (45.53)	191.54 (56.12)	175.54 (51.33)
	95% CI of Geometric Mean	169.20, 207.80	162.38, 225.93	149.74, 205.79
	Median	193.30	194.36	172.52
	Q25, Q75	140.71, 260.48	130.44, 264.39	129.76, 241.74
	Min, Max	65.1, 420.7	73.7, 629.1	58.4, 422.0
	Mean (SD)	204.95 (85.892)	220.10 (128.034)	196.08 (94.217)
	95% CI of Mean	184.61, 225.28	179.69, 260.52	165.11, 227.06

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	112.93 (67.59)	215.93 (61.22)	103.35 (74.82)
	95% CI of Geometric Mean	97.66, 130.58	180.70, 258.01	83.01, 128.68
	Median	105.05	196.56	90.61
	Q25, Q75	81.44, 136.61	150.12, 309.01	70.29, 150.35
	Min, Max	35.0, 3760.9	80.3, 910.2	19.4, 660.4
	Mean (SD)	170.84 (437.017)	255.34 (171.468)	130.15 (110.399)
	95% CI of Mean	67.40, 274.29	201.21, 309.46	93.86, 166.44

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	180.45 (45.71)	191.54 (56.12)	176.47 (51.99)
	95% CI of Geometric Mean	162.65, 200.21	162.38, 225.93	149.91, 207.73
	Median	186.33	194.36	178.30
	Q25, Q75	131.27, 250.16	130.44, 264.39	129.76, 241.74
	Min, Max	65.1, 420.7	73.7, 629.1	58.4, 422.0
	Mean (SD)	197.69 (85.352)	220.10 (128.034)	197.48 (95.119)
	95% CI of Mean	177.33, 218.04	179.69, 260.52	165.76, 229.20

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	96.46 (43.46)	181.74 (59.61)	99.88 (54.04)
	95% CI of Geometric Mean	87.35, 106.53	152.71, 216.29	84.36, 118.24
	Median	98.36	174.44	98.47
	Q25, Q75	74.56, 125.55	142.33, 258.07	78.81, 118.99
	Min, Max	28.7, 270.0	43.6, 811.9	25.1, 411.6
	Mean (SD)	104.65 (43.276)	210.49 (129.104)	114.01 (69.612)
	95% CI of Mean	94.33, 114.98	169.74, 251.25	90.79, 137.22

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	153.54 (49.17)		164.33 (46.40)		149.99 (49.42)	
	95% CI of Geometric Mean	138.24, 170.52		143.20, 188.58		129.16, 174.18	
	Median	148.89		147.85		160.00	
	Q25, Q75	103.64, 223.56		120.55, 218.60		108.09, 203.20	
	Min, Max	60.1, 409.2		76.4, 517.8		56.8, 416.0	
	Mean (SD)	170.58 (79.619)		182.00 (92.668)		166.12 (76.252)	
	95% CI of Mean	152.63, 188.54		153.12, 210.88		141.73, 190.51	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	101.89 (47.83)		156.27 (43.45)		103.71 (47.59)	
	95% CI of Geometric Mean	91.98, 112.88		137.27, 177.89		89.75, 119.84	
	Median	93.61	-34.21	143.89	-4.65	105.53	-29.56
	Q25, Q75	77.09, 134.80	-43.82, -21.10	105.97, 208.79	-13.91, 9.26	79.68, 139.27	-43.68, -20.45
	Min, Max	40.9, 435.8	-71.3, 59.9	89.4, 409.0	-35.5, 73.1	35.3, 288.9	-70.9, 80.1
	Mean (SD)	113.71 (61.841)	-30.82 (21.039)	171.19 (81.497)	-3.00 (20.152)	114.43 (53.066)	-26.95 (27.023)
	95% CI of Mean	99.76, 127.65	-35.56, -26.07	145.79, 196.59	-9.29, 3.28	97.46, 131.41	-35.59, -18.30

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	64.58 (46.54)		127.86 (44.01)		63.83 (56.02)	
	95% CI of Geometric Mean	58.44, 71.37		112.14, 145.77		54.01, 75.45	
	Median	64.74	-58.67	118.81	-19.48	67.29	-55.36
	Q25, Q75	44.40, 85.02	-65.68, -50.45	93.91, 184.18	-31.35, -12.22	51.08, 87.05	-67.17, -42.90
	Min, Max	28.9, 301.1	-78.7, 7.4	65.6, 304.9	-51.7, 41.2	10.6, 144.8	-86.6, 1.3
	Mean (SD)	71.85 (39.515)	-55.39 (17.096)	139.74 (61.965)	-20.46 (17.254)	71.62 (32.476)	-53.91 (18.344)
	95% CI of Mean	62.93, 80.76	-59.25, -51.53	120.42, 159.05	-25.84, -15.08	61.23, 82.01	-59.78, -48.03

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	73.97 (53.24)		153.78 (47.80)		80.17 (58.16)	
	95% CI of Geometric Mean	66.09, 82.79		133.51, 177.13		67.46, 95.28	
	Median	69.45	-51.54	155.83	-8.74	78.97	-47.96
	Q25, Q75	53.62, 100.78	-62.38, -36.54	110.28, 226.28	-17.10, 3.80	55.19, 101.56	-58.23, -34.47
	Min, Max	26.9, 339.5	-84.5, 16.3	73.2, 376.8	-41.6, 110.9	28.0, 611.4	-76.8, 147.3
	Mean (SD)	84.38 (49.865)	-48.34 (19.173)	170.12 (79.087)	-3.56 (26.337)	96.29 (90.380)	-40.88 (35.278)
	95% CI of Mean	73.14, 95.63	-52.66, -44.01	145.47, 194.77	-11.77, 4.65	67.38, 125.20	-52.16, -29.59

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	64.75 (49.25)		144.31 (47.47)		59.88 (54.06)	
	95% CI of Geometric Mean	58.29, 71.93		125.40, 166.08		50.92, 70.41	
	Median	64.63	-58.86	140.31	-13.32	57.55	-59.92
	Q25, Q75	47.47, 81.54	-67.60, -43.86	100.00, 205.85	-21.92, -0.28	42.71, 78.65	-67.82, -50.18
	Min, Max	21.7, 266.7	-80.1, 0.1	70.5, 392.4	-43.4, 60.0	18.8, 336.9	-83.4, 36.3
	Mean (SD)	72.79 (42.007)	-54.61 (18.444)	159.92 (77.672)	-10.62 (17.673)	69.18 (50.355)	-57.06 (19.412)
	95% CI of Mean	63.31, 82.26	-58.78, -50.45	135.71, 184.13	-16.13, -5.10	53.07, 85.29	-63.28, -50.85

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	46.59 (48.51)		122.90 (55.00)		42.46 (52.90)	
	95% CI of Geometric Mean	41.99, 51.68		104.71, 144.26		36.21, 49.77	
	Median	44.23	-68.36	110.33	-26.82	44.99	-71.45
	Q25, Q75	33.93, 62.08	-77.16, -60.27	84.16, 177.65	-34.33, -15.86	32.34, 57.46	-77.07, -62.10
	Min, Max	17.4, 196.7	-86.1, 0.0	50.9, 386.0	-53.5, 73.8	16.1, 144.8	-89.8, -42.5
	Mean (SD)	52.25 (29.386)	-67.40 (13.247)	140.77 (80.111)	-23.00 (21.008)	47.93 (25.754)	-69.36 (11.704)
	95% CI of Mean	45.62, 58.88	-70.39, -64.41	115.80, 165.74	-29.55, -16.44	39.69, 56.17	-73.10, -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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	100.08 (49.73)		184.63 (43.91)		95.04 (62.51)	
	95% CI of Geometric Mean	90.01, 111.27		161.98, 210.44		79.09, 114.20	
	Median	100.62	-32.83	189.74	12.82	97.57	-35.47
	Q25, Q75	75.96, 133.75	-54.12, -8.09	140.43, 237.59	-4.75, 36.46	63.60, 132.90	-53.49, -12.80
	Min, Max	33.2, 354.3	-78.9, 248.9	57.6, 460.8	-49.4, 96.4	26.2, 418.5	-87.7, 112.0
	Mean (SD)	111.49 (55.049)	-24.71 (48.721)	200.82 (84.654)	16.62 (31.571)	112.05 (73.144)	-27.74 (38.393)
	95% CI of Mean	99.07, 123.91	-35.70, -13.72	174.44, 227.21	6.77, 26.46	88.66, 135.45	-40.03, -15.46

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	98.10 (68.27)		190.26 (55.20)		89.23 (69.43)	
	95% CI of Geometric Mean	85.33, 112.79		162.01, 223.43		73.00, 109.05	
	Median	89.36	-39.72	184.08	15.86	91.93	-42.15
	Q25, Q75	67.89, 134.17	-56.98, -12.72	136.99, 229.89	-15.50, 51.63	60.10, 140.22	-56.52, -12.44
	Min, Max	29.9, 2915.4	-76.1, 1953.9	57.1, 839.1	-49.9, 235.7	17.1, 420.3	-87.7, 64.5
	Mean (SD)	141.74 (323.255)	-4.45 (228.996)	219.38 (142.482)	26.52 (58.322)	107.43 (72.105)	-31.61 (37.030)
	95% CI of Mean	68.85, 214.63	-56.08, 47.19	174.97, 263.78	8.34, 44.70	84.36, 130.49	-43.46, -19.77

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	86.47 (47.59)		168.78 (44.61)		87.47 (52.98)	
	95% CI of Geometric Mean	78.09, 95.75		147.79, 192.75		74.60, 102.56	
	Median	88.24	-46.12	166.56	11.51	89.15	-44.06
	Q25, Q75	62.39, 115.03	-60.07, -22.38	126.76, 230.88	-3.32, 30.30	66.71, 122.01	-58.45, -20.43
	Min, Max	31.6, 293.9	-87.1, 89.5	64.8, 478.5	-62.8, 67.3	26.2, 267.9	-87.7, 90.6
	Mean (SD)	95.87 (47.170)	-36.09 (35.262)	184.22 (80.379)	7.68 (30.380)	98.10 (48.121)	-32.89 (37.966)
	95% CI of Mean	85.23, 106.51	-44.05, -28.14	159.17, 209.28	-1.79, 17.15	82.71, 113.49	-45.04, -20.74

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	184.09 (47.24)	194.88 (56.81)	178.47 (50.68)
	95% CI of Geometric Mean	166.36, 203.69	165.27, 229.80	153.16, 207.96
	Median	192.83	194.52	178.41
	Q25, Q75	136.86, 260.48	130.44, 290.34	133.97, 244.39
	Min, Max	65.1, 420.7	73.7, 629.1	58.4, 422.0
	Mean (SD)	202.43 (87.257)	224.30 (129.352)	198.66 (92.941)
	95% CI of Mean	182.75, 222.11	183.98, 264.61	168.94, 228.39

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	118.37 (41.84)	187.38 (62.45)	112.00 (51.03)
	95% CI of Geometric Mean	108.12, 129.59	156.70, 224.08	96.02, 130.63
	Median	112.87	177.37	113.71
	Q25, Q75	92.08, 158.13	133.54, 285.29	72.86, 149.91
	Min, Max	49.8, 270.4	49.4, 594.3	38.4, 513.5
	Mean (SD)	128.16 (52.712)	218.72 (124.391)	126.78 (77.923)
	95% CI of Mean	116.27, 140.05	179.95, 257.49	101.86, 151.71

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	76.24 (43.48)	159.35 (58.19)	73.61 (54.49)
	95% CI of Geometric Mean	69.41, 83.75	134.67, 188.56	62.53, 86.66
	Median	70.81	139.06	72.04
	Q25, Q75	56.77, 102.53	117.26, 235.08	55.32, 105.94
	Min, Max	33.0, 215.2	44.7, 474.3	16.3, 213.4
	Mean (SD)	83.45 (38.871)	183.60 (102.665)	82.88 (40.673)
	95% CI of Mean	74.68, 92.22	151.61, 215.60	69.87, 95.89

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	90.04 (45.00)	187.83 (50.29)	95.74 (60.00)
	95% CI of Geometric Mean	81.73, 99.20	161.99, 217.79	80.17, 114.32
	Median	92.44	179.24	95.83
	Q25, Q75	65.47, 117.80	138.69, 253.23	72.94, 125.05
	Min, Max	37.6, 262.5	72.5, 568.8	25.9, 720.8
	Mean (SD)	98.81 (45.205)	210.47 (108.781)	115.12 (106.066)
	95% CI of Mean	88.62, 109.01	176.57, 244.38	81.19, 149.05

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	79.01 (46.26)	164.86 (57.20)	68.83 (57.40)
	95% CI of Geometric Mean	71.54, 87.26	139.67, 194.59	58.03, 81.65
	Median	76.75	164.82	64.94
	Q25, Q75	58.81, 104.80	121.28, 227.85	48.29, 91.26
	Min, Max	23.3, 214.0	36.5, 461.3	24.2, 474.0
	Mean (SD)	87.08 (40.674)	188.22 (99.609)	81.80 (70.510)
	95% CI of Mean	77.90, 96.25	157.18, 219.27	59.25, 104.36

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	54.48 (41.73)	152.31 (57.43)	51.29 (53.72)
	95% CI of Geometric Mean	49.77, 59.63	128.96, 179.88	43.66, 60.26
	Median	53.11	143.53	52.50
	Q25, Q75	44.43, 66.00	105.25, 213.17	37.83, 72.36
	Min, Max	16.2, 172.9	58.5, 545.6	13.2, 165.6
	Mean (SD)	59.16 (26.910)	176.91 (109.087)	57.90 (30.122)
	95% CI of Mean	53.09, 65.24	142.92, 210.91	48.26, 67.54

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	118.43 (51.64)	215.33 (54.02)	100.94 (60.86)
	95% CI of Geometric Mean	106.13, 132.15	183.91, 252.10	84.34, 120.79
	Median	116.94	225.43	97.37
	Q25, Q75	93.13, 157.86	151.35, 330.62	79.53, 133.61
	Min, Max	30.0, 517.2	49.6, 562.0	23.1, 705.6
	Mean (SD)	133.68 (75.581)	241.41 (111.849)	120.85 (104.813)
	95% CI of Mean	116.63, 150.72	206.55, 276.27	87.33, 154.38

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	112.50 (65.75)	219.07 (61.33)	100.84 (75.67)
	95% CI of Geometric Mean	98.27, 128.78	183.70, 261.25	81.32, 125.06
	Median	105.03	198.20	90.61
	Q25, Q75	80.37, 136.61	150.12, 324.79	69.81, 149.94
	Min, Max	35.0, 3760.9	80.3, 910.2	19.4, 660.4
	Mean (SD)	166.27 (417.321)	258.69 (170.754)	127.41 (108.607)
	95% CI of Mean	72.17, 260.36	205.48, 311.91	92.67, 162.15

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	98.18 (43.96)	185.15 (60.41)	98.36 (55.50)
	95% CI of Geometric Mean	89.30, 107.95	155.60, 220.29	83.34, 116.09
	Median	98.36	174.69	99.97
	Q25, Q75	75.20, 126.04	142.33, 263.74	78.78, 122.32
	Min, Max	28.7, 292.6	43.6, 811.9	25.1, 411.6
	Mean (SD)	106.96 (46.853)	214.92 (130.702)	112.60 (68.158)
	95% CI of Mean	96.39, 117.53	174.18, 255.65	90.80, 134.41

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	4.45 (178.22)		3.97 (137.45)		4.13 (166.37)	
	95% CI of Geometric Mean	3.38, 5.86		2.87, 5.47		2.84, 6.00	
	Median	4.01		4.24		3.65	
	Q25, Q75	2.48, 9.14		2.06, 6.72		1.96, 8.59	
	Min, Max	0.1, 86.2		0.5, 93.8		0.4, 132.3	
	Mean (SD)	8.98 (13.824)		7.95 (16.491)		9.26 (21.186)	
	95% CI of Mean	5.82, 12.15		2.81, 13.10		2.39, 16.13	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.43 (174.65)		3.35 (132.00)		0.55 (294.36)	
	95% CI of Geometric Mean	1.09, 1.88		2.45, 4.59		0.33, 0.90	
	Median	1.04	-69.23	3.41	-17.78	0.42	-87.88
	Q25, Q75	0.74, 2.84	-77.99, -55.87	1.65, 5.05	-27.84, 0.19	0.19, 1.07	-91.59, -81.09
	Min, Max	0.1, 35.9	-87.5, 34.9	0.6, 97.1	-59.8, 87.8	0.1, 132.6	-97.0, 0.3
	Mean (SD)	3.41 (6.318)	-62.71 (23.278)	6.96 (15.758)	-11.10 (30.459)	4.55 (21.199)	-82.09 (18.180)
	95% CI of Mean	1.96, 4.86	-68.04, -57.39	2.05, 11.88	-20.60, -1.61	-2.33, 11.43	-87.99, -76.19

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.15 (122.89)		3.61 (134.25)		0.19 (160.14)	
	95% CI of Geometric Mean	0.92, 1.44		2.62, 4.96		0.13, 0.28	
	Median	0.97	-75.87	3.28	-11.95	0.16	-95.77
	Q25, Q75	0.68, 1.79	-82.06, -65.40	1.97, 5.57	-26.07, 5.20	0.12, 0.22	-97.48, -91.98
	Min, Max	0.1, 18.4	-90.5, 23.8	0.4, 89.8	-40.3, 65.4	0.1, 37.2	-99.2, -54.6
	Mean (SD)	1.99 (3.017)	-68.51 (23.153)	7.29 (15.385)	-6.19 (24.660)	1.21 (5.934)	-92.70 (8.734)
	95% CI of Mean	1.30, 2.69	-73.81, -63.22	2.49, 12.09	-13.88, 1.49	-0.72, 3.14	-95.54, -89.87

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.29 (102.72)		3.98 (132.86)		0.17 (94.40)	
	95% CI of Geometric Mean	1.06, 1.57		2.90, 5.45		0.12, 0.22	
	Median	1.07	-73.43	3.48	0.01	0.16	-96.41
	Q25, Q75	0.78, 1.98	-81.92, -60.90	2.29, 6.42	-22.54, 23.67	0.12, 0.18	-97.89, -92.41
	Min, Max	0.2, 14.4	-91.9, 315.8	0.6, 92.7	-40.5, 100.3	0.0, 6.0	-99.3, -57.3
	Mean (SD)	1.93 (2.251)	-60.22 (51.414)	7.98 (16.427)	5.10 (33.574)	0.33 (0.936)	-93.60 (8.415)
	95% CI of Mean	1.41, 2.45	-71.98, -48.47	2.86, 13.11	-5.37, 15.56	0.02, 0.63	-96.33, -90.87

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.04 (109.47)		4.09 (179.38)		0.14 (67.92)	
	95% CI of Geometric Mean	0.84, 1.28		2.81, 5.95		0.11, 0.18	
	Median	0.90	-79.05	3.46	-2.79	0.14	-96.08
	Q25, Q75	0.57, 1.69	-84.90, -65.77	2.34, 5.97	-25.46, 15.05	0.10, 0.18	-98.49, -92.99
	Min, Max	0.1, 11.6	-92.1, 35.9	0.6, 301.9	-51.8, 4017.7	0.1, 1.5	-99.6, -61.8
	Mean (SD)	1.60 (1.920)	-71.42 (21.432)	14.38 (47.861)	95.17 (620.997)	0.19 (0.238)	-94.01 (7.690)
	95% CI of Mean	1.15, 2.04	-76.32, -66.51	-0.53, 29.30	-98.35, 288.69	0.10, 0.27	-96.51, -91.51

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.20 (116.15)		4.10 (145.51)		0.15 (51.01)	
	95% CI of Geometric Mean	0.97, 1.49		2.94, 5.73		0.12, 0.18	
	Median	1.13	-75.79	4.00	-1.52	0.15	-96.61
	Q25, Q75	0.72, 1.86	-82.67, -60.04	2.42, 6.44	-21.62, 16.22	0.11, 0.18	-98.35, -93.33
	Min, Max	0.1, 16.4	-91.7, 53.9	0.5, 91.5	-52.4, 527.9	0.1, 0.5	-99.6, -64.8
	Mean (SD)	1.95 (2.685)	-65.80 (28.301)	8.79 (17.566)	20.30 (97.580)	0.16 (0.091)	-93.89 (7.353)
	95% CI of Mean	1.33, 2.57	-72.27, -59.33	3.31, 14.27	-10.11, 50.72	0.13, 0.20	-96.28, -91.50

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	4.49 (182.25)		3.98 (140.19)		4.13 (166.37)	
	95% CI of Geometric Mean	3.39, 5.94		2.86, 5.54		2.84, 6.00	
	Median	4.01		4.40		3.65	
	Q25, Q75	2.50, 9.39		2.06, 6.72		1.96, 8.59	
	Min, Max	0.1, 86.2		0.5, 93.8		0.4, 132.3	
	Mean (SD)	9.13 (13.981)		8.06 (16.680)		9.26 (21.186)	
	95% CI of Mean	5.89, 12.38		2.80, 13.33		2.39, 16.13	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.26 (117.65)		4.10 (138.18)		0.20 (139.43)	
	95% CI of Geometric Mean	1.01, 1.57		2.95, 5.68		0.14, 0.29	
	Median	1.17	-75.33	3.55	6.23	0.16	-95.32
	Q25, Q75	0.73, 2.16	-85.41, -50.94	2.46, 6.28	-22.19, 34.42	0.10, 0.28	-97.45, -91.99
	Min, Max	0.2, 14.6	-94.8, 677.8	0.6, 87.4	-78.3, 417.8	0.1, 8.4	-99.5, -32.6
	Mean (SD)	2.06 (2.718)	-46.69 (113.808)	8.56 (17.502)	20.48 (84.768)	0.49 (1.344)	-90.34 (14.206)
	95% CI of Mean	1.42, 2.69	-73.06, -20.32	3.03, 14.09	-6.28, 47.24	0.05, 0.93	-94.95, -85.73

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	4.83 (164.49)		3.98 (140.19)		4.12 (170.41)	
	95% CI of Geometric Mean	3.68, 6.34		2.86, 5.54		2.80, 6.04	
	Median	4.15		4.40		3.64	
	Q25, Q75	2.54, 9.39		2.06, 6.72		1.96, 8.59	
	Min, Max	0.1, 86.2		0.5, 93.8		0.4, 132.3	
	Mean (SD)	9.41 (14.180)		8.06 (16.680)		9.38 (21.456)	
	95% CI of Mean	6.05, 12.78		2.80, 13.33		2.32, 16.44	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.14 (131.87)		3.76 (140.07)		0.23 (172.12)	
	95% CI of Geometric Mean	0.90, 1.45		2.70, 5.23		0.15, 0.34	
	Median	1.08	-78.23	3.77	-5.89	0.16	-95.07
	Q25, Q75	0.68, 2.00	-85.66, -62.01	2.39, 5.58	-40.00, 22.27	0.12, 0.43	-96.98, -85.90
	Min, Max	0.2, 36.5	-95.4, 58.7	0.4, 64.7	-84.4, 311.8	0.0, 8.1	-99.8, -42.5
	Mean (SD)	2.19 (4.610)	-68.83 (27.327)	7.14 (12.526)	14.25 (82.684)	0.62 (1.496)	-89.08 (13.731)
	95% CI of Mean	1.09, 3.28	-75.30, -62.36	3.18, 11.10	-11.86, 40.35	0.12, 1.11	-93.60, -84.56

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	4.70 (180.70)		3.98 (140.19)		4.10 (174.70)	
	95% CI of Geometric Mean	3.52, 6.27		2.86, 5.54		2.76, 6.09	
	Median	4.08		4.40		3.63	
	Q25, Q75	2.50, 9.42		2.06, 6.72		1.96, 8.59	
	Min, Max	0.1, 86.2		0.5, 93.8		0.4, 132.3	
	Mean (SD)	9.48 (14.287)		8.06 (16.680)		9.51 (21.738)	
	95% CI of Mean	6.06, 12.89		2.80, 13.33		2.26, 16.76	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.40 (107.51)		4.28 (151.07)		0.26 (191.99)	
	95% CI of Geometric Mean	1.13, 1.73		3.03, 6.05		0.17, 0.40	
	Median	1.25	-73.70	3.85	7.21	0.21	-93.95
	Q25, Q75	0.85, 1.99	-83.13, -51.90	2.17, 6.79	-29.77, 66.48	0.12, 0.45	-97.68, -78.76
	Min, Max	0.2, 25.2	-95.3, 294.0	0.5, 138.8	-67.0, 785.7	0.0, 16.7	-99.5, -24.4
	Mean (SD)	2.25 (3.456)	-54.33 (59.831)	9.87 (23.239)	34.37 (132.710)	0.88 (2.751)	-86.48 (17.371)
	95% CI of Mean	1.42, 3.08	-68.60, -40.06	2.53, 17.21	-7.53, 76.26	-0.05, 1.80	-92.28, -80.69

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	5.36 (178.85)	4.70 (146.81)	4.96 (168.86)
	95% CI of Geometric Mean	4.07, 7.05	3.36, 6.57	3.40, 7.23
	Median	5.76	5.11	4.41
	Q25, Q75	2.67, 10.15	2.56, 8.35	2.16, 10.26
	Min, Max	0.1, 70.8	0.5, 87.9	0.5, 136.3
	Mean (SD)	10.26 (13.840)	9.08 (16.426)	10.65 (21.894)
	95% CI of Mean	7.09, 13.42	3.95, 14.20	3.54, 17.75

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.67 (177.69)	4.02 (147.61)	0.60 (276.36)
	95% CI of Geometric Mean	1.26, 2.19	2.87, 5.62	0.37, 0.97
	Median	1.30	4.10	0.55
	Q25, Q75	0.83, 3.37	2.24, 5.82	0.19, 1.16
	Min, Max	0.2, 37.6	0.5, 82.9	0.1, 64.4
	Mean (SD)	3.90 (7.018)	8.06 (15.196)	2.95 (10.384)
	95% CI of Mean	2.29, 5.51	3.32, 12.80	-0.42, 6.32

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.37 (125.12)	4.50 (153.22)	0.22 (144.25)
	95% CI of Geometric Mean	1.09, 1.71	3.19, 6.34	0.15, 0.31
	Median	1.15	5.10	0.20
	Q25, Q75	0.80, 2.63	2.65, 7.26	0.13, 0.24
	Min, Max	0.1, 15.2	0.4, 89.6	0.0, 29.1
	Mean (SD)	2.30 (3.043)	8.98 (16.734)	1.02 (4.641)
	95% CI of Mean	1.60, 3.00	3.76, 14.20	-0.49, 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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.57 (99.84)	4.89 (138.38)	0.20 (101.53)
	95% CI of Geometric Mean	1.29, 1.90	3.53, 6.75	0.15, 0.27
	Median	1.44	4.96	0.19
	Q25, Q75	0.91, 2.39	2.66, 8.21	0.14, 0.26
	Min, Max	0.2, 13.2	0.7, 91.9	0.0, 9.4
	Mean (SD)	2.27 (2.358)	9.52 (18.175)	0.45 (1.486)
	95% CI of Mean	1.72, 2.81	3.85, 15.19	-0.04, 0.93

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.27 (112.18)	4.67 (180.25)	0.16 (57.81)
	95% CI of Geometric Mean	1.03, 1.56	3.21, 6.80	0.13, 0.20
	Median	1.16	4.53	0.15
	Q25, Q75	0.80, 1.79	2.42, 7.13	0.13, 0.21
	Min, Max	0.1, 11.4	0.5, 226.2	0.1, 1.6
	Mean (SD)	1.96 (2.316)	13.46 (36.975)	0.20 (0.239)
	95% CI of Mean	1.43, 2.50	1.94, 24.99	0.12, 0.29

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.40 (119.51)	5.09 (152.04)	0.18 (48.07)
	95% CI of Geometric Mean	1.12, 1.74	3.61, 7.16	0.15, 0.21
	Median	1.25	5.47	0.17
	Q25, Q75	0.80, 2.23	2.76, 7.79	0.14, 0.26
	Min, Max	0.1, 12.8	0.6, 88.7	0.1, 0.5
	Mean (SD)	2.25 (2.750)	10.28 (18.568)	0.20 (0.093)
	95% CI of Mean	1.62, 2.89	4.49, 16.07	0.16, 0.23

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	5.37 (182.12)	4.68 (149.80)	4.96 (168.86)
	95% CI of Geometric Mean	4.05, 7.11	3.32, 6.60	3.40, 7.23
	Median	5.76	4.82	4.41
	Q25, Q75	2.81, 10.27	2.56, 8.35	2.16, 10.26
	Min, Max	0.1, 70.8	0.5, 87.9	0.5, 136.3
	Mean (SD)	10.38 (13.998)	9.16 (16.622)	10.65 (21.894)
	95% CI of Mean	7.13, 13.62	3.91, 14.41	3.54, 17.75

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.49 (116.17)	4.74 (152.66)	0.22 (112.35)
	95% CI of Geometric Mean	1.20, 1.85	3.35, 6.70	0.16, 0.30
	Median	1.38	5.09	0.17
	Q25, Q75	0.85, 2.50	2.29, 7.43	0.13, 0.27
	Min, Max	0.2, 19.8	0.8, 135.0	0.1, 1.9
	Mean (SD)	2.40 (3.131)	10.45 (22.363)	0.36 (0.452)
	95% CI of Mean	1.67, 3.13	3.39, 17.52	0.21, 0.51

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	5.79 (163.97)	4.68 (149.80)	4.93 (172.84)
	95% CI of Geometric Mean	4.41, 7.59	3.32, 6.60	3.34, 7.26
	Median	5.99	4.82	4.38
	Q25, Q75	2.95, 10.27	2.56, 8.35	2.16, 10.26
	Min, Max	0.1, 70.8	0.5, 87.9	0.5, 136.3
	Mean (SD)	10.71 (14.161)	9.16 (16.622)	10.76 (22.177)
	95% CI of Mean	7.35, 14.06	3.91, 14.41	3.46, 18.05

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.32 (125.45)	4.29 (154.09)	0.26 (151.22)
	95% CI of Geometric Mean	1.04, 1.66	3.02, 6.08	0.17, 0.37
	Median	1.38	4.24	0.17
	Q25, Q75	0.74, 2.12	2.12, 8.43	0.14, 0.41
	Min, Max	0.1, 30.7	0.6, 76.1	0.1, 7.9
	Mean (SD)	2.32 (4.055)	8.35 (13.960)	0.61 (1.358)
	95% CI of Mean	1.36, 3.29	3.93, 12.76	0.16, 1.06

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	5.56 (184.99)	4.68 (149.80)	4.96 (177.16)
	95% CI of Geometric Mean	4.15, 7.44	3.32, 6.60	3.33, 7.38
	Median	5.88	4.82	4.41
	Q25, Q75	2.85, 12.33	2.56, 8.35	2.16, 10.26
	Min, Max	0.1, 70.8	0.5, 87.9	0.5, 136.3
	Mean (SD)	10.75 (14.295)	9.16 (16.622)	10.94 (22.454)
	95% CI of Mean	7.33, 14.16	3.91, 14.41	3.45, 18.43

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.58 (116.20)	4.65 (162.61)	0.30 (169.48)
	95% CI of Geometric Mean	1.26, 1.97	3.24, 6.66	0.20, 0.44
	Median	1.45	4.28	0.21
	Q25, Q75	0.98, 2.39	1.99, 8.65	0.14, 0.51
	Min, Max	0.2, 21.2	0.5, 215.4	0.1, 7.3
	Mean (SD)	2.51 (3.311)	12.10 (33.948)	0.74 (1.513)
	95% CI of Mean	1.72, 3.31	1.38, 22.82	0.23, 1.25

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	4.36 (175.83)		3.97 (137.45)		4.31 (170.49)	
	95% CI of Geometric Mean	3.33, 5.70		2.87, 5.47		2.96, 6.26	
	Median	3.88		4.24		3.87	
	Q25, Q75	2.18, 8.89		2.06, 6.72		2.08, 8.92	
	Min, Max	0.1, 86.2		0.5, 93.8		0.4, 132.3	
	Mean (SD)	8.80 (13.689)		7.95 (16.491)		9.58 (21.010)	
	95% CI of Mean	5.71, 11.90		2.81, 13.10		2.86, 16.31	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.44 (170.66)		3.35 (132.00)		0.57 (295.38)	
	95% CI of Geometric Mean	1.10, 1.88		2.45, 4.59		0.35, 0.93	
	Median	1.06	-68.82	3.41	-17.78	0.43	-87.77
	Q25, Q75	0.77, 2.75	-77.85, -55.69	1.65, 5.05	-27.84, 0.19	0.21, 1.16	-91.55, -81.35
	Min, Max	0.1, 35.9	-87.5, 34.9	0.6, 97.1	-59.8, 87.8	0.1, 132.6	-97.0, 0.3
	Mean (SD)	3.37 (6.240)	-61.31 (24.599)	6.96 (15.758)	-11.10 (30.459)	4.51 (20.927)	-82.23 (17.967)
	95% CI of Mean	1.95, 4.78	-66.86, -55.76	2.05, 11.88	-20.60, -1.61	-2.19, 11.20	-87.98, -76.48

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.16 (120.88)		3.61 (134.25)		0.19 (156.76)	
	95% CI of Geometric Mean	0.93, 1.44		2.62, 4.96		0.13, 0.28	
	Median	0.99	-75.20	3.28	-11.95	0.16	-95.94
	Q25, Q75	0.68, 1.91	-81.72, -61.90	1.97, 5.57	-26.07, 5.20	0.12, 0.22	-97.63, -92.22
	Min, Max	0.1, 18.4	-90.5, 23.8	0.4, 89.8	-40.3, 65.4	0.1, 37.2	-99.2, -54.6
	Mean (SD)	1.98 (2.979)	-67.26 (24.346)	7.29 (15.385)	-6.19 (24.660)	1.18 (5.859)	-92.86 (8.676)
	95% CI of Mean	1.31, 2.66	-72.75, -61.76	2.49, 12.09	-13.88, 1.49	-0.70, 3.06	-95.64, -90.08

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.29 (101.20)		3.98 (132.86)		0.17 (93.21)	
	95% CI of Geometric Mean	1.07, 1.57		2.90, 5.45		0.12, 0.22	
	Median	1.07	-73.37	3.48	0.01	0.16	-96.45
	Q25, Q75	0.79, 2.00	-81.43, -59.79	2.29, 6.42	-22.54, 23.67	0.12, 0.19	-97.99, -93.02
	Min, Max	0.2, 14.4	-91.9, 315.8	0.6, 92.7	-40.5, 100.3	0.0, 6.0	-99.3, -57.3
	Mean (SD)	1.92 (2.224)	-59.29 (51.216)	7.98 (16.427)	5.10 (33.574)	0.32 (0.924)	-93.73 (8.348)
	95% CI of Mean	1.41, 2.43	-70.84, -47.73	2.86, 13.11	-5.37, 15.56	0.02, 0.62	-96.41, -91.06

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.04 (108.12)		4.09 (179.38)		0.14 (67.75)	
	95% CI of Geometric Mean	0.85, 1.28		2.81, 5.95		0.11, 0.18	
	Median	0.90	-78.37	3.46	-2.79	0.14	-96.16
	Q25, Q75	0.58, 1.75	-84.85, -65.01	2.34, 5.97	-25.46, 15.05	0.10, 0.18	-98.59, -93.41
	Min, Max	0.1, 11.6	-92.1, 35.9	0.6, 301.9	-51.8, 4017.7	0.1, 1.5	-99.6, -61.8
	Mean (SD)	1.59 (1.898)	-70.35 (22.680)	14.38 (47.861)	95.17 (620.997)	0.19 (0.235)	-94.13 (7.629)
	95% CI of Mean	1.16, 2.03	-75.46, -65.23	-0.53, 29.30	-98.35, 288.69	0.11, 0.27	-96.58, -91.69

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.20 (114.32)		4.10 (145.51)		0.15 (51.20)	
	95% CI of Geometric Mean	0.97, 1.48		2.94, 5.73		0.12, 0.18	
	Median	1.13	-75.46	4.00	-1.52	0.15	-96.66
	Q25, Q75	0.72, 1.88	-82.59, -56.89	2.42, 6.44	-21.62, 16.22	0.11, 0.18	-98.50, -93.39
	Min, Max	0.1, 16.4	-91.7, 53.9	0.5, 91.5	-52.4, 527.9	0.1, 0.5	-99.6, -64.8
	Mean (SD)	1.94 (2.652)	-64.72 (28.974)	8.79 (17.566)	20.30 (97.580)	0.17 (0.091)	-94.02 (7.300)
	95% CI of Mean	1.33, 2.54	-71.26, -58.19	3.31, 14.27	-10.11, 50.72	0.13, 0.20	-96.36, -91.68

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.26 (113.61)		4.08 (135.52)		0.20 (136.64)	
	95% CI of Geometric Mean	1.02, 1.56		2.96, 5.61		0.14, 0.29	
	Median	1.19	-75.31	3.53	6.05	0.17	-95.42
	Q25, Q75	0.73, 2.08	-83.89, -49.28	2.46, 6.28	-22.19, 34.42	0.10, 0.28	-97.63, -92.03
	Min, Max	0.2, 14.6	-94.8, 677.8	0.6, 87.4	-78.3, 417.8	0.1, 8.4	-99.5, -32.6
	Mean (SD)	2.02 (2.653)	-46.39 (111.014)	8.43 (17.305)	20.00 (83.788)	0.48 (1.327)	-90.56 (14.087)
	95% CI of Mean	1.42, 2.62	-71.42, -21.35	3.04, 13.83	-6.12, 46.11	0.06, 0.91	-95.07, -86.05

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.15 (123.63)		3.75 (137.30)		0.22 (165.01)	
	95% CI of Geometric Mean	0.92, 1.44		2.72, 5.17		0.15, 0.33	
	Median	1.10	-75.84	3.72	-4.33	0.16	-95.37
	Q25, Q75	0.70, 1.95	-85.18, -57.54	2.39, 5.58	-40.00, 22.27	0.12, 0.35	-97.20, -87.99
	Min, Max	0.2, 36.5	-95.4, 503.5	0.4, 64.7	-84.4, 311.8	0.0, 8.1	-99.8, -42.5
	Mean (SD)	2.11 (4.404)	-58.89 (70.499)	7.05 (12.386)	13.91 (81.699)	0.60 (1.460)	-89.53 (13.521)
	95% CI of Mean	1.11, 3.11	-74.79, -42.99	3.18, 10.91	-11.56, 39.37	0.12, 1.07	-93.86, -85.20

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.36 (102.48)		4.26 (148.06)		0.30 (290.16)	
	95% CI of Geometric Mean	1.12, 1.66		3.04, 5.96		0.18, 0.48	
	Median	1.22	-67.82	3.65	7.11	0.22	-93.99
	Q25, Q75	0.85, 1.89	-82.96, -51.21	2.17, 6.79	-29.77, 66.48	0.12, 0.46	-97.70, -78.04
	Min, Max	0.2, 25.2	-95.3, 294.0	0.5, 138.8	-67.0, 785.7	0.0, 75.0	-99.5, 1489.6
	Mean (SD)	2.14 (3.291)	-53.01 (57.761)	9.72 (22.976)	33.55 (131.189)	2.69 (12.021)	-47.66 (249.858)
	95% CI of Mean	1.40, 2.89	-66.04, -39.98	2.56, 16.89	-7.34, 74.44	-1.16, 6.54	-127.57, 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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	5.23 (177.20)	4.70 (146.81)	5.12 (169.69)
	95% CI of Geometric Mean	3.99, 6.84	3.36, 6.57	3.53, 7.44
	Median	5.70	5.11	4.57
	Q25, Q75	2.44, 10.03	2.56, 8.35	2.30, 12.09
	Min, Max	0.1, 70.8	0.5, 87.9	0.5, 136.3
	Mean (SD)	10.05 (13.721)	9.08 (16.426)	10.83 (21.644)
	95% CI of Mean	6.95, 13.15	3.95, 14.20	3.90, 17.76

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.68 (173.54)	4.02 (147.61)	0.62 (272.53)
	95% CI of Geometric Mean	1.28, 2.19	2.87, 5.62	0.38, 0.99
	Median	1.33	4.10	0.55
	Q25, Q75	0.84, 3.36	2.24, 5.82	0.20, 1.29
	Min, Max	0.2, 37.6	0.5, 82.9	0.1, 64.4
	Mean (SD)	3.85 (6.932)	8.06 (15.196)	2.92 (10.252)
	95% CI of Mean	2.28, 5.42	3.32, 12.80	-0.36, 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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.37 (122.95)	4.50 (153.22)	0.22 (141.20)
	95% CI of Geometric Mean	1.10, 1.71	3.19, 6.34	0.15, 0.31
	Median	1.17	5.10	0.20
	Q25, Q75	0.81, 2.60	2.65, 7.26	0.13, 0.24
	Min, Max	0.1, 15.2	0.4, 89.6	0.0, 29.1
	Mean (SD)	2.28 (3.006)	8.98 (16.734)	1.00 (4.583)
	95% CI of Mean	1.60, 2.97	3.76, 14.20	-0.47, 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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.58 (98.21)	4.89 (138.38)	0.20 (99.71)
	95% CI of Geometric Mean	1.30, 1.90	3.53, 6.75	0.15, 0.27
	Median	1.44	4.96	0.19
	Q25, Q75	0.94, 2.36	2.66, 8.21	0.15, 0.25
	Min, Max	0.2, 13.2	0.7, 91.9	0.0, 9.4
	Mean (SD)	2.26 (2.328)	9.52 (18.175)	0.44 (1.467)
	95% CI of Mean	1.73, 2.79	3.85, 15.19	-0.03, 0.91

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.27 (110.52)	4.67 (180.25)	0.17 (57.08)
	95% CI of Geometric Mean	1.03, 1.56	3.21, 6.80	0.13, 0.20
	Median	1.16	4.53	0.15
	Q25, Q75	0.82, 1.85	2.42, 7.13	0.13, 0.21
	Min, Max	0.1, 11.4	0.5, 226.2	0.1, 1.6
	Mean (SD)	1.96 (2.288)	13.46 (36.975)	0.20 (0.235)
	95% CI of Mean	1.43, 2.48	1.94, 24.99	0.12, 0.28

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.41 (117.46)	5.09 (152.04)	0.18 (47.44)
	95% CI of Geometric Mean	1.14, 1.74	3.61, 7.16	0.15, 0.21
	Median	1.26	5.47	0.17
	Q25, Q75	0.84, 2.22	2.76, 7.79	0.14, 0.25
	Min, Max	0.1, 12.8	0.6, 88.7	0.1, 0.5
	Mean (SD)	2.24 (2.717)	10.28 (18.568)	0.20 (0.092)
	95% CI of Mean	1.62, 2.86	4.49, 16.07	0.16, 0.23

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.50 (111.96)	4.76 (149.57)	0.22 (110.26)
	95% CI of Geometric Mean	1.22, 1.84	3.39, 6.68	0.16, 0.29
	Median	1.38	5.11	0.17
	Q25, Q75	0.85, 2.31	2.29, 7.43	0.13, 0.25
	Min, Max	0.2, 19.8	0.8, 135.0	0.1, 1.9
	Mean (SD)	2.36 (3.056)	10.34 (22.100)	0.35 (0.447)
	95% CI of Mean	1.67, 3.06	3.45, 17.23	0.20, 0.50

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.32 (118.46)	4.32 (151.08)	0.25 (145.25)
	95% CI of Geometric Mean	1.07, 1.64	3.07, 6.07	0.17, 0.36
	Median	1.38	4.51	0.17
	Q25, Q75	0.76, 2.12	2.12, 8.43	0.14, 0.37
	Min, Max	0.1, 30.7	0.6, 76.1	0.1, 7.9
	Mean (SD)	2.25 (3.878)	8.28 (13.794)	0.59 (1.326)
	95% CI of Mean	1.37, 3.13	3.98, 12.59	0.16, 1.02

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.55 (108.94)	4.67 (159.21)	0.33 (259.44)
	95% CI of Geometric Mean	1.26, 1.89	3.29, 6.64	0.21, 0.53
	Median	1.40	4.30	0.21
	Q25, Q75	0.98, 2.33	1.99, 8.65	0.14, 0.54
	Min, Max	0.2, 21.2	0.5, 215.4	0.1, 78.4
	Mean (SD)	2.40 (3.157)	11.95 (33.546)	2.66 (12.375)
	95% CI of Mean	1.68, 3.12	1.49, 22.41	-1.30, 6.62

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	9.33 (46.05)		8.75 (55.39)		7.99 (66.08)	
	95% CI of Geometric Mean	8.44, 10.32		7.44, 10.29		6.57, 9.71	
	Median	10.01		8.68		7.86	
	Q25, Q75	6.71, 12.52		6.60, 12.33		5.40, 12.51	
	Min, Max	2.5, 26.1		2.3, 19.9		1.1, 23.1	
	Mean (SD)	10.23 (4.462)		9.87 (4.681)		9.33 (5.023)	
	95% CI of Mean	9.21, 11.25		8.40, 11.33		7.69, 10.96	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	4.42 (44.09)		8.67 (57.57)		3.89 (61.01)	
	95% CI of Geometric Mean	4.01, 4.87		7.33, 10.25		3.23, 4.67	
	Median	4.50	-53.31	8.50	2.42	4.08	-53.31
	Q25, Q75	3.46, 5.73	-60.15, -44.82	6.18, 13.96	-13.56, 10.84	2.73, 6.03	-62.32, -32.82
	Min, Max	1.5, 12.8	-79.2, 5.2	2.2, 19.5	-41.1, 66.6	1.3, 10.9	-83.9, 27.9
	Mean (SD)	4.82 (2.114)	-50.67 (15.263)	9.85 (4.764)	1.46 (22.000)	4.50 (2.444)	-47.24 (22.128)
	95% CI of Mean	4.33, 5.31	-54.17, -47.18	8.36, 11.34	-5.40, 8.32	3.70, 5.29	-54.42, -40.06

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.07 (53.90)		8.00 (55.42)		2.00 (56.85)	
	95% CI of Geometric Mean	1.84, 2.32		6.81, 9.41		1.68, 2.38	
	Median	2.05	-78.36	7.81	-8.37	2.04	-75.48
	Q25, Q75	1.43, 2.97	-83.43, -70.75	5.29, 12.33	-20.58, 7.94	1.26, 3.13	-81.71, -66.46
	Min, Max	0.6, 10.2	-93.7, -30.4	2.0, 18.2	-43.3, 31.2	0.8, 6.6	-92.5, -3.8
	Mean (SD)	2.36 (1.418)	-75.38 (12.029)	9.03 (4.273)	-6.71 (18.774)	2.30 (1.289)	-71.62 (16.372)
	95% CI of Mean	2.03, 2.69	-78.14, -72.63	7.69, 10.36	-12.56, -0.85	1.88, 2.73	-76.93, -66.31

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.45 (43.52)		8.10 (70.19)		1.45 (53.75)	
	95% CI of Geometric Mean	1.31, 1.60		6.64, 9.87		1.23, 1.71	
	Median	1.38	-85.09	7.81	-3.45	1.29	-81.33
	Q25, Q75	1.17, 1.78	-88.89, -78.69	5.62, 12.33	-18.83, 3.78	1.03, 2.11	-87.59, -76.01
	Min, Max	0.7, 7.8	-94.2, -46.6	1.0, 20.7	-54.0, 89.7	0.5, 5.4	-95.3, 60.4
	Mean (SD)	1.61 (1.016)	-82.35 (10.014)	9.56 (5.147)	-4.23 (25.860)	1.65 (0.955)	-76.35 (25.517)
	95% CI of Mean	1.37, 1.85	-84.65, -80.06	7.96, 11.17	-12.29, 3.84	1.34, 1.97	-84.62, -68.07

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.28 (41.10)		8.09 (66.71)		1.40 (42.76)	
	95% CI of Geometric Mean	1.17, 1.41		6.69, 9.78		1.22, 1.60	
	Median	1.27	-85.36	9.00	-0.22	1.33	-82.00
	Q25, Q75	1.00, 1.59	-89.97, -80.89	5.79, 12.51	-16.19, 8.99	1.10, 1.60	-89.25, -74.71
	Min, Max	0.6, 6.8	-94.7, -53.9	0.9, 19.3	-58.2, 43.5	0.6, 3.6	-93.2, 8.0
	Mean (SD)	1.41 (0.824)	-84.47 (8.391)	9.38 (4.591)	-4.25 (23.878)	1.52 (0.703)	-79.09 (16.794)
	95% CI of Mean	1.21, 1.60	-86.40, -82.55	7.94, 10.81	-11.70, 3.19	1.29, 1.75	-84.54, -73.64

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.97 (51.82)		9.50 (52.09)		2.16 (46.98)	
	95% CI of Geometric Mean	1.76, 2.21		8.15, 11.07		1.87, 2.50	
	Median	2.09	-79.21	9.36	5.32	2.43	-71.64
	Q25, Q75	1.36, 2.95	-85.96, -68.90	6.85, 14.11	-4.74, 27.11	1.56, 3.04	-83.02, -61.30
	Min, Max	0.6, 6.8	-92.1, 69.4	3.3, 22.5	-27.9, 86.7	0.5, 4.1	-92.3, 187.0
	Mean (SD)	2.22 (1.148)	-74.36 (21.468)	10.63 (4.988)	10.87 (23.756)	2.35 (0.848)	-64.19 (43.721)
	95% CI of Mean	1.96, 2.49	-79.27, -69.45	9.07, 12.19	3.46, 18.28	2.07, 2.63	-78.36, -50.01

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	9.41 (46.22)		8.68 (55.82)		7.99 (66.08)	
	95% CI of Geometric Mean	8.49, 10.43		7.36, 10.23		6.57, 9.71	
	Median	10.17		8.50		7.86	
	Q25, Q75	6.75, 12.52		6.60, 12.20		5.40, 12.51	
	Min, Max	2.5, 26.1		2.3, 19.9		1.1, 23.1	
	Mean (SD)	10.32 (4.483)		9.81 (4.723)		9.33 (5.023)	
	95% CI of Mean	9.27, 11.36		8.31, 11.30		7.69, 10.96	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.06 (79.68)		9.25 (50.54)		1.98 (49.92)	
	95% CI of Geometric Mean	1.74, 2.42		7.95, 10.76		1.69, 2.31	
	Median	1.90	-78.84	9.63	10.68	2.07	-76.87
	Q25, Q75	1.32, 2.86	-85.14, -70.63	6.69, 12.94	-10.31, 25.61	1.44, 3.01	-85.48, -58.02
	Min, Max	0.4, 13.9	-96.9, 34.8	2.3, 19.5	-48.5, 174.6	0.6, 4.9	-93.8, 125.5
	Mean (SD)	2.74 (2.708)	-70.01 (28.507)	10.21 (4.307)	13.45 (43.238)	2.19 (0.977)	-66.03 (36.535)
	95% CI of Mean	2.10, 3.37	-76.62, -63.40	8.85, 11.58	-0.20, 27.11	1.87, 2.51	-77.88, -54.18

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	9.51 (45.02)		8.68 (55.82)		8.02 (67.09)	
	95% CI of Geometric Mean	8.59, 10.54		7.36, 10.23		6.56, 9.80	
	Median	10.16		8.50		8.27	
	Q25, Q75	6.93, 12.52		6.60, 12.20		5.40, 12.51	
	Min, Max	2.5, 26.1		2.3, 19.9		1.1, 23.1	
	Mean (SD)	10.39 (4.453)		9.81 (4.723)		9.39 (5.076)	
	95% CI of Mean	9.33, 11.45		8.31, 11.30		7.71, 11.06	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.85 (72.44)		9.51 (62.64)		2.10 (71.38)	
	95% CI of Geometric Mean	1.58, 2.16		7.93, 11.41		1.70, 2.60	
	Median	1.62	-81.24	9.30	9.73	1.97	-74.09
	Q25, Q75	1.19, 2.47	-88.76, -67.93	7.11, 14.61	-10.71, 36.31	1.38, 2.85	-86.30, -46.27
	Min, Max	0.5, 8.8	-96.0, 4.4	2.2, 25.6	-54.7, 146.1	0.6, 9.4	-95.2, 29.8
	Mean (SD)	2.33 (1.895)	-74.18 (22.037)	11.04 (5.990)	17.84 (45.494)	2.60 (1.929)	-62.15 (33.351)
	95% CI of Mean	1.88, 2.79	-79.40, -68.96	9.15, 12.94	3.48, 32.20	1.96, 3.24	-73.12, -51.18

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	9.26 (46.86)		8.68 (55.82)		7.99 (68.16)	
	95% CI of Geometric Mean	8.32, 10.30		7.36, 10.23		6.50, 9.82	
	Median	9.82		8.50		7.86	
	Q25, Q75	6.66, 12.00		6.60, 12.20		5.40, 12.51	
	Min, Max	2.5, 26.1		2.3, 19.9		1.1, 23.1	
	Mean (SD)	10.18 (4.556)		9.81 (4.723)		9.40 (5.145)	
	95% CI of Mean	9.09, 11.27		8.31, 11.30		7.68, 11.12	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.07 (57.88)		9.62 (57.48)		2.35 (68.75)	
	95% CI of Geometric Mean	1.82, 2.36		8.12, 11.39		1.90, 2.89	
	Median	1.96	-77.96	9.21	10.74	2.06	-74.43
	Q25, Q75	1.48, 2.96	-85.38, -65.03	7.14, 12.85	-17.17, 32.41	1.63, 3.65	-85.94, -51.01
	Min, Max	0.6, 10.0	-95.3, -2.5	3.3, 22.9	-57.1, 441.9	0.7, 8.1	-93.9, 315.5
	Mean (SD)	2.42 (1.607)	-72.57 (18.830)	11.00 (5.730)	24.84 (81.210)	2.83 (1.809)	-50.96 (72.443)
	95% CI of Mean	2.03, 2.81	-77.07, -68.08	9.18, 12.81	-0.80, 50.48	2.22, 3.43	-75.12, -26.80

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	11.23 (50.38)	10.38 (66.13)	9.60 (65.57)
	95% CI of Geometric Mean	10.07, 12.53	8.60, 12.53	7.90, 11.65
	Median	12.13	12.15	9.43
	Q25, Q75	8.07, 16.19	7.27, 16.49	6.56, 13.94
	Min, Max	2.3, 28.1	2.7, 35.4	1.2, 28.3
	Mean (SD)	12.44 (5.368)	12.16 (6.587)	11.20 (6.200)
	95% CI of Mean	11.20, 13.67	10.10, 14.21	9.19, 13.22

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	5.13 (48.34)	10.39 (75.01)	4.25 (60.88)
	95% CI of Geometric Mean	4.62, 5.70	8.44, 12.80	3.54, 5.10
	Median	5.75	12.09	4.49
	Q25, Q75	4.05, 6.94	6.47, 17.08	2.98, 6.20
	Min, Max	1.2, 15.1	1.7, 34.0	1.0, 18.1
	Mean (SD)	5.64 (2.404)	12.50 (7.052)	4.94 (2.990)
	95% CI of Mean	5.09, 6.19	10.30, 14.70	3.96, 5.91

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.45 (55.46)	9.97 (70.64)	2.33 (50.02)
	95% CI of Geometric Mean	2.17, 2.76	8.17, 12.17	2.00, 2.72
	Median	2.44	10.54	2.09
	Q25, Q75	1.67, 3.60	7.46, 17.05	1.72, 3.47
	Min, Max	0.6, 8.9	2.0, 26.2	1.1, 7.2
	Mean (SD)	2.79 (1.552)	11.82 (6.307)	2.62 (1.393)
	95% CI of Mean	2.43, 3.15	9.85, 13.79	2.16, 3.07

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.76 (42.43)	9.89 (80.27)	1.75 (49.71)
	95% CI of Geometric Mean	1.60, 1.93	7.93, 12.32	1.50, 2.04
	Median	1.63	11.80	1.74
	Q25, Q75	1.37, 2.08	7.52, 16.22	1.31, 2.53
	Min, Max	0.8, 11.2	1.2, 35.6	0.7, 4.0
	Mean (SD)	1.96 (1.358)	12.09 (7.084)	1.95 (0.919)
	95% CI of Mean	1.64, 2.27	9.88, 14.30	1.64, 2.25

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.56 (45.45)	9.24 (76.50)	1.62 (36.98)
	95% CI of Geometric Mean	1.41, 1.73	7.47, 11.42	1.44, 1.82
	Median	1.52	10.38	1.58
	Q25, Q75	1.16, 1.99	6.37, 15.01	1.19, 2.17
	Min, Max	0.7, 10.3	1.1, 28.2	0.9, 3.6
	Mean (SD)	1.76 (1.244)	11.08 (5.994)	1.72 (0.641)
	95% CI of Mean	1.47, 2.05	9.21, 12.96	1.51, 1.94

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.31 (55.18)	11.78 (60.35)	2.64 (43.42)
	95% CI of Geometric Mean	2.05, 2.60	9.89, 14.01	2.30, 3.03
	Median	2.07	13.18	2.82
	Q25, Q75	1.54, 3.62	8.22, 18.13	2.14, 3.57
	Min, Max	0.6, 8.5	3.3, 33.0	0.7, 4.8
	Mean (SD)	2.63 (1.415)	13.50 (6.722)	2.84 (0.976)
	95% CI of Mean	2.30, 2.96	11.40, 15.60	2.52, 3.16

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	11.27 (50.00)	10.21 (65.81)	9.60 (65.57)
	95% CI of Geometric Mean	10.09, 12.57	8.44, 12.34	7.90, 11.65
	Median	12.13	12.02	9.43
	Q25, Q75	8.22, 16.09	7.27, 16.25	6.56, 13.94
	Min, Max	2.3, 28.1	2.7, 35.4	1.2, 28.3
	Mean (SD)	12.45 (5.347)	11.95 (6.531)	11.20 (6.200)
	95% CI of Mean	11.21, 13.70	9.89, 14.02	9.19, 13.22

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.43 (83.24)	10.69 (66.69)	2.12 (55.62)
	95% CI of Geometric Mean	2.05, 2.88	8.83, 12.95	1.79, 2.51
	Median	2.14	11.10	2.29
	Q25, Q75	1.41, 3.39	7.13, 17.41	1.45, 3.31
	Min, Max	0.6, 24.1	2.8, 27.8	0.8, 5.5
	Mean (SD)	3.36 (3.754)	12.54 (6.576)	2.40 (1.198)
	95% CI of Mean	2.48, 4.23	10.46, 14.62	2.01, 2.80

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	11.40 (47.43)	10.21 (65.81)	9.60 (66.62)
	95% CI of Geometric Mean	10.24, 12.69	8.44, 12.34	7.86, 11.72
	Median	12.15	12.02	9.34
	Q25, Q75	8.26, 16.30	7.27, 16.25	6.56, 13.94
	Min, Max	2.3, 24.5	2.7, 35.4	1.2, 28.3
	Mean (SD)	12.48 (5.019)	11.95 (6.531)	11.25 (6.276)
	95% CI of Mean	11.28, 13.67	9.89, 14.02	9.18, 13.32

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.13 (74.13)	10.85 (66.03)	2.39 (81.74)
	95% CI of Geometric Mean	1.82, 2.50	8.97, 13.13	1.88, 3.03
	Median	1.97	12.06	2.45
	Q25, Q75	1.32, 2.85	7.00, 15.75	1.27, 3.83
	Min, Max	0.6, 16.5	2.3, 31.0	0.6, 13.3
	Mean (SD)	2.78 (2.715)	12.73 (6.941)	3.11 (2.616)
	95% CI of Mean	2.13, 3.42	10.53, 14.92	2.24, 3.97

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	10.95 (49.17)	10.21 (65.81)	9.66 (67.56)
	95% CI of Geometric Mean	9.79, 12.24	8.44, 12.34	7.87, 11.86
	Median	11.38	12.02	9.43
	Q25, Q75	7.92, 15.89	7.27, 16.25	6.56, 13.94
	Min, Max	2.3, 24.5	2.7, 35.4	1.2, 28.3
	Mean (SD)	12.06 (5.066)	11.95 (6.531)	11.35 (6.333)
	95% CI of Mean	10.85, 13.28	9.89, 14.02	9.23, 13.46

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.34 (67.76)	10.44 (65.53)	2.66 (77.23)
	95% CI of Geometric Mean	2.01, 2.71	8.64, 12.62	2.11, 3.34
	Median	2.03	11.55	2.11
	Q25, Q75	1.53, 3.61	6.73, 15.39	1.58, 5.04
	Min, Max	0.5, 10.8	2.3, 31.7	1.0, 9.8
	Mean (SD)	2.85 (2.067)	12.21 (6.537)	3.37 (2.495)
	95% CI of Mean	2.35, 3.35	10.14, 14.27	2.53, 4.21

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	9.32 (45.77)		8.75 (55.39)		8.14 (66.67)	
	95% CI of Geometric Mean	8.44, 10.29		7.44, 10.29		6.70, 9.89	
	Median	10.01		8.68		8.27	
	Q25, Q75	6.66, 12.52		6.60, 12.33		5.49, 12.54	
	Min, Max	2.5, 26.1		2.3, 19.9		1.1, 23.1	
	Mean (SD)	10.21 (4.431)		9.87 (4.681)		9.52 (5.113)	
	95% CI of Mean	9.20, 11.21		8.40, 11.33		7.88, 11.16	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	4.45 (43.84)		8.67 (57.57)		3.96 (61.74)	
	95% CI of Geometric Mean	4.05, 4.90		7.33, 10.25		3.30, 4.75	
	Median	4.55	-53.08	8.50	2.42	4.12	-52.41
	Q25, Q75	3.52, 5.77	-60.10, -44.57	6.18, 13.96	-13.56, 10.84	2.74, 6.30	-61.68, -32.95
	Min, Max	1.5, 12.8	-79.2, 5.2	2.2, 19.5	-41.1, 66.6	1.3, 10.9	-83.9, 27.9
	Mean (SD)	4.85 (2.097)	-50.05 (16.121)	9.85 (4.764)	1.46 (22.000)	4.59 (2.488)	-47.35 (21.853)
	95% CI of Mean	4.38, 5.33	-53.69, -46.41	8.36, 11.34	-5.40, 8.32	3.79, 5.39	-54.34, -40.35

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.11 (55.29)		8.00 (55.42)		2.04 (57.28)	
	95% CI of Geometric Mean	1.87, 2.37		6.81, 9.41		1.71, 2.42	
	Median	2.07	-78.16	7.81	-8.37	2.06	-75.55
	Q25, Q75	1.43, 3.08	-83.27, -70.67	5.29, 12.33	-20.58, 7.94	1.29, 3.15	-80.90, -67.02
	Min, Max	0.6, 10.2	-93.7, 0.0	2.0, 18.2	-43.3, 31.2	0.8, 6.6	-92.5, -3.8
	Mean (SD)	2.42 (1.474)	-74.41 (14.621)	9.03 (4.273)	-6.71 (18.774)	2.34 (1.296)	-71.77 (16.187)
	95% CI of Mean	2.09, 2.76	-77.71, -71.11	7.69, 10.36	-12.56, -0.85	1.92, 2.76	-76.95, -66.59

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.47 (47.26)		8.10 (70.19)		1.49 (55.84)	
	95% CI of Geometric Mean	1.32, 1.63		6.64, 9.87		1.25, 1.76	
	Median	1.38	-85.09	7.81	-3.45	1.32	-81.32
	Q25, Q75	1.16, 1.78	-89.03, -78.60	5.62, 12.33	-18.83, 3.78	1.04, 2.11	-87.53, -76.17
	Min, Max	0.7, 7.8	-94.2, 0.0	1.0, 20.7	-54.0, 89.7	0.5, 5.4	-95.3, 60.4
	Mean (SD)	1.66 (1.144)	-81.44 (13.656)	9.56 (5.147)	-4.23 (25.860)	1.71 (1.006)	-76.38 (25.188)
	95% CI of Mean	1.40, 1.93	-84.52, -78.35	7.96, 11.17	-12.29, 3.84	1.38, 2.03	-84.44, -68.32

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.31 (45.26)		8.09 (66.71)		1.43 (45.71)	
	95% CI of Geometric Mean	1.19, 1.45		6.69, 9.78		1.24, 1.65	
	Median	1.27	-85.36	9.00	-0.22	1.33	-81.85
	Q25, Q75	1.02, 1.62	-89.75, -80.42	5.79, 12.51	-16.19, 8.99	1.11, 1.61	-89.12, -76.09
	Min, Max	0.6, 6.8	-94.7, 0.0	0.9, 19.3	-58.2, 43.5	0.6, 3.9	-93.2, 8.0
	Mean (SD)	1.47 (0.991)	-83.41 (12.654)	9.38 (4.591)	-4.25 (23.878)	1.58 (0.787)	-79.05 (16.579)
	95% CI of Mean	1.25, 1.70	-86.26, -80.55	7.94, 10.81	-11.70, 3.19	1.32, 1.84	-84.36, -73.75

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.01 (53.27)		9.50 (52.09)		2.19 (47.42)	
	95% CI of Geometric Mean	1.79, 2.25		8.15, 11.07		1.90, 2.54	
	Median	2.12	-79.21	9.36	5.32	2.45	-71.75
	Q25, Q75	1.36, 2.99	-85.79, -68.64	6.85, 14.11	-4.74, 27.11	1.59, 3.05	-83.02, -61.34
	Min, Max	0.6, 6.8	-92.1, 69.4	3.3, 22.5	-27.9, 86.7	0.5, 4.1	-92.3, 187.0
	Mean (SD)	2.28 (1.228)	-73.49 (22.815)	10.63 (4.988)	10.87 (23.756)	2.39 (0.871)	-64.52 (43.208)
	95% CI of Mean	2.00, 2.56	-78.64, -68.34	9.07, 12.19	3.46, 18.28	2.10, 2.67	-78.34, -50.69

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.08 (78.79)		9.31 (50.09)		2.01 (50.61)	
	95% CI of Geometric Mean	1.77, 2.44		8.03, 10.80		1.72, 2.35	
	Median	1.91	-78.00	9.63	10.15	2.07	-77.14
	Q25, Q75	1.33, 2.86	-84.50, -70.62	6.69, 12.94	-10.31, 25.61	1.45, 3.07	-85.23, -58.39
	Min, Max	0.4, 13.9	-96.9, 34.8	2.3, 19.5	-48.5, 174.6	0.6, 4.9	-93.8, 125.5
	Mean (SD)	2.75 (2.674)	-69.34 (28.938)	10.26 (4.267)	13.13 (42.758)	2.24 (1.001)	-66.32 (36.109)
	95% CI of Mean	2.14, 3.36	-75.87, -62.81	8.93, 11.60	-0.20, 26.46	1.91, 2.56	-77.87, -54.76

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.97 (75.68)		9.57 (61.92)		2.14 (70.13)	
	95% CI of Geometric Mean	1.68, 2.29		8.01, 11.43		1.74, 2.62	
	Median	1.67	-80.33	9.58	8.64	2.05	-74.09
	Q25, Q75	1.25, 2.53	-88.33, -64.07	7.11, 14.61	-10.71, 36.31	1.39, 2.87	-85.60, -47.63
	Min, Max	0.5, 8.8	-96.0, 16.3	2.2, 25.6	-54.7, 146.1	0.6, 9.4	-95.2, 29.8
	Mean (SD)	2.51 (2.001)	-71.38 (25.032)	11.07 (5.920)	17.41 (45.020)	2.62 (1.891)	-62.70 (32.591)
	95% CI of Mean	2.05, 2.96	-77.03, -65.73	9.22, 12.92	3.38, 31.45	2.01, 3.23	-73.13, -52.28

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.16 (61.90)		9.67 (56.84)		2.33 (67.81)	
	95% CI of Geometric Mean	1.89, 2.46		8.20, 11.41		1.91, 2.84	
	Median	1.98	-77.44	9.70	9.81	2.11	-74.69
	Q25, Q75	1.48, 3.08	-85.38, -64.80	7.14, 12.85	-17.17, 32.41	1.60, 3.68	-86.49, -51.17
	Min, Max	0.6, 10.0	-95.3, 0.0	3.3, 22.9	-57.1, 441.9	0.7, 8.1	-93.9, 315.5
	Mean (SD)	2.57 (1.747)	-71.25 (20.422)	11.03 (5.663)	24.25 (80.305)	2.79 (1.770)	-52.99 (70.008)
	95% CI of Mean	2.17, 2.97	-75.86, -66.64	9.26, 12.80	-0.78, 49.28	2.22, 3.36	-75.39, -30.60

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	11.18 (50.03)	10.38 (66.13)	9.69 (64.98)
	95% CI of Geometric Mean	10.04, 12.44	8.60, 12.53	8.01, 11.72
	Median	12.13	12.15	9.44
	Q25, Q75	7.92, 16.09	7.27, 16.49	6.61, 14.03
	Min, Max	2.3, 28.1	2.7, 35.4	1.2, 28.3
	Mean (SD)	12.36 (5.334)	12.16 (6.587)	11.28 (6.137)
	95% CI of Mean	11.16, 13.57	10.10, 14.21	9.31, 13.24

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	5.17 (47.96)	10.39 (75.01)	4.28 (60.17)
	95% CI of Geometric Mean	4.66, 5.74	8.44, 12.80	3.58, 5.11
	Median	5.78	12.09	4.53
	Q25, Q75	4.06, 6.95	6.47, 17.08	3.10, 6.11
	Min, Max	1.2, 15.1	1.7, 34.0	1.0, 18.1
	Mean (SD)	5.68 (2.383)	12.50 (7.052)	4.95 (2.953)
	95% CI of Mean	5.13, 6.22	10.30, 14.70	4.00, 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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.49 (56.37)	9.97 (70.64)	2.35 (49.56)
	95% CI of Geometric Mean	2.21, 2.81	8.17, 12.17	2.02, 2.73
	Median	2.50	10.54	2.16
	Q25, Q75	1.68, 3.63	7.46, 17.05	1.74, 3.36
	Min, Max	0.6, 8.9	2.0, 26.2	1.1, 7.2
	Mean (SD)	2.85 (1.603)	11.82 (6.307)	2.63 (1.377)
	95% CI of Mean	2.49, 3.22	9.85, 13.79	2.19, 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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.78 (45.25)	9.89 (80.27)	1.78 (50.05)
	95% CI of Geometric Mean	1.61, 1.97	7.93, 12.32	1.52, 2.07
	Median	1.63	11.80	1.74
	Q25, Q75	1.38, 2.10	7.52, 16.22	1.33, 2.62
	Min, Max	0.8, 11.2	1.2, 35.6	0.7, 4.0
	Mean (SD)	2.02 (1.457)	12.09 (7.084)	1.98 (0.926)
	95% CI of Mean	1.68, 2.35	9.88, 14.30	1.67, 2.28

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1.60 (48.76)	9.24 (76.50)	1.65 (38.11)
	95% CI of Geometric Mean	1.44, 1.78	7.47, 11.42	1.46, 1.86
	Median	1.53	10.38	1.59
	Q25, Q75	1.17, 2.02	6.37, 15.01	1.19, 2.25
	Min, Max	0.7, 10.3	1.1, 28.2	0.9, 3.6
	Mean (SD)	1.83 (1.363)	11.08 (5.994)	1.76 (0.670)
	95% CI of Mean	1.52, 2.14	9.21, 12.96	1.54, 1.98

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.35 (56.30)	11.78 (60.35)	2.65 (42.91)
	95% CI of Geometric Mean	2.08, 2.65	9.89, 14.01	2.32, 3.03
	Median	2.11	13.18	2.85
	Q25, Q75	1.54, 3.65	8.22, 18.13	2.14, 3.54
	Min, Max	0.6, 8.5	3.3, 33.0	0.7, 4.8
	Mean (SD)	2.69 (1.481)	13.50 (6.722)	2.84 (0.964)
	95% CI of Mean	2.35, 3.03	11.40, 15.60	2.53, 3.16

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.46 (82.17)	10.86 (66.82)	2.14 (55.25)
	95% CI of Geometric Mean	2.09, 2.90	8.98, 13.13	1.81, 2.53
	Median	2.20	11.79	2.30
	Q25, Q75	1.43, 3.39	7.13, 18.53	1.45, 3.26
	Min, Max	0.6, 24.1	2.8, 27.8	0.8, 5.5
	Mean (SD)	3.37 (3.684)	12.73 (6.612)	2.42 (1.188)
	95% CI of Mean	2.53, 4.20	10.67, 14.80	2.04, 2.81

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.26 (77.87)	11.02 (66.12)	2.41 (79.30)
	95% CI of Geometric Mean	1.93, 2.64	9.13, 13.30	1.93, 3.02
	Median	2.04	12.37	2.53
	Q25, Q75	1.35, 3.00	7.00, 16.67	1.39, 3.82
	Min, Max	0.6, 16.5	2.3, 31.0	0.6, 13.3
	Mean (SD)	2.97 (2.783)	12.91 (6.961)	3.10 (2.549)
	95% CI of Mean	2.33, 3.60	10.74, 15.09	2.28, 3.92

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.45 (71.01)	10.61 (65.77)	2.62 (75.38)
	95% CI of Geometric Mean	2.12, 2.84	8.80, 12.80	2.11, 3.25
	Median	2.06	11.68	2.26
	Q25, Q75	1.64, 3.74	6.73, 16.30	1.56, 4.74
	Min, Max	0.5, 12.2	2.3, 31.7	1.0, 9.8
	Mean (SD)	3.05 (2.319)	12.40 (6.584)	3.29 (2.424)
	95% CI of Mean	2.52, 3.57	10.35, 14.46	2.51, 4.07

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	61.45 (50.43)		57.24 (52.76)		53.48 (57.96)	
	95% CI of Geometric Mean	55.12, 68.52		49.04, 66.80		44.92, 63.68	
	Median	60.86		60.15		55.77	
	Q25, Q75	46.28, 85.56		46.27, 73.05		35.93, 85.71	
	Min, Max	13.7, 151.1		14.3, 144.7		18.5, 140.4	
	Mean (SD)	68.16 (30.265)		63.80 (28.923)		61.35 (32.462)	
	95% CI of Mean	61.24, 75.08		54.79, 72.82		50.83, 71.88	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	12.73 (48.15)		48.86 (56.27)		11.32 (52.25)	
	95% CI of Geometric Mean	11.46, 14.13		41.49, 57.54		9.65, 13.28	
	Median	12.27	-80.04	55.32	-11.54	11.62	-78.42
	Q25, Q75	8.70, 18.27	-83.50, -74.18	33.78, 74.02	-24.76, 1.94	8.17, 16.06	-84.12, -71.03
	Min, Max	5.5, 45.1	-92.0, -53.2	15.6, 127.7	-58.2, 41.9	5.0, 42.8	-92.7, -56.9
	Mean (SD)	14.16 (7.081)	-78.08 (7.769)	55.32 (26.767)	-11.78 (22.058)	12.86 (7.569)	-77.49 (7.808)
	95% CI of Mean	12.54, 15.78	-79.86, -76.30	46.97, 63.67	-18.66, -4.90	10.40, 15.32	-80.02, -74.95

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.59 (44.54)		48.18 (59.59)		4.57 (58.68)	
	95% CI of Geometric Mean	5.07, 6.17		40.57, 57.21		3.83, 5.46	
	Median	5.47	-90.69	50.28	-14.96	4.73	-91.55
	Q25, Q75	4.09, 7.43	-92.68, -88.91	35.87, 68.79	-27.01, 5.00	3.09, 6.54	-93.87, -88.12
	Min, Max	2.0, 14.0	-96.6, -70.5	10.4, 120.0	-63.9, 32.8	1.7, 16.7	-97.0, -78.3
	Mean (SD)	6.10 (2.601)	-90.19 (4.255)	55.07 (27.498)	-12.81 (22.506)	5.28 (3.069)	-90.54 (4.362)
	95% CI of Mean	5.50, 6.70	-91.17, -89.21	46.50, 63.65	-19.83, -5.79	4.28, 6.28	-91.96, -89.12

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.32 (53.59)		50.03 (56.81)		3.05 (57.90)	
	95% CI of Geometric Mean	2.96, 3.73		42.42, 58.99		2.56, 3.63	
	Median	3.62	-94.76	51.93	-11.66	2.91	-94.16
	Q25, Q75	2.15, 4.74	-96.12, -93.07	36.46, 68.54	-26.58, 0.05	1.95, 4.65	-96.02, -91.84
	Min, Max	1.1, 9.6	-98.2, -82.9	13.5, 130.5	-63.4, 51.0	1.2, 11.5	-98.0, -82.1
	Mean (SD)	3.74 (1.805)	-93.96 (3.043)	56.83 (28.290)	-9.63 (23.618)	3.53 (2.106)	-93.46 (3.625)
	95% CI of Mean	3.32, 4.16	-94.66, -93.26	48.01, 65.65	-17.00, -2.27	2.84, 4.22	-94.64, -92.28

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.65 (42.52)		49.91 (55.51)		3.69 (55.76)	
	95% CI of Geometric Mean	3.32, 4.01		42.46, 58.66		3.11, 4.37	
	Median	3.84	-94.01	54.49	-8.51	3.90	-93.20
	Q25, Q75	2.81, 4.74	-95.36, -91.73	39.47, 69.70	-21.88, 7.93	2.23, 5.86	-94.57, -90.34
	Min, Max	1.4, 10.8	-98.2, -83.2	14.4, 114.9	-65.3, 76.2	1.8, 14.5	-97.9, -61.9
	Mean (SD)	3.96 (1.687)	-93.43 (3.051)	56.12 (25.707)	-8.47 (27.409)	4.24 (2.485)	-91.87 (5.914)
	95% CI of Mean	3.57, 4.35	-94.13, -92.73	48.10, 64.14	-17.01, 0.08	3.43, 5.05	-93.80, -89.95

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.14 (43.77)		53.27 (51.00)		2.85 (42.13)	
	95% CI of Geometric Mean	2.85, 3.46		45.86, 61.89		2.50, 3.26	
	Median	3.11	-94.80	60.85	-5.99	2.60	-94.66
	Q25, Q75	2.45, 4.05	-96.33, -93.21	39.67, 74.60	-17.48, 18.83	2.14, 4.06	-96.37, -92.04
	Min, Max	1.3, 10.6	-98.3, -78.6	15.4, 124.4	-51.4, 45.6	1.4, 6.6	-97.9, -64.4
	Mean (SD)	3.43 (1.529)	-94.13 (3.575)	58.97 (25.194)	-3.64 (24.480)	3.10 (1.326)	-93.49 (5.500)
	95% CI of Mean	3.08, 3.78	-94.95, -93.31	51.11, 66.82	-11.27, 4.00	2.66, 3.53	-95.27, -91.70

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	61.85 (50.98)		56.74 (53.10)		53.48 (57.96)	
	95% CI of Geometric Mean	55.33, 69.14		48.48, 66.41		44.92, 63.68	
	Median	62.57		59.93		55.77	
	Q25, Q75	46.67, 86.35		46.27, 72.61		35.93, 85.71	
	Min, Max	13.7, 151.1		14.3, 144.7		18.5, 140.4	
	Mean (SD)	68.69 (30.496)		63.36 (29.138)		61.35 (32.462)	
	95% CI of Mean	61.62, 75.76		54.16, 72.56		50.83, 71.88	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.70 (101.96)		49.94 (50.40)		3.22 (64.23)	
	95% CI of Geometric Mean	3.04, 4.51		42.97, 58.04		2.65, 3.90	
	Median	3.09	-94.76	53.92	-11.21	3.13	-93.32
	Q25, Q75	2.14, 5.23	-96.56, -91.48	38.32, 66.05	-33.59, 12.48	1.97, 5.36	-97.16, -88.96
	Min, Max	1.3, 307.4	-98.5, 234.8	14.4, 120.6	-66.3, 198.5	1.2, 11.6	-98.6, -77.5
	Mean (SD)	8.62 (35.448)	-87.57 (39.162)	55.19 (23.697)	-4.13 (44.558)	3.83 (2.438)	-91.88 (6.019)
	95% CI of Mean	0.40, 16.84	-96.64, -78.49	47.70, 62.67	-18.20, 9.94	3.03, 4.62	-93.83, -89.92

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	63.78 (48.17)		56.74 (53.10)		53.92 (58.55)	
	95% CI of Geometric Mean	57.24, 71.07		48.48, 66.41		45.11, 64.46	
	Median	63.36		59.93		56.99	
	Q25, Q75	46.97, 86.43		46.27, 72.61		35.93, 85.71	
	Min, Max	13.7, 151.1		14.3, 144.7		18.5, 140.4	
	Mean (SD)	70.18 (30.003)		63.36 (29.138)		61.94 (32.690)	
	95% CI of Mean	63.07, 77.28		54.16, 72.56		51.19, 72.69	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.36 (89.84)		50.66 (57.76)		3.59 (85.21)	
	95% CI of Geometric Mean	2.80, 4.04		42.77, 60.02		2.81, 4.58	
	Median	2.70	-95.21	50.17	-9.30	3.09	-94.44
	Q25, Q75	2.09, 4.26	-97.08, -92.68	41.99, 69.60	-19.29, 12.31	2.14, 5.24	-96.62, -89.57
	Min, Max	0.9, 87.0	-98.7, -5.2	11.7, 140.7	-75.8, 250.0	1.1, 26.5	-98.5, -37.9
	Mean (SD)	5.46 (10.908)	-91.83 (12.822)	57.47 (28.316)	-0.51 (51.579)	5.02 (5.604)	-89.13 (13.838)
	95% CI of Mean	2.88, 8.05	-94.87, -88.79	48.53, 66.42	-16.80, 15.77	3.17, 6.86	-93.68, -84.58

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	61.92 (50.98)		56.74 (53.10)		53.14 (58.53)	
	95% CI of Geometric Mean	55.21, 69.45		48.48, 66.41		44.34, 63.69	
	Median	62.57		59.93		55.77	
	Q25, Q75	46.79, 84.77		46.27, 72.61		35.93, 73.35	
	Min, Max	13.7, 151.1		14.3, 144.7		18.5, 140.4	
	Mean (SD)	68.75 (30.499)		63.36 (29.138)		61.11 (32.733)	
	95% CI of Mean	61.47, 76.03		54.16, 72.56		50.19, 72.03	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.55 (88.21)		55.34 (62.05)		4.22 (97.91)	
	95% CI of Geometric Mean	2.96, 4.26		46.21, 66.26		3.20, 5.55	
	Median	2.92	-94.59	55.57	-3.48	3.43	-91.41
	Q25, Q75	1.99, 5.66	-97.01, -89.46	37.88, 85.96	-18.11, 18.77	2.44, 7.74	-96.88, -79.07
	Min, Max	1.1, 31.7	-98.5, -65.5	14.5, 147.8	-66.4, 247.9	1.3, 24.2	-99.1, -30.8
	Mean (SD)	4.95 (5.169)	-92.01 (7.322)	64.24 (35.172)	7.68 (55.735)	5.99 (5.662)	-86.11 (15.217)
	95% CI of Mean	3.72, 6.19	-93.76, -90.26	53.14, 75.35	-9.92, 25.28	4.10, 7.89	-91.19, -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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	73.95 (54.36)	67.88 (64.52)	64.25 (54.40)
	95% CI of Geometric Mean	65.83, 83.08	56.48, 81.58	54.47, 75.78
	Median	77.09	78.59	59.73
	Q25, Q75	54.18, 107.75	45.31, 103.04	45.88, 103.10
	Min, Max	12.8, 171.1	13.4, 175.4	19.8, 154.3
	Mean (SD)	82.79 (37.067)	78.42 (38.281)	72.63 (36.334)
	95% CI of Mean	74.32, 91.27	66.48, 90.35	60.85, 84.41

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	14.79 (48.60)	58.59 (75.64)	12.38 (54.88)
	95% CI of Geometric Mean	13.31, 16.44	47.51, 72.26	10.48, 14.62
	Median	15.04	67.34	12.12
	Q25, Q75	10.46, 22.52	39.80, 94.32	9.29, 16.10
	Min, Max	4.3, 37.3	9.9, 183.8	3.6, 76.0
	Mean (SD)	16.37 (7.408)	70.67 (40.250)	14.46 (11.470)
	95% CI of Mean	14.68, 18.07	58.12, 83.21	10.73, 18.18

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.62 (43.36)	60.04 (76.80)	5.32 (52.00)
	95% CI of Geometric Mean	6.02, 7.28	48.56, 74.24	4.54, 6.24
	Median	6.59	62.44	5.25
	Q25, Q75	5.27, 8.87	50.25, 105.08	3.49, 7.90
	Min, Max	2.0, 13.1	9.5, 162.3	1.9, 15.0
	Mean (SD)	7.16 (2.734)	72.28 (39.068)	5.96 (2.907)
	95% CI of Mean	6.53, 7.79	60.10, 84.46	5.01, 6.91

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	4.03 (51.57)	61.10 (69.15)	3.68 (49.60)
	95% CI of Geometric Mean	3.60, 4.51	50.28, 74.25	3.15, 4.29
	Median	4.25	64.57	3.29
	Q25, Q75	2.71, 6.08	40.14, 92.26	2.38, 5.48
	Min, Max	1.3, 8.7	15.7, 176.9	1.3, 11.4
	Mean (SD)	4.49 (1.976)	72.55 (40.537)	4.11 (2.113)
	95% CI of Mean	4.03, 4.95	59.91, 85.19	3.42, 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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	4.45 (49.01)	57.02 (67.51)	4.28 (42.48)
	95% CI of Geometric Mean	4.00, 4.96	47.10, 69.02	3.75, 4.89
	Median	4.86	61.37	4.40
	Q25, Q75	3.03, 6.73	36.84, 91.45	3.20, 5.85
	Min, Max	1.5, 9.9	12.5, 160.9	1.6, 10.0
	Mean (SD)	4.91 (2.043)	66.97 (35.724)	4.62 (1.777)
	95% CI of Mean	4.44, 5.38	55.83, 78.11	4.04, 5.20

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3.67 (48.08)	66.02 (63.10)	3.48 (37.12)
	95% CI of Geometric Mean	3.31, 4.08	55.12, 79.07	3.10, 3.92
	Median	3.55	74.41	3.57
	Q25, Q75	2.59, 5.24	49.43, 97.96	2.65, 4.38
	Min, Max	0.9, 10.2	17.3, 155.1	2.0, 8.9
	Mean (SD)	4.07 (1.901)	75.99 (36.802)	3.72 (1.478)
	95% CI of Mean	3.63, 4.51	64.52, 87.46	3.24, 4.21

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	74.04 (54.66)	66.73 (64.10)	64.25 (54.40)
	95% CI of Geometric Mean	65.76, 83.35	55.45, 80.31	54.47, 75.78
	Median	77.09	77.84	59.73
	Q25, Q75	55.47, 108.94	45.31, 98.52	45.88, 103.10
	Min, Max	12.8, 171.1	13.4, 175.4	19.8, 154.3
	Mean (SD)	82.95 (37.233)	77.00 (37.618)	72.63 (36.334)
	95% CI of Mean	74.32, 91.58	65.12, 88.88	60.85, 84.41

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	4.38 (104.57)	57.74 (68.92)	3.44 (59.79)
	95% CI of Geometric Mean	3.58, 5.35	47.42, 70.30	2.87, 4.12
	Median	4.27	65.18	3.16
	Q25, Q75	2.25, 6.36	41.67, 98.35	2.11, 5.15
	Min, Max	1.0, 301.1	12.3, 139.1	1.5, 12.1
	Mean (SD)	9.43 (34.718)	67.82 (34.355)	4.02 (2.481)
	95% CI of Mean	1.38, 17.47	56.97, 78.67	3.21, 4.83

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	76.42 (51.86)	66.73 (64.10)	64.57 (55.11)
	95% CI of Geometric Mean	68.08, 85.79	55.45, 80.31	54.52, 76.49
	Median	81.14	77.84	60.09
	Q25, Q75	55.99, 109.08	45.31, 98.52	45.88, 103.10
	Min, Max	12.8, 171.1	13.4, 175.4	19.8, 154.3
	Mean (SD)	84.87 (36.878)	77.00 (37.618)	73.14 (36.677)
	95% CI of Mean	76.14, 93.61	65.12, 88.88	61.08, 85.20

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3.88 (96.37)	57.81 (68.26)	4.08 (94.89)
	95% CI of Geometric Mean	3.20, 4.70	47.55, 70.28	3.13, 5.31
	Median	3.20	64.39	3.71
	Q25, Q75	2.12, 4.89	42.83, 77.00	2.10, 6.25
	Min, Max	1.1, 80.9	10.0, 169.5	1.4, 37.7
	Mean (SD)	6.22 (10.674)	68.20 (37.719)	6.08 (7.671)
	95% CI of Mean	3.69, 8.75	56.29, 80.11	3.56, 8.61

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	73.25 (55.26)	66.73 (64.10)	64.23 (55.85)
	95% CI of Geometric Mean	64.76, 82.84	55.45, 80.31	53.99, 76.42
	Median	77.09	77.84	59.73
	Q25, Q75	52.89, 108.94	45.31, 98.52	45.88, 103.10
	Min, Max	12.8, 171.1	13.4, 175.4	19.8, 154.3
	Mean (SD)	82.19 (36.918)	77.00 (37.618)	73.00 (37.171)
	95% CI of Mean	73.38, 91.00	65.12, 88.88	60.60, 85.40

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	4.00 (91.12)	60.09 (77.15)	4.78 (101.69)
	95% CI of Geometric Mean	3.32, 4.82	48.42, 74.55	3.60, 6.33
	Median	3.17	69.50	4.18
	Q25, Q75	2.29, 6.62	46.13, 86.93	2.63, 7.28
	Min, Max	0.8, 30.2	12.8, 210.3	1.2, 35.3
	Mean (SD)	5.68 (5.960)	73.40 (44.334)	7.06 (7.517)
	95% CI of Mean	4.26, 7.11	59.40, 87.40	4.55, 9.57

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	61.59 (50.18)		57.24 (52.76)		54.73 (59.56)	
	95% CI of Geometric Mean	55.34, 68.53		49.04, 66.80		45.89, 65.29	
	Median	60.86		60.15		56.99	
	Q25, Q75	45.90, 86.35		46.27, 73.05		36.47, 89.16	
	Min, Max	13.7, 151.1		14.3, 144.7		18.5, 140.4	
	Mean (SD)	68.25 (30.165)		63.80 (28.923)		63.19 (34.084)	
	95% CI of Mean	61.45, 75.06		54.79, 72.82		52.29, 74.10	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	12.96 (50.15)		48.86 (56.27)		11.55 (53.34)	
	95% CI of Geometric Mean	11.65, 14.43		41.49, 57.54		9.83, 13.55	
	Median	12.43	-80.04	55.32	-11.54	11.67	-78.58
	Q25, Q75	8.74, 18.58	-83.56, -74.16	33.78, 74.02	-24.76, 1.94	8.27, 16.11	-84.02, -71.83
	Min, Max	5.5, 45.7	-92.0, 0.0	15.6, 127.7	-58.2, 41.9	5.0, 42.8	-92.7, -56.9
	Mean (SD)	14.57 (7.849)	-77.16 (11.735)	55.32 (26.767)	-11.78 (22.058)	13.16 (7.703)	-77.59 (7.736)
	95% CI of Mean	12.80, 16.35	-79.81, -74.51	46.97, 63.67	-18.66, -4.90	10.69, 15.63	-80.07, -75.11

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.77 (51.39)		48.18 (59.59)		4.69 (61.00)	
	95% CI of Geometric Mean	5.17, 6.44		40.57, 57.21		3.92, 5.62	
	Median	5.76	-90.69	50.28	-14.96	4.78	-91.52
	Q25, Q75	4.16, 7.60	-92.68, -88.84	35.87, 68.79	-27.01, 5.00	3.10, 6.66	-93.64, -88.12
	Min, Max	2.0, 45.7	-96.6, 0.0	10.4, 120.0	-63.9, 32.8	1.7, 16.7	-97.0, -78.3
	Mean (SD)	6.64 (5.172)	-89.05 (11.046)	55.07 (27.498)	-12.81 (22.506)	5.48 (3.276)	-90.53 (4.306)
	95% CI of Mean	5.46, 7.81	-91.55, -86.56	46.50, 63.65	-19.83, -5.79	4.43, 6.53	-91.91, -89.15

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.45 (63.07)		50.03 (56.81)		3.16 (63.12)	
	95% CI of Geometric Mean	3.02, 3.93		42.42, 58.99		2.62, 3.81	
	Median	3.71	-94.76	51.93	-11.66	3.01	-94.07
	Q25, Q75	2.17, 4.83	-96.10, -92.81	36.46, 68.54	-26.58, 0.05	1.96, 4.67	-95.94, -91.83
	Min, Max	1.1, 45.7	-98.2, 0.0	13.5, 130.5	-63.4, 51.0	1.2, 13.2	-98.0, -82.1
	Mean (SD)	4.29 (5.077)	-92.77 (11.058)	56.83 (28.290)	-9.63 (23.618)	3.77 (2.578)	-93.38 (3.614)
	95% CI of Mean	3.14, 5.44	-95.27, -90.28	48.01, 65.65	-17.00, -2.27	2.94, 4.60	-94.54, -92.22

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.79 (52.72)		49.91 (55.51)		3.81 (59.63)	
	95% CI of Geometric Mean	3.38, 4.24		42.46, 58.66		3.19, 4.55	
	Median	3.93	-94.01	54.49	-8.51	3.95	-93.12
	Q25, Q75	2.82, 4.94	-95.32, -91.69	39.47, 69.70	-21.88, 7.93	2.25, 5.96	-94.54, -90.28
	Min, Max	1.4, 45.7	-98.2, 0.0	14.4, 114.9	-65.3, 76.2	1.8, 14.5	-97.9, -61.9
	Mean (SD)	4.51 (5.015)	-92.25 (11.002)	56.12 (25.707)	-8.47 (27.409)	4.46 (2.831)	-91.83 (5.843)
	95% CI of Mean	3.38, 5.65	-94.73, -89.76	48.10, 64.14	-17.01, 0.08	3.55, 5.37	-93.71, -89.96

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.27 (55.00)		53.27 (51.00)		2.97 (49.32)	
	95% CI of Geometric Mean	2.91, 3.68		45.86, 61.89		2.55, 3.45	
	Median	3.16	-94.80	60.85	-5.99	2.63	-94.60
	Q25, Q75	2.47, 4.47	-96.32, -92.99	39.67, 74.60	-17.48, 18.83	2.16, 4.08	-96.30, -91.66
	Min, Max	1.3, 45.7	-98.3, 0.0	15.4, 124.4	-51.4, 45.6	1.4, 13.2	-97.9, -64.4
	Mean (SD)	3.99 (5.022)	-92.94 (11.229)	58.97 (25.194)	-3.64 (24.480)	3.35 (2.062)	-93.40 (5.453)
	95% CI of Mean	2.85, 5.13	-95.47, -90.40	51.11, 66.82	-11.27, 4.00	2.69, 4.01	-95.15, -91.66

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.82 (106.43)		50.53 (50.44)		3.33 (68.66)	
	95% CI of Geometric Mean	3.13, 4.65		43.56, 58.62		2.73, 4.07	
	Median	3.17	-94.47	55.37	-10.00	3.13	-93.29
	Q25, Q75	2.21, 5.23	-96.54, -91.48	38.32, 71.81	-33.59, 12.48	2.00, 5.40	-97.00, -88.99
	Min, Max	1.3, 307.4	-98.5, 234.8	14.4, 120.6	-66.3, 198.5	1.2, 13.2	-98.6, -77.5
	Mean (SD)	8.90 (34.786)	-86.68 (39.427)	55.83 (23.767)	-4.03 (44.016)	4.06 (2.824)	-91.83 (5.947)
	95% CI of Mean	1.06, 16.75	-95.58, -77.79	48.41, 63.24	-17.75, 9.69	3.15, 4.97	-93.74, -89.93

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.62 (97.83)		51.25 (57.59)		3.63 (88.40)	
	95% CI of Geometric Mean	3.00, 4.36		43.37, 60.55		2.85, 4.64	
	Median	2.78	-94.73	53.98	-8.55	3.09	-94.44
	Q25, Q75	2.19, 4.84	-96.97, -90.19	41.99, 69.63	-19.29, 12.31	2.08, 5.56	-96.58, -89.90
	Min, Max	0.9, 87.0	-98.7, 0.0	11.7, 140.7	-75.8, 250.0	1.1, 26.5	-98.5, -37.9
	Mean (SD)	6.08 (11.420)	-89.98 (16.465)	58.06 (28.222)	-0.50 (50.946)	5.14 (5.638)	-89.33 (13.521)
	95% CI of Mean	3.50, 8.66	-93.70, -86.27	49.26, 66.86	-16.38, 15.38	3.33, 6.94	-93.65, -85.00

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3.76 (95.01)		55.86 (61.57)		4.36 (101.51)	
	95% CI of Geometric Mean	3.14, 4.51		46.81, 66.66		3.32, 5.71	
	Median	2.98	-94.43	56.73	-2.43	3.50	-91.03
	Q25, Q75	2.02, 6.35	-97.01, -88.03	37.88, 85.96	-18.11, 18.77	2.34, 8.84	-96.83, -80.08
	Min, Max	1.1, 45.7	-98.5, 0.0	14.5, 147.8	-66.4, 247.9	1.3, 24.2	-99.1, -30.8
	Mean (SD)	5.55 (6.796)	-90.54 (12.782)	64.66 (34.848)	7.50 (55.064)	6.24 (5.706)	-86.46 (14.714)
	95% CI of Mean	4.01, 7.09	-93.43, -87.66	53.80, 75.53	-9.67, 24.66	4.41, 8.07	-91.17, -81.75

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	73.84 (53.92)	67.88 (64.52)	65.13 (54.48)
	95% CI of Geometric Mean	65.88, 82.75	56.48, 81.58	55.32, 76.67
	Median	77.09	78.59	60.09
	Q25, Q75	52.89, 106.56	45.31, 103.04	47.70, 104.71
	Min, Max	12.8, 171.1	13.4, 175.4	19.8, 154.3
	Mean (SD)	82.56 (36.813)	78.42 (38.281)	73.58 (36.365)
	95% CI of Mean	74.25, 90.86	66.48, 90.35	61.94, 85.21

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	15.06 (50.32)	58.59 (75.64)	12.47 (54.32)
	95% CI of Geometric Mean	13.52, 16.77	47.51, 72.26	10.59, 14.67
	Median	15.11	67.34	12.44
	Q25, Q75	10.53, 22.73	39.80, 94.32	9.30, 16.19
	Min, Max	4.3, 49.7	9.9, 183.8	3.6, 76.0
	Mean (SD)	16.82 (8.229)	70.67 (40.250)	14.51 (11.327)
	95% CI of Mean	14.96, 18.68	58.12, 83.21	10.88, 18.13

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.81 (49.66)	60.04 (76.80)	5.41 (52.70)
	95% CI of Geometric Mean	6.12, 7.58	48.56, 74.24	4.62, 6.35
	Median	6.67	62.44	5.40
	Q25, Q75	5.30, 9.03	50.25, 105.08	3.68, 7.96
	Min, Max	2.0, 49.7	9.5, 162.3	1.9, 15.0
	Mean (SD)	7.72 (5.523)	72.28 (39.068)	6.08 (2.961)
	95% CI of Mean	6.47, 8.97	60.10, 84.46	5.12, 7.03

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	4.20 (60.86)	61.10 (69.15)	3.77 (52.36)
	95% CI of Geometric Mean	3.69, 4.77	50.28, 74.25	3.22, 4.42
	Median	4.34	64.57	3.56
	Q25, Q75	2.74, 6.18	40.14, 92.26	2.46, 5.54
	Min, Max	1.3, 49.7	15.7, 176.9	1.3, 11.4
	Mean (SD)	5.11 (5.488)	72.55 (40.537)	4.27 (2.324)
	95% CI of Mean	3.87, 6.35	59.91, 85.19	3.52, 5.02

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	4.62 (57.59)	57.02 (67.51)	4.38 (44.69)
	95% CI of Geometric Mean	4.09, 5.22	47.10, 69.02	3.82, 5.03
	Median	4.89	61.37	4.44
	Q25, Q75	3.04, 6.73	36.84, 91.45	3.34, 5.87
	Min, Max	1.5, 49.7	12.5, 160.9	1.6, 10.6
	Mean (SD)	5.51 (5.463)	66.97 (35.724)	4.77 (1.992)
	95% CI of Mean	4.27, 6.75	55.83, 78.11	4.13, 5.41

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3.82 (58.25)	66.02 (63.10)	3.58 (41.18)
	95% CI of Geometric Mean	3.38, 4.32	55.12, 79.07	3.15, 4.07
	Median	3.59	74.41	3.59
	Q25, Q75	2.60, 5.59	49.43, 97.96	2.70, 4.38
	Min, Max	0.9, 49.7	17.3, 155.1	2.0, 10.6
	Mean (SD)	4.68 (5.501)	75.99 (36.802)	3.89 (1.818)
	95% CI of Mean	3.43, 5.92	64.52, 87.46	3.31, 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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	4.52 (108.81)	58.93 (69.79)	3.54 (62.45)
	95% CI of Geometric Mean	3.70, 5.52	48.43, 71.72	2.94, 4.26
	Median	4.32	66.83	3.30
	Q25, Q75	2.35, 6.82	41.67, 99.86	2.13, 5.28
	Min, Max	1.0, 301.1	12.3, 139.1	1.5, 12.1
	Mean (SD)	9.76 (34.128)	69.46 (35.558)	4.19 (2.660)
	95% CI of Mean	2.06, 17.46	58.37, 80.54	3.33, 5.04

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	4.15 (104.11)	59.01 (69.15)	4.11 (95.04)
	95% CI of Geometric Mean	3.41, 5.04	48.56, 71.70	3.17, 5.31
	Median	3.26	64.47	3.71
	Q25, Q75	2.14, 6.16	42.83, 100.70	2.11, 6.37
	Min, Max	1.1, 80.9	10.0, 169.5	1.4, 37.7
	Mean (SD)	6.90 (11.389)	69.83 (38.726)	6.10 (7.533)
	95% CI of Mean	4.32, 9.47	57.76, 81.90	3.68, 8.51

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	4.27 (96.36)	61.27 (77.63)	4.90 (102.24)
	95% CI of Geometric Mean	3.56, 5.14	49.46, 75.90	3.73, 6.43
	Median	3.20	70.73	4.22
	Q25, Q75	2.33, 7.28	46.13, 97.07	2.57, 9.05
	Min, Max	0.8, 49.7	12.8, 210.3	1.2, 35.3
	Mean (SD)	6.33 (7.587)	74.91 (44.865)	7.18 (7.358)
	95% CI of Mean	4.61, 8.04	60.92, 88.89	4.83, 9.54

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	15.49 (53.02)		15.32 (52.41)		13.64 (58.66)	
	95% CI of Geometric Mean	13.82, 17.37		13.13, 17.87		11.43, 16.28	
	Median	16.71		15.35		14.13	
	Q25, Q75	11.07, 21.67		11.83, 21.03		9.81, 20.74	
	Min, Max	4.0, 52.4		3.8, 37.6		3.8, 37.0	
	Mean (SD)	17.44 (8.698)		17.08 (7.882)		15.65 (8.256)	
	95% CI of Mean	15.44, 19.43		14.62, 19.54		12.97, 18.33	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	4.95 (43.56)		13.69 (51.51)		4.12 (57.08)	
	95% CI of Geometric Mean	4.49, 5.45		11.77, 15.93		3.46, 4.90	
	Median	4.85	-68.65	13.37	-8.45	4.51	-66.58
	Q25, Q75	3.66, 6.56	-74.54, -60.74	9.61, 20.22	-20.52, 1.12	2.71, 5.69	-77.39, -60.52
	Min, Max	1.8, 19.3	-85.4, -33.7	4.6, 32.8	-45.2, 33.9	1.6, 15.3	-86.3, -38.8
	Mean (SD)	5.41 (2.602)	-66.65 (10.287)	15.26 (6.944)	-8.58 (18.923)	4.75 (2.799)	-67.43 (12.500)
	95% CI of Mean	4.81, 6.01	-69.01, -64.30	13.09, 17.42	-14.48, -2.68	3.83, 5.66	-71.48, -63.37

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.36 (37.78)		13.29 (59.10)		2.62 (39.71)	
	95% CI of Geometric Mean	2.16, 2.57		11.20, 15.77		2.31, 2.97	
	Median	2.38	-84.74	12.99	-12.45	2.66	-81.31
	Q25, Q75	1.82, 3.04	-87.83, -80.41	9.90, 20.53	-23.47, -1.65	1.98, 3.23	-82.83, -74.61
	Min, Max	1.1, 5.5	-94.2, -58.2	2.6, 30.9	-50.1, 41.5	1.3, 7.3	-94.0, -53.9
	Mean (SD)	2.51 (0.916)	-83.45 (7.110)	15.11 (7.221)	-11.46 (17.933)	2.82 (1.216)	-79.05 (8.615)
	95% CI of Mean	2.30, 2.73	-85.08, -81.82	12.85, 17.36	-17.06, -5.87	2.43, 3.22	-81.85, -76.25

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.98 (34.31)		13.78 (53.35)		2.16 (40.65)	
	95% CI of Geometric Mean	1.83, 2.14		11.78, 16.11		1.90, 2.46	
	Median	2.00	-87.52	13.45	-10.48	2.07	-84.44
	Q25, Q75	1.56, 2.47	-90.47, -82.32	10.19, 20.04	-21.25, -0.21	1.71, 2.52	-88.87, -79.01
	Min, Max	0.8, 4.3	-95.0, -51.2	4.1, 32.9	-43.0, 58.7	0.8, 6.2	-93.7, -23.2
	Mean (SD)	2.09 (0.687)	-85.64 (7.800)	15.50 (7.594)	-7.70 (22.166)	2.34 (1.034)	-81.71 (12.195)
	95% CI of Mean	1.93, 2.25	-87.42, -83.85	13.13, 17.87	-14.61, -0.79	2.00, 2.68	-85.66, -77.75

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.87 (39.48)		13.86 (55.13)		1.99 (46.31)	
	95% CI of Geometric Mean	1.71, 2.05		11.80, 16.28		1.72, 2.30	
	Median	2.03	-87.79	14.68	-7.52	1.96	-86.72
	Q25, Q75	1.45, 2.38	-90.95, -82.92	10.21, 22.16	-21.95, 2.61	1.56, 2.50	-89.50, -77.11
	Min, Max	0.8, 4.0	-95.5, -54.1	3.8, 32.4	-58.3, 49.1	0.8, 6.1	-94.0, -48.3
	Mean (SD)	2.00 (0.725)	-86.27 (7.624)	15.59 (7.165)	-6.62 (22.812)	2.20 (1.103)	-83.32 (9.533)
	95% CI of Mean	1.83, 2.17	-88.02, -84.53	13.35, 17.83	-13.73, 0.49	1.84, 2.56	-86.41, -80.22

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.97 (38.56)		14.23 (52.99)		2.04 (34.85)	
	95% CI of Geometric Mean	1.80, 2.15		12.18, 16.62		1.82, 2.28	
	Median	1.90	-86.46	14.77	-6.20	2.02	-85.56
	Q25, Q75	1.52, 2.57	-91.79, -82.41	9.71, 22.49	-19.29, 3.25	1.72, 2.31	-89.34, -78.63
	Min, Max	0.7, 4.1	-95.2, -41.0	3.6, 31.7	-45.3, 50.6	0.9, 5.1	-94.8, -49.5
	Mean (SD)	2.10 (0.776)	-85.26 (9.149)	15.90 (7.206)	-4.74 (21.481)	2.17 (0.831)	-83.02 (9.574)
	95% CI of Mean	1.92, 2.29	-87.36, -83.16	13.65, 18.15	-11.44, 1.96	1.89, 2.44	-86.12, -79.91

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	15.55 (53.75)		15.18 (52.69)		13.64 (58.66)	
	95% CI of Geometric Mean	13.83, 17.48		12.98, 17.75		11.43, 16.28	
	Median	16.85		15.26		14.13	
	Q25, Q75	11.04, 22.32		11.83, 20.00		9.81, 20.74	
	Min, Max	4.0, 52.4		3.8, 37.6		3.8, 37.0	
	Mean (SD)	17.54 (8.792)		16.95 (7.933)		15.65 (8.256)	
	95% CI of Mean	15.50, 19.58		14.44, 19.46		12.97, 18.33	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.19 (48.75)		14.03 (45.53)		2.08 (41.60)	
	95% CI of Geometric Mean	1.96, 2.44		12.23, 16.10		1.82, 2.38	
	Median	2.07	-86.66	14.02	0.43	2.02	-85.39
	Q25, Q75	1.48, 3.10	-91.15, -77.29	11.92, 19.42	-23.53, 10.63	1.61, 2.80	-90.18, -77.04
	Min, Max	0.9, 6.0	-96.3, -5.5	3.7, 29.4	-65.3, 133.5	1.0, 5.8	-95.4, -43.3
	Mean (SD)	2.45 (1.256)	-82.46 (13.853)	15.25 (5.951)	-2.13 (34.379)	2.26 (1.004)	-81.49 (12.336)
	95% CI of Mean	2.15, 2.74	-85.67, -79.24	13.36, 17.13	-12.99, 8.72	1.93, 2.59	-85.49, -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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	16.05 (52.21)		15.18 (52.69)		13.64 (59.57)	
	95% CI of Geometric Mean	14.28, 18.03		12.98, 17.75		11.37, 16.35	
	Median	17.10		15.26		14.23	
	Q25, Q75	11.28, 22.41		11.83, 20.00		9.81, 20.74	
	Min, Max	4.0, 52.4		3.8, 37.6		3.8, 37.0	
	Mean (SD)	17.98 (8.726)		16.95 (7.933)		15.70 (8.361)	
	95% CI of Mean	15.91, 20.05		14.44, 19.46		12.95, 18.45	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.37 (52.54)		14.00 (62.11)		2.64 (56.53)	
	95% CI of Geometric Mean	2.10, 2.66		11.68, 16.77		2.21, 3.14	
	Median	2.19	-84.55	14.65	0.60	2.37	-81.98
	Q25, Q75	1.90, 2.90	-90.06, -78.60	10.77, 18.91	-23.33, 12.66	1.93, 3.44	-88.95, -69.16
	Min, Max	0.9, 12.8	-96.3, -29.6	1.9, 38.6	-85.6, 106.3	1.0, 9.9	-95.2, 0.0
	Mean (SD)	2.74 (1.953)	-81.88 (12.956)	16.01 (7.870)	-0.58 (35.574)	3.07 (2.033)	-73.88 (21.963)
	95% CI of Mean	2.27, 3.20	-84.96, -78.81	13.52, 18.50	-11.81, 10.65	2.39, 3.74	-81.11, -66.66

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	15.69 (54.21)		15.18 (52.69)		13.48 (59.96)	
	95% CI of Geometric Mean	13.90, 17.72		12.98, 17.75		11.20, 16.23	
	Median	16.85		15.26		14.13	
	Q25, Q75	11.10, 22.41		11.83, 20.00		9.81, 20.61	
	Min, Max	4.0, 52.4		3.8, 37.6		3.8, 37.0	
	Mean (SD)	17.73 (8.913)		16.95 (7.933)		15.56 (8.433)	
	95% CI of Mean	15.60, 19.86		14.44, 19.46		12.75, 18.38	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.34 (44.51)		14.84 (54.45)		2.63 (57.54)	
	95% CI of Geometric Mean	2.11, 2.59		12.63, 17.44		2.20, 3.15	
	Median	2.39	-85.80	16.88	-8.29	2.63	-83.95
	Q25, Q75	1.73, 2.99	-90.51, -77.73	11.71, 18.66	-16.14, 20.89	1.63, 3.43	-89.13, -60.70
	Min, Max	0.9, 6.6	-95.0, -9.1	4.6, 41.4	-53.9, 258.5	1.1, 8.5	-95.9, -6.8
	Mean (SD)	2.55 (1.124)	-81.75 (13.780)	16.71 (8.098)	6.31 (53.015)	3.05 (1.839)	-74.09 (20.621)
	95% CI of Mean	2.28, 2.83	-85.04, -78.46	14.15, 19.27	-10.43, 23.05	2.43, 3.67	-80.97, -67.21

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	18.65 (56.57)	18.17 (63.30)	16.39 (56.72)
	95% CI of Geometric Mean	16.53, 21.04	15.16, 21.77	13.80, 19.45
	Median	19.06	20.30	16.96
	Q25, Q75	12.86, 29.16	13.02, 26.63	11.26, 23.65
	Min, Max	3.8, 47.9	4.6, 55.5	4.1, 42.5
	Mean (SD)	21.14 (10.205)	21.01 (10.858)	18.70 (9.954)
	95% CI of Mean	18.80, 23.48	17.63, 24.40	15.47, 21.93

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	5.75 (43.17)	16.42 (69.38)	4.51 (58.64)
	95% CI of Geometric Mean	5.23, 6.32	13.50, 19.97	3.77, 5.38
	Median	6.17	17.69	4.38
	Q25, Q75	4.30, 7.81	11.42, 25.34	3.34, 6.08
	Min, Max	1.9, 11.7	2.7, 53.1	1.6, 27.2
	Mean (SD)	6.22 (2.387)	19.44 (10.936)	5.33 (4.206)
	95% CI of Mean	5.67, 6.77	16.03, 22.86	3.97, 6.70

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.79 (41.21)	16.57 (77.34)	3.05 (35.07)
	95% CI of Geometric Mean	2.54, 3.06	13.38, 20.51	2.72, 3.41
	Median	2.77	17.31	2.99
	Q25, Q75	2.12, 3.64	12.99, 27.86	2.52, 4.08
	Min, Max	1.0, 6.2	1.4, 44.6	1.5, 6.6
	Mean (SD)	3.01 (1.212)	19.84 (10.640)	3.23 (1.142)
	95% CI of Mean	2.73, 3.29	16.52, 23.16	2.85, 3.60

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.41 (31.84)	16.83 (61.47)	2.61 (39.07)
	95% CI of Geometric Mean	2.24, 2.59	14.10, 20.08	2.31, 2.95
	Median	2.46	17.65	2.65
	Q25, Q75	2.08, 2.89	12.49, 26.07	2.15, 3.29
	Min, Max	1.0, 4.8	4.7, 48.6	1.1, 5.6
	Mean (SD)	2.52 (0.758)	19.51 (10.675)	2.79 (1.054)
	95% CI of Mean	2.34, 2.70	16.18, 22.84	2.45, 3.14

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.28 (35.78)	15.84 (63.51)	2.31 (35.73)
	95% CI of Geometric Mean	2.11, 2.48	13.21, 18.99	2.06, 2.59
	Median	2.34	17.18	2.29
	Q25, Q75	1.81, 2.95	10.32, 24.32	1.83, 3.10
	Min, Max	1.1, 4.9	3.8, 48.5	1.2, 5.2
	Mean (SD)	2.42 (0.818)	18.42 (10.008)	2.46 (0.899)
	95% CI of Mean	2.23, 2.61	15.30, 21.55	2.16, 2.75

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.30 (37.33)	17.63 (61.26)	2.49 (35.01)
	95% CI of Geometric Mean	2.11, 2.50	14.79, 21.03	2.23, 2.79
	Median	2.49	17.08	2.48
	Q25, Q75	1.92, 2.93	14.06, 27.68	2.08, 3.30
	Min, Max	0.9, 4.5	4.2, 42.9	1.2, 5.1
	Mean (SD)	2.44 (0.788)	20.25 (9.979)	2.63 (0.889)
	95% CI of Mean	2.25, 2.62	17.13, 23.36	2.34, 2.93

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	18.61 (56.81)	17.85 (62.74)	16.39 (56.72)
	95% CI of Geometric Mean	16.46, 21.04	14.88, 21.41	13.80, 19.45
	Median	19.06	19.78	16.96
	Q25, Q75	12.87, 28.87	13.02, 26.11	11.26, 23.65
	Min, Max	3.8, 47.9	4.6, 55.5	4.1, 42.5
	Mean (SD)	21.12 (10.231)	20.61 (10.672)	18.70 (9.954)
	95% CI of Mean	18.74, 23.49	17.24, 23.99	15.47, 21.93

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.59 (44.74)	16.22 (59.60)	2.23 (36.05)
	95% CI of Geometric Mean	2.34, 2.86	13.63, 19.31	1.98, 2.50
	Median	2.36	16.68	2.36
	Q25, Q75	2.01, 3.48	11.55, 24.32	1.82, 2.85
	Min, Max	1.1, 9.4	4.5, 41.8	0.6, 3.8
	Mean (SD)	2.85 (1.421)	18.54 (9.132)	2.35 (0.702)
	95% CI of Mean	2.52, 3.19	15.66, 21.43	2.11, 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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	19.23 (55.62)	17.85 (62.74)	16.33 (57.54)
	95% CI of Geometric Mean	17.00, 21.75	14.88, 21.41	13.69, 19.47
	Median	19.25	19.78	16.65
	Q25, Q75	13.11, 30.22	13.02, 26.11	11.26, 23.65
	Min, Max	3.8, 47.9	4.6, 55.5	4.1, 42.5
	Mean (SD)	21.71 (10.249)	20.61 (10.672)	18.70 (10.088)
	95% CI of Mean	19.28, 24.14	17.24, 23.99	15.38, 22.02

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.73 (56.93)	15.97 (67.05)	2.99 (67.18)
	95% CI of Geometric Mean	2.40, 3.10	13.17, 19.36	2.45, 3.66
	Median	2.50	16.73	2.70
	Q25, Q75	1.91, 3.57	10.37, 22.86	1.88, 4.09
	Min, Max	1.1, 11.8	3.3, 48.3	0.8, 13.6
	Mean (SD)	3.20 (2.172)	18.80 (10.580)	3.67 (2.800)
	95% CI of Mean	2.68, 3.71	15.46, 22.15	2.74, 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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	18.56 (58.15)	17.85 (62.74)	16.30 (58.44)
	95% CI of Geometric Mean	16.32, 21.12	14.88, 21.41	13.60, 19.53
	Median	19.06	19.78	16.34
	Q25, Q75	12.80, 29.44	13.02, 26.11	11.26, 23.65
	Min, Max	3.8, 47.9	4.6, 55.5	4.1, 42.5
	Mean (SD)	21.17 (10.433)	20.61 (10.672)	18.73 (10.225)
	95% CI of Mean	18.68, 23.66	17.24, 23.99	15.32, 22.15

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.64 (46.66)	16.12 (63.84)	2.98 (60.32)
	95% CI of Geometric Mean	2.37, 2.94	13.40, 19.39	2.47, 3.59
	Median	2.56	16.92	2.63
	Q25, Q75	2.00, 3.40	10.68, 23.31	1.93, 4.44
	Min, Max	0.8, 10.0	4.8, 59.3	1.2, 12.4
	Mean (SD)	2.91 (1.429)	18.85 (10.739)	3.51 (2.315)
	95% CI of Mean	2.57, 3.26	15.45, 22.24	2.74, 4.29

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	15.56 (53.52)		15.32 (52.41)		13.92 (59.69)	
	95% CI of Geometric Mean	13.89, 17.43		13.13, 17.87		11.66, 16.62	
	Median	16.71		15.35		14.23	
	Q25, Q75	11.04, 22.32		11.83, 21.03		9.87, 20.80	
	Min, Max	4.0, 52.4		3.8, 37.6		3.8, 37.0	
	Mean (SD)	17.55 (8.827)		17.08 (7.882)		16.03 (8.497)	
	95% CI of Mean	15.55, 19.54		14.62, 19.54		13.31, 18.75	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.01 (43.89)		13.69 (51.51)		4.20 (58.02)	
	95% CI of Geometric Mean	4.55, 5.51		11.77, 15.93		3.53, 5.00	
	Median	4.89	-68.65	13.37	-8.45	4.57	-67.22
	Q25, Q75	3.67, 6.60	-74.89, -60.57	9.61, 20.22	-20.52, 1.12	2.72, 5.93	-76.73, -60.96
	Min, Max	1.8, 19.3	-85.4, 0.0	4.6, 32.8	-45.2, 33.9	1.6, 15.3	-86.3, -38.8
	Mean (SD)	5.48 (2.619)	-65.98 (12.762)	15.26 (6.944)	-8.58 (18.923)	4.85 (2.844)	-67.51 (12.350)
	95% CI of Mean	4.89, 6.08	-68.86, -63.10	13.09, 17.42	-14.48, -2.68	3.94, 5.77	-71.47, -63.56

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.42 (41.94)		13.29 (59.10)		2.63 (39.28)	
	95% CI of Geometric Mean	2.21, 2.66		11.20, 15.77		2.33, 2.97	
	Median	2.39	-84.74	12.99	-12.45	2.69	-81.36
	Q25, Q75	1.82, 3.20	-87.71, -80.26	9.90, 20.53	-23.47, -1.65	2.01, 3.23	-83.05, -75.02
	Min, Max	1.1, 9.8	-94.2, 0.0	2.6, 30.9	-50.1, 41.5	1.3, 7.3	-94.0, -53.9
	Mean (SD)	2.64 (1.249)	-82.41 (11.776)	15.11 (7.221)	-11.46 (17.933)	2.83 (1.201)	-79.32 (8.672)
	95% CI of Mean	2.35, 2.92	-85.07, -79.75	12.85, 17.36	-17.06, -5.87	2.44, 3.22	-82.10, -76.54

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.04 (39.34)		13.78 (53.35)		2.18 (40.60)	
	95% CI of Geometric Mean	1.86, 2.22		11.78, 16.11		1.92, 2.48	
	Median	2.05	-87.52	13.45	-10.48	2.11	-84.68
	Q25, Q75	1.57, 2.54	-90.48, -82.19	10.19, 20.04	-21.25, -0.21	1.73, 2.68	-88.92, -79.52
	Min, Max	0.8, 9.8	-95.0, 0.0	4.1, 32.9	-43.0, 58.7	0.8, 6.2	-93.7, -23.2
	Mean (SD)	2.21 (1.113)	-84.60 (12.399)	15.50 (7.594)	-7.70 (22.166)	2.36 (1.029)	-81.91 (12.106)
	95% CI of Mean	1.95, 2.46	-87.40, -81.80	13.13, 17.87	-14.61, -0.79	2.03, 2.69	-85.79, -78.03

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1.93 (44.44)		13.86 (55.13)		2.02 (46.34)	
	95% CI of Geometric Mean	1.74, 2.12		11.80, 16.28		1.75, 2.33	
	Median	2.05	-87.79	14.68	-7.52	2.00	-87.11
	Q25, Q75	1.46, 2.43	-90.70, -82.72	10.21, 22.16	-21.95, 2.61	1.65, 2.51	-89.65, -78.22
	Min, Max	0.8, 9.8	-95.5, 0.0	3.8, 32.4	-58.3, 49.1	0.8, 6.1	-94.0, -48.3
	Mean (SD)	2.12 (1.147)	-85.22 (12.343)	15.59 (7.165)	-6.62 (22.812)	2.22 (1.099)	-83.48 (9.466)
	95% CI of Mean	1.86, 2.38	-88.01, -82.43	13.35, 17.83	-13.73, 0.49	1.87, 2.58	-86.51, -80.45

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.02 (43.10)		14.23 (52.99)		2.06 (35.13)	
	95% CI of Geometric Mean	1.83, 2.22		12.18, 16.62		1.85, 2.31	
	Median	1.91	-86.46	14.77	-6.20	2.03	-85.58
	Q25, Q75	1.53, 2.76	-91.68, -82.34	9.71, 22.49	-19.29, 3.25	1.72, 2.32	-89.57, -79.16
	Min, Max	0.7, 9.8	-95.2, 0.0	3.6, 31.7	-45.3, 50.6	0.9, 5.1	-94.8, -49.5
	Mean (SD)	2.21 (1.166)	-84.24 (13.240)	15.90 (7.206)	-4.74 (21.481)	2.19 (0.835)	-83.18 (9.512)
	95% CI of Mean	1.95, 2.48	-87.23, -81.25	13.65, 18.15	-11.44, 1.96	1.92, 2.46	-86.23, -80.14

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.24 (51.53)		14.19 (45.63)		2.10 (41.62)	
	95% CI of Geometric Mean	2.00, 2.50		12.39, 16.25		1.85, 2.40	
	Median	2.12	-86.66	14.18	0.22	2.04	-85.65
	Q25, Q75	1.49, 3.15	-91.15, -76.61	11.92, 19.70	-23.53, 10.63	1.61, 2.86	-89.99, -77.32
	Min, Max	0.9, 9.8	-96.3, 0.0	3.7, 29.4	-65.3, 133.5	1.0, 5.8	-95.4, -43.3
	Mean (SD)	2.54 (1.488)	-81.51 (16.492)	15.42 (5.983)	-2.08 (33.959)	2.28 (1.001)	-81.69 (12.247)
	95% CI of Mean	2.20, 2.88	-85.24, -77.79	13.55, 17.29	-12.67, 8.50	1.96, 2.61	-85.62, -77.77

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.44 (54.52)		14.16 (61.82)		2.62 (55.67)	
	95% CI of Geometric Mean	2.17, 2.74		11.85, 16.91		2.21, 3.09	
	Median	2.21	-84.22	14.66	0.30	2.37	-83.29
	Q25, Q75	1.92, 2.96	-89.84, -75.89	10.77, 20.55	-23.33, 12.66	1.92, 3.41	-89.38, -69.43
	Min, Max	0.9, 12.8	-96.3, 0.0	1.9, 38.6	-85.6, 106.3	1.0, 9.9	-95.2, 0.0
	Mean (SD)	2.85 (2.049)	-79.84 (16.454)	16.17 (7.838)	-0.57 (35.137)	3.03 (1.994)	-74.64 (21.653)
	95% CI of Mean	2.38, 3.31	-83.55, -76.12	13.72, 18.61	-11.52, 10.39	2.39, 3.68	-81.57, -67.71

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2.41 (47.81)		14.99 (54.18)		2.59 (56.13)	
	95% CI of Geometric Mean	2.17, 2.67		12.79, 17.56		2.19, 3.07	
	Median	2.46	-85.03	17.23	-8.27	2.61	-85.70
	Q25, Q75	1.76, 3.12	-90.44, -75.74	11.71, 19.89	-16.14, 20.89	1.62, 3.37	-89.37, -62.33
	Min, Max	0.9, 9.8	-96.3, 0.0	4.6, 41.4	-53.9, 258.5	1.1, 8.5	-95.9, -6.8
	Mean (SD)	2.68 (1.388)	-80.36 (16.455)	16.85 (8.048)	6.16 (52.374)	2.99 (1.791)	-75.26 (20.249)
	95% CI of Mean	2.36, 3.00	-84.07, -76.64	14.33, 19.36	-10.17, 22.48	2.41, 3.57	-81.74, -68.78

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	18.65 (56.73)	18.17 (63.30)	16.57 (56.44)
	95% CI of Geometric Mean	16.55, 21.02	15.16, 21.77	14.00, 19.61
	Median	19.06	20.30	17.23
	Q25, Q75	12.84, 29.44	13.02, 26.63	11.59, 23.82
	Min, Max	3.8, 47.9	4.6, 55.5	4.1, 42.5
	Mean (SD)	21.17 (10.243)	21.01 (10.858)	18.87 (9.881)
	95% CI of Mean	18.85, 23.48	17.63, 24.40	15.70, 22.03

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	5.82 (43.38)	16.42 (69.38)	4.54 (58.01)
	95% CI of Geometric Mean	5.29, 6.39	13.50, 19.97	3.81, 5.40
	Median	6.20	17.69	4.39
	Q25, Q75	4.35, 7.83	11.42, 25.34	3.47, 6.04
	Min, Max	1.9, 11.7	2.7, 53.1	1.6, 27.2
	Mean (SD)	6.30 (2.415)	19.44 (10.936)	5.35 (4.153)
	95% CI of Mean	5.75, 6.85	16.03, 22.86	4.02, 6.68

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.86 (44.36)	16.57 (77.34)	3.03 (34.73)
	95% CI of Geometric Mean	2.59, 3.15	13.38, 20.51	2.72, 3.38
	Median	2.79	17.31	2.98
	Q25, Q75	2.15, 3.69	12.99, 27.86	2.53, 3.98
	Min, Max	1.0, 10.7	1.4, 44.6	1.5, 6.6
	Mean (SD)	3.13 (1.491)	19.84 (10.640)	3.21 (1.132)
	95% CI of Mean	2.79, 3.47	16.52, 23.16	2.84, 3.58

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.48 (37.36)	16.83 (61.47)	2.61 (38.53)
	95% CI of Geometric Mean	2.28, 2.69	14.10, 20.08	2.31, 2.94
	Median	2.48	17.65	2.60
	Q25, Q75	2.10, 2.93	12.49, 26.07	2.17, 3.28
	Min, Max	1.0, 10.7	4.7, 48.6	1.1, 5.6
	Mean (SD)	2.66 (1.231)	19.51 (10.675)	2.79 (1.041)
	95% CI of Mean	2.38, 2.94	16.18, 22.84	2.45, 3.12

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.35 (40.64)	15.84 (63.51)	2.32 (35.27)
	95% CI of Geometric Mean	2.15, 2.57	13.21, 18.99	2.07, 2.59
	Median	2.37	17.18	2.32
	Q25, Q75	1.81, 3.04	10.32, 24.32	1.83, 2.99
	Min, Max	1.1, 10.7	3.8, 48.5	1.2, 5.2
	Mean (SD)	2.55 (1.253)	18.42 (10.008)	2.46 (0.888)
	95% CI of Mean	2.26, 2.84	15.30, 21.55	2.17, 2.75

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.36 (41.73)	17.63 (61.26)	2.49 (34.53)
	95% CI of Geometric Mean	2.15, 2.59	14.79, 21.03	2.23, 2.78
	Median	2.53	17.08	2.51
	Q25, Q75	1.92, 2.98	14.06, 27.68	2.08, 3.28
	Min, Max	0.9, 10.7	4.2, 42.9	1.2, 5.1
	Mean (SD)	2.56 (1.223)	20.25 (9.979)	2.63 (0.878)
	95% CI of Mean	2.28, 2.84	17.13, 23.36	2.35, 2.92

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.65 (47.06)	16.55 (60.65)	2.23 (35.62)
	95% CI of Geometric Mean	2.39, 2.94	13.90, 19.71	2.00, 2.50
	Median	2.37	17.02	2.37
	Q25, Q75	2.01, 3.51	11.55, 25.17	1.82, 2.83
	Min, Max	1.1, 10.7	4.5, 41.8	0.6, 3.8
	Mean (SD)	2.96 (1.645)	18.99 (9.482)	2.35 (0.694)
	95% CI of Mean	2.58, 3.33	16.03, 21.95	2.12, 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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.80 (58.27)	16.30 (67.94)	2.96 (65.51)
	95% CI of Geometric Mean	2.47, 3.17	13.45, 19.76	2.44, 3.58
	Median	2.57	16.82	2.59
	Q25, Q75	1.94, 3.57	10.37, 23.47	1.91, 4.03
	Min, Max	1.1, 11.8	3.3, 48.3	0.8, 13.6
	Mean (SD)	3.30 (2.280)	19.25 (10.841)	3.60 (2.743)
	95% CI of Mean	2.78, 3.82	15.86, 22.63	2.72, 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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2.73 (48.94)	16.44 (64.79)	2.91 (58.51)
	95% CI of Geometric Mean	2.46, 3.04	13.67, 19.78	2.44, 3.47
	Median	2.73	17.28	2.52
	Q25, Q75	2.05, 3.64	10.68, 27.91	1.93, 4.42
	Min, Max	0.8, 10.7	4.8, 59.3	1.2, 12.4
	Mean (SD)	3.06 (1.649)	19.29 (10.991)	3.41 (2.253)
	95% CI of Mean	2.68, 3.43	15.86, 22.72	2.69, 4.14

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		38		39	
	Missing, n (%)	0		4 (9.5)		0	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	128.19 (63.22)		136.04 (82.18)		120.54 (78.75)	
	95% CI of Geometric Mean	112.28, 146.36		107.42, 172.27		96.23, 150.98	
	Median	127.02		136.00		111.86	
	Q25, Q75	96.41, 165.19		94.31, 197.64		79.96, 161.29	
	Min, Max	26.9, 1407.1		33.1, 1037.7		36.3, 1014.9	
	Mean (SD)	156.99 (161.717)		179.00 (174.709)		163.06 (188.569)	
	95% CI of Mean	120.03, 193.95		121.56, 236.43		101.93, 224.19	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	40	38	39	39
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	58.50 (71.48)		133.33 (110.43)		66.21 (77.95)	
	95% CI of Geometric Mean	50.51, 67.75		100.21, 177.40		52.95, 82.78	
	Median	54.56	-52.29	135.23	-10.27	57.00	-46.66
	Q25, Q75	39.34, 80.32	-66.83, -39.78	82.77, 197.61	-20.83, 0.27	42.23, 77.40	-59.17, -30.94
	Min, Max	18.1, 858.4	-85.3, 83.5	27.0, 2705.5	-53.3, 23.0	26.7, 935.4	-73.8, 27.9
	Mean (SD)	77.91 (103.152)	-49.42 (26.074)	228.04 (428.881)	-11.80 (17.892)	96.55 (151.924)	-40.57 (25.779)
	95% CI of Mean	54.33, 101.48	-55.38, -43.45	90.88, 365.21	-17.69, -5.92	47.30, 145.80	-48.93, -32.21

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	40	38	39	39
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	45.54 (61.56)		126.46 (91.44)		50.19 (61.58)	
	95% CI of Geometric Mean	40.00, 51.84		98.55, 162.26		41.76, 60.33	
	Median	44.86	-64.56	124.60	-14.77	44.56	-56.15
	Q25, Q75	31.10, 59.12	-76.23, -54.81	70.09, 189.73	-28.42, 0.42	33.29, 65.40	-71.81, -47.36
	Min, Max	16.4, 479.9	-85.2, 59.1	26.7, 1462.7	-74.0, 56.5	16.7, 352.8	-94.8, 1.1
	Mean (SD)	56.19 (58.282)	-59.14 (25.494)	180.84 (232.661)	-11.04 (28.957)	61.09 (55.219)	-52.47 (24.175)
	95% CI of Mean	42.87, 69.51	-64.97, -53.31	106.43, 255.26	-20.56, -1.52	43.19, 79.00	-60.31, -44.62

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	40	38	39	39
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	44.50 (55.25)		129.82 (76.94)		49.68 (53.84)	
	95% CI of Geometric Mean	39.55, 50.08		104.38, 161.46		42.18, 58.51	
	Median	42.13	-65.20	120.48	-8.79	42.88	-62.04
	Q25, Q75	31.31, 58.44	-75.56, -55.07	89.29, 188.28	-26.40, 11.10	34.82, 68.68	-71.62, -48.74
	Min, Max	15.5, 312.8	-87.7, 51.0	28.5, 936.9	-82.6, 99.5	24.0, 242.7	-86.6, 60.4
	Mean (SD)	52.50 (42.758)	-60.59 (23.339)	167.54 (157.089)	-3.67 (37.161)	57.70 (40.716)	-50.87 (34.159)
	95% CI of Mean	42.72, 62.27	-65.93, -55.25	117.30, 217.79	-15.89, 8.55	44.50, 70.90	-61.95, -39.80

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	40	38	39	39
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	47.65 (62.10)		133.09 (73.99)		54.29 (65.04)	
	95% CI of Geometric Mean	41.82, 54.30		107.74, 164.41		44.78, 65.82	
	Median	44.57	-61.31	126.96	-5.04	48.08	-55.89
	Q25, Q75	33.63, 63.04	-73.33, -51.83	94.11, 197.00	-19.81, 24.14	37.99, 71.56	-70.89, -34.04
	Min, Max	15.6, 358.3	-89.2, 685.3	23.6, 705.5	-83.1, 98.7	15.2, 230.1	-83.4, 36.0
	Mean (SD)	57.75 (49.546)	-49.82 (88.208)	165.45 (127.256)	-0.02 (38.982)	65.67 (47.894)	-46.93 (32.789)
	95% CI of Mean	46.43, 69.08	-69.98, -29.66	124.75, 206.15	-12.84, 12.80	50.14, 81.20	-57.56, -36.30

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	40	38	39	39
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	51.64 (59.64)		127.28 (73.01)		48.82 (58.50)	
	95% CI of Geometric Mean	45.52, 58.59		103.27, 156.88		40.94, 58.21	
	Median	47.18	-64.25	124.37	-2.51	42.81	-60.29
	Q25, Q75	33.92, 63.95	-72.78, -47.11	79.25, 198.01	-17.88, 15.33	34.48, 79.06	-74.46, -37.77
	Min, Max	22.1, 288.7	-89.5, 419.1	35.7, 493.3	-87.5, 63.8	17.5, 198.5	-83.9, 16.1
	Mean (SD)	62.08 (49.440)	-46.70 (65.683)	156.86 (109.079)	-3.37 (32.702)	57.38 (39.048)	-52.53 (28.630)
	95% CI of Mean	50.77, 73.38	-61.72, -31.69	121.97, 191.75	-14.12, 7.38	44.72, 70.05	-61.81, -43.24

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		37		39	
	Missing, n (%)	0		4 (9.8)		0	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	128.73 (63.67)		132.01 (80.05)		120.54 (78.75)	
	95% CI of Geometric Mean	112.45, 147.36		104.40, 166.93		96.23, 150.98	
	Median	127.02		135.36		111.86	
	Q25, Q75	96.56, 165.79		94.31, 196.30		79.96, 161.29	
	Min, Max	26.9, 1407.1		33.1, 1037.7		36.3, 1014.9	
	Mean (SD)	158.02 (163.618)		172.68 (172.661)		163.06 (188.569)	
	95% CI of Mean	120.11, 195.93		115.10, 230.25		101.93, 224.19	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	39	37	39	39
	Missing, n (%)	0	0	2 (4.9)	4 (9.8)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	57.46 (77.34)		110.84 (58.05)		66.40 (75.59)	
	95% CI of Geometric Mean	49.03, 67.34		93.07, 132.01		53.39, 82.57	
	Median	49.37	-60.99	121.62	-15.90	62.50	-46.94
	Q25, Q75	34.82, 81.43	-72.18, -25.41	70.48, 161.99	-28.44, 13.05	42.52, 85.38	-67.68, -17.72
	Min, Max	16.7, 433.0	-89.9, 129.9	27.6, 290.3	-84.4, 91.9	16.0, 582.0	-82.4, 170.9
	Mean (SD)	76.07 (74.650)	-43.41 (42.120)	125.95 (60.834)	-11.95 (33.786)	87.10 (93.330)	-29.54 (55.280)
	95% CI of Mean	58.77, 93.37	-53.17, -33.65	106.22, 145.67	-23.22, -0.68	56.84, 117.36	-47.46, -11.62

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		37		38	
	Missing, n (%)	0		4 (9.8)		0	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	134.78 (61.06)		132.01 (80.05)		123.80 (77.15)	
	95% CI of Geometric Mean	117.97, 154.00		104.40, 166.93		98.89, 154.98	
	Median	131.76		135.36		115.56	
	Q25, Q75	101.85, 171.11		94.31, 196.30		83.15, 161.29	
	Min, Max	26.9, 1407.1		33.1, 1037.7		36.3, 1014.9	
	Mean (SD)	163.48 (165.392)		172.68 (172.661)		166.20 (190.064)	
	95% CI of Mean	124.33, 202.63		115.10, 230.25		103.72, 228.68	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	40	37	38	38
	Missing, n (%)	0	0	1 (2.4)	4 (9.8)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	56.15 (82.35)		136.16 (77.40)		57.57 (72.19)	
	95% CI of Geometric Mean	47.35, 66.58		109.37, 169.52		46.53, 71.23	
	Median	48.36	-63.89	132.74	-10.32	54.11	-53.26
	Q25, Q75	38.05, 74.53	-74.28, -36.09	96.03, 173.40	-23.85, 27.36	35.73, 77.00	-78.77, -3.89
	Min, Max	17.5, 839.6	-89.4, 317.3	29.6, 1908.8	-79.4, 191.3	19.8, 529.3	-91.6, 146.4
	Mean (SD)	80.07 (112.225)	-42.82 (61.871)	189.50 (289.477)	7.22 (60.145)	75.36 (85.052)	-35.64 (54.934)
	95% CI of Mean	53.51, 106.64	-57.47, -28.17	96.92, 282.09	-12.84, 27.27	47.40, 103.32	-53.70, -17.58

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		37		37	
	Missing, n (%)	0		4 (9.8)		0	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	125.94 (55.81)		132.01 (80.05)		124.94 (78.15)	
	95% CI of Geometric Mean	111.23, 142.59		104.40, 166.93		99.25, 157.29	
	Median	127.02		135.36		119.27	
	Q25, Q75	97.07, 165.79		94.31, 196.30		83.15, 161.29	
	Min, Max	26.9, 365.7		33.1, 1037.7		36.3, 1014.9	
	Mean (SD)	142.71 (72.811)		172.68 (172.661)		168.31 (192.233)	
	95% CI of Mean	125.34, 160.07		115.10, 230.25		104.21, 232.41	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	40	37	37	37
	Missing, n (%)	0	0	1 (2.4)	4 (9.8)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	68.35 (130.11)		125.64 (100.72)		77.86 (121.03)	
	95% CI of Geometric Mean	53.91, 86.67		96.13, 164.20		56.72, 106.88	
	Median	51.40	-58.22	124.60	-8.70	68.68	-53.82
	Q25, Q75	38.76, 84.73	-70.12, -16.48	77.90, 173.78	-35.74, 13.02	35.97, 119.62	-62.41, -6.44
	Min, Max	15.3, 2348.0	-86.0, 3223.3	34.4, 1525.2	-85.6, 680.8	21.7, 1519.5	-88.4, 609.5
	Mean (SD)	164.91 (413.643)	31.91 (418.625)	200.69 (301.846)	13.69 (123.152)	148.46 (279.504)	1.94 (146.841)
	95% CI of Mean	66.28, 263.55	-67.91, 131.74	104.15, 297.23	-27.38, 54.75	55.26, 241.65	-47.02, 50.91

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	38	39
	Missing, n (%)	0	4 (9.5)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	154.26 (68.16)	161.17 (88.56)	144.80 (84.82)
	95% CI of Geometric Mean	133.95, 177.66	125.51, 206.98	114.05, 183.83
	Median	152.55	176.83	140.77
	Q25, Q75	111.25, 212.13	97.44, 236.16	104.33, 183.11
	Min, Max	38.1, 2153.6	31.0, 1076.8	39.0, 1782.4
	Mean (SD)	198.22 (251.363)	217.90 (210.672)	212.27 (314.136)
	95% CI of Mean	140.77, 255.66	148.65, 287.15	110.44, 314.11

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	40	39
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	67.99 (68.57)	158.24 (118.78)	72.39 (74.60)
	95% CI of Geometric Mean	58.99, 78.36	117.22, 213.61	58.34, 89.81
	Median	59.60	162.16	60.23
	Q25, Q75	43.28, 98.61	86.60, 252.64	47.23, 91.42
	Min, Max	26.2, 1138.8	20.7, 2352.6	31.7, 737.0
	Mean (SD)	89.77 (129.713)	264.51 (412.846)	101.67 (141.155)
	95% CI of Mean	60.13, 119.42	132.47, 396.54	55.91, 147.43

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	40	39
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	53.91 (57.52)	157.20 (102.45)	58.42 (60.48)
	95% CI of Geometric Mean	47.71, 60.93	119.89, 206.12	48.75, 70.02
	Median	53.39	169.59	59.55
	Q25, Q75	40.70, 66.23	102.66, 258.64	42.35, 72.71
	Min, Max	20.7, 825.3	27.1, 1397.7	18.3, 511.9
	Mean (SD)	67.64 (93.366)	226.71 (250.850)	71.70 (76.214)
	95% CI of Mean	46.30, 88.98	146.48, 306.94	46.99, 96.41

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	40	39
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	54.01 (53.25)	158.03 (75.27)	59.93 (56.44)
	95% CI of Geometric Mean	48.18, 60.55	127.54, 195.79	50.53, 71.08
	Median	49.50	162.67	54.30
	Q25, Q75	42.21, 64.95	108.89, 203.59	43.83, 70.32
	Min, Max	23.1, 483.8	30.0, 903.8	26.9, 327.9
	Mean (SD)	64.50 (63.030)	199.94 (170.205)	71.02 (56.207)
	95% CI of Mean	50.09, 78.91	145.50, 254.38	52.79, 89.24

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	40	39
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	58.18 (61.90)	152.68 (79.47)	62.99 (67.45)
	95% CI of Geometric Mean	51.08, 66.27	122.06, 190.96	51.64, 76.82
	Median	53.45	151.02	59.57
	Q25, Q75	38.78, 81.19	112.77, 219.80	39.90, 75.97
	Min, Max	21.2, 477.5	16.9, 729.2	24.1, 432.0
	Mean (SD)	71.04 (64.760)	193.18 (153.991)	79.94 (78.317)
	95% CI of Mean	56.24, 85.85	143.92, 242.43	54.55, 105.34

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	40	39
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	60.38 (57.25)	156.45 (75.02)	59.60 (60.36)
	95% CI of Geometric Mean	53.46, 68.20	126.34, 193.72	49.74, 71.41
	Median	54.74	176.19	55.00
	Q25, Q75	47.99, 69.18	118.12, 223.66	42.28, 72.33
	Min, Max	22.9, 564.3	35.4, 688.4	23.9, 382.3
	Mean (SD)	73.40 (73.132)	191.28 (127.273)	72.95 (66.900)
	95% CI of Mean	56.68, 90.11	150.57, 231.98	51.26, 94.64

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	37	39
	Missing, n (%)	0	4 (9.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	154.10 (67.63)	154.97 (84.10)	144.80 (84.82)
	95% CI of Geometric Mean	133.67, 177.65	121.43, 197.77	114.05, 183.83
	Median	152.55	176.33	140.77
	Q25, Q75	112.41, 211.74	97.44, 230.21	104.33, 183.11
	Min, Max	38.1, 2153.6	31.0, 1076.8	39.0, 1782.4
	Mean (SD)	197.96 (253.842)	205.18 (198.239)	212.27 (314.136)
	95% CI of Mean	139.14, 256.77	139.08, 271.28	110.44, 314.11

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	39	39
	Missing, n (%)	0	2 (4.9)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	68.02 (82.90)	127.82 (67.52)	71.08 (84.83)
	95% CI of Geometric Mean	57.52, 80.43	104.79, 155.92	55.98, 90.24
	Median	54.11	144.45	59.00
	Q25, Q75	41.68, 98.18	86.93, 198.17	42.83, 96.14
	Min, Max	22.8, 713.7	27.4, 341.1	11.5, 450.5
	Mean (SD)	96.06 (113.785)	149.91 (78.930)	95.54 (91.744)
	95% CI of Mean	69.69, 122.43	124.32, 175.50	65.79, 125.28

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	37	38
	Missing, n (%)	0	4 (9.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	161.51 (66.09)	154.97 (84.10)	148.25 (84.05)
	95% CI of Geometric Mean	140.06, 186.24	121.43, 197.77	116.58, 188.51
	Median	156.99	176.33	142.87
	Q25, Q75	116.47, 213.78	97.44, 230.21	113.83, 183.11
	Min, Max	38.1, 2153.6	31.0, 1076.8	39.0, 1782.4
	Mean (SD)	205.94 (258.208)	205.18 (198.239)	216.30 (317.330)
	95% CI of Mean	144.82, 267.06	139.08, 271.28	111.99, 320.61

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	40	38
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	64.51 (91.13)	155.70 (85.75)	65.60 (78.83)
	95% CI of Geometric Mean	53.67, 77.55	122.79, 197.43	52.19, 82.44
	Median	56.75	157.09	58.17
	Q25, Q75	39.70, 83.56	117.87, 200.97	41.98, 101.46
	Min, Max	18.7, 988.2	31.1, 3326.4	8.2, 415.8
	Mean (SD)	98.41 (143.217)	243.28 (505.956)	84.25 (73.761)
	95% CI of Mean	64.50, 132.31	81.46, 405.10	60.00, 108.50

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	37	37
	Missing, n (%)	0	4 (9.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	148.96 (58.69)	154.97 (84.10)	151.02 (84.20)
	95% CI of Geometric Mean	130.83, 169.60	121.43, 197.77	118.31, 192.77
	Median	155.16	176.33	144.97
	Q25, Q75	110.10, 211.74	97.44, 230.21	119.37, 183.11
	Min, Max	38.1, 810.6	31.0, 1076.8	39.0, 1782.4
	Mean (SD)	172.45 (109.263)	205.18 (198.239)	220.13 (320.816)
	95% CI of Mean	146.39, 198.50	139.08, 271.28	113.16, 327.10

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	40	37
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	77.14 (127.45)	138.12 (108.24)	88.17 (122.79)
	95% CI of Geometric Mean	61.03, 97.51	104.22, 183.05	64.04, 121.39
	Median	59.86	138.78	83.53
	Q25, Q75	43.65, 88.20	68.65, 205.45	43.25, 117.79
	Min, Max	16.9, 2339.1	26.7, 1935.1	22.1, 1066.1
	Mean (SD)	177.33 (415.836)	235.80 (396.784)	157.70 (239.813)
	95% CI of Mean	78.17, 276.49	108.90, 362.70	77.74, 237.66

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		38		40	
	Missing, n (%)	0		4 (9.5)		0	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	128.81 (62.97)		136.04 (82.18)		122.09 (78.15)	
	95% CI of Geometric Mean	113.07, 146.74		107.42, 172.27		97.89, 152.26	
	Median	127.02		136.00		115.56	
	Q25, Q75	96.56, 165.79		94.31, 197.64		81.55, 168.25	
	Min, Max	26.9, 1407.1		33.1, 1037.7		36.3, 1014.9	
	Mean (SD)	157.37 (160.066)		179.00 (174.709)		164.01 (186.233)	
	95% CI of Mean	121.28, 193.46		121.56, 236.43		104.44, 223.57	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	40	38	40	40
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	59.12 (70.83)		133.33 (110.43)		67.00 (77.28)	
	95% CI of Geometric Mean	51.20, 68.27		100.21, 177.40		53.83, 83.39	
	Median	54.82	-52.29	135.23	-10.27	57.50	-46.83
	Q25, Q75	39.37, 81.00	-67.03, -39.45	82.77, 197.61	-20.83, 0.27	43.84, 80.95	-58.69, -31.75
	Min, Max	18.1, 858.4	-85.3, 83.5	27.0, 2705.5	-53.3, 23.0	26.7, 935.4	-73.8, 27.9
	Mean (SD)	78.18 (101.828)	-49.02 (26.419)	228.04 (428.881)	-11.80 (17.892)	96.80 (149.972)	-40.73 (25.467)
	95% CI of Mean	55.22, 101.15	-54.98, -43.05	90.88, 365.21	-17.69, -5.92	48.83, 144.77	-48.88, -32.58

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	40	38	40	40
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	45.83 (61.57)		126.46 (91.44)		51.59 (64.02)	
	95% CI of Geometric Mean	40.33, 52.08		98.55, 162.26		42.77, 62.24	
	Median	44.86	-64.56	124.60	-14.77	44.56	-55.90
	Q25, Q75	31.25, 60.37	-76.43, -54.69	70.09, 189.73	-28.42, 0.42	33.79, 66.03	-71.11, -45.50
	Min, Max	16.4, 479.9	-85.7, 59.1	26.7, 1462.7	-74.0, 56.5	16.7, 352.8	-94.8, 1.1
	Mean (SD)	56.45 (57.763)	-58.73 (26.221)	180.84 (232.661)	-11.04 (28.957)	63.34 (56.325)	-51.78 (24.257)
	95% CI of Mean	43.42, 69.48	-64.64, -52.81	106.43, 255.26	-20.56, -1.52	45.32, 81.35	-59.54, -44.01

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	40	38	40	40
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	44.68 (55.72)		129.82 (76.94)		51.08 (56.71)	
	95% CI of Geometric Mean	39.73, 50.24		104.38, 161.46		43.14, 60.48	
	Median	42.13	-65.20	120.48	-8.79	42.99	-61.62
	Q25, Q75	31.21, 58.74	-75.60, -54.93	89.29, 188.28	-26.40, 11.10	34.89, 69.95	-70.95, -44.93
	Min, Max	15.5, 312.8	-88.8, 51.0	28.5, 936.9	-82.6, 99.5	24.0, 242.7	-86.6, 60.4
	Mean (SD)	52.75 (42.605)	-60.17 (24.257)	167.54 (157.089)	-3.67 (37.161)	60.03 (42.806)	-50.23 (33.967)
	95% CI of Mean	43.14, 62.36	-65.65, -54.70	117.30, 217.79	-15.89, 8.55	46.34, 73.72	-61.09, -39.36

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	40	38	40	40
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	48.28 (62.02)		133.09 (73.99)		55.69 (66.90)	
	95% CI of Geometric Mean	42.45, 54.91		107.74, 164.41		45.85, 67.66	
	Median	45.18	-61.31	126.96	-5.04	48.13	-55.80
	Q25, Q75	33.88, 64.95	-73.58, -51.54	94.11, 197.00	-19.81, 24.14	38.02, 74.30	-70.82, -29.49
	Min, Max	15.6, 358.3	-89.2, 685.3	23.6, 705.5	-83.1, 98.7	15.2, 230.1	-83.4, 36.0
	Mean (SD)	58.36 (49.112)	-49.49 (87.281)	165.45 (127.256)	-0.02 (38.982)	67.80 (49.158)	-46.38 (32.552)
	95% CI of Mean	47.28, 69.44	-69.17, -29.80	124.75, 206.15	-12.84, 12.80	52.07, 83.52	-56.80, -35.97

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	40	38	40	40
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	52.29 (59.49)		127.28 (73.01)		50.22 (61.26)	
	95% CI of Geometric Mean	46.18, 59.21		103.27, 156.88		41.92, 60.16	
	Median	48.56	-64.25	124.37	-2.51	43.18	-59.71
	Q25, Q75	33.92, 71.23	-72.68, -46.56	79.25, 198.01	-17.88, 15.33	34.48, 79.32	-73.51, -36.71
	Min, Max	22.1, 288.7	-89.5, 419.1	35.7, 493.3	-87.5, 63.8	17.5, 198.5	-83.9, 16.1
	Mean (SD)	62.66 (48.971)	-46.41 (65.099)	156.86 (109.079)	-3.37 (32.702)	59.72 (41.282)	-51.84 (28.596)
	95% CI of Mean	51.61, 73.71	-61.09, -31.73	121.97, 191.75	-14.12, 7.38	46.51, 72.93	-60.99, -42.69

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	40	38	40	40
	Missing, n (%)	0	0	2 (4.8)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	57.99 (75.20)		114.55 (62.10)		67.78 (76.14)	
	95% CI of Geometric Mean	49.86, 67.45		95.42, 137.51		54.59, 84.14	
	Median	51.45	-60.99	122.56	-15.86	62.50	-45.56
	Q25, Q75	36.08, 81.43	-72.18, -13.67	71.00, 162.04	-28.44, 13.05	42.59, 102.55	-65.95, -19.77
	Min, Max	16.7, 433.0	-89.9, 129.9	27.6, 412.8	-84.4, 91.9	16.0, 582.0	-82.4, 170.9
	Mean (SD)	75.77 (72.785)	-43.14 (41.670)	133.12 (75.251)	-11.64 (33.383)	88.70 (92.676)	-29.42 (54.572)
	95% CI of Mean	59.36, 92.19	-52.54, -33.74	109.05, 157.19	-22.62, -0.66	59.05, 118.34	-46.88, -11.97

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	41	38	40	40
	Missing, n (%)	0	0	1 (2.4)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	57.07 (81.95)		139.90 (79.28)		58.13 (73.32)	
	95% CI of Geometric Mean	48.55, 67.09		112.22, 174.40		47.12, 71.70	
	Median	50.66	-60.71	133.60	-9.44	54.11	-52.63
	Q25, Q75	38.76, 74.53	-74.16, -27.27	98.00, 174.21	-23.85, 27.36	34.99, 80.09	-77.41, -7.46
	Min, Max	17.5, 839.6	-89.4, 317.3	29.6, 1908.8	-79.4, 191.3	19.8, 529.3	-91.6, 146.4
	Mean (SD)	80.64 (109.174)	-37.41 (68.697)	194.95 (287.955)	7.03 (59.338)	76.17 (84.000)	-35.13 (53.553)
	95% CI of Mean	56.02, 105.26	-52.90, -21.92	104.06, 285.85	-12.48, 26.54	49.30, 103.04	-52.27, -18.00

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	41	38	40	40
	Missing, n (%)	0	0	1 (2.4)	4 (9.5)	0	0
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	75.38 (148.53)		129.34 (102.42)		76.01 (118.52)	
	95% CI of Geometric Mean	59.09, 96.15		98.99, 168.98		56.33, 102.57	
	Median	54.17	-56.50	124.75	-7.08	67.41	-51.76
	Q25, Q75	39.62, 91.60	-70.12, -13.34	80.80, 177.36	-35.74, 13.02	35.79, 122.53	-61.75, -9.33
	Min, Max	15.3, 2348.0	-86.0, 3223.3	34.4, 1525.2	-85.6, 680.8	21.7, 1519.5	-88.4, 609.5
	Mean (SD)	195.07 (451.731)	43.96 (414.471)	205.86 (299.884)	13.33 (121.497)	142.83 (269.713)	-0.93 (141.513)
	95% CI of Mean	93.22, 296.93	-49.49, 137.41	111.20, 300.52	-26.61, 53.27	56.56, 229.09	-46.19, 44.33

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	38	40
	Missing, n (%)	0	4 (9.5)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	154.44 (67.60)	161.17 (88.56)	145.27 (83.45)
	95% CI of Geometric Mean	134.49, 177.36	125.51, 206.98	115.13, 183.30
	Median	152.55	176.83	142.87
	Q25, Q75	110.10, 212.52	97.44, 236.16	109.08, 177.53
	Min, Max	38.1, 2153.6	31.0, 1076.8	39.0, 1782.4
	Mean (SD)	197.64 (248.357)	217.90 (210.672)	211.09 (310.172)
	95% CI of Mean	141.64, 253.64	148.65, 287.15	111.88, 310.29

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	40	40
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	68.68 (67.92)	158.24 (118.78)	72.35 (73.42)
	95% CI of Geometric Mean	59.77, 78.91	117.22, 213.61	58.64, 89.26
	Median	61.80	162.16	61.89
	Q25, Q75	43.44, 99.14	86.60, 252.64	47.42, 90.72
	Min, Max	26.2, 1138.8	20.7, 2352.6	31.7, 737.0
	Mean (SD)	90.06 (128.032)	264.51 (412.846)	100.90 (139.419)
	95% CI of Mean	61.19, 118.93	132.47, 396.54	56.31, 145.49

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	40	40
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	54.11 (57.59)	157.20 (102.45)	59.50 (61.08)
	95% CI of Geometric Mean	47.95, 61.05	119.89, 206.12	49.69, 71.24
	Median	53.39	169.59	59.64
	Q25, Q75	40.50, 66.45	102.66, 258.64	43.34, 75.18
	Min, Max	20.7, 825.3	27.1, 1397.7	18.3, 511.9
	Mean (SD)	67.73 (92.320)	226.71 (250.850)	72.94 (75.637)
	95% CI of Mean	46.91, 88.55	146.48, 306.94	48.74, 97.13

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	40	40
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	54.38 (53.20)	158.03 (75.27)	61.00 (57.06)
	95% CI of Geometric Mean	48.59, 60.87	127.54, 195.79	51.47, 72.29
	Median	49.50	162.67	54.78
	Q25, Q75	42.43, 65.12	108.89, 203.59	44.44, 71.94
	Min, Max	23.1, 483.8	30.0, 903.8	26.9, 327.9
	Mean (SD)	64.81 (62.417)	199.94 (170.205)	72.27 (56.047)
	95% CI of Mean	50.73, 78.89	145.50, 254.38	54.34, 90.20

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	40	40
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	58.92 (61.68)	152.68 (79.47)	64.03 (67.57)
	95% CI of Geometric Mean	51.83, 66.97	122.06, 190.96	52.62, 77.90
	Median	54.43	151.02	60.64
	Q25, Q75	39.33, 82.03	112.77, 219.80	40.74, 76.20
	Min, Max	21.2, 477.5	16.9, 729.2	24.1, 432.0
	Mean (SD)	71.68 (64.056)	193.18 (153.991)	80.98 (77.582)
	95% CI of Mean	57.23, 86.12	143.92, 242.43	56.16, 105.79

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	40	40
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	61.15 (57.12)	156.45 (75.02)	60.67 (60.88)
	95% CI of Geometric Mean	54.24, 68.94	126.34, 193.72	50.69, 72.60
	Median	55.25	176.19	55.74
	Q25, Q75	48.00, 71.55	118.12, 223.66	42.29, 73.40
	Min, Max	22.9, 564.3	35.4, 688.4	23.9, 382.3
	Mean (SD)	74.06 (72.300)	191.28 (127.273)	74.16 (66.477)
	95% CI of Mean	57.75, 90.36	150.57, 231.98	52.89, 95.42

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	40	40
	Missing, n (%)	0	2 (4.8)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	68.67 (80.63)	133.32 (74.01)	72.03 (84.14)
	95% CI of Geometric Mean	58.54, 80.56	107.91, 164.70	57.00, 91.03
	Median	56.34	147.99	59.94
	Q25, Q75	41.75, 98.94	87.55, 199.04	43.30, 102.79
	Min, Max	22.8, 713.7	27.4, 688.4	11.5, 450.5
	Mean (SD)	95.47 (110.912)	163.38 (115.415)	96.18 (90.652)
	95% CI of Mean	70.45, 120.48	126.46, 200.29	67.19, 125.18

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	41	40
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	65.24 (89.43)	161.45 (89.80)	65.88 (77.78)
	95% CI of Geometric Mean	54.88, 77.55	126.65, 205.80	52.87, 82.10
	Median	59.14	158.00	58.17
	Q25, Q75	40.00, 83.56	118.27, 201.77	42.13, 104.20
	Min, Max	18.7, 988.2	31.1, 3326.4	8.2, 415.8
	Mean (SD)	97.73 (138.060)	254.14 (504.405)	84.12 (72.401)
	95% CI of Mean	66.60, 128.86	94.92, 413.35	60.96, 107.28

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	41	40
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	85.59 (143.71)	143.64 (112.62)	85.48 (118.94)
	95% CI of Geometric Mean	67.42, 108.66	107.95, 191.14	63.30, 115.42
	Median	60.67	141.56	82.17
	Q25, Q75	45.73, 103.01	70.38, 206.47	42.43, 119.51
	Min, Max	16.9, 2414.0	26.7, 1935.1	22.1, 1066.1
	Mean (SD)	211.38 (474.389)	246.84 (398.119)	150.93 (231.902)
	95% CI of Mean	104.42, 318.35	121.17, 372.51	76.75, 225.10

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	75.32 (59.07)		75.19 (66.49)		76.74 (60.82)	
	95% CI of Geometric Mean	66.47, 85.36		62.27, 90.80		63.97, 92.05	
	Median	79.12		76.74		77.50	
	Q25, Q75	48.29, 105.98		55.40, 115.38		49.66, 116.97	
	Min, Max	19.7, 312.1		16.0, 219.3		18.3, 261.9	
	Mean (SD)	86.86 (48.424)		88.51 (50.182)		88.58 (48.361)	
	95% CI of Mean	75.78, 97.93		72.87, 104.16		72.90, 104.26	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	28.82 (59.59)		68.81 (63.53)		31.39 (61.82)	
	95% CI of Geometric Mean	25.40, 32.69		57.39, 82.51		26.10, 37.75	
	Median	30.61	-62.59	70.25	-8.73	29.38	-58.36
	Q25, Q75	19.72, 39.36	-69.03, -52.74	44.92, 100.98	-19.59, 10.24	23.13, 48.96	-65.85, -52.88
	Min, Max	8.0, 106.2	-84.0, -8.6	13.0, 196.4	-44.3, 40.3	8.1, 106.0	-77.1, -23.9
	Mean (SD)	33.23 (18.106)	-59.46 (14.558)	79.95 (42.867)	-6.42 (20.021)	36.48 (20.635)	-57.43 (12.412)
	95% CI of Mean	29.09, 37.37	-62.79, -56.13	66.59, 93.32	-12.66, -0.17	29.79, 43.18	-61.45, -53.40

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	15.79 (53.15)		65.74 (67.93)		16.45 (54.19)	
	95% CI of Geometric Mean	14.08, 17.70		54.25, 79.66		13.95, 19.40	
	Median	17.03	-79.08	66.53	-14.60	18.03	-77.78
	Q25, Q75	11.18, 21.81	-82.56, -73.18	46.61, 97.10	-24.22, 3.51	13.43, 21.99	-82.59, -72.69
	Min, Max	5.0, 62.1	-93.6, -58.0	12.7, 187.7	-52.5, 27.1	3.7, 38.2	-88.4, -60.3
	Mean (SD)	17.80 (9.262)	-77.86 (7.231)	77.91 (45.058)	-10.36 (20.065)	18.35 (8.057)	-77.67 (6.394)
	95% CI of Mean	15.67, 19.92	-79.52, -76.21	63.86, 91.96	-16.62, -4.10	15.73, 20.97	-79.75, -75.60

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	13.41 (55.21)		65.96 (67.40)		13.28 (60.15)	
	95% CI of Geometric Mean	11.92, 15.10		54.51, 79.83		11.09, 15.91	
	Median	13.96	-82.07	65.28	-12.04	13.60	-82.72
	Q25, Q75	9.33, 18.34	-85.21, -77.34	47.77, 102.51	-22.13, 0.00	10.53, 18.36	-86.47, -78.91
	Min, Max	3.5, 58.4	-92.1, -65.2	13.4, 201.4	-52.1, 59.1	2.8, 33.0	-90.8, -68.9
	Mean (SD)	15.30 (8.658)	-81.12 (6.471)	78.04 (44.994)	-9.26 (24.108)	15.14 (7.298)	-81.82 (5.870)
	95% CI of Mean	13.32, 17.29	-82.60, -79.63	64.01, 92.06	-16.77, -1.74	12.77, 17.51	-83.73, -79.91

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	12.11 (56.77)		66.34 (73.24)		12.05 (61.81)	
	95% CI of Geometric Mean	10.72, 13.67		54.09, 81.38		10.02, 14.49	
	Median	12.94	-84.01	59.00	-10.69	13.54	-84.51
	Q25, Q75	8.25, 17.95	-86.70, -78.58	48.76, 107.57	-27.34, 6.46	9.63, 16.81	-87.55, -79.98
	Min, Max	3.0, 46.6	-93.6, -67.0	11.9, 205.8	-53.7, 63.8	2.7, 32.4	-92.3, -71.5
	Mean (SD)	13.84 (7.527)	-82.75 (6.497)	80.16 (48.215)	-8.49 (24.983)	13.79 (6.679)	-83.56 (5.095)
	95% CI of Mean	12.12, 15.57	-84.24, -81.26	65.13, 95.19	-16.28, -0.70	11.62, 15.96	-85.22, -81.90

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	12.43 (51.65)		68.17 (66.90)		11.78 (59.97)	
	95% CI of Geometric Mean	11.12, 13.90		56.39, 82.40		9.84, 14.10	
	Median	12.85	-83.75	67.79	-9.77	13.04	-84.71
	Q25, Q75	9.07, 17.51	-86.57, -78.82	46.26, 109.62	-24.65, 13.55	8.08, 17.81	-88.58, -80.20
	Min, Max	3.7, 44.2	-94.6, -66.0	16.3, 206.1	-45.6, 55.5	2.5, 27.8	-92.6, -70.1
	Mean (SD)	13.95 (7.064)	-82.39 (6.338)	80.71 (46.922)	-6.18 (25.177)	13.43 (6.393)	-83.70 (5.733)
	95% CI of Mean	12.33, 15.56	-83.84, -80.93	66.08, 95.33	-14.03, 1.67	11.35, 15.51	-85.56, -81.84

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	76.09 (59.26)		74.17 (66.61)		76.74 (60.82)	
	95% CI of Geometric Mean	67.00, 86.41		61.26, 89.81		63.97, 92.05	
	Median	80.18		76.34		77.50	
	Q25, Q75	49.27, 106.00		55.40, 114.11		49.66, 116.97	
	Min, Max	19.7, 312.1		16.0, 219.3		18.3, 261.9	
	Mean (SD)	87.74 (48.704)		87.46 (50.336)		88.58 (48.361)	
	95% CI of Mean	76.45, 99.03		71.57, 103.36		72.90, 104.26	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	9.19 (59.35)		76.97 (62.58)		8.76 (74.54)	
	95% CI of Geometric Mean	8.08, 10.44		64.19, 92.28		7.05, 10.87	
	Median	8.53	-87.80	79.21	11.70	9.22	-89.25
	Q25, Q75	6.28, 12.49	-91.51, -83.28	59.05, 110.62	-22.43, 30.04	5.84, 13.66	-91.87, -86.43
	Min, Max	3.2, 45.5	-95.7, -56.4	18.4, 214.7	-71.5, 178.1	1.7, 31.3	-94.8, -55.8
	Mean (SD)	10.88 (7.812)	-85.80 (9.093)	88.96 (46.072)	13.35 (49.576)	10.70 (6.828)	-86.90 (8.209)
	95% CI of Mean	9.07, 12.70	-87.92, -83.69	74.41, 103.50	-2.30, 29.00	8.48, 12.92	-89.57, -84.24

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	79.11 (55.92)		74.17 (66.61)		75.52 (60.62)	
	95% CI of Geometric Mean	69.91, 89.50		61.26, 89.81		62.83, 90.76	
	Median	81.17		76.34		76.86	
	Q25, Q75	56.09, 109.68		55.40, 114.11		49.66, 116.00	
	Min, Max	25.8, 312.1		16.0, 219.3		18.3, 261.9	
	Mean (SD)	90.11 (48.275)		87.46 (50.336)		87.20 (48.219)	
	95% CI of Mean	78.68, 101.54		71.57, 103.36		71.34, 103.05	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	7.84 (73.32)		76.89 (73.60)		8.05 (112.43)	
	95% CI of Geometric Mean	6.71, 9.16		62.46, 94.64		5.97, 10.84	
	Median	6.94	-90.89	80.32	15.85	7.03	-91.96
	Q25, Q75	5.16, 9.94	-93.69, -83.83	50.68, 133.07	-17.49, 33.23	4.22, 15.80	-94.08, -85.43
	Min, Max	2.4, 99.6	-96.8, 1.2	13.9, 236.6	-76.9, 140.7	1.8, 47.5	-96.6, -24.9
	Mean (SD)	10.62 (13.883)	-87.23 (13.472)	92.65 (54.489)	13.67 (46.960)	12.16 (12.290)	-83.12 (19.891)
	95% CI of Mean	7.33, 13.91	-90.43, -84.04	75.44, 109.85	-1.15, 28.50	8.11, 16.20	-89.67, -76.58

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	76.96 (58.77)		74.17 (66.61)		74.32 (60.48)	
	95% CI of Geometric Mean	67.58, 87.64		61.26, 89.81		61.69, 89.53	
	Median	80.18		76.34		76.23	
	Q25, Q75	55.86, 106.00		55.40, 114.11		49.66, 111.19	
	Min, Max	19.7, 312.1		16.0, 219.3		18.3, 261.9	
	Mean (SD)	88.56 (49.011)		87.46 (50.336)		85.87 (48.176)	
	95% CI of Mean	76.87, 100.25		71.57, 103.36		69.80, 101.94	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	7.91 (75.41)		83.98 (67.73)		8.41 (134.46)	
	95% CI of Geometric Mean	6.74, 9.29		69.17, 101.95		5.99, 11.81	
	Median	6.66	-90.04	87.16	13.64	5.85	-92.30
	Q25, Q75	5.12, 11.99	-93.23, -84.13	50.17, 128.94	-7.67, 46.04	3.82, 23.50	-95.01, -73.87
	Min, Max	2.2, 68.4	-96.7, -4.4	18.2, 262.4	-46.9, 251.7	1.6, 50.2	-97.1, -22.9
	Mean (SD)	10.37 (10.301)	-86.31 (14.391)	99.36 (56.104)	21.70 (51.700)	14.16 (15.160)	-79.89 (23.339)
	95% CI of Mean	7.90, 12.83	-89.75, -82.88	81.64, 117.07	5.38, 38.02	9.10, 19.22	-87.68, -72.10

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	90.64 (63.40)	89.17 (77.62)	92.18 (62.86)
	95% CI of Geometric Mean	79.36, 103.52	71.99, 110.46	76.45, 111.15
	Median	96.57	103.88	100.00
	Q25, Q75	59.68, 137.67	56.79, 139.07	63.23, 128.89
	Min, Max	18.4, 271.0	19.2, 246.2	19.7, 265.7
	Mean (SD)	105.69 (57.159)	109.15 (64.490)	106.43 (55.038)
	95% CI of Mean	92.63, 118.76	89.05, 129.25	88.58, 124.28

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	33.50 (69.77)	82.52 (85.23)	34.32 (68.19)
	95% CI of Geometric Mean	29.00, 38.69	65.54, 103.89	28.09, 41.94
	Median	36.81	100.52	35.06
	Q25, Q75	22.01, 53.48	51.19, 132.42	21.64, 50.52
	Min, Max	6.2, 119.9	14.9, 279.8	9.1, 188.4
	Mean (SD)	40.04 (23.243)	103.77 (65.192)	41.54 (30.629)
	95% CI of Mean	34.72, 45.35	83.45, 124.09	31.61, 51.47

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	18.69 (62.09)	81.94 (85.49)	19.15 (58.65)
	95% CI of Geometric Mean	16.40, 21.30	65.04, 103.21	16.05, 22.85
	Median	19.97	83.66	19.79
	Q25, Q75	11.61, 29.82	50.32, 158.95	13.23, 29.49
	Min, Max	5.0, 48.7	13.7, 271.3	4.8, 46.7
	Mean (SD)	21.72 (11.578)	103.51 (66.952)	21.72 (10.031)
	95% CI of Mean	19.07, 24.37	82.65, 124.38	18.46, 24.97

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	16.28 (58.98)	80.57 (76.52)	16.02 (59.01)
	95% CI of Geometric Mean	14.36, 18.45	65.20, 99.55	13.41, 19.13
	Median	17.51	89.56	17.05
	Q25, Q75	11.20, 24.79	47.04, 124.76	10.70, 23.69
	Min, Max	3.3, 42.7	15.6, 244.8	3.1, 35.0
	Mean (SD)	18.66 (9.485)	98.81 (61.267)	18.14 (8.255)
	95% CI of Mean	16.48, 20.83	79.72, 117.91	15.46, 20.82

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	14.78 (60.92)	75.79 (85.54)	13.98 (70.57)
	95% CI of Geometric Mean	13.00, 16.81	60.16, 95.48	11.37, 17.18
	Median	16.74	81.23	15.10
	Q25, Q75	9.98, 21.79	51.93, 136.76	9.76, 21.74
	Min, Max	4.0, 41.5	11.8, 227.2	2.1, 40.5
	Mean (SD)	17.06 (8.847)	95.31 (60.384)	16.53 (8.853)
	95% CI of Mean	15.03, 19.08	76.49, 114.13	13.65, 19.40

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	14.54 (57.54)	84.47 (74.91)	14.38 (58.08)
	95% CI of Geometric Mean	12.86, 16.43	68.61, 104.01	12.07, 17.13
	Median	15.62	88.05	14.35
	Q25, Q75	9.69, 22.38	53.72, 122.01	10.18, 23.65
	Min, Max	4.9, 41.6	18.9, 254.0	3.1, 35.9
	Mean (SD)	16.64 (8.567)	103.39 (65.152)	16.35 (7.932)
	95% CI of Mean	14.67, 18.60	83.08, 123.70	13.77, 18.93

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	91.09 (63.04)	87.24 (76.69)	92.18 (62.86)
	95% CI of Geometric Mean	79.66, 104.15	70.38, 108.13	76.45, 111.15
	Median	96.57	102.58	100.00
	Q25, Q75	60.24, 136.92	56.79, 137.16	63.23, 128.89
	Min, Max	18.4, 271.0	19.2, 246.2	19.7, 265.7
	Mean (SD)	106.06 (57.230)	106.46 (62.860)	106.43 (55.038)
	95% CI of Mean	92.79, 119.32	86.61, 126.30	88.58, 124.28

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	10.87 (68.41)	88.98 (77.33)	9.37 (71.57)
	95% CI of Geometric Mean	9.41, 12.55	71.69, 110.45	7.60, 11.54
	Median	10.89	94.50	10.12
	Q25, Q75	6.53, 15.36	62.61, 150.86	5.57, 14.59
	Min, Max	3.4, 69.7	22.9, 287.0	1.9, 30.0
	Mean (SD)	13.38 (10.615)	109.90 (70.593)	11.29 (6.885)
	95% CI of Mean	10.92, 15.85	87.61, 132.19	9.05, 13.52

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	94.79 (59.90)	87.24 (76.69)	90.43 (62.22)
	95% CI of Geometric Mean	83.14, 108.07	70.38, 108.13	74.93, 109.14
	Median	97.47	102.58	98.96
	Q25, Q75	60.60, 138.50	56.79, 137.16	63.23, 128.13
	Min, Max	26.1, 271.0	19.2, 246.2	19.7, 265.7
	Mean (SD)	109.19 (57.044)	106.46 (62.860)	104.20 (53.958)
	95% CI of Mean	95.69, 122.70	86.61, 126.30	86.46, 121.94

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	9.04 (79.44)	87.73 (82.07)	9.14 (114.11)
	95% CI of Geometric Mean	7.66, 10.67	69.95, 110.04	6.77, 12.35
	Median	8.40	81.50	7.84
	Q25, Q75	6.05, 10.97	59.68, 151.96	4.33, 14.88
	Min, Max	2.4, 81.9	14.7, 324.7	2.1, 59.7
	Mean (SD)	12.30 (14.025)	110.74 (76.302)	14.27 (15.691)
	95% CI of Mean	8.98, 15.62	86.65, 134.83	9.11, 19.43

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	91.03 (63.54)	87.24 (76.69)	89.83 (63.04)
	95% CI of Geometric Mean	79.22, 104.59	70.38, 108.13	74.07, 108.95
	Median	96.79	102.58	97.91
	Q25, Q75	60.24, 136.92	56.79, 137.16	63.23, 128.13
	Min, Max	18.4, 271.0	19.2, 246.2	19.7, 265.7
	Mean (SD)	106.09 (57.159)	106.46 (62.860)	103.89 (54.669)
	95% CI of Mean	92.46, 119.72	86.61, 126.30	85.66, 122.12

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	8.93 (84.94)	91.18 (83.48)	9.53 (132.23)
	95% CI of Geometric Mean	7.49, 10.65	72.48, 114.71	6.81, 13.33
	Median	8.13	92.63	6.66
	Q25, Q75	5.71, 11.69	64.11, 170.37	4.52, 19.89
	Min, Max	2.2, 91.3	12.0, 375.8	2.2, 66.5
	Mean (SD)	12.29 (13.390)	114.06 (74.299)	16.30 (18.702)
	95% CI of Mean	9.09, 15.49	90.60, 137.51	10.06, 22.54

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	74.82 (59.52)		75.19 (66.49)		77.82 (60.80)	
	95% CI of Geometric Mean	66.08, 84.72		62.27, 90.80		65.04, 93.12	
	Median	79.12		76.74		78.13	
	Q25, Q75	47.31, 106.00		55.40, 115.38		53.91, 117.20	
	Min, Max	19.7, 312.1		16.0, 219.3		18.3, 261.9	
	Mean (SD)	86.42 (48.271)		88.51 (50.182)		89.73 (48.288)	
	95% CI of Mean	75.53, 97.31		72.87, 104.16		74.28, 105.18	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	28.95 (58.80)		68.81 (63.53)		31.53 (60.98)	
	95% CI of Geometric Mean	25.60, 32.74		57.39, 82.51		26.34, 37.75	
	Median	31.34	-62.59	70.25	-8.73	29.57	-58.44
	Q25, Q75	19.97, 39.23	-69.02, -52.39	44.92, 100.98	-19.59, 10.24	23.33, 48.73	-66.12, -53.36
	Min, Max	8.0, 106.2	-84.0, 0.0	13.0, 196.4	-44.3, 40.3	8.1, 106.0	-77.1, -23.9
	Mean (SD)	33.26 (17.877)	-58.77 (15.885)	79.95 (42.867)	-6.42 (20.021)	36.51 (20.369)	-57.79 (12.469)
	95% CI of Mean	29.22, 37.30	-62.36, -55.18	66.59, 93.32	-12.66, -0.17	29.99, 43.03	-61.79, -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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	16.00 (53.29)		65.74 (67.93)		16.45 (53.40)	
	95% CI of Geometric Mean	14.29, 17.91		54.25, 79.66		14.01, 19.31	
	Median	17.21	-79.04	66.53	-14.60	18.00	-78.18
	Q25, Q75	11.21, 22.13	-82.51, -73.10	46.61, 97.10	-24.22, 3.51	13.50, 21.84	-82.88, -72.99
	Min, Max	5.0, 62.1	-93.6, 0.0	12.7, 187.7	-52.5, 27.1	3.7, 38.2	-88.4, -60.3
	Mean (SD)	18.03 (9.282)	-76.88 (11.345)	77.91 (45.058)	-10.36 (20.065)	18.30 (7.960)	-77.93 (6.516)
	95% CI of Mean	15.93, 20.13	-79.44, -74.32	63.86, 91.96	-16.62, -4.10	15.75, 20.85	-80.02, -75.84

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	13.60 (55.55)		65.96 (67.40)		13.35 (59.37)	
	95% CI of Geometric Mean	12.09, 15.29		54.51, 79.83		11.19, 15.92	
	Median	14.19	-82.07	65.28	-12.04	14.13	-82.76
	Q25, Q75	9.37, 18.34	-85.16, -76.54	47.77, 102.51	-22.13, 0.00	10.78, 18.28	-86.50, -79.01
	Min, Max	3.5, 58.4	-92.1, 0.0	13.4, 201.4	-52.1, 59.1	2.8, 33.0	-90.8, -68.9
	Mean (SD)	15.53 (8.734)	-80.12 (11.197)	78.04 (44.994)	-9.26 (24.108)	15.17 (7.206)	-81.97 (5.873)
	95% CI of Mean	13.56, 17.50	-82.65, -77.59	64.01, 92.06	-16.77, -1.74	12.86, 17.48	-83.86, -80.09

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	12.30 (57.39)		66.34 (73.24)		12.14 (61.13)	
	95% CI of Geometric Mean	10.90, 13.88		54.09, 81.38		10.13, 14.54	
	Median	13.03	-84.01	59.00	-10.69	13.81	-84.55
	Q25, Q75	8.27, 17.97	-86.56, -78.25	48.76, 107.57	-27.34, 6.46	9.89, 16.68	-87.60, -80.10
	Min, Max	3.0, 46.6	-93.6, 0.0	11.9, 205.8	-53.7, 63.8	2.7, 32.4	-92.3, -71.5
	Mean (SD)	14.10 (7.689)	-81.71 (11.359)	80.16 (48.215)	-8.49 (24.983)	13.85 (6.605)	-83.67 (5.076)
	95% CI of Mean	12.36, 15.84	-84.28, -79.15	65.13, 95.19	-16.28, -0.70	11.73, 15.97	-85.30, -82.04

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	12.65 (52.49)		68.17 (66.90)		11.88 (59.37)	
	95% CI of Geometric Mean	11.31, 14.14		56.39, 82.40		9.96, 14.16	
	Median	12.93	-83.59	67.79	-9.77	13.27	-84.72
	Q25, Q75	9.10, 17.71	-86.51, -78.46	46.26, 109.62	-24.65, 13.55	8.24, 17.76	-88.24, -80.42
	Min, Max	3.7, 44.2	-94.6, 0.0	16.3, 206.1	-45.6, 55.5	2.5, 27.8	-92.6, -70.1
	Mean (SD)	14.23 (7.261)	-81.33 (11.232)	80.71 (46.922)	-6.18 (25.177)	13.50 (6.327)	-83.80 (5.698)
	95% CI of Mean	12.59, 15.87	-83.87, -78.80	66.08, 95.33	-14.03, 1.67	11.47, 15.53	-85.63, -81.98

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	9.35 (59.91)		77.96 (62.44)		8.89 (74.36)	
	95% CI of Geometric Mean	8.25, 10.60		65.19, 93.22		7.19, 11.00	
	Median	8.59	-87.80	79.70	9.78	9.27	-89.16
	Q25, Q75	6.42, 12.49	-91.20, -83.25	59.05, 116.00	-22.43, 30.04	5.89, 14.92	-91.72, -86.73
	Min, Max	3.2, 45.5	-95.7, 0.0	18.4, 214.7	-71.5, 178.1	1.7, 31.3	-94.8, -55.8
	Mean (SD)	11.10 (7.960)	-84.64 (13.208)	89.97 (45.980)	13.03 (49.011)	10.84 (6.797)	-86.93 (8.104)
	95% CI of Mean	9.30, 12.90	-87.62, -81.66	75.64, 104.30	-2.25, 28.31	8.66, 13.02	-89.52, -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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	8.15 (79.00)		77.88 (73.21)		8.40 (111.93)	
	95% CI of Geometric Mean	6.96, 9.54		63.49, 95.52		6.29, 11.21	
	Median	7.07	-90.33	83.13	12.25	7.78	-91.73
	Q25, Q75	5.23, 10.64	-93.59, -83.49	50.68, 133.07	-17.49, 33.23	4.32, 17.35	-94.07, -84.89
	Min, Max	2.2, 99.6	-96.8, 1.9	13.9, 236.6	-76.9, 140.7	1.8, 47.5	-96.6, -24.9
	Mean (SD)	11.22 (13.977)	-84.42 (19.328)	93.58 (54.154)	13.35 (46.431)	12.51 (12.089)	-83.27 (19.390)
	95% CI of Mean	8.07, 14.38	-88.78, -80.06	76.69, 110.46	-1.13, 27.82	8.64, 16.38	-89.48, -77.07

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	8.16 (76.52)		84.88 (67.25)		8.66 (130.31)	
	95% CI of Geometric Mean	7.00, 9.52		70.16, 102.68		6.30, 11.92	
	Median	6.83	-89.75	88.89	12.15	5.91	-91.37
	Q25, Q75	5.16, 12.20	-93.30, -83.56	50.17, 129.30	-7.67, 46.04	4.05, 22.80	-95.07, -76.89
	Min, Max	2.2, 68.4	-96.7, 0.0	18.2, 262.4	-46.9, 251.7	1.6, 50.2	-97.1, -22.9
	Mean (SD)	10.70 (10.305)	-84.42 (18.125)	100.12 (55.638)	21.18 (51.176)	14.19 (14.692)	-80.61 (22.609)
	95% CI of Mean	8.37, 13.03	-88.51, -80.33	82.78, 117.47	5.23, 37.14	9.49, 18.89	-87.84, -73.37

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	89.71 (63.85)	89.17 (77.62)	92.60 (62.00)
	95% CI of Geometric Mean	78.63, 102.36	71.99, 110.46	77.16, 111.13
	Median	96.57	103.88	101.14
	Q25, Q75	59.12, 136.92	56.79, 139.07	66.22, 128.51
	Min, Max	18.4, 271.0	19.2, 246.2	19.7, 265.7
	Mean (SD)	104.81 (56.995)	109.15 (64.490)	106.53 (54.332)
	95% CI of Mean	91.95, 117.66	89.05, 129.25	89.15, 123.91

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	33.63 (68.79)	82.52 (85.23)	34.05 (67.40)
	95% CI of Geometric Mean	29.22, 38.70	65.54, 103.89	27.99, 41.42
	Median	36.81	100.52	34.96
	Q25, Q75	22.41, 53.44	51.19, 132.42	22.30, 50.38
	Min, Max	6.2, 119.9	14.9, 279.8	9.1, 188.4
	Mean (SD)	40.02 (22.956)	103.77 (65.192)	41.13 (30.347)
	95% CI of Mean	34.84, 45.20	83.45, 124.09	31.42, 50.84

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	18.89 (61.72)	81.94 (85.49)	18.97 (58.20)
	95% CI of Geometric Mean	16.61, 21.47	65.04, 103.21	15.96, 22.55
	Median	20.25	83.66	19.78
	Q25, Q75	11.62, 29.95	50.32, 158.95	13.15, 28.81
	Min, Max	5.0, 48.7	13.7, 271.3	4.8, 46.7
	Mean (SD)	21.90 (11.511)	103.51 (66.952)	21.50 (9.996)
	95% CI of Mean	19.30, 24.50	82.65, 124.38	18.30, 24.70

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	16.56 (59.35)	80.57 (76.52)	15.94 (58.26)
	95% CI of Geometric Mean	14.62, 18.74	65.20, 99.55	13.40, 18.95
	Median	17.66	89.56	16.79
	Q25, Q75	11.21, 25.15	47.04, 124.76	11.26, 23.22
	Min, Max	3.3, 42.7	15.6, 244.8	3.1, 35.0
	Mean (SD)	18.98 (9.588)	98.81 (61.267)	18.02 (8.188)
	95% CI of Mean	16.82, 21.15	79.72, 117.91	15.39, 20.64

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	15.01 (61.20)	75.79 (85.54)	13.96 (69.48)
	95% CI of Geometric Mean	13.22, 17.05	60.16, 95.48	11.41, 17.06
	Median	16.96	81.23	14.66
	Q25, Q75	10.09, 21.79	51.93, 136.76	10.53, 21.46
	Min, Max	4.0, 41.5	11.8, 227.2	2.1, 40.5
	Mean (SD)	17.33 (8.952)	95.31 (60.384)	16.44 (8.755)
	95% CI of Mean	15.31, 19.36	76.49, 114.13	13.63, 19.24

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	14.79 (58.11)	84.47 (74.91)	14.35 (57.24)
	95% CI of Geometric Mean	13.09, 16.71	68.61, 104.01	12.10, 17.02
	Median	15.71	88.05	14.34
	Q25, Q75	9.95, 23.76	53.72, 122.01	10.32, 23.41
	Min, Max	4.9, 41.6	18.9, 254.0	3.1, 35.9
	Mean (SD)	16.95 (8.719)	103.39 (65.152)	16.27 (7.846)
	95% CI of Mean	14.98, 18.93	83.08, 123.70	13.75, 18.78

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	11.07 (68.32)	90.92 (78.16)	9.45 (70.74)
	95% CI of Geometric Mean	9.62, 12.73	73.31, 112.75	7.70, 11.58
	Median	10.96	95.36	10.32
	Q25, Q75	7.27, 15.43	62.61, 153.73	5.59, 14.57
	Min, Max	3.4, 69.7	22.9, 287.0	1.9, 30.0
	Mean (SD)	13.60 (10.613)	112.51 (71.746)	11.33 (6.802)
	95% CI of Mean	11.21, 16.00	90.15, 134.87	9.15, 13.51

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	9.34 (85.86)	89.67 (82.83)	9.49 (113.41)
	95% CI of Geometric Mean	7.90, 11.05	71.58, 112.33	7.09, 12.70
	Median	8.51	83.28	7.93
	Q25, Q75	6.05, 13.26	59.68, 154.33	4.82, 16.56
	Min, Max	2.4, 81.9	14.7, 324.7	2.1, 59.7
	Mean (SD)	13.04 (14.622)	113.33 (77.210)	14.61 (15.459)
	95% CI of Mean	9.73, 16.34	89.26, 137.40	9.66, 19.56

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	9.27 (84.37)	93.11 (84.04)	9.74 (128.42)
	95% CI of Geometric Mean	7.85, 10.94	74.14, 116.93	7.10, 13.36
	Median	8.37	93.19	6.93
	Q25, Q75	6.11, 12.99	64.11, 171.43	4.54, 22.06
	Min, Max	2.2, 91.3	12.0, 375.8	2.2, 66.5
	Mean (SD)	12.63 (13.140)	116.57 (75.167)	16.27 (18.170)
	95% CI of Mean	9.67, 15.60	93.14, 140.00	10.45, 22.09

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3203.95 (86.85)		3148.47 (92.32)		3201.31 (93.26)	
	95% CI of Geometric Mean	2699.53,		2465.16,		2477.20,	
		3802.62		4021.17		4137.07	
	Median	3094.98		3346.38		2686.57	
	Q25, Q75	1707.46,		2133.66,		1753.85,	
		5168.72		5342.47		6075.76	
	Min, Max	572.7, 18905.5		184.8, 14128.6		625.4, 18930.0	
	Mean (SD)	4269.71		4015.41		4371.94	
		(3697.443)		(2788.832)		(3844.896)	
	95% CI of Mean	3424.80,		3146.35,		3125.57,	
		5114.62		4884.48		5618.32	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2257.61 (76.22)		3064.87 (86.29)		2443.50 (79.68)	
	95% CI of Geometric Mean	1934.14, 2635.18		2429.17, 3866.92		1946.74, 3067.01	
	Median	2167.30	-29.67	3225.13	0.14	2184.21	-26.46
	Q25, Q75	1368.27, 3283.20	-41.88, -18.27	2059.88, 4951.72	-15.38, 9.44	1289.75, 4406.08	-39.24, -1.02
	Min, Max	513.7, 15368.6	-73.5, 56.3	196.8, 12148.0	-44.4, 86.8	850.9, 9973.3	-67.2, 45.6
	Mean (SD)	2867.14 (2349.346)	-26.38 (22.813)	3821.79 (2499.071)	0.01 (24.525)	3133.21 (2413.647)	-19.34 (27.387)
	95% CI of Mean	2330.28, 3403.99	-31.60, -21.16	3043.02, 4600.56	-7.64, 7.65	2350.79, 3915.63	-28.23, -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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1648.96 (66.10)		2780.38 (95.80)		1750.27 (63.14)	
	95% CI of Geometric Mean	1437.02, 1892.16		2162.23, 3575.26		1450.64, 2111.79	
	Median	1678.86	-45.29	3167.88	-9.93	1821.14	-49.48
	Q25, Q75	1083.98, 2340.01	-61.06, -33.51	1984.38, 4176.78	-21.32, 4.82	1121.83, 2737.34	-58.92, -26.17
	Min, Max	369.8, 9425.3	-75.5, 16.8	145.7, 15657.4	-53.2, 70.1	634.1, 7203.4	-75.6, 15.9
	Mean (SD)	1994.77 (1456.936)	-45.32 (19.019)	3651.66 (2939.287)	-8.03 (26.493)	2072.24 (1327.778)	-41.17 (23.102)
	95% CI of Mean	1661.84, 2327.70	-49.67, -40.97	2735.70, 4567.61	-16.29, 0.23	1641.82, 2502.66	-48.66, -33.68

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1304.19 (69.35)		2592.67 (99.69)		1391.59 (67.75)	
	95% CI of Geometric Mean	1130.20, 1504.97		2001.37, 3358.67		1140.22, 1698.38	
	Median	1283.61	-58.23	2713.99	-17.26	1529.71	-55.20
	Q25, Q75	806.65, 1840.45	-71.02, -43.43	1693.93, 4420.00	-28.56, -1.49	885.71, 1937.72	-69.71, -41.99
	Min, Max	391.0, 7093.0	-83.3, 0.1	134.8, 13270.1	-62.2, 80.7	418.4, 7533.3	-77.7, -7.9
	Mean (SD)	1610.88 (1253.520)	-55.67 (18.714)	3476.27 (2873.661)	-13.87 (26.990)	1701.04 (1307.284)	-53.01 (19.030)
	95% CI of Mean	1324.44, 1897.33	-59.95, -51.39	2580.77, 4371.77	-22.28, -5.45	1277.26, 2124.82	-59.19, -46.84

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1353.29 (60.46)		2678.42 (96.57)		1446.90 (70.82)	
	95% CI of Geometric Mean	1191.25, 1537.37		2079.82, 3449.29		1176.75, 1779.07	
	Median	1185.06	-56.05	3033.36	-11.18	1407.22	-52.51
	Q25, Q75	895.49, 2042.76	-70.37, -40.28	1791.38, 4122.91	-29.77, 0.00	913.04, 2121.85	-64.96, -39.52
	Min, Max	421.7, 5827.7	-81.4, 0.5	125.0, 11955.4	-51.4, 44.5	514.6, 11456.3	-79.1, 41.1
	Mean (SD)	1595.48 (1040.539)	-53.84 (19.194)	3470.80 (2520.367)	-12.64 (20.197)	1841.46 (1831.349)	-50.44 (23.103)
	95% CI of Mean	1357.70, 1833.26	-58.23, -49.44	2685.39, 4256.20	-18.94, -6.34	1247.80, 2435.11	-57.93, -42.94

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1137.96 (63.92)		2235.37 (94.47)		1113.73 (62.86)	
	95% CI of Geometric Mean	995.50, 1300.81		1742.88, 2867.03		923.72, 1342.83	
	Median	1087.92	-62.33	2501.92	-26.12	1182.41	-64.07
	Q25, Q75	767.08, 1727.46	-74.17, -51.17	1497.40, 3333.33	-41.57, -14.69	719.75, 1406.11	-76.24, -49.72
	Min, Max	390.7, 5784.0	-85.7, -5.2	126.5, 11088.4	-63.2, 29.9	308.2, 6801.6	-87.9, -20.8
	Mean (SD)	1364.63 (958.138)	-61.14 (16.626)	2929.90 (2345.110)	-26.60 (18.875)	1337.92 (1073.093)	-61.24 (17.836)
	95% CI of Mean	1145.68, 1583.58	-64.94, -57.33	2199.11, 3660.69	-32.48, -20.71	990.06, 1685.78	-67.03, -55.46

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3220.10 (88.21)		3144.49 (93.86)		3201.31 (93.26)	
	95% CI of Geometric Mean	2701.09, 3838.85		2446.79, 4041.14		2477.20, 4137.07	
	Median	3094.98		3376.96		2686.57	
	Q25, Q75	1702.34, 5252.43		2133.66, 5342.47		1753.85, 6075.76	
	Min, Max	572.7, 18905.5		184.8, 14128.6		625.4, 18930.0	
	Mean (SD)	4312.00 (3737.663)		4032.48 (2821.257)		4371.94 (3844.896)	
	95% CI of Mean	3446.05, 5177.95		3141.97, 4922.98		3125.57, 5618.32	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1739.46 (70.43)		4038.40 (109.25)		1602.97 (68.40)	
	95% CI of Geometric Mean	1501.61, 2014.97		3052.95, 5341.94		1311.33, 1959.46	
	Median	1641.24	-44.41	4878.47	18.82	1842.59	-47.94
	Q25, Q75	1194.62, 2511.63	-66.26, -16.64	1890.95, 7160.24	-5.07, 60.95	940.92, 2693.37	-68.29, -22.86
	Min, Max	339.4, 6751.0	-81.6, 114.8	209.3, 15710.7	-57.4, 437.4	558.8, 5779.2	-83.6, 49.2
	Mean (SD)	2112.01 (1393.496)	-37.22 (36.139)	5469.74 (3904.770)	43.09 (81.990)	1919.77 (1179.584)	-42.38 (30.856)
	95% CI of Mean	1789.16, 2434.86	-45.60, -28.84	4237.23, 6702.24	17.20, 68.97	1537.39, 2302.15	-52.39, -32.38

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3279.50 (88.62)		3144.49 (93.86)		3192.63 (94.93)	
	95% CI of Geometric Mean	2738.73, 3927.04		2446.79, 4041.14		2453.23, 4154.90	
	Median	3160.92		3376.96		2618.51	
	Q25, Q75	1712.57, 5318.47		2133.66, 5342.47		1753.85, 6075.76	
	Min, Max	572.7, 18905.5		184.8, 14128.6		625.4, 18930.0	
	Mean (SD)	4392.80 (3787.370)		4032.48 (2821.257)		4393.60 (3894.096)	
	95% CI of Mean	3496.34, 5289.26		3141.97, 4922.98		3113.64, 5673.56	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1694.19 (64.18)		3773.50 (96.34)		1641.86 (67.72)	
	95% CI of Geometric Mean	1474.31, 1946.86		2921.95, 4873.21		1341.64, 2009.27	
	Median	1624.03	-53.62	4130.43	21.23	1674.32	-49.52
	Q25, Q75	1371.68, 2531.53	-65.37, -13.82	2593.22, 6423.84	-15.96, 69.88	1000.00, 2584.91	-67.88, -20.87
	Min, Max	493.3, 5570.6	-82.5, 58.5	262.5, 12786.6	-47.3, 177.9	510.9, 8291.1	-83.6, 53.7
	Mean (SD)	1994.35 (1160.483)	-40.33 (32.574)	4868.44 (3147.842)	30.00 (53.265)	1987.38 (1433.289)	-40.05 (33.523)
	95% CI of Mean	1719.66, 2269.04	-48.05, -32.62	3874.85, 5862.02	13.18, 46.82	1516.27, 2458.50	-51.07, -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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3306.42 (89.14)		3144.49 (93.86)		3087.76 (92.35)	
	95% CI of Geometric Mean	2755.33, 3967.72		2446.79, 4041.14		2376.49, 4011.92	
	Median	3168.19		3376.96		2550.46	
	Q25, Q75	1702.34, 5318.47		2133.66, 5342.47		1753.85, 5972.46	
	Min, Max	572.7, 18905.5		184.8, 14128.6		625.4, 18930.0	
	Mean (SD)	4430.43 (3801.676)		4032.48 (2821.257)		4215.43 (3787.532)	
	95% CI of Mean	3523.95, 5336.92		3141.97, 4922.98		2952.60, 5478.26	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1741.53 (65.54)		3739.46 (103.15)		1633.12 (81.68)	
	95% CI of Geometric Mean	1510.19, 2008.30		2858.39, 4892.12		1286.77, 2072.69	
	Median	1716.55	-47.33	3559.13	12.12	1799.52	-48.08
	Q25, Q75	1097.09, 2865.38	-64.50, -23.80	2592.59, 5719.42	-7.03, 58.67	928.05, 2526.32	-68.69, -17.10
	Min, Max	541.7, 7396.3	-85.3, 69.8	185.7, 19069.8	-50.7, 301.4	477.8, 7776.7	-89.6, 78.9
	Mean (SD)	2083.00 (1361.465)	-39.29 (33.957)	5119.75 (4392.666)	33.12 (70.964)	2082.13 (1550.601)	-35.41 (40.960)
	95% CI of Mean	1758.37, 2407.64	-47.39, -31.19	3733.25, 6506.25	10.72, 55.53	1565.12, 2599.13	-49.07, -21.75

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3855.61 (78.53)	3733.82 (82.05)	3845.62 (81.25)
	95% CI of Geometric Mean	3290.86, 4517.27	2985.78, 4669.28	3053.05, 4843.95
	Median	3914.34	4372.65	3896.83
	Q25, Q75	2376.18, 6233.96	2770.56, 5730.76	2170.64, 6496.42
	Min, Max	630.4, 17578.8	329.0, 15438.3	947.7, 16650.4
	Mean (SD)	4871.87 (3576.949)	4596.90 (2866.904)	4859.55 (3402.697)
	95% CI of Mean	4054.50, 5689.24	3703.51, 5490.30	3756.52, 5962.58

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2623.90 (64.92)	3675.15 (89.14)	2671.63 (72.21)
	95% CI of Geometric Mean	2291.37, 3004.68	2895.93, 4664.03	2165.62, 3295.86
	Median	2500.22	4276.92	2502.72
	Q25, Q75	1656.21, 3589.28	2409.24, 6101.84	1857.45, 3954.60
	Min, Max	670.2, 14671.8	342.7, 15409.2	613.1, 12444.0
	Mean (SD)	3174.97 (2389.578)	4671.43 (3117.532)	3289.39 (2392.285)
	95% CI of Mean	2628.93, 3721.02	3699.93, 5642.92	2513.89, 4064.88

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1952.30 (55.27)	3465.26 (94.83)	2037.19 (57.14)
	95% CI of Geometric Mean	1735.04, 2196.77	2699.91, 4447.57	1714.76, 2420.25
	Median	2017.64	3812.08	2003.49
	Q25, Q75	1378.67, 2696.38	2221.35, 5530.14	1372.85, 2758.85
	Min, Max	406.3, 6736.3	247.1, 20353.5	479.7, 8932.5
	Mean (SD)	2227.56 (1230.583)	4575.39 (3667.991)	2348.29 (1456.961)
	95% CI of Mean	1946.36, 2508.77	3432.36, 5718.42	1875.99, 2820.59

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1582.94 (52.48)	3166.74 (94.95)	1678.67 (55.48)
	95% CI of Geometric Mean	1414.23, 1771.76	2466.74, 4065.40	1419.18, 1985.60
	Median	1610.80	3141.53	1689.34
	Q25, Q75	1137.60, 2031.33	2250.36, 5323.40	1073.52, 2282.38
	Min, Max	456.0, 6296.9	233.5, 16005.9	623.1, 5900.9
	Mean (SD)	1801.05 (1062.488)	4155.89 (3164.826)	1930.00 (1162.485)
	95% CI of Mean	1558.25, 2043.84	3169.66, 5142.13	1553.16, 2306.84

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1652.28 (50.86)	3059.73 (87.97)	1678.72 (57.66)
	95% CI of Geometric Mean	1480.78, 1843.64	2416.75, 3873.78	1411.09, 1997.11
	Median	1606.49	3331.70	1659.84
	Q25, Q75	1105.11, 2236.76	2272.04, 5050.24	1081.50, 2197.62
	Min, Max	501.7, 4797.1	212.2, 13101.0	602.2, 6818.0
	Mean (SD)	1854.45 (951.013)	3838.53 (2491.751)	1947.47 (1220.937)
	95% CI of Mean	1637.13, 2071.77	3062.04, 4615.02	1551.68, 2343.26

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1330.54 (50.62)	2770.15 (89.85)	1359.65 (52.32)
	95% CI of Geometric Mean	1192.98, 1483.95	2179.67, 3520.60	1159.27, 1594.66
	Median	1330.67	2725.77	1395.24
	Q25, Q75	956.14, 1831.55	1910.59, 4140.90	981.43, 1744.60
	Min, Max	448.7, 4458.1	217.1, 14920.3	429.1, 5004.7
	Mean (SD)	1496.93 (808.902)	3595.15 (2835.107)	1539.95 (895.978)
	95% CI of Mean	1312.08, 1681.78	2711.66, 4478.64	1249.50, 1830.40

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3854.75 (79.81)	3698.22 (82.96)	3845.62 (81.25)
	95% CI of Geometric Mean	3276.12, 4535.57	2943.04, 4647.18	3053.05, 4843.95
	Median	3914.34	4344.54	3896.83
	Q25, Q75	2362.92, 6376.32	2770.56, 5730.76	2170.64, 6496.42
	Min, Max	630.4, 17578.8	329.0, 15438.3	947.7, 16650.4
	Mean (SD)	4897.11 (3620.737)	4574.14 (2898.674)	4859.55 (3402.697)
	95% CI of Mean	4058.25, 5735.97	3659.20, 5489.08	3756.52, 5962.58

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2057.66 (62.11)	4668.89 (104.62)	1714.69 (72.32)
	95% CI of Geometric Mean	1802.61, 2348.80	3559.20, 6124.57	1389.57, 2115.87
	Median	2179.56	5447.94	1688.50
	Q25, Q75	1415.61, 3017.80	2625.38, 8921.47	1003.00, 2490.99
	Min, Max	391.5, 7656.0	360.3, 21129.6	460.0, 7166.3
	Mean (SD)	2394.70 (1366.582)	6199.44 (4220.011)	2114.69 (1509.572)
	95% CI of Mean	2078.08, 2711.31	4867.44, 7531.45	1625.34, 2604.04

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3929.73 (80.02)	3698.22 (82.96)	3823.15 (82.51)
	95% CI of Geometric Mean	3326.96, 4641.71	2943.04, 4647.18	3016.89, 4844.88
	Median	4024.24	4344.54	3876.22
	Q25, Q75	2389.44, 6449.30	2770.56, 5730.76	2170.64, 6496.42
	Min, Max	630.4, 17578.8	329.0, 15438.3	947.7, 16650.4
	Mean (SD)	4987.62 (3657.672)	4574.14 (2898.674)	4860.99 (3448.361)
	95% CI of Mean	4121.85, 5853.38	3659.20, 5489.08	3727.53, 5994.44

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1953.30 (55.13)	4305.90 (85.33)	1865.17 (72.63)
	95% CI of Geometric Mean	1729.09, 2206.58	3409.45, 5438.05	1505.96, 2310.06
	Median	1991.82	4337.52	1892.55
	Q25, Q75	1362.47, 2839.02	2806.70, 7116.64	1139.99, 2797.36
	Min, Max	637.4, 5866.9	498.0, 16005.2	390.3, 9733.3
	Mean (SD)	2220.37 (1161.148)	5417.49 (3517.475)	2295.15 (1683.650)
	95% CI of Mean	1945.53, 2495.22	4307.24, 6527.75	1741.75, 2848.56

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3910.93 (82.08)	3698.22 (82.96)	3732.22 (81.67)
	95% CI of Geometric Mean	3295.81, 4640.85	2943.04, 4647.18	2940.73, 4736.73
	Median	4069.52	4344.54	3855.60
	Q25, Q75	2362.92, 6449.30	2770.56, 5730.76	2170.64, 6388.27
	Min, Max	630.4, 17578.8	329.0, 15438.3	947.7, 16650.4
	Mean (SD)	5002.31 (3693.074)	4574.14 (2898.674)	4740.57 (3413.973)
	95% CI of Mean	4121.72, 5882.89	3659.20, 5489.08	3602.29, 5878.85

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1965.42 (61.45)	4060.33 (94.06)	1849.21 (76.30)
	95% CI of Geometric Mean	1717.32, 2249.38	3158.19, 5220.16	1475.39, 2317.74
	Median	1882.17	4086.18	1718.04
	Q25, Q75	1323.30, 2854.88	2788.60, 6415.93	1184.70, 2555.12
	Min, Max	503.6, 6832.8	290.5, 18984.6	485.0, 8138.2
	Mean (SD)	2300.80 (1370.359)	5369.66 (4313.880)	2329.86 (1768.152)
	95% CI of Mean	1974.05, 2627.56	4008.02, 6731.29	1740.33, 2919.40

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3162.52 (87.60)		3148.47 (92.32)		3287.45 (94.48)	
	95% CI of Geometric Mean	2667.73,		2465.16,		2546.39,	
		3749.08		4021.17		4244.17	
	Median	3094.98		3346.38		2805.55	
	Q25, Q75	1702.34,		2133.66,		1794.83,	
		5085.01		5342.47		6091.21	
	Min, Max	572.7, 18905.5		184.8, 14128.6		625.4, 18930.0	
	Mean (SD)	4225.21		4015.41		4494.13	
		(3669.117)		(2788.832)		(3873.153)	
	95% CI of Mean	3397.94,		3146.35,		3255.43,	
		5052.47		4884.48		5732.83	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2229.40 (76.14)		3064.87 (86.29)		2497.66 (80.36)	
	95% CI of Geometric Mean	1914.16, 2596.56		2429.17, 3866.92		1992.97, 3130.17	
	Median	2154.00	-29.67	3225.13	0.14	2253.87	-28.05
	Q25, Q75	1359.83, 3253.52	-42.24, -17.83	2059.88, 4951.72	-15.38, 9.44	1298.99, 4460.42	-39.03, -2.20
	Min, Max	513.7, 15368.6	-73.5, 56.3	196.8, 12148.0	-44.4, 86.8	850.9, 9973.3	-67.2, 45.6
	Mean (SD)	2832.57 (2330.736)	-26.33 (22.855)	3821.79 (2499.071)	0.01 (24.525)	3201.72 (2421.582)	-19.77 (27.170)
	95% CI of Mean	2307.06, 3358.07	-31.49, -21.17	3043.02, 4600.56	-7.64, 7.65	2427.25, 3976.18	-28.47, -11.08

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1637.60 (65.61)		2780.38 (95.80)		1772.07 (62.87)	
	95% CI of Geometric Mean	1430.93, 1874.12		2162.23, 3575.26		1473.42, 2131.25	
	Median	1678.86	-45.29	3167.88	-9.93	1828.12	-49.78
	Q25, Q75	1081.75, 2304.76	-59.44, -33.20	1984.38, 4176.78	-21.32, 4.82	1143.03, 2804.44	-60.43, -26.42
	Min, Max	369.8, 9425.3	-75.5, 16.8	145.7, 15657.4	-53.2, 70.1	634.1, 7203.4	-75.6, 15.9
	Mean (SD)	1977.87 (1443.494)	-44.89 (19.512)	3651.66 (2939.287)	-8.03 (26.493)	2092.23 (1316.724)	-41.86 (23.224)
	95% CI of Mean	1652.41, 2303.34	-49.30, -40.49	2735.70, 4567.61	-16.29, 0.23	1671.11, 2513.34	-49.30, -34.43

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1291.98 (68.62)		2592.67 (99.69)		1417.03 (68.12)	
	95% CI of Geometric Mean	1123.13, 1486.21		2001.37, 3358.67		1163.13, 1726.34	
	Median	1263.31	-58.23	2713.99	-17.26	1537.01	-55.99
	Q25, Q75	810.71, 1837.90	-71.06, -43.20	1693.93, 4420.00	-28.56, -1.49	901.44, 1977.10	-69.66, -42.26
	Min, Max	391.0, 7093.0	-83.3, 0.1	134.8, 13270.1	-62.2, 80.7	418.4, 7533.3	-77.7, -7.9
	Mean (SD)	1592.75 (1242.239)	-55.24 (19.690)	3476.27 (2873.661)	-13.87 (26.990)	1730.30 (1303.619)	-53.41 (18.954)
	95% CI of Mean	1312.67, 1872.84	-59.69, -50.80	2580.77, 4371.77	-22.28, -5.45	1313.38, 2147.22	-59.48, -47.35

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1343.09 (59.83)		2678.42 (96.57)		1471.91 (70.96)	
	95% CI of Geometric Mean	1185.60, 1521.50		2079.82, 3449.29		1200.01, 1805.41	
	Median	1180.16	-56.05	3033.36	-11.18	1433.07	-52.77
	Q25, Q75	890.24, 2039.80	-70.44, -40.20	1791.38, 4122.91	-29.77, 0.00	959.68, 2128.44	-66.97, -40.41
	Min, Max	421.7, 5827.7	-81.4, 0.5	125.0, 11955.4	-51.4, 44.5	514.6, 11456.3	-79.1, 41.1
	Mean (SD)	1580.60 (1031.274)	-53.39 (20.023)	3470.80 (2520.367)	-12.64 (20.197)	1867.21 (1815.040)	-50.90 (22.992)
	95% CI of Mean	1348.08, 1813.12	-57.91, -48.87	2685.39, 4256.20	-18.94, -6.34	1286.72, 2447.69	-58.26, -43.54

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1131.18 (63.09)		2235.37 (94.47)		1140.42 (64.40)	
	95% CI of Geometric Mean	992.77, 1288.88		1742.88, 2867.03		944.62, 1376.80	
	Median	1053.24	-62.33	2501.92	-26.12	1194.84	-64.48
	Q25, Q75	773.49, 1722.72	-74.86, -49.77	1497.40, 3333.33	-41.57, -14.69	730.08, 1417.01	-76.20, -50.37
	Min, Max	390.7, 5784.0	-85.7, 0.0	126.5, 11088.4	-63.2, 29.9	308.2, 6801.6	-87.9, -20.8
	Mean (SD)	1352.75 (948.482)	-60.57 (17.922)	2929.90 (2345.110)	-26.60 (18.875)	1376.26 (1086.647)	-61.44 (17.648)
	95% CI of Mean	1138.89, 1566.60	-64.62, -56.52	2199.11, 3660.69	-32.48, -20.71	1028.73, 1723.79	-67.09, -55.79

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1745.82 (71.00)		4019.49 (107.42)		1626.50 (68.25)	
	95% CI of Geometric Mean	1511.61, 2016.32		3059.34, 5280.97		1334.64, 1982.19	
	Median	1641.24	-43.08	4762.66	17.01	1845.07	-48.75
	Q25, Q75	1194.62, 2511.63	-66.26, -16.31	1890.95, 7160.24	-5.07, 60.95	978.56, 2713.87	-68.58, -23.83
	Min, Max	339.4, 6751.0	-81.6, 114.8	209.3, 15710.7	-57.4, 437.4	558.8, 5779.2	-83.6, 49.2
	Mean (SD)	2130.69 (1436.466)	-35.38 (38.296)	5418.45 (3871.151)	42.06 (81.256)	1943.56 (1174.048)	-43.05 (30.747)
	95% CI of Mean	1806.81, 2454.57	-44.01, -26.74	4212.11, 6624.79	16.73, 67.39	1568.08, 2319.05	-52.89, -33.21

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1668.36 (62.13)		3761.90 (94.78)		1669.89 (66.50)	
	95% CI of Geometric Mean	1466.73, 1897.71		2931.31, 4827.84		1376.07, 2026.45	
	Median	1613.10	-48.80	4093.25	20.09	1688.87	-49.52
	Q25, Q75	1192.31, 2454.09	-64.55, -13.82	2593.22, 6423.84	-15.96, 69.88	1031.82, 2642.82	-68.26, -22.29
	Min, Max	493.3, 5570.6	-82.5, 58.5	262.5, 12786.6	-47.3, 177.9	510.9, 8291.1	-83.6, 53.7
	Mean (SD)	1951.17 (1126.360)	-39.32 (32.131)	4831.47 (3118.433)	29.29 (52.815)	2005.99 (1403.267)	-40.97 (32.991)
	95% CI of Mean	1697.21, 2205.13	-46.57, -32.07	3859.69, 5803.25	12.82, 45.75	1557.20, 2454.78	-51.52, -30.41

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	1690.42 (67.27)		3728.77 (101.42)		1653.48 (78.61)	
	95% CI of Geometric Mean	1472.88, 1940.08		2869.12, 4845.99		1324.53, 2064.13	
	Median	1659.13	-47.33	3544.73	10.84	1800.23	-48.87
	Q25, Q75	1057.14, 2783.36	-61.62, -21.18	2592.59, 5719.42	-7.03, 58.67	933.99, 2587.94	-69.29, -18.69
	Min, Max	487.4, 7396.3	-85.3, 69.8	185.7, 19069.8	-50.7, 301.4	477.8, 7776.7	-89.6, 78.9
	Mean (SD)	2036.70 (1347.611)	-38.23 (34.406)	5076.80 (4347.686)	32.34 (70.279)	2077.63 (1500.205)	-37.87 (40.566)
	95% CI of Mean	1732.86, 2340.55		3721.96, 6431.64		1597.84, 2557.43	

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3791.75 (79.78)	3733.82 (82.05)	3911.65 (81.11)
	95% CI of Geometric Mean	3236.84, 4441.79	2985.78, 4669.28	3116.08, 4910.33
	Median	3914.34	4372.65	3906.23
	Q25, Q75	2362.92, 6091.60	2770.56, 5730.76	2212.84, 6591.45
	Min, Max	630.4, 17578.8	329.0, 15438.3	947.7, 16650.4
	Mean (SD)	4812.88 (3558.505)	4596.90 (2866.904)	4928.00 (3386.573)
	95% CI of Mean	4010.56, 5615.20	3703.51, 5490.30	3844.92, 6011.08

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2589.85 (65.32)	3675.15 (89.14)	2697.17 (71.46)
	95% CI of Geometric Mean	2264.18, 2962.37	2895.93, 4664.03	2196.38, 3312.15
	Median	2500.22	4276.92	2540.08
	Q25, Q75	1642.17, 3551.16	2409.24, 6101.84	1906.83, 3931.76
	Min, Max	670.2, 14671.8	342.7, 15409.2	613.1, 12444.0
	Mean (SD)	3138.90 (2372.444)	4671.43 (3117.532)	3304.87 (2363.446)
	95% CI of Mean	2603.99, 3673.81	3699.93, 5642.92	2549.00, 4060.75

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1933.25 (55.20)	3465.26 (94.83)	2043.55 (56.34)
	95% CI of Geometric Mean	1721.03, 2171.64	2699.91, 4447.57	1727.67, 2417.18
	Median	1960.72	3812.08	2024.40
	Q25, Q75	1373.85, 2678.66	2221.35, 5530.14	1414.77, 2756.94
	Min, Max	406.3, 6736.3	247.1, 20353.5	479.7, 8932.5
	Mean (SD)	2206.35 (1223.591)	4575.39 (3667.991)	2347.27 (1438.176)
	95% CI of Mean	1930.47, 2482.23	3432.36, 5718.42	1887.31, 2807.22

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1572.73 (52.08)	3166.74 (94.95)	1692.07 (54.97)
	95% CI of Geometric Mean	1408.27, 1756.40	2466.74, 4065.40	1435.67, 1994.26
	Median	1582.24	3141.53	1689.96
	Q25, Q75	1134.26, 2013.06	2250.36, 5323.40	1105.92, 2294.87
	Min, Max	456.0, 6296.9	233.5, 16005.9	623.1, 5900.9
	Mean (SD)	1787.32 (1053.145)	4155.89 (3164.826)	1939.44 (1149.035)
	95% CI of Mean	1549.87, 2024.77	3169.66, 5142.13	1571.95, 2306.92

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1638.97 (50.58)	3059.73 (87.97)	1692.12 (57.10)
	95% CI of Geometric Mean	1471.76, 1825.17	2416.75, 3873.78	1427.74, 2005.47
	Median	1597.16	3331.70	1674.79
	Q25, Q75	1099.73, 2198.12	2272.04, 5050.24	1113.97, 2218.03
	Min, Max	501.7, 4797.1	212.2, 13101.0	602.2, 6818.0
	Mean (SD)	1838.55 (944.727)	3838.53 (2491.751)	1956.47 (1206.525)
	95% CI of Mean	1625.54, 2051.56	3062.04, 4615.02	1570.60, 2342.34

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1322.86 (50.07)	2770.15 (89.85)	1377.75 (52.41)
	95% CI of Geometric Mean	1189.07, 1471.70	2179.67, 3520.60	1176.92, 1612.85
	Median	1307.31	2725.77	1418.89
	Q25, Q75	958.42, 1765.21	1910.59, 4140.90	1018.24, 1821.86
	Min, Max	448.7, 4458.1	217.1, 14920.3	429.1, 5004.7
	Mean (SD)	1485.89 (801.419)	3595.15 (2835.107)	1559.13 (892.702)
	95% CI of Mean	1305.19, 1666.58	2711.66, 4478.64	1273.63, 1844.64

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2065.95 (62.54)	4687.75 (102.88)	1727.46 (71.41)
	95% CI of Geometric Mean	1814.95, 2351.65	3597.29, 6108.75	1406.86, 2121.12
	Median	2179.56	5489.04	1721.35
	Q25, Q75	1415.61, 3017.80	2625.38, 8921.47	1030.49, 2464.60
	Min, Max	391.5, 7656.0	360.3, 21129.6	460.0, 7166.3
	Mean (SD)	2410.22 (1384.798)	6183.51 (4169.509)	2119.51 (1490.404)
	95% CI of Mean	2098.00, 2722.45	4884.19, 7482.82	1642.85, 2596.17

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1913.17 (54.49)	4331.63 (84.12)	1887.33 (70.62)
	95% CI of Geometric Mean	1705.41, 2146.23	3448.68, 5440.64	1539.92, 2313.11
	Median	1981.37	4876.32	2095.16
	Q25, Q75	1362.47, 2774.06	2806.70, 7116.64	1149.73, 2775.53
	Min, Max	637.4, 5866.9	498.0, 16005.2	390.3, 9733.3
	Mean (SD)	2170.68 (1132.563)	5420.18 (3474.358)	2298.53 (1640.027)
	95% CI of Mean	1915.32, 2426.04	4337.49, 6502.87	1774.02, 2823.04

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	1919.40 (63.05)	4090.31 (92.73)	1859.32 (73.14)
	95% CI of Geometric Mean	1684.68, 2186.82	3199.99, 5228.33	1508.13, 2292.28
	Median	1871.59	4121.58	1742.42
	Q25, Q75	1188.52, 2854.88	2788.60, 6415.93	1226.72, 2486.63
	Min, Max	503.6, 6832.8	290.5, 18984.6	485.0, 8138.2
	Mean (SD)	2259.22 (1354.575)	5373.48 (4261.019)	2308.49 (1705.094)
	95% CI of Mean	1953.80, 2564.63	4045.65, 6701.31	1763.17, 2853.82

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	83.73 (85.49)		82.00 (69.49)		71.96 (66.07)	
	95% CI of Geometric Mean	70.69, 99.18		67.42, 99.71		59.20, 87.47	
	Median	77.92		86.65		68.48	
	Q25, Q75	54.75, 142.11		59.54, 118.41		42.74, 123.97	
	Min, Max	13.6, 365.7		16.5, 318.4		18.4, 220.3	
	Mean (SD)	108.14 (79.820)		97.94 (61.598)		85.28 (50.216)	
	95% CI of Mean	89.89, 126.38		78.74, 117.14		69.00, 101.57	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	34.89 (69.66)		75.93 (60.05)		29.62 (68.43)	
	95% CI of Geometric Mean	30.22, 40.29		63.87, 90.27		24.22, 36.21	
	Median	31.70	-59.08	76.71	-8.87	32.04	-57.41
	Q25, Q75	22.28, 56.81	-68.48, -47.10	56.97, 108.94	-23.17, 8.61	20.45, 47.76	-70.17, -40.58
	Min, Max	10.4, 212.1	-82.6, 34.9	16.6, 230.0	-59.1, 122.0	6.1, 92.3	-89.7, 23.3
	Mean (SD)	43.08 (33.414)	-53.79 (24.169)	87.34 (46.756)	-2.85 (32.194)	35.10 (20.142)	-52.90 (25.483)
	95% CI of Mean	35.44, 50.72	-59.31, -48.26	72.77, 101.92	-12.89, 7.19	28.57, 41.63	-61.16, -44.63

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	19.60 (57.06)		69.15 (68.31)		18.72 (44.22)	
	95% CI of Geometric Mean	17.35, 22.13		57.02, 83.86		16.32, 21.47	
	Median	20.78	-77.94	73.73	-21.46	18.66	-75.45
	Q25, Q75	14.94, 25.06	-85.91, -61.44	47.66, 112.53	-28.23, 0.00	15.19, 22.28	-84.88, -56.30
	Min, Max	4.6, 76.7	-94.4, 23.8	13.3, 233.9	-50.9, 102.8	7.4, 53.0	-92.1, 9.8
	Mean (SD)	22.56 (13.340)	-70.62 (21.730)	81.88 (46.681)	-11.24 (31.541)	20.43 (9.161)	-66.55 (27.129)
	95% CI of Mean	19.51, 25.61	-75.59, -65.65	67.33, 96.44	-21.07, -1.41	17.45, 23.40	-75.35, -57.75

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	17.46 (51.65)		67.93 (73.82)		18.21 (50.97)	
	95% CI of Geometric Mean	15.62, 19.52		55.30, 83.43		15.58, 21.28	
	Median	18.27	-79.86	74.14	-18.22	18.14	-77.30
	Q25, Q75	13.02, 23.19	-87.38, -65.66	45.72, 109.72	-29.93, 4.03	15.01, 22.81	-84.41, -57.90
	Min, Max	5.4, 66.0	-94.7, 44.4	13.9, 209.5	-69.5, 98.6	6.0, 62.2	-93.9, 41.3
	Mean (SD)	19.68 (10.728)	-73.08 (22.938)	81.70 (46.811)	-11.42 (34.424)	20.40 (10.667)	-66.68 (28.192)
	95% CI of Mean	17.22, 22.14	-78.33, -67.84	67.11, 96.30	-22.16, -0.69	16.94, 23.86	-75.82, -57.54

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	17.97 (66.48)		73.90 (67.62)		18.20 (50.49)	
	95% CI of Geometric Mean	15.64, 20.64		61.03, 89.48		15.59, 21.25	
	Median	18.16	-79.08	84.03	-7.13	19.00	-77.34
	Q25, Q75	12.20, 23.82	-85.76, -67.96	50.43, 113.53	-26.42, 11.55	12.94, 22.81	-83.00, -58.36
	Min, Max	4.0, 89.9	-94.4, 35.9	15.8, 203.6	-56.7, 54.3	7.6, 60.7	-93.5, 25.7
	Mean (SD)	21.72 (15.793)	-73.12 (20.832)	86.68 (45.386)	-6.20 (26.216)	20.47 (11.318)	-66.19 (29.816)
	95% CI of Mean	18.11, 25.33	-77.89, -68.36	72.53, 100.83	-14.37, 1.98	16.80, 24.15	-75.86, -56.52

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	20.72 (49.56)		75.10 (63.71)		17.84 (46.35)	
	95% CI of Geometric Mean	18.61, 23.07		62.60, 90.08		15.45, 20.58	
	Median	19.94	-75.77	89.74	-9.14	18.52	-78.62
	Q25, Q75	15.36, 27.90	-84.18, -61.92	45.35, 114.51	-23.52, 12.71	14.14, 23.06	-84.76, -62.23
	Min, Max	4.8, 79.6	-93.2, 53.9	17.8, 177.6	-55.3, 105.5	7.4, 50.6	-93.5, 16.1
	Mean (SD)	23.11 (11.835)	-68.42 (25.608)	86.67 (42.089)	-3.79 (31.763)	19.61 (9.164)	-67.04 (28.608)
	95% CI of Mean	20.40, 25.82	-74.27, -62.56	73.55, 99.79	-13.70, 6.11	16.63, 22.59	-76.32, -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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	85.03 (85.90)		81.35 (70.25)		71.96 (66.07)	
	95% CI of Geometric Mean	71.57, 101.02		66.60, 99.35		59.20, 87.47	
	Median	79.07		86.43		68.48	
	Q25, Q75	55.01, 144.66		59.54, 118.41		42.74, 123.97	
	Min, Max	13.6, 365.7		16.5, 318.4		18.4, 220.3	
	Mean (SD)	109.74 (80.267)		97.56 (62.313)		85.28 (50.216)	
	95% CI of Mean	91.14, 128.34		77.88, 117.23		69.00, 101.57	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	34.53 (102.87)		89.38 (68.64)		28.34 (82.22)	
	95% CI of Geometric Mean	28.35, 42.04		73.46, 108.75		22.45, 35.78	
	Median	32.25	-62.14	94.90	5.86	25.05	-60.49
	Q25, Q75	20.42, 61.10	-77.10, -31.38	68.12, 132.18	-6.43, 41.09	18.01, 34.63	-79.09, -46.79
	Min, Max	3.9, 286.2	-93.2, 539.8	11.1, 287.3	-77.1, 461.1	9.7, 364.6	-88.2, 206.8
	Mean (SD)	50.42 (53.100)	-33.69 (98.389)	104.66 (55.742)	25.69 (82.740)	40.69 (58.329)	-43.27 (63.545)
	95% CI of Mean	38.11, 62.73	-56.49, -10.89	87.06, 122.26	-0.44, 51.81	21.78, 59.61	-63.88, -22.67

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	87.50 (85.32)		81.35 (70.25)		71.24 (66.68)	
	95% CI of Geometric Mean	73.44, 104.24		66.60, 99.35		58.36, 86.95	
	Median	85.35		86.43		68.43	
	Q25, Q75	55.75, 155.60		59.54, 118.41		42.74, 123.97	
	Min, Max	13.6, 365.7		16.5, 318.4		18.4, 220.3	
	Mean (SD)	112.37 (80.819)		97.56 (62.313)		84.74 (50.773)	
	95% CI of Mean	93.24, 131.51		77.88, 117.23		68.05, 101.43	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	30.93 (145.26)		90.12 (79.76)		28.95 (93.65)	
	95% CI of Geometric Mean	24.03, 39.80		72.22, 112.47		22.30, 37.58	
	Median	25.07	-67.79	91.14	3.36	32.83	-60.71
	Q25, Q75	16.21, 57.36	-82.77, -50.51	62.53, 131.25	-23.91, 54.03	14.74, 54.12	-79.22, -18.31
	Min, Max	5.7, 4242.4	-94.6, 7088.3	19.4, 470.9	-73.9, 801.8	5.4, 107.2	-94.6, 134.6
	Mean (SD)	102.68 (500.568)	52.67 (850.223)	115.65 (96.005)	41.88 (143.796)	37.99 (26.712)	-39.82 (55.579)
	95% CI of Mean	-15.81, 221.16	-148.58, 253.92	85.34, 145.96	-3.51, 87.27	29.21, 46.78	-58.10, -21.55

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	88.20 (84.22)		81.35 (70.25)		72.17 (67.07)	
	95% CI of Geometric Mean	74.07, 105.03		66.60, 99.35		58.89, 88.43	
	Median	88.61		86.43		68.48	
	Q25, Q75	55.01, 155.60		59.54, 118.41		42.74, 123.97	
	Min, Max	13.6, 365.7		16.5, 318.4		18.4, 220.3	
	Mean (SD)	113.02 (81.156)		97.56 (62.313)		85.84 (51.012)	
	95% CI of Mean	93.67, 132.38		77.88, 117.23		68.83, 102.85	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	30.02 (82.33)		86.92 (66.68)		28.88 (85.51)	
	95% CI of Geometric Mean	25.29, 35.65		71.78, 105.27		22.56, 36.98	
	Median	27.14	-70.78	91.09	9.36	29.74	-56.92
	Q25, Q75	18.77, 52.59	-80.79, -45.78	60.67, 148.46	-17.54, 41.48	17.27, 51.42	-77.07, -31.94
	Min, Max	7.7, 188.8	-92.8, 203.5	19.4, 236.6	-71.6, 348.5	5.2, 164.0	-92.2, 123.4
	Mean (SD)	39.54 (34.490)	-49.20 (56.520)	102.07 (54.954)	21.49 (71.249)	37.87 (31.738)	-46.51 (45.369)
	95% CI of Mean	31.31, 47.77	-62.68, -35.71	84.72, 119.42	-1.00, 43.99	27.28, 48.45	-61.64, -31.37

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	100.76 (90.22)	97.24 (76.12)	86.45 (67.99)
	95% CI of Geometric Mean	84.47, 120.19	78.76, 120.05	70.79, 105.57
	Median	109.94	107.24	85.47
	Q25, Q75	61.16, 192.36	75.48, 133.49	54.97, 154.58
	Min, Max	12.7, 395.3	15.5, 379.2	29.4, 258.4
	Mean (SD)	129.36 (85.120)	118.97 (78.490)	103.00 (59.946)
	95% CI of Mean	109.90, 148.81	94.50, 143.43	83.56, 122.43

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	40.56 (66.34)	91.05 (80.45)	32.38 (74.94)
	95% CI of Geometric Mean	35.32, 46.56	73.05, 113.48	26.08, 40.21
	Median	41.17	102.83	35.94
	Q25, Q75	24.16, 59.10	59.40, 128.29	20.22, 53.47
	Min, Max	9.2, 165.2	10.3, 340.0	6.5, 109.2
	Mean (SD)	48.46 (30.455)	111.46 (67.939)	39.64 (25.380)
	95% CI of Mean	41.50, 55.43	90.28, 132.63	31.41, 47.87

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	23.20 (51.28)	86.18 (79.57)	21.79 (47.23)
	95% CI of Geometric Mean	20.77, 25.92	69.28, 107.20	18.84, 25.21
	Median	23.99	94.47	23.71
	Q25, Q75	16.72, 29.55	58.69, 135.97	17.51, 29.86
	Min, Max	5.7, 78.1	13.6, 253.4	4.9, 40.8
	Mean (SD)	26.13 (14.436)	105.70 (63.961)	23.69 (8.775)
	95% CI of Mean	22.83, 29.44	85.77, 125.64	20.84, 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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	21.19 (40.74)	82.97 (79.27)	21.96 (51.74)
	95% CI of Geometric Mean	19.37, 23.18	66.74, 103.14	18.75, 25.72
	Median	21.93	92.89	23.26
	Q25, Q75	17.58, 26.68	57.05, 142.66	19.39, 31.08
	Min, Max	6.0, 76.1	15.0, 258.9	4.8, 56.0
	Mean (SD)	22.89 (10.082)	101.59 (60.423)	24.26 (10.117)
	95% CI of Mean	20.59, 25.20	82.75, 120.42	20.97, 27.54

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	21.94 (62.02)	84.42 (81.94)	21.12 (39.75)
	95% CI of Geometric Mean	19.25, 25.00	67.52, 105.55	18.65, 23.92
	Median	21.01	104.90	19.83
	Q25, Q75	15.31, 29.93	58.72, 136.89	16.49, 28.63
	Min, Max	4.9, 82.5	8.5, 283.6	9.0, 42.3
	Mean (SD)	25.96 (16.876)	103.14 (59.481)	22.66 (8.627)
	95% CI of Mean	22.10, 29.82	84.60, 121.68	19.85, 25.46

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	24.23 (45.24)	93.06 (68.06)	21.77 (43.84)
	95% CI of Geometric Mean	21.95, 26.74	76.78, 112.79	19.00, 24.95
	Median	25.48	101.96	21.50
	Q25, Q75	19.24, 32.41	66.62, 140.59	17.14, 30.73
	Min, Max	8.3, 69.4	17.7, 224.9	6.9, 43.8
	Mean (SD)	26.46 (11.336)	108.75 (54.537)	23.58 (9.142)
	95% CI of Mean	23.86, 29.05	91.75, 125.75	20.61, 26.55

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	101.79 (90.46)	95.67 (76.12)	86.45 (67.99)
	95% CI of Geometric Mean	85.09, 121.77	77.28, 118.43	70.79, 105.57
	Median	109.94	105.11	85.47
	Q25, Q75	61.52, 194.18	75.48, 132.27	54.97, 154.58
	Min, Max	12.7, 395.3	15.5, 379.2	29.4, 258.4
	Mean (SD)	130.64 (85.601)	117.25 (78.662)	103.00 (59.946)
	95% CI of Mean	110.80, 150.47	92.42, 142.08	83.56, 122.43

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	40.84 (107.05)	103.34 (81.84)	30.32 (82.29)
	95% CI of Geometric Mean	33.35, 50.01	82.43, 129.55	24.01, 38.28
	Median	35.89	120.71	26.26
	Q25, Q75	21.80, 70.78	72.19, 168.01	21.02, 38.18
	Min, Max	5.8, 374.4	13.7, 394.2	5.8, 254.9
	Mean (SD)	61.53 (69.436)	126.83 (75.287)	41.64 (46.301)
	95% CI of Mean	45.44, 77.63	103.06, 150.60	26.63, 56.66

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	104.85 (89.32)	95.67 (76.12)	85.30 (68.33)
	95% CI of Geometric Mean	87.46, 125.69	77.28, 118.43	69.59, 104.56
	Median	113.59	105.11	82.76
	Q25, Q75	61.52, 196.13	75.48, 132.27	54.97, 154.58
	Min, Max	12.7, 395.3	15.5, 379.2	29.4, 258.4
	Mean (SD)	133.71 (85.955)	117.25 (78.662)	101.93 (60.376)
	95% CI of Mean	113.36, 154.06	92.42, 142.08	82.08, 121.78

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	35.66 (149.55)	102.84 (92.75)	32.89 (97.03)
	95% CI of Geometric Mean	27.58, 46.09	80.19, 131.88	25.16, 42.99
	Median	29.44	96.34	31.17
	Q25, Q75	16.55, 67.67	67.35, 161.46	17.69, 55.32
	Min, Max	4.1, 5472.9	17.6, 763.2	9.7, 168.4
	Mean (SD)	127.75 (646.612)	139.52 (130.271)	45.70 (39.844)
	95% CI of Mean	-25.31, 280.80	98.39, 180.64	32.60, 58.80

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	104.33 (90.49)	95.67 (76.12)	87.23 (67.38)
	95% CI of Geometric Mean	86.75, 125.46	77.28, 118.43	71.13, 106.97
	Median	111.99	105.11	85.47
	Q25, Q75	61.52, 196.13	75.48, 132.27	56.81, 154.58
	Min, Max	12.7, 395.3	15.5, 379.2	29.4, 258.4
	Mean (SD)	133.64 (86.618)	117.25 (78.662)	103.68 (60.228)
	95% CI of Mean	112.98, 154.30	92.42, 142.08	83.59, 123.77

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	33.88 (74.00)	94.38 (85.19)	32.70 (83.15)
	95% CI of Geometric Mean	28.94, 39.67	74.75, 119.17	25.68, 41.65
	Median	31.88	95.83	30.94
	Q25, Q75	21.30, 59.31	64.11, 156.51	19.34, 51.36
	Min, Max	8.3, 165.7	14.4, 401.4	7.2, 225.8
	Mean (SD)	42.24 (31.207)	118.83 (78.699)	43.46 (41.644)
	95% CI of Mean	34.79, 49.68	93.98, 143.68	29.57, 57.35

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	82.69 (88.46)		82.00 (69.49)		73.16 (66.24)	
	95% CI of Geometric Mean	69.66, 98.16		67.42, 99.71		60.32, 88.73	
	Median	77.92		86.65		69.16	
	Q25, Q75	54.50, 144.66		59.54, 118.41		43.37, 123.98	
	Min, Max	13.6, 365.7		16.5, 318.4		18.4, 220.3	
	Mean (SD)	107.77 (79.813)		97.94 (61.598)		86.63 (50.297)	
	95% CI of Mean	89.77, 125.77		78.74, 117.14		70.54, 102.72	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	34.64 (69.56)		75.93 (60.05)		30.20 (68.99)	
	95% CI of Geometric Mean	30.06, 39.91		63.87, 90.27		24.73, 36.88	
	Median	31.70	-59.08	76.71	-8.87	32.73	-57.40
	Q25, Q75	21.85, 56.19	-68.69, -46.86	56.97, 108.94	-23.17, 8.61	20.78, 47.93	-70.01, -41.90
	Min, Max	10.4, 212.1	-82.6, 34.9	16.6, 230.0	-59.1, 122.0	6.1, 92.3	-89.7, 23.3
	Mean (SD)	42.74 (33.126)	-53.36 (24.735)	87.34 (46.756)	-2.85 (32.194)	35.84 (20.418)	-52.92 (25.154)
	95% CI of Mean	35.26, 50.21	-58.94, -47.78	72.77, 101.92	-12.89, 7.19	29.30, 42.37	-60.97, -44.87

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	19.51 (56.31)		69.15 (68.31)		18.97 (44.51)	
	95% CI of Geometric Mean	17.33, 21.97		57.02, 83.86		16.55, 21.73	
	Median	20.43	-77.94	73.73	-21.46	19.06	-75.89
	Q25, Q75	14.97, 24.95	-86.30, -61.16	47.66, 112.53	-28.23, 0.00	15.56, 23.97	-84.68, -57.52
	Min, Max	4.6, 76.7	-94.4, 23.8	13.3, 233.9	-50.9, 102.8	7.4, 53.0	-92.1, 9.8
	Mean (SD)	22.40 (13.202)	-69.96 (23.001)	81.88 (46.681)	-11.24 (31.541)	20.71 (9.210)	-66.82 (26.834)
	95% CI of Mean	19.42, 25.38	-75.16, -64.77	67.33, 96.44	-21.07, -1.41	17.76, 23.66	-75.41, -58.24

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	17.38 (51.01)		67.93 (73.82)		18.46 (51.16)	
	95% CI of Geometric Mean	15.59, 19.37		55.30, 83.43		15.82, 21.54	
	Median	17.95	-79.86	74.14	-18.22	18.82	-77.34
	Q25, Q75	13.09, 23.06	-87.40, -65.29	45.72, 109.72	-29.93, 4.03	15.30, 22.81	-83.97, -58.16
	Min, Max	5.4, 66.0	-94.7, 44.4	13.9, 209.5	-69.5, 98.6	6.0, 62.2	-93.9, 41.3
	Mean (SD)	19.55 (10.620)	-72.39 (24.207)	81.70 (46.811)	-11.42 (34.424)	20.68 (10.674)	-66.95 (27.880)
	95% CI of Mean	17.15, 21.95	-77.85, -66.93	67.11, 96.30	-22.16, -0.69	17.26, 24.09	-75.87, -58.03

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	18.02 (65.70)		73.90 (67.62)		18.45 (50.70)	
	95% CI of Geometric Mean	15.74, 20.64		61.03, 89.48		15.83, 21.51	
	Median	18.16	-79.08	84.03	-7.13	19.01	-77.37
	Q25, Q75	12.50, 24.27	-85.70, -67.72	50.43, 113.53	-26.42, 11.55	13.03, 23.42	-82.99, -58.36
	Min, Max	4.0, 89.9	-94.4, 35.9	15.8, 203.6	-56.7, 54.3	7.6, 60.7	-93.5, 25.7
	Mean (SD)	21.71 (15.614)	-72.33 (22.207)	86.68 (45.386)	-6.20 (26.216)	20.75 (11.307)	-66.47 (29.484)
	95% CI of Mean	18.18, 25.23	-77.34, -67.32	72.53, 100.83	-14.37, 1.98	17.13, 24.37	-75.90, -57.03

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	20.55 (49.18)		75.10 (63.71)		18.09 (46.75)	
	95% CI of Geometric Mean	18.50, 22.83		62.60, 90.08		15.69, 20.86	
	Median	19.51	-75.77	89.74	-9.14	18.70	-78.61
	Q25, Q75	15.26, 27.90	-84.26, -61.61	45.35, 114.51	-23.52, 12.71	14.29, 23.06	-84.66, -64.02
	Min, Max	4.8, 79.6	-93.2, 53.9	17.8, 177.6	-55.3, 105.5	7.4, 50.6	-93.5, 16.1
	Mean (SD)	22.90 (11.751)	-67.84 (26.573)	86.67 (42.089)	-3.79 (31.763)	19.91 (9.239)	-67.30 (28.286)
	95% CI of Mean	20.25, 25.56	-73.83, -61.84	73.55, 99.79	-13.70, 6.11	16.95, 22.87	-76.35, -58.25

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	34.14 (100.00)		89.89 (67.78)		28.42 (80.89)	
	95% CI of Geometric Mean	28.29, 41.19		74.22, 108.88		22.64, 35.66	
	Median	32.00	-60.31	95.28	5.51	25.18	-62.67
	Q25, Q75	20.42, 59.64	-77.10, -31.13	68.12, 132.18	-6.43, 41.09	18.21, 34.58	-78.24, -48.67
	Min, Max	3.9, 286.2	-93.2, 539.8	11.1, 287.3	-77.1, 461.1	9.7, 364.6	-88.2, 206.8
	Mean (SD)	49.33 (51.953)	-33.66 (96.062)	104.87 (55.075)	25.07 (81.821)	40.46 (57.595)	-44.13 (62.956)
	95% CI of Mean	37.61, 61.05	-55.32, -11.99	87.70, 122.03	-0.43, 50.58	22.04, 58.89	-64.27, -23.99

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	30.97 (138.85)		90.62 (78.66)		28.59 (91.29)	
	95% CI of Geometric Mean	24.51, 39.13		72.99, 112.50		22.28, 36.68	
	Median	26.59	-67.17	91.97	2.82	31.95	-65.24
	Q25, Q75	16.21, 57.36	-79.71, -42.31	62.53, 131.25	-23.91, 54.03	15.45, 53.97	-80.60, -19.74
	Min, Max	5.7, 4242.4	-94.6, 7088.3	19.4, 470.9	-73.9, 801.8	5.4, 107.2	-94.6, 134.6
	Mean (SD)	97.03 (477.689)	49.11 (811.605)	115.60 (94.828)	40.88 (142.178)	37.28 (26.263)	-41.89 (54.902)
	95% CI of Mean	-10.68, 204.73	-133.88, 232.11	86.05, 145.16	-3.43, 85.19	28.88, 45.69	-59.45, -24.32

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	29.37 (80.54)		87.48 (65.89)		28.21 (82.59)	
	95% CI of Geometric Mean	25.04, 34.45		72.55, 105.49		22.40, 35.53	
	Median	26.17	-67.44	91.95	8.13	28.98	-58.33
	Q25, Q75	17.68, 49.21	-80.45, -38.78	60.67, 148.46	-17.54, 41.48	16.98, 46.31	-77.57, -35.45
	Min, Max	7.7, 188.8	-92.8, 203.5	19.4, 236.6	-71.6, 348.5	5.2, 164.0	-92.2, 123.4
	Mean (SD)	38.42 (33.323)	-48.15 (54.684)	102.34 (54.309)	20.98 (70.453)	36.68 (30.841)	-48.52 (44.286)
	95% CI of Mean	30.90, 45.93	-60.49, -35.82	85.41, 119.27	-0.98, 42.94	26.81, 46.55	-62.69, -34.35

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	99.15 (93.20)	97.24 (76.12)	87.05 (67.15)
	95% CI of Geometric Mean	82.95, 118.50	78.76, 120.05	71.62, 105.81
	Median	109.94	107.24	85.78
	Q25, Q75	60.81, 190.54	75.48, 133.49	55.89, 149.01
	Min, Max	12.7, 395.3	15.5, 379.2	29.4, 258.4
	Mean (SD)	128.46 (85.114)	118.97 (78.490)	103.28 (59.199)
	95% CI of Mean	109.26, 147.65	94.50, 143.43	84.34, 122.22

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	40.24 (66.50)	91.05 (80.45)	32.61 (73.95)
	95% CI of Geometric Mean	35.10, 46.12	73.05, 113.48	26.40, 40.29
	Median	41.17	102.83	36.20
	Q25, Q75	23.91, 59.00	59.40, 128.29	21.06, 49.51
	Min, Max	9.2, 165.2	10.3, 340.0	6.5, 109.2
	Mean (SD)	48.11 (30.275)	111.46 (67.939)	39.72 (25.058)
	95% CI of Mean	41.28, 54.94	90.28, 132.63	31.70, 47.74

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	23.03 (50.80)	86.18 (79.57)	21.87 (46.63)
	95% CI of Geometric Mean	20.67, 25.66	69.28, 107.20	18.97, 25.21
	Median	23.77	94.47	23.91
	Q25, Q75	16.77, 29.26	58.69, 135.97	17.98, 29.82
	Min, Max	5.7, 78.1	13.6, 253.4	4.9, 40.8
	Mean (SD)	25.91 (14.315)	105.70 (63.961)	23.73 (8.665)
	95% CI of Mean	22.68, 29.14	85.77, 125.64	20.96, 26.51

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	21.15 (40.29)	82.97 (79.27)	22.04 (51.05)
	95% CI of Geometric Mean	19.38, 23.09	66.74, 103.14	18.89, 25.71
	Median	21.93	92.89	23.34
	Q25, Q75	17.56, 26.55	57.05, 142.66	19.41, 30.05
	Min, Max	6.0, 76.1	15.0, 258.9	4.8, 56.0
	Mean (SD)	22.82 (9.975)	101.59 (60.423)	24.28 (9.988)
	95% CI of Mean	20.57, 25.08	82.75, 120.42	21.08, 27.48

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	22.00 (61.50)	84.42 (81.94)	21.21 (39.32)
	95% CI of Geometric Mean	19.35, 25.00	67.52, 105.55	18.79, 23.95
	Median	21.01	104.90	19.89
	Q25, Q75	15.35, 30.43	58.72, 136.89	16.69, 28.44
	Min, Max	4.9, 82.5	8.5, 283.6	9.0, 42.3
	Mean (SD)	25.96 (16.722)	103.14 (59.481)	22.72 (8.526)
	95% CI of Mean	22.18, 29.73	84.60, 121.68	19.99, 25.45

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	24.03 (44.94)	93.06 (68.06)	21.86 (43.30)
	95% CI of Geometric Mean	21.81, 26.47	76.78, 112.79	19.14, 24.96
	Median	25.31	101.96	21.63
	Q25, Q75	19.16, 32.09	66.62, 140.59	17.74, 29.78
	Min, Max	8.3, 69.4	17.7, 224.9	6.9, 43.8
	Mean (SD)	26.23 (11.275)	108.75 (54.537)	23.62 (9.028)
	95% CI of Mean	23.69, 28.78	91.75, 125.75	20.73, 26.52

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	40.39 (104.54)	104.84 (81.45)	30.18 (81.02)
	95% CI of Geometric Mean	33.27, 49.04	83.94, 130.94	24.04, 37.88
	Median	35.89	122.47	26.14
	Q25, Q75	21.80, 70.76	72.19, 169.44	21.06, 37.51
	Min, Max	5.8, 374.4	13.7, 394.2	5.8, 254.9
	Mean (SD)	60.27 (67.944)	128.32 (74.987)	41.24 (45.777)
	95% CI of Mean	44.95, 75.60	104.94, 151.69	26.59, 55.88

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	35.51 (141.78)	104.35 (92.12)	32.31 (94.27)
	95% CI of Geometric Mean	28.02, 45.00	81.73, 133.22	25.03, 41.71
	Median	30.64	97.58	25.88
	Q25, Q75	16.74, 63.79	67.35, 172.64	17.73, 54.26
	Min, Max	4.1, 5472.9	17.6, 763.2	9.7, 168.4
	Mean (SD)	119.97 (617.074)	140.70 (128.902)	44.58 (39.127)
	95% CI of Mean	-19.16, 259.11	100.53, 180.88	32.06, 57.10

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	33.35 (72.49)	95.96 (85.01)	31.72 (80.32)
	95% CI of Geometric Mean	28.80, 38.61	76.25, 120.76	25.31, 39.76
	Median	31.54	103.79	30.66
	Q25, Q75	20.79, 55.92	64.11, 157.17	19.34, 48.96
	Min, Max	8.3, 165.7	14.4, 401.4	7.2, 225.8
	Mean (SD)	41.34 (30.297)	120.51 (78.492)	41.85 (40.426)
	95% CI of Mean	34.51, 48.18	96.04, 144.97	28.91, 54.78

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	300.07 (54.75)		298.73 (52.04)		298.08 (46.40)	
	95% CI of Geometric Mean	266.94, 337.32		256.46, 347.96		258.32, 343.96	
	Median	295.33		292.04		302.37	
	Q25, Q75	228.56, 419.34		235.84, 456.43		204.52, 451.61	
	Min, Max	91.9, 1098.6		118.3, 715.8		138.5, 692.6	
	Mean (SD)	341.31 (185.048)		334.65 (161.383)		328.05 (148.990)	
	95% CI of Mean	299.02, 383.60		284.35, 384.94		279.74, 376.35	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	115.14 (36.56)		244.79 (52.70)		103.15 (31.08)	
	95% CI of Geometric Mean	106.19, 124.85		209.79, 285.63		93.48, 113.82	
	Median	113.14	-60.96	245.15	-17.02	95.82	-66.28
	Q25, Q75	90.28, 147.27	-70.59, -51.71	167.11, 353.51	-33.14, 1.35	86.32, 127.76	-73.13, -53.15
	Min, Max	53.7, 326.5	-86.2, 2.3	97.0, 714.6	-61.4, 39.8	61.5, 226.2	-88.6, -7.9
	Mean (SD)	122.77 (47.446)	-57.76 (19.719)	276.37 (145.354)	-14.08 (26.313)	108.23 (37.062)	-61.96 (17.949)
	95% CI of Mean	111.92, 133.62	-62.27, -53.25	231.07, 321.67	-22.28, -5.87	96.21, 120.25	-67.79, -56.14

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	121.98 (33.76)		263.28 (50.99)		114.44 (36.36)	
	95% CI of Geometric Mean	113.16, 131.50		226.65, 305.83		102.08, 128.29	
	Median	120.11	-56.55	272.95	-17.45	105.56	-60.83
	Q25, Q75	99.73, 146.20	-71.32, -40.45	186.09, 366.41	-26.12, 3.73	92.41, 136.36	-74.39, -47.64
	Min, Max	64.0, 292.9	-86.9, 47.6	87.8, 710.5	-54.1, 125.9	69.0, 344.9	-87.6, 1.2
	Mean (SD)	128.94 (46.187)	-53.47 (25.322)	293.62 (139.232)	-7.30 (32.808)	122.63 (54.428)	-56.59 (22.189)
	95% CI of Mean	118.38, 139.50	-59.26, -47.68	250.23, 337.01	-17.53, 2.93	104.99, 140.28	-63.79, -49.39

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	115.03 (43.50)		263.67 (50.03)		100.19 (37.80)	
	95% CI of Geometric Mean	104.59, 126.51		227.56, 305.52		88.99, 112.79	
	Median	121.41	-59.52	267.79	-12.26	93.81	-64.75
	Q25, Q75	84.38, 147.45	-74.14, -45.09	189.50, 384.83	-28.36, 2.52	75.44, 130.64	-78.00, -52.07
	Min, Max	46.1, 338.5	-90.7, 53.0	84.7, 710.5	-62.1, 105.2	46.6, 208.7	-87.5, -7.8
	Mean (SD)	125.44 (55.207)	-55.23 (27.131)	293.36 (138.848)	-7.06 (31.137)	107.07 (41.066)	-61.62 (20.233)
	95% CI of Mean	112.82, 138.06	-61.44, -49.03	250.09, 336.63	-16.76, 2.65	93.75, 120.38	-68.18, -55.05

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	122.86 (41.94)		293.04 (48.86)		120.89 (44.57)	
	95% CI of Geometric Mean	112.06, 134.70		253.70, 338.49		105.31, 138.78	
	Median	121.18	-60.55	295.49	3.76	110.32	-56.23
	Q25, Q75	90.50, 172.51	-72.15, -39.18	208.91, 386.95	-17.34, 15.98	87.39, 169.53	-72.71, -42.69
	Min, Max	55.7, 262.9	-90.3, 124.7	96.3, 710.5	-66.9, 153.5	57.7, 271.4	-87.2, 53.7
	Mean (SD)	132.95 (53.219)	-50.61 (36.339)	325.26 (154.847)	3.31 (35.117)	131.96 (56.322)	-53.64 (25.917)
	95% CI of Mean	120.79, 145.12	-58.91, -42.30	277.00, 373.52	-7.64, 14.26	113.69, 150.22	-62.05, -45.23

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	124.47 (34.20)		286.80 (44.27)		113.48 (42.70)	
	95% CI of Geometric Mean	115.36, 134.30		251.37, 327.21		99.38, 129.59	
	Median	123.53	-60.56	283.71	-0.96	112.07	-60.84
	Q25, Q75	98.78, 167.12	-72.35, -37.14	205.63, 384.74	-17.35, 16.57	82.35, 147.55	-75.85, -42.64
	Min, Max	63.3, 226.6	-85.9, 90.7	143.0, 710.5	-55.7, 56.1	41.8, 268.4	-87.6, 77.6
	Mean (SD)	131.32 (42.918)	-50.77 (31.779)	313.48 (138.768)	0.27 (28.726)	123.15 (52.138)	-54.44 (30.289)
	95% CI of Mean	121.51, 141.13	-58.03, -43.50	270.23, 356.73	-8.68, 9.23	106.25, 140.06	-64.26, -44.62

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	303.34 (54.98)		292.48 (50.41)		298.08 (46.40)	
	95% CI of Geometric Mean	269.29, 341.70		251.69, 339.88		258.32, 343.96	
	Median	301.22		290.28		302.37	
	Q25, Q75	231.04, 424.62		235.84, 439.19		204.52, 451.61	
	Min, Max	91.9, 1098.6		118.3, 715.8		138.5, 692.6	
	Mean (SD)	345.03 (186.059)		325.48 (151.913)		328.05 (148.990)	
	95% CI of Mean	301.92, 388.15		277.53, 373.44		279.74, 376.35	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	131.25 (47.98)		286.13 (43.02)		133.11 (53.32)	
	95% CI of Geometric Mean	118.11, 145.84		251.23, 325.87		113.18, 156.54	
	Median	133.77	-59.16	316.27	1.02	148.94	-42.64
	Q25, Q75	87.33, 197.53	-74.19, -35.35	220.89, 362.94	-25.02, 22.40	83.33, 187.18	-76.91, -23.17
	Min, Max	65.0, 326.7	-89.0, 128.0	119.3, 666.1	-81.0, 188.2	53.0, 313.9	-90.7, 80.1
	Mean (SD)	145.44 (67.643)	-44.94 (44.370)	309.76 (123.667)	8.46 (50.302)	149.05 (68.300)	-41.85 (40.257)
	95% CI of Mean	129.76, 161.12	-55.22, -34.65	270.72, 348.80	-7.42, 24.34	126.91, 171.20	-54.91, -28.80

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	311.52 (53.51)		292.48 (50.41)		292.86 (45.45)	
	95% CI of Geometric Mean	276.63, 350.81		251.69, 339.88		253.98, 337.68	
	Median	306.79		290.28		295.45	
	Q25, Q75	233.57, 428.37		235.84, 439.19		204.52, 411.52	
	Min, Max	91.9, 1098.6		118.3, 715.8		138.5, 692.6	
	Mean (SD)	352.28 (185.995)		325.48 (151.913)		321.31 (144.852)	
	95% CI of Mean	308.25, 396.31		277.53, 373.44		273.70, 368.93	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	121.00 (35.93)		269.06 (48.87)		120.42 (38.92)	
	95% CI of Geometric Mean	111.42, 131.41		232.50, 311.38		106.43, 136.24	
	Median	121.03	-61.77	289.13	-7.92	116.62	-59.17
	Q25, Q75	97.89, 151.39	-75.44, -41.60	215.35, 351.97	-28.29, 21.81	94.39, 147.24	-77.63, -36.31
	Min, Max	55.3, 375.1	-85.8, 81.3	90.9, 825.5	-81.1, 88.0	46.7, 274.1	-86.1, 95.6
	Mean (SD)	128.72 (49.409)	-54.39 (28.974)	298.62 (144.753)	-0.36 (37.954)	129.19 (52.025)	-48.84 (38.095)
	95% CI of Mean	117.02, 140.42	-61.25, -47.53	252.92, 344.31	-12.34, 11.63	112.09, 146.30	-61.36, -36.31

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	307.33 (55.04)		292.48 (50.41)		288.17 (44.79)	
	95% CI of Geometric Mean	271.85, 347.43		251.69, 339.88		249.88, 332.33	
	Median	306.19		290.28		288.52	
	Q25, Q75	231.04, 424.62		235.84, 439.19		204.52, 383.02	
	Min, Max	91.9, 1098.6		118.3, 715.8		138.5, 692.6	
	Mean (SD)	349.60 (188.533)		325.48 (151.913)		315.63 (142.486)	
	95% CI of Mean	304.64, 394.56		277.53, 373.44		268.11, 363.14	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	154.30 (52.87)		299.41 (46.17)		158.57 (56.78)	
	95% CI of Geometric Mean	137.07, 173.70		260.62, 343.97		132.95, 189.14	
	Median	136.90	-51.98	319.92	-9.32	150.00	-41.83
	Q25, Q75	103.59, 227.75	-70.21, -15.02	225.05, 416.89	-21.73, 39.21	104.27, 255.56	-67.48, -8.68
	Min, Max	59.3, 383.5	-87.6, 209.9	92.6, 691.7	-67.4, 351.5	57.0, 538.1	-88.3, 210.4
	Mean (SD)	174.93 (91.715)	-33.72 (56.714)	327.18 (135.397)	15.67 (70.758)	182.05 (102.084)	-26.90 (61.940)
	95% CI of Mean	153.05, 196.80	-47.25, -20.19	284.44, 369.92	-6.67, 38.01	148.01, 216.09	-47.56, -6.24

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	361.10 (59.40)	354.27 (69.89)	358.08 (51.86)
	95% CI of Geometric Mean	318.47, 409.44	291.06, 431.21	305.68, 419.45
	Median	379.48	352.84	362.04
	Q25, Q75	244.36, 535.42	220.89, 501.73	237.11, 478.28
	Min, Max	92.8, 1255.0	118.0, 1300.5	130.0, 952.8
	Mean (SD)	416.69 (228.548)	432.25 (294.504)	401.97 (202.877)
	95% CI of Mean	364.46, 468.92	340.47, 524.03	336.20, 467.74

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	133.82 (40.35)	293.53 (74.73)	112.78 (35.15)
	95% CI of Geometric Mean	122.45, 146.25	238.51, 361.24	100.96, 125.98
	Median	130.11	295.02	108.16
	Q25, Q75	98.44, 172.42	160.81, 467.52	96.00, 134.55
	Min, Max	57.2, 344.5	104.2, 1185.0	62.1, 376.8
	Mean (SD)	144.56 (60.690)	365.24 (257.550)	120.26 (52.676)
	95% CI of Mean	130.69, 158.44	284.97, 445.50	103.18, 137.34

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	144.42 (39.28)	328.13 (67.09)	133.20 (31.58)
	95% CI of Geometric Mean	132.44, 157.49	271.36, 396.78	120.52, 147.20
	Median	142.40	357.84	130.73
	Q25, Q75	112.89, 185.36	180.50, 504.50	102.80, 173.88
	Min, Max	45.7, 360.1	102.9, 1185.0	79.8, 341.4
	Mean (SD)	154.78 (58.771)	390.85 (237.374)	139.93 (48.844)
	95% CI of Mean	141.35, 168.22	316.87, 464.82	124.09, 155.77

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	139.61 (38.69)	322.05 (60.29)	120.85 (37.25)
	95% CI of Geometric Mean	128.19, 152.05	270.75, 383.08	107.52, 135.83
	Median	136.97	313.32	121.81
	Q25, Q75	105.59, 170.78	209.66, 500.25	101.77, 149.88
	Min, Max	70.4, 485.7	123.8, 1185.0	36.7, 305.1
	Mean (SD)	150.76 (69.509)	376.13 (227.495)	128.38 (46.350)
	95% CI of Mean	134.87, 166.65	305.23, 447.03	113.35, 143.41

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	150.00 (35.64)	334.76 (63.31)	140.26 (34.38)
	95% CI of Geometric Mean	138.60, 162.34	279.36, 401.16	125.86, 156.32
	Median	152.77	324.24	140.61
	Q25, Q75	121.05, 192.62	236.39, 481.67	108.82, 168.49
	Min, Max	73.4, 326.7	71.8, 1185.0	59.3, 277.0
	Mean (SD)	158.97 (54.711)	395.21 (248.962)	147.96 (49.287)
	95% CI of Mean	146.46, 171.48	317.62, 472.80	131.98, 163.94

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	145.53 (36.45)	355.41 (55.91)	138.54 (36.43)
	95% CI of Geometric Mean	134.25, 157.77	302.09, 418.14	123.56, 155.34
	Median	145.53	354.80	140.11
	Q25, Q75	113.87, 185.57	216.28, 510.84	102.10, 178.23
	Min, Max	43.3, 291.0	169.9, 1185.0	60.4, 301.0
	Mean (SD)	154.36 (52.799)	408.02 (231.106)	147.15 (52.753)
	95% CI of Mean	142.29, 166.43	336.00, 480.05	130.05, 164.26

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	363.13 (59.41)	343.99 (66.95)	358.08 (51.86)
	95% CI of Geometric Mean	319.70, 412.46	283.87, 416.84	305.68, 419.45
	Median	379.48	351.46	362.04
	Q25, Q75	246.93, 535.57	220.89, 498.74	237.11, 478.28
	Min, Max	92.8, 1255.0	118.0, 1300.5	130.0, 952.8
	Mean (SD)	418.98 (229.793)	413.89 (272.743)	401.97 (202.877)
	95% CI of Mean	365.74, 472.22	327.80, 499.99	336.20, 467.74

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	155.25 (39.39)	330.80 (55.67)	142.38 (55.95)
	95% CI of Geometric Mean	142.17, 169.54	280.76, 389.75	120.22, 168.63
	Median	141.03	302.06	140.78
	Q25, Q75	117.97, 222.63	238.48, 497.32	101.63, 223.38
	Min, Max	53.9, 348.7	65.1, 948.2	39.5, 324.2
	Mean (SD)	166.63 (63.860)	375.96 (198.943)	160.99 (77.172)
	95% CI of Mean	151.83, 181.43	313.16, 438.75	135.97, 186.01

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	373.29 (57.44)	343.99 (66.95)	350.69 (50.51)
	95% CI of Geometric Mean	328.97, 423.58	283.87, 416.84	299.83, 410.17
	Median	392.73	351.46	354.00
	Q25, Q75	246.97, 547.58	220.89, 498.74	237.11, 465.10
	Min, Max	92.8, 1255.0	118.0, 1300.5	130.0, 952.8
	Mean (SD)	427.59 (229.471)	413.89 (272.743)	391.74 (195.148)
	95% CI of Mean	373.27, 481.91	327.80, 499.99	327.59, 455.89

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	139.51 (35.69)	307.02 (59.31)	136.79 (59.09)
	95% CI of Geometric Mean	128.53, 151.42	258.17, 365.12	114.27, 163.75
	Median	141.65	293.49	134.93
	Q25, Q75	112.35, 187.65	202.85, 424.76	113.08, 172.38
	Min, Max	50.8, 308.5	133.4, 1002.2	18.5, 397.7
	Mean (SD)	147.57 (48.574)	357.80 (214.590)	156.69 (87.247)
	95% CI of Mean	136.06, 159.07	290.06, 425.53	128.01, 185.37

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	363.52 (59.77)	343.99 (66.95)	348.32 (51.06)
	95% CI of Geometric Mean	318.63, 414.72	283.87, 416.84	296.67, 408.96
	Median	379.48	351.46	345.96
	Q25, Q75	246.97, 535.57	220.89, 498.74	237.11, 465.10
	Min, Max	92.8, 1255.0	118.0, 1300.5	130.0, 952.8
	Mean (SD)	419.96 (231.923)	413.89 (272.743)	390.14 (197.587)
	95% CI of Mean	364.66, 475.27	327.80, 499.99	324.26, 456.03

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	174.14 (49.20)	325.10 (51.68)	179.56 (54.49)
	95% CI of Geometric Mean	155.84, 194.59	278.82, 379.06	151.48, 212.83
	Median	175.05	326.74	183.27
	Q25, Q75	125.57, 236.47	239.58, 407.03	137.76, 257.50
	Min, Max	47.4, 456.4	96.8, 990.6	39.1, 492.5
	Mean (SD)	192.81 (87.121)	365.04 (189.385)	201.92 (97.675)
	95% CI of Mean	172.04, 213.59	305.25, 424.82	169.35, 234.49

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	298.57 (55.56)		298.73 (52.04)		298.92 (45.79)	
	95% CI of Geometric Mean	265.61, 335.61		256.46, 347.96		259.99, 343.67	
	Median	295.33		292.04		303.80	
	Q25, Q75	226.09, 424.62		235.84, 456.43		211.45, 431.57	
	Min, Max	91.9, 1098.6		118.3, 715.8		138.5, 692.6	
	Mean (SD)	340.49 (185.165)		334.65 (161.383)		328.18 (147.070)	
	95% CI of Mean	298.74, 382.25		284.35, 384.94		281.14, 375.22	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	115.04 (36.10)		244.79 (52.70)		104.30 (31.53)	
	95% CI of Geometric Mean	106.31, 124.49		209.79, 285.63		94.52, 115.10	
	Median	113.14	-60.96	245.15	-17.02	95.86	-65.80
	Q25, Q75	90.62, 147.17	-70.60, -51.41	167.11, 353.51	-33.14, 1.35	86.34, 128.26	-72.63, -52.82
	Min, Max	53.7, 326.5	-86.2, 2.3	97.0, 714.6	-61.4, 39.8	61.5, 226.2	-88.6, -7.9
	Mean (SD)	122.49 (46.891)	-57.30 (20.690)	276.37 (145.354)	-14.08 (26.313)	109.55 (37.522)	-61.71 (17.792)
	95% CI of Mean	111.91, 133.07	-61.97, -52.63	231.07, 321.67	-22.28, -5.87	97.55, 121.56	-67.40, -56.01

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	123.01 (34.18)		263.28 (50.99)		116.47 (37.77)	
	95% CI of Geometric Mean	114.12, 132.58		226.65, 305.83		103.63, 130.90	
	Median	121.18	-56.15	272.95	-17.45	105.77	-60.04
	Q25, Q75	99.83, 146.49	-70.84, -40.10	186.09, 366.41	-26.12, 3.73	93.21, 136.53	-73.81, -47.04
	Min, Max	64.0, 292.9	-86.9, 47.6	87.8, 710.5	-54.1, 125.9	69.0, 344.9	-87.6, 1.2
	Mean (SD)	130.19 (47.084)	-52.78 (25.714)	293.62 (139.232)	-7.30 (32.808)	125.35 (56.403)	-55.94 (22.284)
	95% CI of Mean	119.57, 140.81	-58.58, -46.98	250.23, 337.01	-17.53, 2.93	107.31, 143.39	-63.07, -48.81

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	115.12 (42.89)		263.67 (50.03)		102.30 (39.89)	
	95% CI of Geometric Mean	104.93, 126.29		227.56, 305.52		90.47, 115.68	
	Median	121.41	-59.52	267.79	-12.26	94.97	-64.50
	Q25, Q75	85.57, 146.11	-74.28, -44.19	189.50, 384.83	-28.36, 2.52	76.58, 134.46	-77.90, -50.68
	Min, Max	46.1, 338.5	-90.7, 53.0	84.7, 710.5	-62.1, 105.2	46.6, 231.2	-87.5, -7.8
	Mean (SD)	125.27 (54.500)	-54.80 (27.614)	293.36 (138.848)	-7.06 (31.137)	110.17 (45.040)	-60.84 (20.564)
	95% CI of Mean	112.97, 137.56	-61.03, -48.57	250.09, 336.63	-16.76, 2.65	95.76, 124.58	-67.42, -54.26

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	123.26 (41.46)		293.04 (48.86)		122.87 (45.35)	
	95% CI of Geometric Mean	112.67, 134.85		253.70, 338.49		107.00, 141.10	
	Median	121.68	-60.55	295.49	3.76	118.36	-56.05
	Q25, Q75	91.12, 170.49	-71.85, -37.50	208.91, 386.95	-17.34, 15.98	87.69, 170.20	-72.65, -39.79
	Min, Max	55.7, 262.9	-90.3, 124.7	96.3, 710.5	-66.9, 153.5	57.7, 271.4	-87.2, 53.7
	Mean (SD)	133.15 (52.619)	-50.18 (36.376)	325.26 (154.847)	3.31 (35.117)	134.44 (57.769)	-53.07 (25.840)
	95% CI of Mean	121.28, 145.02	-58.39, -41.97	277.00, 373.52	-7.64, 14.26	115.96, 152.92	-61.33, -44.80

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	125.29 (34.32)		286.80 (44.27)		115.52 (43.85)	
	95% CI of Geometric Mean	116.21, 135.09		251.37, 327.21		101.02, 132.11	
	Median	123.78	-59.42	283.71	-0.96	112.22	-60.47
	Q25, Q75	100.37, 169.58	-72.29, -36.13	205.63, 384.74	-17.35, 16.57	83.70, 149.97	-74.49, -39.50
	Min, Max	63.3, 226.6	-85.9, 90.7	143.0, 710.5	-55.7, 56.1	41.8, 268.4	-87.6, 77.6
	Mean (SD)	132.23 (43.331)	-50.20 (31.897)	313.48 (138.768)	0.27 (28.726)	125.86 (54.228)	-53.85 (30.134)
	95% CI of Mean	122.46, 142.01	-57.40, -43.00	270.23, 356.73	-8.68, 9.23	108.51, 143.20	-63.49, -44.20

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	129.98 (47.38)		292.39 (45.13)		134.96 (53.46)	
	95% CI of Geometric Mean	117.43, 143.86		255.68, 334.37		114.96, 158.43	
	Median	132.21	-59.16	317.86	0.51	150.33	-41.41
	Q25, Q75	87.33, 190.66	-74.19, -29.56	220.89, 363.64	-25.02, 22.40	87.64, 188.99	-76.46, -23.31
	Min, Max	65.0, 326.7	-89.0, 128.0	119.3, 710.5	-81.0, 188.2	53.0, 313.9	-90.7, 80.1
	Mean (SD)	143.79 (66.666)	-44.62 (44.007)	319.30 (136.911)	8.26 (49.702)	151.11 (68.659)	-41.57 (39.777)
	95% CI of Mean	128.75, 158.82	-54.55, -34.70	276.63, 361.97	-7.24, 23.75	129.14, 173.07	-54.30, -28.85

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	121.18 (35.37)		275.35 (51.02)		121.06 (40.18)	
	95% CI of Geometric Mean	112.15, 130.94		237.02, 319.88		106.97, 137.01	
	Median	119.54	-60.47	291.18	-7.07	116.62	-59.17
	Q25, Q75	97.92, 150.00	-73.87, -39.18	215.35, 362.62	-28.29, 21.81	93.73, 152.33	-77.74, -33.47
	Min, Max	55.3, 375.1	-85.8, 81.3	90.9, 825.5	-81.1, 88.0	46.7, 274.1	-86.7, 95.6
	Mean (SD)	128.72 (48.821)	-51.86 (30.838)	308.43 (156.467)	-0.35 (37.488)	130.45 (53.864)	-49.33 (37.707)
	95% CI of Mean	117.71, 139.73	-58.82, -44.91	259.66, 357.19	-12.04, 11.34	113.22, 147.69	-61.39, -37.26

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	151.05 (56.01)		305.63 (47.86)		154.97 (57.17)	
	95% CI of Geometric Mean	134.26, 169.93		265.29, 352.10		130.73, 183.71	
	Median	130.94	-51.98	322.15	-9.13	149.78	-44.25
	Q25, Q75	101.88, 227.75	-70.21, -13.55	225.05, 427.22	-21.73, 39.21	100.00, 246.58	-71.96, -9.88
	Min, Max	46.4, 383.5	-87.6, 209.9	92.6, 710.5	-67.4, 351.5	57.0, 538.1	-88.3, 210.4
	Mean (SD)	173.31 (94.524)	-32.77 (57.297)	336.31 (146.234)	15.30 (69.932)	178.34 (100.850)	-29.90 (60.877)
	95% CI of Mean	151.99, 194.62	-45.69, -19.84	290.73, 381.88	-6.50, 37.10	146.08, 210.59	-49.37, -10.43

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	357.97 (60.12)	354.27 (69.89)	355.67 (51.33)
	95% CI of Geometric Mean	315.83, 405.73	291.06, 431.21	304.71, 415.17
	Median	379.48	352.84	354.00
	Q25, Q75	241.79, 535.27	220.89, 501.73	240.45, 471.69
	Min, Max	92.8, 1255.0	118.0, 1300.5	130.0, 952.8
	Mean (SD)	414.07 (228.024)	432.25 (294.504)	398.76 (201.287)
	95% CI of Mean	362.66, 465.49	340.47, 524.03	334.38, 463.14

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	133.64 (39.80)	293.53 (74.73)	112.64 (34.69)
	95% CI of Geometric Mean	122.57, 145.71	238.51, 361.24	101.12, 125.46
	Median	130.11	295.02	107.64
	Q25, Q75	99.18, 172.18	160.81, 467.52	96.96, 133.19
	Min, Max	57.2, 344.5	104.2, 1185.0	62.1, 376.8
	Mean (SD)	144.11 (59.970)	365.24 (257.550)	119.93 (52.037)
	95% CI of Mean	130.59, 157.64	284.97, 445.50	103.29, 136.58

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	145.21 (39.23)	328.13 (67.09)	134.31 (31.64)
	95% CI of Geometric Mean	133.34, 158.15	271.36, 396.78	121.67, 148.26
	Median	142.40	357.84	133.18
	Q25, Q75	113.17, 186.74	180.50, 504.50	103.86, 174.01
	Min, Max	45.7, 360.1	102.9, 1185.0	79.8, 341.4
	Mean (SD)	155.60 (58.847)	390.85 (237.374)	141.07 (48.756)
	95% CI of Mean	142.32, 168.87	316.87, 464.82	125.48, 156.67

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	140.13 (38.37)	322.05 (60.29)	122.16 (37.44)
	95% CI of Geometric Mean	128.90, 152.35	270.75, 383.08	108.79, 137.17
	Median	136.97	313.32	123.89
	Q25, Q75	106.31, 172.43	209.66, 500.25	103.51, 151.09
	Min, Max	70.4, 485.7	123.8, 1185.0	36.7, 305.1
	Mean (SD)	151.11 (68.817)	376.13 (227.495)	129.82 (46.644)
	95% CI of Mean	135.58, 166.63	305.23, 447.03	114.90, 144.74

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	150.42 (35.41)	334.76 (63.31)	141.25 (34.24)
	95% CI of Geometric Mean	139.20, 162.54	279.36, 401.16	126.98, 157.13
	Median	152.77	324.24	142.12
	Q25, Q75	121.84, 195.41	236.39, 481.67	109.24, 171.25
	Min, Max	73.4, 326.7	71.8, 1185.0	59.3, 277.0
	Mean (SD)	159.28 (54.375)	395.21 (248.962)	148.91 (49.018)
	95% CI of Mean	147.02, 171.55	317.62, 472.80	133.23, 164.59

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	146.53 (36.72)	355.41 (55.91)	139.56 (36.26)
	95% CI of Geometric Mean	135.23, 158.76	302.09, 418.14	124.72, 156.17
	Median	145.53	354.80	140.20
	Q25, Q75	115.09, 186.32	216.28, 510.84	104.90, 179.60
	Min, Max	43.3, 291.0	169.9, 1185.0	60.4, 301.0
	Mean (SD)	155.57 (53.786)	408.02 (231.106)	148.12 (52.429)
	95% CI of Mean	143.44, 167.71	336.00, 480.05	131.34, 164.89

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	153.81 (38.57)	341.00 (59.39)	143.34 (55.33)
	95% CI of Geometric Mean	141.42, 167.29	287.32, 404.71	121.50, 169.10
	Median	138.59	305.32	142.30
	Q25, Q75	119.34, 213.92	238.48, 509.57	103.23, 223.26
	Min, Max	53.9, 348.7	65.1, 1185.0	39.5, 324.2
	Mean (SD)	164.74 (62.756)	395.22 (232.807)	161.61 (76.277)
	95% CI of Mean	150.58, 178.89	322.67, 467.77	137.21, 186.01

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	138.96 (35.69)	317.06 (63.36)	136.82 (57.87)
	95% CI of Geometric Mean	128.52, 150.25	264.55, 379.98	115.21, 162.49
	Median	141.56	295.41	134.93
	Q25, Q75	112.35, 184.60	202.85, 469.26	109.43, 175.39
	Min, Max	50.8, 308.5	133.4, 1185.0	18.5, 397.7
	Mean (SD)	147.01 (48.392)	377.49 (247.425)	156.04 (85.561)
	95% CI of Mean	136.10, 157.93	300.38, 454.60	128.67, 183.41

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	171.51 (49.63)	335.26 (55.76)	174.26 (54.33)
	95% CI of Geometric Mean	154.29, 190.66	285.08, 394.28	148.10, 205.04
	Median	169.98	327.16	181.08
	Q25, Q75	124.39, 236.47	239.58, 433.83	122.64, 253.37
	Min, Max	47.4, 456.4	96.8, 1185.0	39.1, 492.5
	Mean (SD)	190.38 (87.246)	384.56 (225.834)	196.28 (96.667)
	95% CI of Mean	170.70, 210.05	314.18, 454.94	165.36, 227.20

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3026.36 (51.17)		3383.70 (58.34)		2718.95 (46.94)	
	95% CI of Geometric Mean	2710.62, 3378.88		2858.58, 4005.28		2352.81, 3142.07	
	Median	2881.24		3267.28		2774.19	
	Q25, Q75	2197.12, 3968.43		2382.20, 4637.83		1883.33, 3793.60	
	Min, Max	1021.3, 12119.9		964.3, 14637.1		1239.6, 7274.3	
	Mean (SD)	3423.54 (1955.716)		3922.31 (2428.051)		3000.87 (1406.558)	
	95% CI of Mean	2976.64, 3870.45		3165.67, 4678.95		2544.91, 3456.82	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2743.03 (49.90)		3029.06 (64.03)		2616.07 (50.77)	
	95% CI of Geometric Mean	2462.87, 3055.05		2523.40, 3636.06		2239.92, 3055.39	
	Median	2576.38	-9.57	2877.09	-8.08	2785.64	-6.88
	Q25, Q75	1997.76, 3680.72	-18.57, 4.35	2086.49, 4950.00	-20.27, 6.05	1879.40, 3701.66	-23.04, 11.90
	Min, Max	865.3, 10090.6	-71.3, 74.5	739.0, 15660.0	-56.4, 31.3	1083.7, 6682.6	-48.6, 226.3
	Mean (SD)	3082.47 (1689.770)	-6.48 (22.960)	3638.66 (2661.252)	-8.31 (19.430)	2912.29 (1344.155)	3.53 (48.127)
	95% CI of Mean	2696.34, 3468.61	-11.73, -1.23	2809.35, 4467.97	-14.37, -2.25	2476.56, 3348.02	-12.08, 19.13

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2632.95 (40.12)		2982.10 (55.69)		2677.74 (43.90)	
	95% CI of Geometric Mean	2410.51, 2875.90		2536.19, 3506.41		2337.09, 3068.05	
	Median	2567.59	-13.11	2819.81	-7.25	2554.52	4.40
	Q25, Q75	2009.00, 3319.54	-23.28, 2.44	1984.25, 4042.74	-21.69, 0.29	1887.57, 3750.00	-25.39, 25.38
	Min, Max	1300.0, 9516.1	-87.8, 134.8	947.8, 14322.7	-65.4, 60.2	1012.3, 6122.2	-55.3, 143.5
	Mean (SD)	2849.87 (1291.379)	-7.54 (31.688)	3450.81 (2277.756)	-8.29 (25.064)	2914.78 (1227.851)	6.83 (44.551)
	95% CI of Mean	2554.77, 3144.97	-14.79, -0.30	2741.01, 4160.61	-16.10, -0.47	2516.75, 3312.81	-7.62, 21.27

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2082.24 (52.60)		2325.10 (67.49)		1853.29 (47.82)	
	95% CI of Geometric Mean	1859.90, 2331.15		1921.00, 2814.20		1599.77, 2146.98	
	Median	1954.42	-32.45	2181.12	-33.48	1818.18	-35.39
	Q25, Q75	1514.27, 2838.82	-39.42, -18.15	1592.23, 3097.46	-40.72, -15.15	1346.63, 2857.14	-46.08, -13.01
	Min, Max	744.7, 12189.9	-70.1, 74.7	595.4, 12419.0	-76.2, 31.2	832.5, 3944.6	-66.2, 46.8
	Mean (SD)	2383.20 (1565.923)	-27.94 (23.305)	2832.16 (2130.521)	-27.40 (23.832)	2042.91 (900.714)	-28.22 (24.711)
	95% CI of Mean	2025.37, 2741.03	-33.27, -22.61	2168.24, 3496.08	-34.83, -19.97	1750.93, 2334.90	-36.23, -20.20

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2040.92 (53.12)		2466.23 (64.06)		1860.37 (52.28)	
	95% CI of Geometric Mean	1821.18, 2287.17		2054.36, 2960.67		1586.37, 2181.69	
	Median	1924.33	-31.38	2316.19	-28.42	2016.81	-34.08
	Q25, Q75	1447.91, 2588.34	-42.06, -21.20	1719.63, 3638.25	-37.03, -12.55	1279.72, 2694.44	-46.82, -3.72
	Min, Max	742.9, 11092.3	-75.5, 57.3	1000.0, 12739.4	-61.4, 61.8	685.9, 4354.8	-64.1, 35.5
	Mean (SD)	2353.27 (1595.302)	-28.73 (24.326)	2977.51 (2236.274)	-24.14 (22.992)	2079.54 (964.910)	-27.23 (26.421)
	95% CI of Mean	1988.72, 2717.82	-34.29, -23.16	2280.63, 3674.39	-31.31, -16.97	1766.75, 2392.34	-35.80, -18.66

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2503.48 (50.43)		3108.11 (58.61)		2471.21 (44.32)	
	95% CI of Geometric Mean	2245.48, 2791.11		2623.98, 3681.57		2154.22, 2834.84	
	Median	2537.21	-19.26	3090.19	-10.09	2390.07	-8.09
	Q25, Q75	1978.47, 3397.98	-31.55, 3.02	2000.00, 4387.76	-24.99, 16.34	1820.51, 3781.38	-24.11, 16.89
	Min, Max	617.3, 13199.5	-72.7, 152.5	969.0, 13564.8	-51.6, 62.7	1073.6, 5222.9	-51.9, 83.1
	Mean (SD)	2814.37 (1647.835)	-11.45 (34.908)	3611.77 (2260.973)	-4.40 (27.506)	2689.54 (1102.830)	-4.49 (30.904)
	95% CI of Mean	2437.82, 3190.92	-19.43, -3.47	2907.20, 4316.34	-12.97, 4.18	2332.04, 3047.04	-14.51, 5.53

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3037.40 (51.72)		3327.98 (57.81)		2718.95 (46.94)	
	95% CI of Geometric Mean	2713.45, 3400.02		2809.14, 3942.65		2352.81, 3142.07	
	Median	2881.24		3211.59		2774.19	
	Q25, Q75	2198.51, 3985.82		2382.20, 4548.67		1883.33, 3793.60	
	Min, Max	1021.3, 12119.9		964.3, 14637.1		1239.6, 7274.3	
	Mean (SD)	3442.76 (1976.230)		3854.95 (2418.152)		3000.87 (1406.558)	
	95% CI of Mean	2984.90, 3900.62		3091.68, 4618.21		2544.91, 3456.82	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3017.49 (65.85)		3180.76 (91.63)		2861.17 (58.59)	
	95% CI of Geometric Mean	2625.78, 3467.64		2486.05, 4069.59		2399.23, 3412.04	
	Median	2919.41	-6.43	2858.49	-14.11	2750.00	1.47
	Q25, Q75	2133.95, 4252.34	-23.78, 25.48	2020.30, 4485.60	-32.88, 7.58	2058.82, 4370.75	-22.60, 40.06
	Min, Max	778.4, 43672.5	-82.4, 346.5	766.7, 89903.8	-68.4, 2770.7	847.9, 7064.7	-60.6, 225.5
	Mean (SD)	3872.80 (5089.316)	11.47 (61.724)	5590.91 (13711.05)	67.09 (437.097)	3272.52 (1658.396)	16.56 (58.651)
	95% CI of Mean	2693.70, 5051.91	-2.83, 25.78	1263.17, 9918.66	-70.88, 205.06	2734.92, 3810.11	-2.45, 35.58

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3028.35 (49.58)		3327.98 (57.81)		2703.55 (47.47)	
	95% CI of Geometric Mean	2710.29, 3383.74		2809.14, 3942.65		2331.26, 3135.28	
	Median	2927.01		3211.59		2749.04	
	Q25, Q75	2198.51, 3985.82		2382.20, 4548.67		1883.33, 3793.60	
	Min, Max	1021.3, 12119.9		964.3, 14637.1		1239.6, 7274.3	
	Mean (SD)	3396.23 (1850.867)		3854.95 (2418.152)		2991.04 (1424.082)	
	95% CI of Mean	2958.13, 3834.32		3091.68, 4618.21		2522.95, 3459.13	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3022.87 (64.49)		3420.06 (107.41)		2691.71 (55.37)	
	95% CI of Geometric Mean	2629.05, 3475.67		2593.98, 4509.20		2270.95, 3190.41	
	Median	2933.33	-5.80	2935.78	9.40	2659.23	-2.53
	Q25, Q75	1986.64, 4416.40	-24.24, 29.94	1847.83, 5034.29	-32.74, 27.71	1800.87, 4037.74	-20.81, 16.38
	Min, Max	713.0, 23304.7	-68.4, 455.4	805.4, 114606.7	-74.5, 3559.5	926.6, 8036.8	-51.9, 162.1
	Mean (SD)	3673.00 (3067.693)	11.59 (69.370)	6648.43 (17518.47)	92.77 (557.414)	3062.86 (1619.610)	6.87 (45.757)
	95% CI of Mean	2946.89, 4399.12	-4.83, 28.02	1118.91, 12177.94	-83.17, 268.72	2530.50, 3595.22	-8.17, 21.92

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3018.26 (52.57)		3327.98 (57.81)		2669.33 (47.38)	
	95% CI of Geometric Mean	2682.92, 3395.51		2809.14, 3942.65		2297.45, 3101.41	
	Median	2881.24		3211.59		2723.88	
	Q25, Q75	2195.73, 3951.05		2382.20, 4548.67		1883.33, 3773.58	
	Min, Max	1021.3, 12119.9		964.3, 14637.1		1239.6, 7274.3	
	Mean (SD)	3435.17 (2012.748)		3854.95 (2418.152)		2954.83 (1425.876)	
	95% CI of Mean	2955.25, 3915.10		3091.68, 4618.21		2479.41, 3430.24	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3314.09 (72.17)		3221.80 (105.84)		3249.02 (87.78)	
	95% CI of Geometric Mean	2840.00, 3867.33		2450.54, 4235.78		2525.28, 4180.17	
	Median	3038.51	7.43	2863.31	-5.12	3195.27	11.09
	Q25, Q75	2096.15, 4645.67	-15.91, 42.98	1875.00, 4275.98	-31.28, 22.68	1971.22, 5253.62	-15.33, 47.94
	Min, Max	656.4, 17728.1	-79.0, 458.8	939.1, 73008.1	-69.4, 2231.2	924.4, 38179.1	-45.5, 1896.8
	Mean (SD)	4154.15 (3339.640)	23.73 (76.602)	5830.14 (11959.56)	54.48 (352.866)	4587.99 (6086.687)	75.30 (315.389)
	95% CI of Mean	3357.84, 4950.46	5.46, 42.00	2055.23, 9605.05	-56.90, 165.87	2558.59, 6617.40	-29.86, 180.46

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3641.90 (45.02)	4012.79 (58.42)	3266.18 (41.04)
	95% CI of Geometric Mean	3301.40, 4017.52	3389.34, 4750.91	2874.09, 3711.76
	Median	3436.29	3406.29	3410.13
	Q25, Q75	2695.59, 5075.76	2628.12, 6385.92	2744.67, 4078.40
	Min, Max	1409.8, 10473.3	1714.5, 13649.3	1168.1, 6796.2
	Mean (SD)	3999.93 (1852.855)	4683.01 (2907.754)	3506.11 (1297.570)
	95% CI of Mean	3576.53, 4423.33	3776.88, 5589.13	3085.48, 3926.73

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3188.08 (44.68)	3632.22 (69.72)	2860.32 (44.42)
	95% CI of Geometric Mean	2891.96, 3514.53	2985.35, 4419.25	2492.75, 3282.07
	Median	2974.50	3359.74	2851.20
	Q25, Q75	2320.36, 4336.33	2604.80, 5259.87	2327.63, 3353.60
	Min, Max	1243.7, 11692.2	819.9, 15386.0	1105.6, 6658.4
	Mean (SD)	3498.59 (1652.980)	4438.58 (3163.303)	3122.34 (1377.419)
	95% CI of Mean	3120.86, 3876.32	3452.83, 5424.34	2675.82, 3568.85

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3117.29 (40.86)	3716.67 (54.32)	3116.70 (43.76)
	95% CI of Geometric Mean	2849.64, 3410.09	3172.02, 4354.82	2721.25, 3569.61
	Median	3033.94	3239.99	3102.06
	Q25, Q75	2240.86, 4235.86	2888.64, 4778.40	2462.53, 3766.61
	Min, Max	1047.3, 6922.3	875.6, 12467.5	1244.1, 8825.7
	Mean (SD)	3355.40 (1284.000)	4248.31 (2519.493)	3401.69 (1535.330)
	95% CI of Mean	3061.99, 3648.81	3463.18, 5033.45	2903.98, 3899.39

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2527.28 (47.23)	2839.93 (63.36)	2235.61 (46.00)
	95% CI of Geometric Mean	2281.01, 2800.13	2369.68, 3403.49	1939.64, 2576.73
	Median	2442.47	2602.80	2375.00
	Q25, Q75	1878.65, 3177.68	1942.56, 4053.84	1675.36, 2978.04
	Min, Max	798.3, 13134.0	967.7, 11148.1	841.1, 6273.8
	Mean (SD)	2824.64 (1665.678)	3411.49 (2415.431)	2448.97 (1084.133)
	95% CI of Mean	2444.02, 3205.27	2658.78, 4164.20	2097.53, 2800.41

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2491.83 (52.35)	2817.33 (70.15)	2158.44 (45.13)
	95% CI of Geometric Mean	2226.80, 2788.40	2313.27, 3431.23	1877.31, 2481.66
	Median	2247.12	2530.21	2175.60
	Q25, Q75	1800.96, 3325.75	1896.00, 3607.34	1597.94, 2994.78
	Min, Max	958.8, 11114.6	859.8, 13761.6	735.3, 5840.1
	Mean (SD)	2845.90 (1734.691)	3529.67 (2927.998)	2361.95 (1056.718)
	95% CI of Mean	2449.50, 3242.30	2617.24, 4442.11	2019.40, 2704.50

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2927.14 (50.09)	3851.68 (53.00)	3016.87 (36.94)
	95% CI of Geometric Mean	2627.20, 3261.31	3298.48, 4497.66	2686.67, 3387.65
	Median	3151.83	3486.13	3040.11
	Q25, Q75	2264.77, 3927.51	2812.09, 5163.36	2295.74, 3994.20
	Min, Max	824.2, 9583.9	1516.2, 12141.9	1281.4, 5989.0
	Mean (SD)	3242.95 (1464.843)	4389.07 (2535.323)	3205.67 (1125.705)
	95% CI of Mean	2908.21, 3577.68	3599.01, 5179.14	2840.75, 3570.59

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3636.03 (45.63)	3914.02 (56.17)	3266.18 (41.04)
	95% CI of Geometric Mean	3287.57, 4021.43	3317.74, 4617.46	2874.09, 3711.76
	Median	3419.40	3349.68	3410.13
	Q25, Q75	2669.55, 5214.72	2628.12, 6036.94	2744.67, 4078.40
	Min, Max	1409.8, 10473.3	1714.5, 13649.3	1168.1, 6796.2
	Mean (SD)	4002.81 (1876.417)	4525.32 (2756.084)	3506.11 (1297.570)
	95% CI of Mean	3568.07, 4437.54	3655.39, 5395.25	3085.48, 3926.73

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3569.49 (60.88)	3677.35 (99.85)	3060.58 (57.06)
	95% CI of Geometric Mean	3134.12, 4065.34	2828.35, 4781.21	2576.72, 3635.30
	Median	3534.24	3142.80	3147.53
	Q25, Q75	2554.04, 5241.60	2328.48, 4875.09	2059.11, 4500.07
	Min, Max	1105.6, 31609.6	870.8, 114556.2	806.9, 8252.5
	Mean (SD)	4298.07 (3812.963)	6898.80 (17582.17)	3475.33 (1713.499)
	95% CI of Mean	3414.67, 5181.47	1349.17, 12448.42	2919.87, 4030.78

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3628.79 (44.25)	3914.02 (56.17)	3237.47 (41.20)
	95% CI of Geometric Mean	3283.17, 4010.80	3317.74, 4617.46	2842.46, 3687.37
	Median	3441.90	3349.68	3339.53
	Q25, Q75	2721.62, 5214.72	2628.12, 6036.94	2744.67, 4072.10
	Min, Max	1409.8, 10473.3	1714.5, 13649.3	1168.1, 6796.2
	Mean (SD)	3970.95 (1791.868)	4525.32 (2756.084)	3478.15 (1303.033)
	95% CI of Mean	3546.82, 4395.09	3655.39, 5395.25	3049.85, 3906.45

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3485.18 (55.33)	3902.59 (97.50)	3057.80 (48.24)
	95% CI of Geometric Mean	3083.92, 3938.64	3015.11, 5051.29	2630.98, 3553.87
	Median	3328.48	3183.76	2868.94
	Q25, Q75	2372.48, 4785.00	2346.96, 6051.30	2383.70, 3857.92
	Min, Max	1154.2, 19167.9	1314.8, 154866.6	1121.8, 8750.5
	Mean (SD)	4024.72 (2626.621)	7877.03 (23675.15)	3396.43 (1695.397)
	95% CI of Mean	3403.01, 4646.44	404.23, 15349.84	2839.17, 3953.70

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3570.08 (46.07)	3914.02 (56.17)	3226.45 (41.75)
	95% CI of Geometric Mean	3215.50, 3963.77	3317.74, 4617.46	2822.88, 3687.72
	Median	3375.99	3349.68	3268.93
	Q25, Q75	2644.18, 4936.80	2628.12, 6036.94	2744.67, 4072.10
	Min, Max	1409.8, 10473.3	1714.5, 13649.3	1168.1, 6796.2
	Mean (SD)	3942.11 (1903.479)	4525.32 (2756.084)	3472.89 (1320.598)
	95% CI of Mean	3488.24, 4395.99	3655.39, 5395.25	3032.58, 3913.21

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3740.17 (64.54)	3498.24 (110.07)	3678.92 (79.69)
	95% CI of Geometric Mean	3249.26, 4305.24	2640.78, 4634.12	2912.00, 4647.82
	Median	3643.16	2900.04	3642.08
	Q25, Q75	2453.76, 5468.40	2088.10, 5405.00	2473.52, 4598.10
	Min, Max	860.2, 20655.2	571.1, 92628.7	1126.6, 43628.0
	Mean (SD)	4535.66 (3504.366)	6488.79 (14602.80)	5116.28 (7002.492)
	95% CI of Mean	3700.07, 5371.26	1879.57, 11098.00	2781.53, 7451.03

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2998.09 (52.83)		3383.70 (58.34)		2707.42 (46.37)	
	95% CI of Geometric Mean	2680.81, 3352.91		2858.58, 4005.28		2351.09, 3117.75	
	Median	2881.24		3267.28		2749.04	
	Q25, Q75	2195.73, 3985.82		2382.20, 4637.83		1897.67, 3783.59	
	Min, Max	951.2, 12119.9		964.3, 14637.1		1239.6, 7274.3	
	Mean (SD)	3407.32 (1955.381)		3922.31 (2428.051)		2983.19 (1392.901)	
	95% CI of Mean	2966.44, 3848.19		3165.67, 4678.95		2537.71, 3428.67	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2705.04 (50.97)		3029.06 (64.03)		2619.36 (50.05)	
	95% CI of Geometric Mean	2427.30, 3014.56		2523.40, 3636.06		2251.80, 3046.91	
	Median	2576.38	-9.57	2877.09	-8.08	2783.95	-6.22
	Q25, Q75	1995.52, 3651.03	-18.58, 3.74	2086.49, 4950.00	-20.27, 6.05	1881.39, 3682.38	-22.10, 14.50
	Min, Max	865.3, 10090.6	-71.3, 74.5	739.0, 15660.0	-56.4, 31.3	1083.7, 6682.6	-48.6, 226.3
	Mean (SD)	3049.80 (1685.624)	-6.85 (23.037)	3638.66 (2661.252)	-8.31 (19.430)	2908.25 (1327.055)	3.94 (47.576)
	95% CI of Mean	2669.74, 3429.85	-12.05, -1.66	2809.35, 4467.97	-14.37, -2.25	2483.84, 3332.67	-11.28, 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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2596.27 (41.47)		2982.10 (55.69)		2696.71 (43.55)	
	95% CI of Geometric Mean	2373.27, 2840.22		2536.19, 3506.41		2360.22, 3081.18	
	Median	2558.03	-13.11	2819.81	-7.25	2679.37	4.94
	Q25, Q75	1994.05, 3316.50	-23.46, 1.61	1984.25, 4042.74	-21.69, 0.29	1970.72, 3660.71	-24.82, 28.58
	Min, Max	951.2, 9516.1	-87.8, 134.8	947.8, 14322.7	-65.4, 60.2	1012.3, 6122.2	-55.3, 143.5
	Mean (SD)	2820.28 (1293.233)	-7.96 (31.609)	3450.81 (2277.756)	-8.29 (25.064)	2930.70 (1216.183)	8.03 (44.627)
	95% CI of Mean	2528.69, 3111.86	-15.09, -0.83	2741.01, 4160.61	-16.10, -0.47	2541.74, 3319.66	-6.25, 22.31

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2061.45 (52.78)		2325.10 (67.49)		1883.67 (48.50)	
	95% CI of Geometric Mean	1843.46, 2305.21		1921.00, 2814.20		1626.19, 2181.92	
	Median	1954.42	-32.45	2181.12	-33.48	1821.79	-34.12
	Q25, Q75	1469.14, 2838.14	-39.55, -17.14	1592.23, 3097.46	-40.72, -15.15	1358.96, 2862.14	-45.91, -12.41
	Min, Max	744.7, 12189.9	-70.1, 74.7	595.4, 12419.0	-76.2, 31.2	832.5, 3944.6	-66.2, 54.8
	Mean (SD)	2361.00 (1554.258)	-27.93 (23.423)	2832.16 (2130.521)	-27.40 (23.832)	2080.63 (920.538)	-26.14 (27.703)
	95% CI of Mean	2010.57, 2711.44	-33.22, -22.65	2168.24, 3496.08	-34.83, -19.97	1786.22, 2375.04	-35.01, -17.28

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2023.60 (53.26)		2466.23 (64.06)		1890.69 (52.79)	
	95% CI of Geometric Mean	1807.99, 2264.92		2054.36, 2960.67		1613.44, 2215.57	
	Median	1924.33	-31.38	2316.19	-28.42	2028.09	-33.95
	Q25, Q75	1447.62, 2584.93	-42.25, -20.34	1719.63, 3638.25	-37.03, -12.55	1291.28, 2735.18	-45.64, -3.14
	Min, Max	742.9, 11092.3	-75.5, 57.3	1000.0, 12739.4	-61.4, 61.8	685.9, 4354.8	-64.1, 54.8
	Mean (SD)	2334.00 (1582.457)	-28.65 (24.367)	2977.51 (2236.274)	-24.14 (22.992)	2116.35 (980.487)	-25.18 (29.130)
	95% CI of Mean	1977.21, 2690.80	-34.15, -23.15	2280.63, 3674.39	-31.31, -16.97	1802.77, 2429.93	-34.50, -15.85

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2470.89 (51.19)		3108.11 (58.61)		2493.72 (44.15)	
	95% CI of Geometric Mean	2216.27, 2754.78		2623.98, 3681.57		2178.93, 2853.99	
	Median	2476.23	-19.26	3090.19	-10.09	2399.12	-7.26
	Q25, Q75	1953.60, 3380.95	-31.86, 2.43	2000.00, 4387.76	-24.99, 16.34	1910.26, 3666.51	-23.46, 18.68
	Min, Max	617.3, 13199.5	-72.7, 152.5	969.0, 13564.8	-51.6, 62.7	1073.6, 5222.9	-51.9, 83.1
	Mean (SD)	2784.81 (1640.602)	-11.78 (34.736)	3611.77 (2260.973)	-4.40 (27.506)	2711.10 (1097.100)	-3.01 (31.915)
	95% CI of Mean	2414.90, 3154.71	-19.62, -3.95	2907.20, 4316.34	-12.97, 4.18	2360.22, 3061.97	-13.22, 7.21

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	2959.69 (65.82)		3237.50 (91.46)		2876.67 (57.85)	
	95% CI of Geometric Mean	2585.27, 3388.34		2539.23, 4127.79		2422.52, 3415.97	
	Median	2871.89	-4.13	2902.70	-11.68	2795.35	3.61
	Q25, Q75	2133.95, 4248.37	-23.78, 25.48	2020.30, 4511.15	-32.88, 7.58	2060.47, 4275.70	-21.10, 41.91
	Min, Max	778.4, 43672.5	-82.4, 346.5	766.7, 89903.8	-68.4, 2770.7	847.9, 7064.7	-60.6, 225.5
	Mean (SD)	3790.74 (4971.795)	10.53 (60.582)	5616.94 (13543.86)	65.50 (431.858)	3279.50 (1637.592)	17.52 (58.209)
	95% CI of Mean	2669.77, 4911.71	-3.14, 24.19	1396.37, 9837.51	-69.09, 200.08	2755.76, 3803.23	-1.10, 36.14

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3022.13 (66.74)		3475.06 (106.61)		2726.78 (54.14)	
	95% CI of Geometric Mean	2635.61, 3465.34		2648.78, 4559.10		2318.67, 3206.71	
	Median	2905.80	-3.82	3168.10	8.32	2697.53	-0.05
	Q25, Q75	1986.64, 4416.40	-23.31, 32.31	1847.83, 5104.00	-32.74, 27.71	1809.52, 3970.09	-20.70, 18.60
	Min, Max	713.0, 23304.7	-68.4, 455.4	805.4, 114606.7	-74.5, 3559.5	926.6, 8036.8	-51.9, 162.1
	Mean (SD)	3704.59 (3086.361)	12.14 (67.042)	6649.28 (17303.51)	90.56 (550.760)	3084.10 (1580.386)	7.94 (45.221)
	95% CI of Mean	3008.72, 4400.47	-2.98, 27.26	1257.12, 12041.43	-81.07, 262.20	2578.66, 3589.54	-6.53, 22.41

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	3348.48 (75.91)		3278.27 (105.28)		3279.79 (83.50)	
	95% CI of Geometric Mean	2876.05, 3898.50		2504.74, 4290.67		2599.16, 4138.65	
	Median	3090.61	6.94	2932.65	-4.59	3346.50	9.71
	Q25, Q75	2096.15, 4645.67	-15.91, 42.98	1875.00, 4315.90	-31.28, 22.68	1982.51, 5014.20	-15.28, 48.43
	Min, Max	656.4, 23836.4	-79.0, 1029.0	939.1, 73008.1	-69.4, 2231.2	924.4, 38179.1	-45.5, 1896.8
	Mean (SD)	4318.69 (3907.164)	34.68 (135.720)	5850.47 (11813.54)	53.19 (348.637)	4521.09 (5853.327)	70.94 (303.505)
	95% CI of Mean	3437.76, 5199.63	4.08, 65.29	2169.11, 9531.84	-55.46, 161.83	2649.10, 6393.08	-26.14, 168.01

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3594.61 (47.17)	4012.79 (58.42)	3221.48 (41.55)
	95% CI of Geometric Mean	3249.11, 3976.84	3389.34, 4750.91	2835.50, 3660.01
	Median	3436.29	3406.29	3339.53
	Q25, Q75	2669.55, 4936.80	2628.12, 6385.92	2724.34, 4075.25
	Min, Max	1034.3, 10473.3	1714.5, 13649.3	1168.1, 6796.2
	Mean (SD)	3969.94 (1860.728)	4683.01 (2907.754)	3465.51 (1306.310)
	95% CI of Mean	3550.40, 4389.47	3776.88, 5589.13	3047.72, 3883.29

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3142.39 (46.21)	3632.22 (69.72)	2828.59 (44.47)
	95% CI of Geometric Mean	2845.67, 3470.04	2985.35, 4419.25	2469.32, 3240.13
	Median	2974.50	3359.74	2835.96
	Q25, Q75	2284.52, 4328.45	2604.80, 5259.87	2300.51, 3346.71
	Min, Max	1034.3, 11692.2	819.9, 15386.0	1105.6, 6658.4
	Mean (SD)	3463.00 (1655.360)	4438.58 (3163.303)	3090.05 (1374.896)
	95% CI of Mean	3089.77, 3836.23	3452.83, 5424.34	2650.33, 3529.76

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3065.00 (42.56)	3716.67 (54.32)	3109.84 (43.17)
	95% CI of Geometric Mean	2795.63, 3360.32	3172.02, 4354.82	2724.71, 3549.41
	Median	3006.87	3239.99	3061.35
	Q25, Q75	2208.02, 4202.00	2888.64, 4778.40	2471.47, 3746.73
	Min, Max	1034.3, 6922.3	875.6, 12467.5	1244.1, 8825.7
	Mean (SD)	3314.81 (1297.459)	4248.31 (2519.493)	3387.99 (1517.992)
	95% CI of Mean	3022.27, 3607.35	3463.18, 5033.45	2902.51, 3873.47

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2509.41 (48.07)	2839.93 (63.36)	2249.29 (45.55)
	95% CI of Geometric Mean	2264.26, 2781.11	2369.68, 3403.49	1957.70, 2584.32
	Median	2442.47	2602.80	2394.94
	Q25, Q75	1876.14, 3197.46	1942.56, 4053.84	1699.73, 2964.86
	Min, Max	798.3, 13134.0	967.7, 11148.1	841.1, 6273.8
	Mean (SD)	2811.01 (1658.528)	3411.49 (2415.431)	2459.09 (1072.057)
	95% CI of Mean	2437.06, 3184.95	2658.78, 4164.20	2116.23, 2801.96

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2469.39 (52.84)	2817.33 (70.15)	2173.56 (44.75)
	95% CI of Geometric Mean	2208.01, 2761.71	2313.27, 3431.23	1895.98, 2491.77
	Median	2247.12	2530.21	2198.62
	Q25, Q75	1793.63, 3318.16	1896.00, 3607.34	1599.09, 2924.31
	Min, Max	958.8, 11114.6	859.8, 13761.6	735.3, 5840.1
	Mean (SD)	2824.19 (1724.332)	3529.67 (2927.998)	2374.25 (1045.977)
	95% CI of Mean	2435.41, 3212.98	2617.24, 4442.11	2039.72, 2708.77

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	2889.59 (51.09)	3851.68 (53.00)	3012.68 (36.44)
	95% CI of Geometric Mean	2592.29, 3221.00	3298.48, 4497.66	2690.99, 3372.83
	Median	3124.43	3486.13	2995.53
	Q25, Q75	2264.42, 3902.31	2812.09, 5163.36	2418.89, 3897.48
	Min, Max	824.2, 9583.9	1516.2, 12141.9	1281.4, 5989.0
	Mean (SD)	3211.86 (1467.315)	4389.07 (2535.323)	3196.87 (1112.571)
	95% CI of Mean	2881.02, 3542.69	3599.01, 5179.14	2841.05, 3552.70

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3502.40 (61.45)	3775.75 (101.10)	3055.23 (56.23)
	95% CI of Geometric Mean	3082.83, 3979.07	2907.00, 4904.12	2583.72, 3612.80
	Median	3458.15	3155.95	3114.45
	Q25, Q75	2554.04, 5161.91	2328.48, 5048.28	2173.30, 4490.61
	Min, Max	1034.3, 31609.6	870.8, 114556.2	806.9, 8252.5
	Mean (SD)	4220.40 (3737.688)	6999.97 (17378.80)	3459.79 (1694.241)
	95% CI of Mean	3377.68, 5063.12	1584.35, 12415.59	2917.94, 4001.64

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3465.58 (56.98)	4001.35 (98.50)	3081.83 (47.35)
	95% CI of Geometric Mean	3075.11, 3905.64	3095.74, 5171.88	2668.95, 3558.59
	Median	3407.03	3468.92	2868.94
	Q25, Q75	2372.48, 4848.00	2346.96, 6105.32	2415.07, 4079.66
	Min, Max	1034.3, 19167.9	1314.8, 154866.6	1121.8, 8750.5
	Mean (SD)	4014.66 (2579.827)	7954.92 (23390.10)	3409.99 (1662.678)
	95% CI of Mean	3433.00, 4596.33	666.04, 15243.79	2878.23, 3941.74

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	3802.06 (71.76)	3596.12 (111.34)	3688.08 (76.13)
	95% CI of Geometric Mean	3287.85, 4396.68	2718.41, 4757.22	2970.96, 4578.29
	Median	3643.16	3103.62	3702.10
	Q25, Q75	2453.76, 5468.40	2088.10, 5654.10	2492.17, 4543.19
	Min, Max	860.2, 40019.2	571.1, 92628.7	1126.6, 43628.0
	Mean (SD)	4912.53 (5249.851)	6599.72 (14441.53)	5023.45 (6738.901)
	95% CI of Mean	3728.86, 6096.19	2099.42, 11100.02	2868.24, 7178.66

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	76		42		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.71 (53.92)		5.56 (62.67)		5.40 (67.32)	
	95% CI of Geometric Mean	5.08, 6.41		4.64, 6.65		4.43, 6.59	
	Median	6.03		5.74		5.44	
	Q25, Q75	4.33, 7.91		4.23, 7.49		3.91, 8.38	
	Min, Max	0.8, 18.8		1.3, 16.7		0.9, 15.7	
	Mean (SD)	6.41 (3.103)		6.44 (3.469)		6.36 (3.518)	
	95% CI of Mean	5.69, 7.12		5.35, 7.52		5.21, 7.50	

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.15 (54.19)		5.40 (61.80)		3.32 (68.46)	
	95% CI of Geometric Mean	4.58, 5.79		4.52, 6.45		2.71, 4.07	
	Median	5.19	-8.45	5.38	-0.67	3.51	-39.29
	Q25, Q75	3.74, 6.57	-21.83, 5.30	3.58, 8.46	-11.54, 7.79	2.29, 4.90	-47.13, -30.26
	Min, Max	1.1, 21.1	-59.5, 131.1	1.4, 14.8	-42.1, 83.4	0.6, 11.6	-53.7, 19.6
	Mean (SD)	5.87 (3.457)	-6.26 (27.211)	6.23 (3.223)	-0.76 (21.275)	3.97 (2.422)	-37.18 (14.336)
	95% CI of Mean	5.08, 6.67	-12.49, -0.04	5.22, 7.24	-7.40, 5.87	3.18, 4.76	-41.83, -32.53

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.17 (53.10)		5.16 (61.12)		1.40 (61.71)	
	95% CI of Geometric Mean	4.61, 5.80		4.32, 6.16		1.16, 1.68	
	Median	5.37	-7.47	5.02	-6.89	1.28	-72.96
	Q25, Q75	3.99, 6.67	-26.49, 13.73	3.70, 8.09	-13.25, 2.03	1.08, 2.05	-80.47, -67.94
	Min, Max	1.1, 20.2	-69.6, 79.2	1.1, 15.4	-59.0, 27.0	0.3, 3.9	-86.5, -46.0
	Mean (SD)	5.84 (3.111)	-3.66 (33.487)	5.96 (3.196)	-5.61 (16.008)	1.61 (0.877)	-72.83 (8.874)
	95% CI of Mean	5.13, 6.56	-11.32, 4.00	4.96, 6.96	-10.60, -0.61	1.33, 1.90	-75.71, -69.94

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.37 (47.38)		4.93 (61.47)		0.61 (61.94)	
	95% CI of Geometric Mean	4.84, 5.96		4.13, 5.89		0.50, 0.74	
	Median	5.57	-9.78	4.91	-13.46	0.63	-88.71
	Q25, Q75	4.26, 6.95	-25.13, 15.75	3.53, 7.89	-18.61, 4.65	0.39, 0.93	-91.69, -83.65
	Min, Max	1.8, 15.8	-65.6, 112.5	1.1, 14.6	-53.2, 68.7	0.2, 1.7	-96.5, -68.7
	Mean (SD)	5.93 (2.745)	0.56 (38.709)	5.71 (3.071)	-8.80 (21.997)	0.71 (0.405)	-87.31 (6.053)
	95% CI of Mean	5.29, 6.56	-8.29, 9.41	4.74, 6.67	-15.66, -1.94	0.58, 0.85	-89.28, -85.34

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.57 (44.76)		4.92 (64.62)		0.29 (64.76)	
	95% CI of Geometric Mean	5.05, 6.15		4.09, 5.92		0.23, 0.35	
	Median	5.59	-7.64	4.96	-13.13	0.31	-94.57
	Q25, Q75	4.42, 7.54	-25.81, 23.83	3.16, 8.28	-21.04, 2.76	0.19, 0.42	-96.76, -91.27
	Min, Max	1.8, 13.7	-44.0, 142.3	1.1, 15.5	-56.8, 69.2	0.1, 0.9	-98.4, -78.8
	Mean (SD)	6.07 (2.552)	4.67 (43.566)	5.78 (3.248)	-8.35 (24.398)	0.34 (0.197)	-93.64 (4.024)
	95% CI of Mean	5.48, 6.66	-5.29, 14.63	4.76, 6.80	-15.95, -0.74	0.27, 0.41	-94.95, -92.33

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 10 AM on Day 1 in the SA arm.

**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=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	76	76	42	42	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	6.16 (47.56)		5.22 (63.86)		0.16 (69.36)	
	95% CI of Geometric Mean	5.55, 6.83		4.35, 6.27		0.12, 0.20	
	Median	6.36	0.84	5.65	-4.96	0.15	-96.71
	Q25, Q75	4.80, 8.62	-18.70, 33.27	3.42, 8.77	-18.98, 7.37	0.11, 0.22	-98.43, -94.81
	Min, Max	1.9, 14.7	-44.1, 177.4	1.1, 16.0	-48.4, 67.2	0.0, 0.7	-99.3, -84.6
	Mean (SD)	6.76 (2.857)	16.00 (48.264)	6.08 (3.258)	-3.30 (23.926)	0.19 (0.131)	-96.21 (2.992)
	95% CI of Mean	6.10, 7.42	4.97, 27.03	5.06, 7.10	-10.76, 4.16	0.14, 0.24	-97.18, -95.23

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		41		39	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.76 (54.29)		5.51 (63.22)		5.40 (67.32)	
	95% CI of Geometric Mean	5.11, 6.48		4.58, 6.62		4.43, 6.59	
	Median	6.06		5.73		5.44	
	Q25, Q75	4.38, 7.92		4.23, 7.38		3.91, 8.38	
	Min, Max	0.8, 18.8		1.3, 16.7		0.9, 15.7	
	Mean (SD)	6.46 (3.122)		6.40 (3.504)		6.36 (3.518)	
	95% CI of Mean	5.73, 7.19		5.29, 7.51		5.21, 7.50	

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 10 AM on Day 1 in the SA arm.

**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=74)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	74	74	41	41	39	39
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	6.80 (56.33)		5.76 (72.87)		0.29 (935.57)	
	95% CI of Geometric Mean	6.01, 7.68		4.68, 7.08		0.14, 0.58	
	Median	6.67	14.96	6.20	12.66	0.09	-96.99
	Q25, Q75	4.81, 9.75	-10.29, 56.90	4.25, 9.10	-17.76, 34.00	0.05, 3.01	-99.11, -57.89
	Min, Max	1.6, 24.8	-49.1, 380.6	1.1, 15.1	-73.0, 154.4	0.0, 14.9	-99.6, 56.1
	Mean (SD)	7.78 (4.281)	29.59 (64.517)	6.84 (3.567)	15.41 (50.347)	1.81 (3.138)	-73.23 (42.097)
	95% CI of Mean	6.78, 8.77	14.64, 44.55	5.71, 7.97	-0.49, 31.30	0.79, 2.83	-86.88, -59.58

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		41		38	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.91 (52.13)		5.51 (63.22)		5.29 (66.46)	
	95% CI of Geometric Mean	5.26, 6.65		4.58, 6.62		4.33, 6.46	
	Median	6.26		5.73		5.42	
	Q25, Q75	4.41, 8.12		4.23, 7.38		3.91, 8.29	
	Min, Max	0.8, 18.8		1.3, 16.7		0.9, 15.7	
	Mean (SD)	6.59 (3.104)		6.40 (3.504)		6.20 (3.434)	
	95% CI of Mean	5.85, 7.33		5.29, 7.51		5.07, 7.34	

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 10 AM on Day 1 in the SA arm.

**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=71)		mCC (N=41)		SA (N=38)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	71	71	41	41	38	38
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	6.63 (64.72)		6.05 (80.51)		0.36 (1065.96)	
	95% CI of Geometric Mean	5.76, 7.63		4.83, 7.56		0.17, 0.74	
	Median	7.18	7.87	6.93	13.63	0.42	-91.61
	Q25, Q75	4.70, 9.39	-13.91, 52.00	3.94, 10.60	-14.40, 39.34	0.04, 1.94	-98.94, -68.96
	Min, Max	1.3, 23.9	-50.3, 169.3	1.0, 20.2	-80.3, 154.5	0.0, 11.9	-99.7, 92.9
	Mean (SD)	7.77 (4.395)	22.83 (54.050)	7.44 (4.471)	19.91 (47.524)	2.03 (3.244)	-67.38 (49.851)
	95% CI of Mean	6.72, 8.81	10.04, 35.63	6.03, 8.86	4.90, 34.92	0.95, 3.10	-83.77, -50.99

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		41		37	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.72 (55.18)		5.51 (63.22)		5.19 (66.01)	
	95% CI of Geometric Mean	5.05, 6.47		4.58, 6.62		4.24, 6.35	
	Median	6.06		5.73		5.40	
	Q25, Q75	4.28, 7.92		4.23, 7.38		3.91, 7.34	
	Min, Max	0.8, 18.8		1.3, 16.7		0.9, 15.7	
	Mean (SD)	6.44 (3.154)		6.40 (3.504)		6.08 (3.396)	
	95% CI of Mean	5.68, 7.19		5.29, 7.51		4.94, 7.22	

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 10 AM on Day 1 in the SA arm.

**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=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	41	41	37	37
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	6.85 (63.70)		6.33 (76.08)		0.37 (1087.50)	
	95% CI of Geometric Mean	5.96, 7.88		5.11, 7.84		0.18, 0.78	
	Median	6.48	14.88	7.42	20.55	0.14	-95.71
	Q25, Q75	4.99, 9.07	-10.55, 64.15	4.25, 9.91	-13.22, 44.00	0.05, 3.40	-98.85, -41.74
	Min, Max	1.3, 31.7	-75.8, 341.9	0.9, 21.0	-55.9, 216.2	0.0, 11.9	-99.7, 318.2
	Mean (SD)	8.12 (5.331)	36.47 (78.340)	7.65 (4.432)	25.83 (56.251)	1.99 (2.818)	-58.18 (78.072)
	95% CI of Mean	6.84, 9.39	17.78, 55.15	6.25, 9.06	8.07, 43.59	1.04, 2.93	-84.22, -32.15

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Baseline	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.87 (61.44)	6.59 (80.47)	6.49 (68.01)
	95% CI of Geometric Mean	6.03, 7.82	5.28, 8.22	5.31, 7.93
	Median	7.53	7.54	6.57
	Q25, Q75	4.68, 10.62	4.35, 10.34	4.90, 9.98
	Min, Max	0.8, 27.3	1.4, 21.4	1.0, 17.2
	Mean (SD)	7.89 (4.061)	8.15 (5.027)	7.65 (4.261)
	95% CI of Mean	6.95, 8.82	6.58, 9.72	6.26, 9.03

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 1	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	5.99 (61.23)	6.47 (85.29)	3.63 (77.99)
	95% CI of Geometric Mean	5.26, 6.82	5.14, 8.16	2.90, 4.55
	Median	6.33	8.03	3.50
	Q25, Q75	4.48, 9.06	4.05, 11.57	2.63, 5.25
	Min, Max	1.1, 23.9	0.9, 21.4	0.7, 15.5
	Mean (SD)	6.90 (3.666)	8.12 (5.061)	4.53 (3.198)
	95% CI of Mean	6.06, 7.74	6.54, 9.70	3.49, 5.57

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 2	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.13 (62.73)	6.43 (80.19)	1.63 (71.47)
	95% CI of Geometric Mean	5.37, 6.99	5.16, 8.02	1.31, 2.01
	Median	6.76	6.65	1.88
	Q25, Q75	4.37, 9.36	4.53, 12.11	1.17, 2.45
	Min, Max	0.9, 18.5	1.2, 20.2	0.3, 6.5
	Mean (SD)	7.06 (3.524)	7.99 (5.037)	1.96 (1.266)
	95% CI of Mean	6.25, 7.87	6.41, 9.56	1.55, 2.38

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 3	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.52 (52.66)	6.02 (75.46)	0.74 (68.66)
	95% CI of Geometric Mean	5.82, 7.30	4.88, 7.43	0.60, 0.91
	Median	7.56	5.93	0.83
	Q25, Q75	5.20, 8.93	3.87, 10.65	0.45, 1.28
	Min, Max	2.0, 22.6	1.3, 18.3	0.2, 2.0
	Mean (SD)	7.28 (3.378)	7.37 (4.568)	0.88 (0.506)
	95% CI of Mean	6.51, 8.06	5.94, 8.80	0.71, 1.05

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 4	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.80 (46.68)	5.63 (79.17)	0.33 (76.75)
	95% CI of Geometric Mean	6.14, 7.53	4.52, 7.00	0.26, 0.42
	Median	7.10	6.08	0.39
	Q25, Q75	5.12, 9.02	3.04, 9.28	0.19, 0.60
	Min, Max	1.8, 17.8	1.2, 18.9	0.1, 1.2
	Mean (SD)	7.46 (3.239)	6.96 (4.332)	0.41 (0.259)
	95% CI of Mean	6.72, 8.21	5.60, 8.31	0.32, 0.50

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 10 AM on Day 1 in the SA arm.

**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=76)	mCC (N=42)	SA (N=39)
Day 5	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	7.20 (55.84)	6.47 (76.25)	0.19 (75.22)
	95% CI of Geometric Mean	6.39, 8.11	5.24, 8.00	0.15, 0.24
	Median	8.04	6.49	0.20
	Q25, Q75	5.36, 10.09	4.03, 11.04	0.12, 0.33
	Min, Max	1.8, 16.7	1.2, 16.7	0.0, 0.9
	Mean (SD)	8.08 (3.562)	7.90 (4.686)	0.24 (0.162)
	95% CI of Mean	7.27, 8.90	6.44, 9.37	0.18, 0.29

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Baseline	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.89 (61.43)	6.48 (80.47)	6.49 (68.01)
	95% CI of Geometric Mean	6.04, 7.86	5.18, 8.10	5.31, 7.93
	Median	7.53	7.43	6.57
	Q25, Q75	4.68, 10.53	4.35, 10.04	4.90, 9.98
	Min, Max	0.8, 27.3	1.4, 21.4	1.0, 17.2
	Mean (SD)	7.91 (4.071)	8.03 (5.024)	7.65 (4.261)
	95% CI of Mean	6.96, 8.86	6.44, 9.62	6.26, 9.03

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 10 AM on Day 1 in the SA arm.

**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=74)	mCC (N=41)	SA (N=39)
Day 30	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	8.04 (56.69)	6.66 (82.16)	0.31 (814.09)
	95% CI of Geometric Mean	7.11, 9.09	5.30, 8.36	0.15, 0.61
	Median	8.31	6.93	0.08
	Q25, Q75	5.89, 11.79	3.92, 12.91	0.06, 2.04
	Min, Max	1.6, 24.0	1.4, 21.5	0.0, 13.0
	Mean (SD)	9.16 (4.701)	8.34 (5.310)	1.93 (3.339)
	95% CI of Mean	8.06, 10.25	6.66, 10.02	0.85, 3.02

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Baseline	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	7.09 (58.84)	6.48 (80.47)	6.33 (66.54)
	95% CI of Geometric Mean	6.22, 8.07	5.18, 8.10	5.19, 7.73
	Median	7.55	7.43	6.51
	Q25, Q75	4.69, 10.76	4.35, 10.04	4.90, 9.55
	Min, Max	0.8, 27.3	1.4, 21.4	1.0, 17.2
	Mean (SD)	8.06 (4.060)	8.03 (5.024)	7.42 (4.065)
	95% CI of Mean	7.09, 9.03	6.44, 9.62	6.08, 8.76

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 10 AM on Day 1 in the SA arm.

**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=71)	mCC (N=41)	SA (N=38)
Day 60	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	7.64 (69.02)	6.90 (88.38)	0.41 (1025.39)
	95% CI of Geometric Mean	6.59, 8.87	5.42, 8.77	0.20, 0.84
	Median	8.28	6.77	0.24
	Q25, Q75	5.08, 12.25	5.08, 11.82	0.05, 2.48
	Min, Max	1.4, 30.2	1.0, 29.5	0.0, 15.5
	Mean (SD)	9.04 (5.016)	8.89 (6.313)	2.50 (4.298)
	95% CI of Mean	7.85, 10.23	6.89, 10.89	1.08, 3.92

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Baseline	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.76 (61.93)	6.48 (80.47)	6.27 (67.24)
	95% CI of Geometric Mean	5.90, 7.75	5.18, 8.10	5.11, 7.69
	Median	7.53	7.43	6.45
	Q25, Q75	4.68, 10.53	4.35, 10.04	4.90, 9.55
	Min, Max	0.8, 27.3	1.4, 21.4	1.0, 17.2
	Mean (SD)	7.77 (4.035)	8.03 (5.024)	7.37 (4.111)
	95% CI of Mean	6.81, 8.74	6.44, 9.62	6.00, 8.75

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 10 AM on Day 1 in the SA arm.

**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=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	7.73 (68.38)	6.87 (83.56)	0.42 (997.95)
	95% CI of Geometric Mean	6.67, 8.97	5.46, 8.65	0.20, 0.87
	Median	9.18	6.95	0.14
	Q25, Q75	5.47, 11.73	4.65, 12.07	0.07, 3.53
	Min, Max	1.0, 22.3	1.0, 22.7	0.0, 12.5
	Mean (SD)	9.04 (4.578)	8.57 (5.320)	2.27 (3.330)
	95% CI of Mean	7.94, 10.14	6.88, 10.25	1.16, 3.39

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		42		40	
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.73 (56.15)		5.56 (62.67)		5.43 (66.41)	
	95% CI of Geometric Mean	5.09, 6.45		4.64, 6.65		4.47, 6.60	
	Median	6.03		5.74		5.64	
	Q25, Q75	4.28, 7.92		4.23, 7.49		3.96, 8.34	
	Min, Max	0.8, 18.8		1.3, 16.7		0.9, 15.7	
	Mean (SD)	6.49 (3.336)		6.44 (3.469)		6.36 (3.473)	
	95% CI of Mean	5.74, 7.25		5.35, 7.52		5.25, 7.48	

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.16 (55.61)		5.40 (61.80)		3.37 (68.06)	
	95% CI of Geometric Mean	4.59, 5.81		4.52, 6.45		2.76, 4.10	
	Median	5.19	-8.45	5.38	-0.67	3.64	-38.80
	Q25, Q75	3.71, 6.63	-22.70, 4.30	3.58, 8.46	-11.54, 7.79	2.31, 5.18	-47.06, -30.21
	Min, Max	1.1, 21.1	-59.5, 131.1	1.4, 14.8	-42.1, 83.4	0.6, 11.6	-53.7, 19.6
	Mean (SD)	5.92 (3.532)	-6.41 (26.944)	6.23 (3.223)	-0.76 (21.275)	4.00 (2.403)	-36.71 (14.458)
	95% CI of Mean	5.12, 6.72	-12.49, -0.33	5.22, 7.24	-7.40, 5.87	3.23, 4.78	-41.34, -32.08

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.18 (54.46)		5.16 (61.12)		1.42 (62.46)	
	95% CI of Geometric Mean	4.62, 5.82		4.32, 6.16		1.18, 1.72	
	Median	5.37	-7.47	5.02	-6.89	1.29	-72.89
	Q25, Q75	3.90, 6.78	-27.12, 13.57	3.70, 8.09	-13.25, 2.03	1.09, 2.11	-80.00, -67.15
	Min, Max	1.1, 20.2	-69.6, 79.2	1.1, 15.4	-59.0, 27.0	0.3, 3.9	-86.5, -46.0
	Mean (SD)	5.89 (3.190)	-3.92 (33.159)	5.96 (3.196)	-5.61 (16.008)	1.65 (0.894)	-72.37 (9.216)
	95% CI of Mean	5.16, 6.61	-11.40, 3.57	4.96, 6.96	-10.60, -0.61	1.36, 1.94	-75.33, -69.42

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.37 (48.91)		4.93 (61.47)		0.64 (68.05)	
	95% CI of Geometric Mean	4.84, 5.97		4.13, 5.89		0.52, 0.78	
	Median	5.57	-9.78	4.91	-13.46	0.63	-88.49
	Q25, Q75	4.25, 6.95	-25.33, 15.06	3.53, 7.89	-18.61, 4.65	0.39, 0.97	-91.68, -83.33
	Min, Max	1.8, 15.8	-65.6, 112.5	1.1, 14.6	-53.2, 68.7	0.2, 3.0	-96.5, -54.7
	Mean (SD)	5.96 (2.834)	0.17 (38.347)	5.71 (3.071)	-8.80 (21.997)	0.77 (0.543)	-86.49 (7.891)
	95% CI of Mean	5.32, 6.61	-8.48, 8.83	4.74, 6.67	-15.66, -1.94	0.59, 0.95	-89.02, -83.97

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	5.57 (46.39)		4.92 (64.62)		0.30 (78.52)	
	95% CI of Geometric Mean	5.03, 6.15		4.09, 5.92		0.24, 0.39	
	Median	5.59	-7.64	4.96	-13.13	0.31	-94.38
	Q25, Q75	4.36, 7.54	-25.89, 23.16	3.16, 8.28	-21.04, 2.76	0.19, 0.42	-96.70, -91.18
	Min, Max	1.8, 13.7	-44.0, 142.3	1.1, 15.5	-56.8, 69.2	0.1, 3.0	-98.4, -54.7
	Mean (SD)	6.11 (2.650)	4.18 (43.168)	5.78 (3.248)	-8.35 (24.398)	0.41 (0.469)	-92.67 (7.325)
	95% CI of Mean	5.50, 6.71	-5.55, 13.92	4.76, 6.80	-15.95, -0.74	0.25, 0.56	-95.02, -90.32

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	6.15 (49.65)		5.22 (63.86)		0.17 (90.89)	
	95% CI of Geometric Mean	5.53, 6.85		4.35, 6.27		0.13, 0.22	
	Median	6.36	-0.01	5.65	-4.96	0.15	-96.65
	Q25, Q75	4.80, 8.63	-17.84, 33.00	3.42, 8.77	-18.98, 7.37	0.11, 0.24	-98.38, -94.64
	Min, Max	1.9, 15.1	-44.1, 177.4	1.1, 16.0	-48.4, 67.2	0.0, 3.0	-99.3, -54.7
	Mean (SD)	6.81 (3.018)	15.43 (47.776)	6.08 (3.258)	-3.30 (23.926)	0.26 (0.468)	-95.17 (7.195)
	95% CI of Mean	6.13, 7.50	4.65, 26.20	5.06, 7.10	-10.76, 4.16	0.11, 0.42	-97.48, -92.87

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	6.78 (57.80)		5.80 (72.03)		0.31 (946.65)	
	95% CI of Geometric Mean	6.00, 7.66		4.74, 7.10		0.15, 0.61	
	Median	6.60	14.96	6.60	12.28	0.11	-96.98
	Q25, Q75	4.81, 9.75	-9.79, 56.90	4.25, 9.10	-17.76, 34.00	0.05, 3.02	-99.02, -56.97
	Min, Max	1.6, 24.8	-49.1, 380.6	1.1, 15.1	-73.0, 154.4	0.0, 14.9	-99.6, 56.1
	Mean (SD)	7.81 (4.392)	29.50 (63.211)	6.86 (3.527)	15.04 (49.786)	1.84 (3.103)	-72.77 (41.657)
	95% CI of Mean	6.81, 8.80	15.24, 43.75	5.76, 7.97	-0.48, 30.56	0.84, 2.84	-86.10, -59.44

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	6.56 (63.35)		6.08 (79.44)		0.37 (1012.71)	
	95% CI of Geometric Mean	5.75, 7.48		4.89, 7.57		0.18, 0.74	
	Median	7.12	7.30	6.95	13.33	0.42	-91.61
	Q25, Q75	4.73, 9.30	-13.67, 54.85	3.94, 10.60	-14.40, 39.34	0.05, 2.04	-98.93, -61.84
	Min, Max	1.3, 23.9	-50.3, 279.0	1.0, 20.2	-80.3, 154.5	0.0, 11.9	-99.7, 92.9
	Mean (SD)	7.65 (4.280)	26.91 (61.797)	7.45 (4.417)	19.44 (47.042)	2.00 (3.178)	-67.85 (48.857)
	95% CI of Mean	6.68, 8.62	12.97, 40.85	6.07, 8.83	4.77, 34.10	0.98, 3.03	-83.48, -52.22

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 10 AM on Day 1 in the SA arm.

**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=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	42	42	40	40
	BLOQ, n (%)	0		0		0	
	Geometric Mean (CV%)	6.72 (65.18)		6.36 (75.05)		0.40 (1000.13)	
	95% CI of Geometric Mean	5.87, 7.69		5.16, 7.84		0.20, 0.80	
	Median	6.37	12.73	7.55	18.54	0.25	-95.69
	Q25, Q75	4.89, 9.10	-12.68, 61.83	4.25, 9.91	-13.22, 44.00	0.05, 3.28	-98.88, -45.96
	Min, Max	1.3, 31.7	-75.8, 341.9	0.9, 21.0	-55.9, 216.2	0.0, 11.9	-99.7, 318.2
	Mean (SD)	8.00 (5.237)	34.04 (77.848)	7.66 (4.378)	25.22 (55.704)	1.96 (2.729)	-59.73 (75.379)
	95% CI of Mean	6.81, 9.18	16.48, 51.60	6.29, 9.03	7.85, 42.58	1.08, 2.84	-83.84, -35.61

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Baseline	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.87 (63.07)	6.59 (80.47)	6.46 (67.03)
	95% CI of Geometric Mean	6.02, 7.83	5.28, 8.22	5.31, 7.86
	Median	7.53	7.54	6.51
	Q25, Q75	4.68, 10.72	4.35, 10.34	4.91, 9.77
	Min, Max	0.8, 27.3	1.4, 21.4	1.0, 17.2
	Mean (SD)	7.94 (4.192)	8.15 (5.027)	7.59 (4.220)
	95% CI of Mean	6.99, 8.89	6.58, 9.72	6.24, 8.95

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 1	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.00 (62.62)	6.47 (85.29)	3.63 (76.74)
	95% CI of Geometric Mean	5.26, 6.83	5.14, 8.16	2.92, 4.52
	Median	6.33	8.03	3.57
	Q25, Q75	4.45, 9.20	4.05, 11.57	2.72, 5.17
	Min, Max	1.1, 23.9	0.9, 21.4	0.7, 15.5
	Mean (SD)	6.96 (3.784)	8.12 (5.061)	4.51 (3.160)
	95% CI of Mean	6.10, 7.82	6.54, 9.70	3.49, 5.52

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 2	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.12 (63.61)	6.43 (80.19)	1.64 (70.79)
	95% CI of Geometric Mean	5.36, 6.98	5.16, 8.02	1.33, 2.02
	Median	6.76	6.65	1.89
	Q25, Q75	4.37, 9.47	4.53, 12.11	1.17, 2.45
	Min, Max	0.9, 18.5	1.2, 20.2	0.3, 6.5
	Mean (SD)	7.08 (3.579)	7.99 (5.037)	1.98 (1.252)
	95% CI of Mean	6.26, 7.89	6.41, 9.56	1.57, 2.38

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 3	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.54 (55.30)	6.02 (75.46)	0.76 (71.41)
	95% CI of Geometric Mean	5.82, 7.35	4.88, 7.43	0.61, 0.94
	Median	7.56	5.93	0.85
	Q25, Q75	5.19, 8.98	3.87, 10.65	0.46, 1.29
	Min, Max	2.0, 22.6	1.3, 18.3	0.2, 2.4
	Mean (SD)	7.40 (3.721)	7.37 (4.568)	0.92 (0.557)
	95% CI of Mean	6.56, 8.24	5.94, 8.80	0.73, 1.10

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 4	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	6.79 (48.77)	5.63 (79.17)	0.35 (85.67)
	95% CI of Geometric Mean	6.12, 7.54	4.52, 7.00	0.27, 0.45
	Median	7.10	6.08	0.39
	Q25, Q75	5.08, 9.15	3.04, 9.28	0.19, 0.62
	Min, Max	1.8, 17.8	1.2, 18.9	0.1, 2.4
	Mean (SD)	7.51 (3.393)	6.96 (4.332)	0.46 (0.411)
	95% CI of Mean	6.74, 8.28	5.60, 8.31	0.32, 0.60

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 5	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	7.20 (58.01)	6.47 (76.25)	0.20 (90.54)
	95% CI of Geometric Mean	6.37, 8.13	5.24, 8.00	0.15, 0.27
	Median	8.04	6.49	0.21
	Q25, Q75	5.35, 10.21	4.03, 11.04	0.13, 0.35
	Min, Max	1.8, 19.3	1.2, 16.7	0.0, 2.4
	Mean (SD)	8.16 (3.792)	7.90 (4.686)	0.29 (0.383)
	95% CI of Mean	7.30, 9.02	6.44, 9.37	0.16, 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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 30	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	8.03 (58.92)	6.77 (82.03)	0.33 (813.57)
	95% CI of Geometric Mean	7.09, 9.08	5.41, 8.47	0.16, 0.63
	Median	8.31	7.02	0.08
	Q25, Q75	5.67, 11.79	3.92, 13.25	0.06, 2.24
	Min, Max	1.6, 24.0	1.4, 21.5	0.0, 13.0
	Mean (SD)	9.23 (4.927)	8.46 (5.299)	1.95 (3.297)
	95% CI of Mean	8.11, 10.34	6.80, 10.11	0.89, 3.00

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 60	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	7.52 (68.14)	7.01 (87.98)	0.42 (955.92)
	95% CI of Geometric Mean	6.54, 8.65	5.53, 8.88	0.21, 0.83
	Median	7.94	6.81	0.24
	Q25, Q75	5.08, 11.62	5.08, 11.83	0.06, 2.46
	Min, Max	1.4, 30.2	1.0, 29.5	0.0, 15.5
	Mean (SD)	8.88 (4.949)	8.99 (6.272)	2.44 (4.203)
	95% CI of Mean	7.76, 10.00	7.03, 10.95	1.09, 3.79

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 10 AM on Day 1 in the SA arm.

**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=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	7.63 (69.92)	6.98 (83.29)	0.45 (902.27)
	95% CI of Geometric Mean	6.61, 8.80	5.56, 8.76	0.23, 0.89
	Median	9.18	6.99	0.22
	Q25, Q75	5.25, 11.73	4.65, 12.69	0.07, 3.45
	Min, Max	1.0, 22.3	1.0, 22.7	0.0, 12.5
	Mean (SD)	8.99 (4.672)	8.68 (5.304)	2.21 (3.217)
	95% CI of Mean	7.93, 10.04	7.02, 10.33	1.18, 3.25

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Baseline, 08:00 PM - 09:30 PM	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	12.60 (72.00)	11.27 (65.83)	11.47 (74.94)
	95% CI of Geometric Mean	10.87, 14.61	9.34, 13.59	9.23, 14.25
	Median	13.80	11.20	11.20
	Q25, Q75	7.81, 20.05	8.72, 18.90	7.33, 18.50
	Min, Max	1.2, 44.5	2.3, 31.5	2.5, 35.8
	Mean (SD)	15.17 (9.206)	13.19 (7.062)	14.00 (8.722)
	95% CI of Mean	13.06, 17.28	10.99, 15.40	11.17, 16.84

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 1, 08:00 PM - 09:30 PM	n	76	41	39
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	1 (1.3)	0	8 (20.5)
	Geometric Mean (CV%)	9.88 (95.98)	9.70 (85.42)	0.38 (137.36)
	95% CI of Geometric Mean	8.21, 11.89	7.67, 12.25	0.26, 0.53
	Median	12.30	11.70	0.34
	Q25, Q75	6.71, 17.20	7.66, 14.40	0.23, 0.62
	Min, Max	0.5, 37.3	1.2, 35.0	0.1, 7.0
	Mean (SD)	12.68 (7.901)	12.13 (7.762)	0.73 (1.259)
	95% CI of Mean	10.87, 14.49	9.68, 14.59	0.31, 1.14

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 2, 08:00 PM - 09:30 PM	n	76	41	39
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	29 (74.4)
	Geometric Mean (CV%)	12.31 (65.33)	11.00 (69.69)	0.14 (70.22)
	95% CI of Geometric Mean	10.74, 14.11	9.01, 13.42	0.11, 0.18
	Median	13.20	11.00	0.10
	Q25, Q75	9.12, 19.05	7.72, 17.20	0.10, 0.20
	Min, Max	2.2, 41.7	1.8, 30.3	0.1, 1.1
	Mean (SD)	14.39 (7.718)	12.98 (7.005)	0.19 (0.192)
	95% CI of Mean	12.62, 16.15	10.76, 15.19	0.12, 0.25

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 3, 08:00 PM - 09:30 PM	n	76	41	39
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	33 (84.6)
	Geometric Mean (CV%)	14.82 (62.58)	11.78 (74.39)	0.12 (36.95)
	95% CI of Geometric Mean	12.99, 16.90	9.55, 14.53	0.10, 0.14
	Median	16.50	12.20	0.10
	Q25, Q75	11.35, 21.40	9.20, 15.70	0.10, 0.10
	Min, Max	1.7, 38.5	2.4, 42.8	0.1, 0.3
	Mean (SD)	16.92 (7.877)	14.28 (8.879)	0.13 (0.062)
	95% CI of Mean	15.12, 18.73	11.47, 17.08	0.10, 0.15

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 4, 08:00 PM - 09:30 PM	n	76	41	39
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	37 (94.9)
	Geometric Mean (CV%)	11.86 (74.41)	10.13 (73.96)	0.10 (21.46)
	95% CI of Geometric Mean	10.19, 13.81	8.22, 12.49	0.09, 0.12
	Median	13.35	11.30	0.10
	Q25, Q75	8.27, 18.65	7.30, 14.50	0.10, 0.10
	Min, Max	1.3, 41.0	1.2, 26.5	0.1, 0.3
	Mean (SD)	14.18 (7.788)	12.06 (6.491)	0.11 (0.037)
	95% CI of Mean	12.40, 15.96	10.00, 14.11	0.09, 0.12

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, 15 Min < T0	n	76	41	
	Missing, n (%)	0	1 (2.4)	
	BLOQ, n (%)	8 (10.5)	7 (16.7)	
	Geometric Mean (CV%)	2.66 (105.86)	2.11 (108.48)	
	95% CI of Geometric Mean	2.18, 3.25	1.60, 2.80	
	Median	2.56	2.31	
	Q25, Q75	1.66, 4.60	1.18, 3.97	
	Min, Max	0.5, 15.6	0.5, 9.7	
	Mean (SD)	3.80 (3.420)	2.98 (2.464)	
	95% CI of Mean	3.01, 4.58	2.20, 3.76	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 2 h	n	66	37	
	Missing, n (%)	10 (13.2)	5 (11.9)	
	BLOQ, n (%)	0	2 (4.8)	
	Geometric Mean (CV%)	9.96 (67.24)	6.42 (122.61)	
	95% CI of Geometric Mean	8.56, 11.57	4.66, 8.84	
	Median	11.65	7.25	
	Q25, Q75	5.72, 16.40	4.36, 13.30	
	Min, Max	3.2, 30.2	0.5, 21.2	
	Mean (SD)	11.77 (6.399)	8.85 (5.879)	
	95% CI of Mean	10.19, 13.35	6.89, 10.82	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 4 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	2 (4.8)	
	Geometric Mean (CV%)	10.39 (72.67)	9.18 (115.36)	
	95% CI of Geometric Mean	8.85, 12.20	6.72, 12.54	
	Median	11.15	10.90	
	Q25, Q75	7.39, 15.80	6.79, 15.65	
	Min, Max	2.1, 36.5	0.5, 26.8	
	Mean (SD)	12.52 (7.444)	12.05 (7.132)	
	95% CI of Mean	10.69, 14.36	9.63, 14.46	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 6 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	12.95 (76.09)	10.86 (88.44)	
	95% CI of Geometric Mean	10.96, 15.30	8.39, 14.04	
	Median	14.80	12.70	
	Q25, Q75	8.43, 20.10	7.86, 19.60	
	Min, Max	1.4, 38.8	1.2, 30.9	
	Mean (SD)	15.64 (8.857)	13.58 (7.996)	
	95% CI of Mean	13.46, 17.82	10.87, 16.29	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 8 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	13.03 (69.97)	10.93 (80.83)	
	95% CI of Geometric Mean	11.15, 15.22	8.59, 13.90	
	Median	13.85	11.15	
	Q25, Q75	9.33, 20.60	7.11, 19.95	
	Min, Max	2.1, 46.1	1.7, 32.6	
	Mean (SD)	15.51 (9.003)	13.51 (8.144)	
	95% CI of Mean	13.29, 17.73	10.75, 16.27	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 10 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	14.12 (70.76)	11.67 (80.05)	
	95% CI of Geometric Mean	12.07, 16.52	9.19, 14.81	
	Median	15.10	12.05	
	Q25, Q75	8.91, 22.10	8.07, 20.00	
	Min, Max	2.0, 42.0	1.4, 41.4	
	Mean (SD)	16.83 (9.486)	14.38 (9.078)	
	95% CI of Mean	14.50, 19.17	11.31, 17.46	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 12 h	n	66	37	
	Missing, n (%)	10 (13.2)	5 (11.9)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	15.86 (64.58)	11.98 (75.93)	
	95% CI of Geometric Mean	13.72, 18.35	9.56, 15.01	
	Median	17.20	13.20	
	Q25, Q75	11.60, 23.00	8.60, 18.50	
	Min, Max	2.1, 49.9	1.3, 36.4	
	Mean (SD)	18.38 (9.526)	14.35 (7.930)	
	95% CI of Mean	16.04, 20.73	11.71, 17.00	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 14 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	14.91 (54.52)	12.00 (83.02)	
	95% CI of Geometric Mean	13.14, 16.90	9.39, 15.34	
	Median	15.20	13.75	
	Q25, Q75	10.80, 20.20	7.80, 21.55	
	Min, Max	4.2, 44.9	1.7, 33.5	
	Mean (SD)	16.92 (9.038)	14.67 (8.077)	
	95% CI of Mean	14.69, 19.15	11.93, 17.41	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 16 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	18.16 (57.00)	12.69 (69.73)	
	95% CI of Geometric Mean	15.93, 20.69	10.25, 15.71	
	Median	18.35	14.40	
	Q25, Q75	12.10, 26.00	10.18, 19.40	
	Min, Max	5.1, 47.9	1.6, 35.2	
	Mean (SD)	20.72 (10.629)	14.77 (7.169)	
	95% CI of Mean	18.11, 23.34	12.34, 17.20	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, 08:00 PM - 09:30 PM	n			38
	Missing, n (%)			1 (2.6)
	BLOQ, n (%)			38 (97.4)
	Geometric Mean (CV%)			0.10 (11.28)
	95% CI of Geometric Mean			0.09, 0.11
	Median			0.10
	Q25, Q75			0.10, 0.10
	Min, Max			0.1, 0.2
	Mean (SD)			0.10 (0.017)
	95% CI of Mean			0.09, 0.11

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 6/Discharge Confinement, T0 + 20 h	n	65	37	
	Missing, n (%)	11 (14.5)	5 (11.9)	
	BLOQ, n (%)	1 (1.3)	2 (4.8)	
	Geometric Mean (CV%)	6.89 (86.00)	4.86 (101.45)	
	95% CI of Geometric Mean	5.72, 8.29	3.67, 6.44	
	Median	7.04	6.36	
	Q25, Q75	4.39, 10.10	3.54, 8.51	
	Min, Max	0.5, 32.2	0.5, 17.1	
	Mean (SD)	8.89 (6.705)	6.36 (4.215)	
	95% CI of Mean	7.22, 10.55	4.95, 7.77	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 6/Discharge Confinement, T0 + 24 h	n	49	33	
	Missing, n (%)	27 (35.5)	9 (21.4)	
	BLOQ, n (%)	9 (11.8)	7 (16.7)	
	Geometric Mean (CV%)	2.65 (135.62)	1.95 (120.32)	
	95% CI of Geometric Mean	1.97, 3.55	1.39, 2.74	
	Median	2.85	1.82	
	Q25, Q75	1.72, 4.44	1.14, 4.07	
	Min, Max	0.5, 16.6	0.5, 10.4	
	Mean (SD)	4.21 (4.207)	2.92 (2.660)	
	95% CI of Mean	2.99, 5.42	1.98, 3.87	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 6/Discharge Confinement, 08:00 AM - 09:30 AM	n			39
	BLOQ, n (%)			39 (100.0)
	Geometric Mean (CV%)			0.10 (0.00)
	95% CI of Geometric Mean			,
	Median			0.10
	Q25, Q75			0.10, 0.10
	Min, Max			0.1, 0.1
	Mean (SD)			0.10 (0.000)
	95% CI of Mean			,

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)
Baseline, 08:00 PM - 09:30 PM	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	12.74 (72.34)	11.13 (66.05)	11.47 (74.94)
	95% CI of Geometric Mean	10.95, 14.81	9.20, 13.46	9.23, 14.25
	Median	13.80	11.20	11.20
	Q25, Q75	7.85, 20.40	8.72, 18.40	7.33, 18.50
	Min, Max	1.2, 44.5	2.3, 31.5	2.5, 35.8
	Mean (SD)	15.33 (9.260)	13.05 (7.089)	14.00 (8.722)
	95% CI of Mean	13.18, 17.48	10.81, 15.29	11.17, 16.84

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)
Day 30, 10:00 AM - 11:30 AM	n	74	41	38
	Missing, n (%)	0	0	1 (2.6)
	BLOQ, n (%)	0	0	24 (61.5)
	Geometric Mean (CV%)	12.89 (63.63)	12.35 (71.52)	0.42 (712.39)
	95% CI of Geometric Mean	11.26, 14.76	10.08, 15.13	0.21, 0.80
	Median	14.40	13.50	0.10
	Q25, Q75	10.20, 19.60	10.20, 17.30	0.10, 2.42
	Min, Max	2.1, 31.7	1.6, 34.6	0.1, 26.2
	Mean (SD)	14.87 (7.191)	14.60 (7.855)	3.00 (6.080)
	95% CI of Mean	13.20, 16.54	12.12, 17.09	1.00, 5.00

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)
Baseline, 08:00 PM - 09:30 PM	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	12.92 (68.50)	11.13 (66.05)	11.33 (75.53)
	95% CI of Geometric Mean	11.15, 14.97	9.20, 13.46	9.08, 14.13
	Median	13.80	11.20	10.90
	Q25, Q75	7.97, 20.40	8.72, 18.40	7.33, 17.90
	Min, Max	1.2, 44.5	2.3, 31.5	2.5, 35.8
	Mean (SD)	15.33 (8.962)	13.05 (7.089)	13.89 (8.807)
	95% CI of Mean	13.20, 17.45	10.81, 15.29	10.99, 16.79

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)
Day 60, 10:00 AM - 11:30 AM	n	71	41	38
	BLOQ, n (%)	0	0	19 (50.0)
	Geometric Mean (CV%)	12.88 (72.36)	11.33 (81.44)	0.56 (676.91)
	95% CI of Geometric Mean	11.04, 15.02	9.04, 14.19	0.29, 1.07
	Median	13.70	11.90	0.22
	Q25, Q75	8.56, 20.30	6.56, 18.50	0.10, 3.16
	Min, Max	1.3, 38.2	1.9, 36.8	0.1, 21.6
	Mean (SD)	15.36 (8.474)	13.94 (8.237)	3.08 (5.358)
	95% CI of Mean	13.35, 17.37	11.34, 16.55	1.32, 4.85

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)
Baseline, 08:00 PM - 09:30 PM	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	12.55 (74.40)	11.13 (66.05)	11.03 (73.96)
	95% CI of Geometric Mean	10.71, 14.71	9.20, 13.46	8.84, 13.75
	Median	13.70	11.20	10.60
	Q25, Q75	7.77, 20.40	8.72, 18.40	7.33, 17.00
	Min, Max	1.2, 44.5	2.3, 31.5	2.5, 35.8
	Mean (SD)	15.26 (9.510)	13.05 (7.089)	13.44 (8.487)
	95% CI of Mean	12.99, 17.54	10.81, 15.29	10.61, 16.28

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Nicotine (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)
Day 90, 10:00 AM - 12:30 PM	n	69	41	37
	Missing, n (%)	1 (1.4)	0	0
	BLOQ, n (%)	0	0	20 (54.1)
	Geometric Mean (CV%)	12.69 (75.01)	11.25 (79.68)	0.57 (822.93)
	95% CI of Geometric Mean	10.81, 14.91	9.02, 14.05	0.28, 1.13
	Median	13.20	11.90	0.10
	Q25, Q75	8.74, 19.90	7.48, 19.30	0.10, 5.41
	Min, Max	2.3, 55.9	2.2, 42.7	0.1, 20.1
	Mean (SD)	15.42 (9.460)	14.00 (9.135)	3.16 (4.905)
	95% CI of Mean	13.14, 17.70	11.11, 16.89	1.52, 4.80

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Baseline, 08:00 PM - 09:30 PM	n	76	42	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	153.65 (61.43)	155.44 (62.59)	145.26 (72.50)
	95% CI of Geometric Mean	135.01, 174.86	129.94, 185.94	117.66, 179.33
	Median	172.00	165.00	148.00
	Q25, Q75	118.00, 230.50	114.00, 231.00	107.00, 250.00
	Min, Max	23.0, 357.0	35.4, 380.0	25.4, 353.0
	Mean (SD)	174.82 (77.791)	179.12 (89.226)	172.53 (91.544)
	95% CI of Mean	157.03, 192.60	151.31, 206.93	142.85, 202.21

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 1, 08:00 PM - 09:30 PM	n	76	41	39
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	144.06 (60.80)	149.13 (68.10)	81.26 (68.59)
	95% CI of Geometric Mean	126.73, 163.76	122.73, 181.21	66.44, 99.39
	Median	159.50	151.00	82.90
	Q25, Q75	106.00, 235.50	112.00, 252.00	46.80, 140.00
	Min, Max	28.2, 286.0	33.2, 380.0	19.2, 247.0
	Mean (SD)	164.10 (73.490)	175.40 (92.566)	96.17 (53.059)
	95% CI of Mean	147.31, 180.90	146.17, 204.62	78.96, 113.37

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 2, 08:00 PM - 09:30 PM	n	76	41	39
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	146.31 (55.57)	144.11 (71.07)	34.32 (76.10)
	95% CI of Geometric Mean	129.95, 164.73	117.77, 176.34	27.56, 42.73
	Median	160.50	155.00	38.80
	Q25, Q75	107.00, 224.50	99.50, 242.00	20.40, 61.30
	Min, Max	37.1, 291.0	27.2, 388.0	10.4, 161.0
	Mean (SD)	163.79 (68.811)	170.87 (90.855)	42.42 (29.068)
	95% CI of Mean	148.06, 179.51	142.18, 199.55	32.99, 51.84

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 3, 08:00 PM - 09:30 PM	n	76	41	39
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	152.91 (53.22)	139.07 (74.91)	15.92 (88.44)
	95% CI of Geometric Mean	136.41, 171.40	112.65, 171.69	12.44, 20.37
	Median	171.50	152.00	16.60
	Q25, Q75	124.00, 222.00	103.00, 229.00	10.40, 26.20
	Min, Max	34.1, 319.0	24.8, 390.0	3.7, 99.8
	Mean (SD)	169.50 (67.606)	167.43 (93.090)	21.00 (17.712)
	95% CI of Mean	154.05, 184.96	138.04, 196.82	15.25, 26.74

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 4, 08:00 PM - 09:30 PM	n	75	41	39
	Missing, n (%)	1 (1.3)	1 (2.4)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	156.52 (53.75)	143.22 (77.43)	7.83 (101.82)
	95% CI of Geometric Mean	139.38, 175.76	115.35, 177.81	5.95, 10.30
	Median	179.00	161.00	7.81
	Q25, Q75	116.00, 219.00	114.00, 252.00	5.09, 12.90
	Min, Max	32.4, 300.0	27.8, 382.0	1.6, 70.6
	Mean (SD)	173.20 (66.097)	173.22 (94.312)	11.21 (11.993)
	95% CI of Mean	157.98, 188.41	143.45, 203.00	7.32, 15.10

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, 15 Min < T0	n	76	41	
	Missing, n (%)	0	1 (2.4)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	157.96 (52.71)	140.34 (75.39)	
	95% CI of Geometric Mean	141.06, 176.89	113.56, 173.44	
	Median	176.00	158.00	
	Q25, Q75	125.50, 226.50	107.00, 224.00	
	Min, Max	37.4, 297.0	25.5, 379.0	
	Mean (SD)	174.61 (67.563)	168.53 (91.279)	
	95% CI of Mean	159.16, 190.05	139.71, 197.35	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 2 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	167.01 (50.83)	144.25 (72.17)	
	95% CI of Geometric Mean	148.44, 187.90	115.86, 179.58	
	Median	181.50	158.00	
	Q25, Q75	146.00, 240.00	109.00, 229.00	
	Min, Max	37.3, 329.0	27.1, 353.0	
	Mean (SD)	183.25 (67.978)	170.88 (88.702)	
	95% CI of Mean	166.53, 199.96	140.87, 200.90	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 4 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	158.04 (51.30)	137.87 (73.63)	
	95% CI of Geometric Mean	140.33, 177.99	110.34, 172.27	
	Median	175.00	153.00	
	Q25, Q75	130.00, 221.00	102.00, 221.50	
	Min, Max	35.0, 297.0	25.1, 346.0	
	Mean (SD)	173.61 (64.539)	163.96 (85.351)	
	95% CI of Mean	157.74, 189.48	135.07, 192.84	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 6 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	163.73 (52.44)	142.07 (75.68)	
	95% CI of Geometric Mean	145.04, 184.82	113.14, 178.40	
	Median	181.00	160.00	
	Q25, Q75	136.00, 236.00	109.50, 230.00	
	Min, Max	35.1, 339.0	26.0, 359.0	
	Mean (SD)	180.55 (68.785)	170.14 (90.245)	
	95% CI of Mean	163.63, 197.46	139.60, 200.68	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 8 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	167.07 (51.86)	146.05 (75.52)	
	95% CI of Geometric Mean	148.18, 188.37	116.35, 183.32	
	Median	180.00	166.00	
	Q25, Q75	142.00, 238.00	117.00, 244.00	
	Min, Max	38.3, 325.0	27.9, 373.0	
	Mean (SD)	183.76 (68.546)	174.64 (91.686)	
	95% CI of Mean	166.91, 200.62	143.61, 205.67	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 10 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	172.29 (53.00)	150.00 (75.24)	
	95% CI of Geometric Mean	152.45, 194.71	119.58, 188.16	
	Median	191.50	172.50	
	Q25, Q75	158.00, 252.00	115.50, 240.50	
	Min, Max	34.8, 335.0	30.5, 386.0	
	Mean (SD)	190.00 (71.189)	179.28 (94.172)	
	95% CI of Mean	172.50, 207.51	147.41, 211.15	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 12 h	n	66	37	
	Missing, n (%)	10 (13.2)	5 (11.9)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	182.80 (53.84)	155.23 (76.98)	
	95% CI of Geometric Mean	161.47, 206.94	123.65, 194.87	
	Median	201.50	174.00	
	Q25, Q75	165.00, 267.00	116.00, 263.00	
	Min, Max	33.9, 348.0	29.5, 406.0	
	Mean (SD)	202.01 (75.971)	187.17 (101.433)	
	95% CI of Mean	183.33, 220.69	153.35, 221.00	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 14 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	177.15 (53.38)	153.51 (76.73)	
	95% CI of Geometric Mean	156.63, 200.36	121.93, 193.25	
	Median	192.00	177.50	
	Q25, Q75	159.00, 258.00	121.50, 255.00	
	Min, Max	32.5, 296.0	29.2, 427.0	
	Mean (SD)	195.28 (71.555)	184.55 (99.049)	
	95% CI of Mean	177.68, 212.87	151.03, 218.07	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, T0 + 16 h	n	66	36	
	Missing, n (%)	10 (13.2)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	189.13 (54.36)	160.72 (77.82)	
	95% CI of Geometric Mean	166.89, 214.34	127.33, 202.86	
	Median	204.00	194.00	
	Q25, Q75	168.00, 267.00	125.50, 251.00	
	Min, Max	34.3, 372.0	29.9, 411.0	
	Mean (SD)	209.29 (79.171)	193.36 (101.757)	
	95% CI of Mean	189.83, 228.76	158.92, 227.79	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5, 08:00 PM - 09:30 PM	n			39
	BLOQ, n (%)			4 (10.3)
	Geometric Mean (CV%)			3.41 (132.99)
	95% CI of Geometric Mean			2.45, 4.73
	Median			3.88
	Q25, Q75			1.95, 6.32
	Min, Max			0.5, 42.9
	Mean (SD)			5.59 (7.294)
	95% CI of Mean			3.22, 7.96

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 6/Discharge Confinement, T0 + 20 h	n	64	36	
	Missing, n (%)	12 (15.8)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	189.09 (52.00)	160.15 (74.30)	
	95% CI of Geometric Mean	167.34, 213.67	127.97, 200.43	
	Median	209.00	185.50	
	Q25, Q75	167.50, 264.50	126.50, 253.50	
	Min, Max	38.0, 341.0	29.3, 412.0	
	Mean (SD)	207.82 (76.252)	190.60 (98.236)	
	95% CI of Mean	188.77, 226.87	157.36, 223.84	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 6/Discharge Confinement, T0 + 24 h	n	44	31	
	Missing, n (%)	32 (42.1)	11 (26.2)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	183.02 (51.35)	142.86 (77.89)	
	95% CI of Geometric Mean	157.98, 212.02	110.97, 183.91	
	Median	198.50	162.00	
	Q25, Q75	146.00, 259.50	97.70, 241.00	
	Min, Max	49.8, 316.0	28.5, 417.0	
	Mean (SD)	201.36 (76.625)	173.35 (98.018)	
	95% CI of Mean	178.06, 224.66	137.39, 209.30	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 6/Discharge Confinement, 08:00 AM - 09:30 AM	n			39
	BLOQ, n (%)			6 (15.4)
	Geometric Mean (CV%)			2.91 (140.71)
	95% CI of Geometric Mean			2.07, 4.09
	Median			3.25
	Q25, Q75			1.86, 5.86
	Min, Max			0.5, 37.5
	Mean (SD)			4.94 (6.558)
	95% CI of Mean			2.81, 7.07

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)
Baseline, 08:00 PM - 09:30 PM	n	74	41	39
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	154.94 (61.36)	153.17 (62.47)	145.26 (72.50)
	95% CI of Geometric Mean	135.92, 176.62	127.78, 183.60	117.66, 179.33
	Median	172.00	160.00	148.00
	Q25, Q75	119.00, 231.00	114.00, 224.00	107.00, 250.00
	Min, Max	23.0, 357.0	35.4, 380.0	25.4, 353.0
	Mean (SD)	176.11 (77.845)	176.56 (88.761)	172.53 (91.544)
	95% CI of Mean	158.07, 194.15	148.54, 204.58	142.85, 202.21

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=74)	mCC (N=41)	SA (N=39)
Day 30, 10:00 AM - 11:30 AM	n	74	41	38
	Missing, n (%)	0	0	1 (2.6)
	BLOQ, n (%)	0	0	12 (30.8)
	Geometric Mean (CV%)	194.86 (66.55)	167.30 (80.91)	6.44 (1681.79)
	95% CI of Geometric Mean	169.35, 224.21	133.72, 209.31	2.94, 14.06
	Median	218.50	185.00	3.58
	Q25, Q75	155.00, 299.00	115.00, 280.00	0.50, 84.30
	Min, Max	37.6, 654.0	22.0, 552.0	0.5, 227.0
	Mean (SD)	227.07 (114.870)	205.85 (122.953)	47.68 (70.012)
	95% CI of Mean	200.45, 253.69	167.03, 244.66	24.66, 70.70

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)
Baseline, 08:00 PM - 09:30 PM	n	71	41	38
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	158.58 (57.14)	153.17 (62.47)	142.34 (71.97)
	95% CI of Geometric Mean	139.83, 179.84	127.78, 183.60	115.11, 176.02
	Median	172.00	160.00	147.00
	Q25, Q75	120.00, 230.00	114.00, 224.00	107.00, 231.00
	Min, Max	23.0, 357.0	35.4, 380.0	25.4, 353.0
	Mean (SD)	177.85 (75.626)	176.56 (88.761)	168.81 (89.731)
	95% CI of Mean	159.94, 195.75	148.54, 204.58	139.31, 198.31

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=71)	mCC (N=41)	SA (N=38)
Day 60, 10:00 AM - 11:30 AM	n	71	41	38
	BLOQ, n (%)	0	0	13 (34.2)
	Geometric Mean (CV%)	181.91 (70.86)	164.23 (79.55)	8.28 (2009.04)
	95% CI of Geometric Mean	156.42, 211.56	131.66, 204.85	3.69, 18.52
	Median	214.00	187.00	9.91
	Q25, Q75	130.00, 274.00	108.00, 277.00	0.50, 69.50
	Min, Max	26.7, 583.0	26.7, 439.0	0.5, 411.0
	Mean (SD)	214.42 (110.689)	199.66 (110.489)	57.13 (89.871)
	95% CI of Mean	188.21, 240.62	164.78, 234.54	27.58, 86.67

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)
Baseline, 08:00 PM - 09:30 PM	n	70	41	37
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	151.49 (61.94)	153.17 (62.47)	140.09 (72.14)
	95% CI of Geometric Mean	132.24, 173.55	127.78, 183.60	112.89, 173.84
	Median	170.50	160.00	146.00
	Q25, Q75	117.00, 230.00	114.00, 224.00	107.00, 214.00
	Min, Max	23.0, 357.0	35.4, 380.0	25.4, 353.0
	Mean (SD)	172.59 (76.979)	176.56 (88.761)	166.42 (89.741)
	95% CI of Mean	154.23, 190.95	148.54, 204.58	136.50, 196.35

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Parameter (units): Cotinine (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)
Day 90, 10:00 AM - 12:30 PM	n	69	41	37
	Missing, n (%)	1 (1.4)	0	0
	BLOQ, n (%)	0	0	13 (35.1)
	Geometric Mean (CV%)	183.16 (63.51)	172.69 (78.74)	8.49 (2643.59)
	95% CI of Geometric Mean	159.25, 210.65	138.69, 215.02	3.61, 19.93
	Median	215.00	221.00	6.10
	Q25, Q75	159.00, 260.00	119.00, 299.00	0.50, 124.00
	Min, Max	39.3, 636.0	18.6, 389.0	0.5, 436.0
	Mean (SD)	210.58 (102.090)	207.89 (107.635)	65.63 (96.286)
	95% CI of Mean	186.05, 235.10	173.91, 241.87	33.52, 97.74

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Baseline, 08:00 PM - 09:30 PM	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	12.60 (71.95)	11.27 (65.83)	11.65 (74.75)
	95% CI of Geometric Mean	10.89, 14.58	9.34, 13.59	9.41, 14.42
	Median	13.80	11.20	12.00
	Q25, Q75	7.77, 20.40	8.72, 18.90	7.48, 18.75
	Min, Max	1.2, 44.5	2.3, 31.5	2.5, 35.8
	Mean (SD)	15.17 (9.186)	13.19 (7.062)	14.19 (8.686)
	95% CI of Mean	13.09, 17.24	10.99, 15.40	11.40, 16.97

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 1, 08:00 PM - 09:30 PM	n	78	41	40
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	1 (1.3)	0	8 (20.0)
	Geometric Mean (CV%)	9.79 (94.62)	9.70 (85.42)	0.38 (136.07)
	95% CI of Geometric Mean	8.17, 11.73	7.67, 12.25	0.27, 0.54
	Median	11.45	11.70	0.34
	Q25, Q75	6.65, 17.10	7.66, 14.40	0.23, 0.65
	Min, Max	0.5, 37.3	1.2, 35.0	0.1, 7.0
	Mean (SD)	12.54 (7.849)	12.13 (7.762)	0.73 (1.242)
	95% CI of Mean	10.76, 14.31	9.68, 14.59	0.33, 1.13

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 2, 08:00 PM - 09:30 PM	n	77	41	40
	Missing, n (%)	1 (1.3)	1 (2.4)	0
	BLOQ, n (%)	0	0	29 (72.5)
	Geometric Mean (CV%)	12.31 (64.82)	11.00 (69.69)	0.14 (69.49)
	95% CI of Geometric Mean	10.76, 14.09	9.01, 13.42	0.11, 0.18
	Median	13.10	11.00	0.10
	Q25, Q75	9.23, 19.00	7.72, 17.20	0.10, 0.20
	Min, Max	2.2, 41.7	1.8, 30.3	0.1, 1.1
	Mean (SD)	14.36 (7.671)	12.98 (7.005)	0.19 (0.189)
	95% CI of Mean	12.61, 16.10	10.76, 15.19	0.12, 0.25

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 3, 08:00 PM - 09:30 PM	n	77	41	39
	Missing, n (%)	1 (1.3)	1 (2.4)	1 (2.5)
	BLOQ, n (%)	0	0	33 (82.5)
	Geometric Mean (CV%)	14.95 (62.83)	11.78 (74.39)	0.12 (36.95)
	95% CI of Geometric Mean	13.11, 17.05	9.55, 14.53	0.10, 0.14
	Median	16.60	12.20	0.10
	Q25, Q75	11.40, 21.60	9.20, 15.70	0.10, 0.10
	Min, Max	1.7, 38.5	2.4, 42.8	0.1, 0.3
	Mean (SD)	17.09 (7.970)	14.28 (8.879)	0.13 (0.062)
	95% CI of Mean	15.28, 18.91	11.47, 17.08	0.10, 0.15

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 4, 08:00 PM - 09:30 PM	n	77	41	39
	Missing, n (%)	1 (1.3)	1 (2.4)	1 (2.5)
	BLOQ, n (%)	0	0	37 (92.5)
	Geometric Mean (CV%)	11.91 (73.91)	10.13 (73.96)	0.10 (21.46)
	95% CI of Geometric Mean	10.24, 13.84	8.22, 12.49	0.09, 0.12
	Median	13.70	11.30	0.10
	Q25, Q75	8.46, 18.40	7.30, 14.50	0.10, 0.10
	Min, Max	1.3, 41.0	1.2, 26.5	0.1, 0.3
	Mean (SD)	14.20 (7.738)	12.06 (6.491)	0.11 (0.037)
	95% CI of Mean	12.44, 15.96	10.00, 14.11	0.09, 0.12

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, 15 Min < T0	n	77	41	
	Missing, n (%)	1 (1.3)	1 (2.4)	
	BLOQ, n (%)	8 (10.3)	7 (16.7)	
	Geometric Mean (CV%)	2.66 (104.88)	2.11 (108.48)	
	95% CI of Geometric Mean	2.18, 3.24	1.60, 2.80	
	Median	2.55	2.31	
	Q25, Q75	1.66, 4.54	1.18, 3.97	
	Min, Max	0.5, 15.6	0.5, 9.7	
	Mean (SD)	3.78 (3.401)	2.98 (2.464)	
	95% CI of Mean	3.00, 4.56	2.20, 3.76	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 2 h	n	67	37	
	Missing, n (%)	11 (14.1)	5 (11.9)	
	BLOQ, n (%)	0	2 (4.8)	
	Geometric Mean (CV%)	10.02 (66.91)	6.42 (122.61)	
	95% CI of Geometric Mean	8.63, 11.63	4.66, 8.84	
	Median	12.00	7.25	
	Q25, Q75	5.72, 16.40	4.36, 13.30	
	Min, Max	3.2, 30.2	0.5, 21.2	
	Mean (SD)	11.82 (6.364)	8.85 (5.879)	
	95% CI of Mean	10.26, 13.38	6.89, 10.82	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 4 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	2 (4.8)	
	Geometric Mean (CV%)	10.47 (72.35)	9.18 (115.36)	
	95% CI of Geometric Mean	8.93, 12.27	6.72, 12.54	
	Median	11.20	10.90	
	Q25, Q75	7.39, 16.10	6.79, 15.65	
	Min, Max	2.1, 36.5	0.5, 26.8	
	Mean (SD)	12.58 (7.405)	12.05 (7.132)	
	95% CI of Mean	10.77, 14.39	9.63, 14.46	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 6 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	12.92 (75.40)	10.86 (88.44)	
	95% CI of Geometric Mean	10.97, 15.23	8.39, 14.04	
	Median	14.50	12.70	
	Q25, Q75	8.43, 20.10	7.86, 19.60	
	Min, Max	1.4, 38.8	1.2, 30.9	
	Mean (SD)	15.58 (8.806)	13.58 (7.996)	
	95% CI of Mean	13.42, 17.73	10.87, 16.29	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 8 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	13.07 (69.39)	10.93 (80.83)	
	95% CI of Geometric Mean	11.21, 15.23	8.59, 13.90	
	Median	13.90	11.15	
	Q25, Q75	9.33, 20.60	7.11, 19.95	
	Min, Max	2.1, 46.1	1.7, 32.6	
	Mean (SD)	15.52 (8.935)	13.51 (8.144)	
	95% CI of Mean	13.34, 17.70	10.75, 16.27	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 10 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	14.20 (70.32)	11.67 (80.05)	
	95% CI of Geometric Mean	12.16, 16.57	9.19, 14.81	
	Median	15.10	12.05	
	Q25, Q75	8.91, 22.10	8.07, 20.00	
	Min, Max	2.0, 42.0	1.4, 41.4	
	Mean (SD)	16.89 (9.424)	14.38 (9.078)	
	95% CI of Mean	14.58, 19.19	11.31, 17.46	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 12 h	n	67	37	
	Missing, n (%)	11 (14.1)	5 (11.9)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	15.88 (64.01)	11.98 (75.93)	
	95% CI of Geometric Mean	13.76, 18.33	9.56, 15.01	
	Median	17.20	13.20	
	Q25, Q75	11.60, 23.00	8.60, 18.50	
	Min, Max	2.1, 49.9	1.3, 36.4	
	Mean (SD)	18.37 (9.455)	14.35 (7.930)	
	95% CI of Mean	16.05, 20.68	11.71, 17.00	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 14 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	14.88 (54.08)	12.00 (83.02)	
	95% CI of Geometric Mean	13.14, 16.84	9.39, 15.34	
	Median	14.90	13.75	
	Q25, Q75	10.80, 20.20	7.80, 21.55	
	Min, Max	4.2, 44.9	1.7, 33.5	
	Mean (SD)	16.86 (8.981)	14.67 (8.077)	
	95% CI of Mean	14.67, 19.06	11.93, 17.41	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 16 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	18.27 (56.77)	12.69 (69.73)	
	95% CI of Geometric Mean	16.05, 20.78	10.25, 15.71	
	Median	18.50	14.40	
	Q25, Q75	12.10, 26.10	10.18, 19.40	
	Min, Max	5.1, 47.9	1.6, 35.2	
	Mean (SD)	20.82 (10.575)	14.77 (7.169)	
	95% CI of Mean	18.23, 23.40	12.34, 17.20	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, 08:00 PM - 09:30 PM	n			38
	Missing, n (%)			2 (5.0)
	BLOQ, n (%)			38 (95.0)
	Geometric Mean (CV%)			0.10 (11.28)
	95% CI of Geometric Mean			0.09, 0.11
	Median			0.10
	Q25, Q75			0.10, 0.10
	Min, Max			0.1, 0.2
	Mean (SD)			0.10 (0.017)
	95% CI of Mean			0.09, 0.11

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 6/Discharge Confinement, T0 + 20 h	n	66	37	
	Missing, n (%)	12 (15.4)	5 (11.9)	
	BLOQ, n (%)	1 (1.3)	2 (4.8)	
	Geometric Mean (CV%)	6.93 (85.36)	4.86 (101.45)	
	95% CI of Geometric Mean	5.77, 8.31	3.67, 6.44	
	Median	7.07	6.36	
	Q25, Q75	4.39, 10.10	3.54, 8.51	
	Min, Max	0.5, 32.2	0.5, 17.1	
	Mean (SD)	8.90 (6.655)	6.36 (4.215)	
	95% CI of Mean	7.26, 10.55	4.95, 7.77	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 6/Discharge Confinement, T0 + 24 h	n	49	33	
	Missing, n (%)	29 (37.2)	9 (21.4)	
	BLOQ, n (%)	9 (11.5)	7 (16.7)	
	Geometric Mean (CV%)	2.65 (135.62)	1.95 (120.32)	
	95% CI of Geometric Mean	1.97, 3.55	1.39, 2.74	
	Median	2.85	1.82	
	Q25, Q75	1.72, 4.44	1.14, 4.07	
	Min, Max	0.5, 16.6	0.5, 10.4	
	Mean (SD)	4.21 (4.207)	2.92 (2.660)	
	95% CI of Mean	2.99, 5.42	1.98, 3.87	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 6/Discharge Confinement, 08:00 AM - 09:30 AM	n			39
	Missing, n (%)			1 (2.5)
	BLOQ, n (%)			39 (97.5)
	Geometric Mean (CV%)			0.10 (0.00)
	95% CI of Geometric Mean			,
	Median			0.10
	Q25, Q75			0.10, 0.10
	Min, Max			0.1, 0.1
	Mean (SD)			0.10 (0.000)
	95% CI of Mean			,

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 30, 10:00 AM - 11:30 AM	n	77	41	38
	Missing, n (%)	1 (1.3)	1 (2.4)	2 (5.0)
	BLOQ, n (%)	0	0	24 (60.0)
	Geometric Mean (CV%)	12.78 (64.33)	12.35 (71.52)	0.42 (712.39)
	95% CI of Geometric Mean	11.18, 14.62	10.08, 15.13	0.21, 0.80
	Median	14.30	13.50	0.10
	Q25, Q75	10.20, 19.60	10.20, 17.30	0.10, 2.42
	Min, Max	2.1, 31.7	1.6, 34.6	0.1, 26.2
	Mean (SD)	14.78 (7.181)	14.60 (7.855)	3.00 (6.080)
	95% CI of Mean	13.15, 16.42	12.12, 17.09	1.00, 5.00

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 60, 10:00 AM - 11:30 AM	n	77	41	38
	Missing, n (%)	1 (1.3)	1 (2.4)	2 (5.0)
	BLOQ, n (%)	0	0	19 (47.5)
	Geometric Mean (CV%)	12.99 (69.82)	11.33 (81.44)	0.56 (676.91)
	95% CI of Geometric Mean	11.26, 15.00	9.04, 14.19	0.29, 1.07
	Median	13.70	11.90	0.22
	Q25, Q75	8.96, 19.90	6.56, 18.50	0.10, 3.16
	Min, Max	1.3, 38.2	1.9, 36.8	0.1, 21.6
	Mean (SD)	15.34 (8.239)	13.94 (8.237)	3.08 (5.358)
	95% CI of Mean	13.47, 17.22	11.34, 16.55	1.32, 4.85

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Nicotine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 90, 10:00 AM - 12:30 PM	n	76	41	38
	Missing, n (%)	2 (2.6)	1 (2.4)	2 (5.0)
	BLOQ, n (%)	0	0	20 (50.0)
	Geometric Mean (CV%)	12.54 (74.43)	11.25 (79.68)	0.61 (838.01)
	95% CI of Geometric Mean	10.77, 14.60	9.02, 14.05	0.30, 1.20
	Median	13.05	11.90	0.10
	Q25, Q75	8.61, 20.05	7.48, 19.30	0.10, 6.20
	Min, Max	2.3, 55.9	2.2, 42.7	0.1, 20.1
	Mean (SD)	15.23 (9.343)	14.00 (9.135)	3.24 (4.863)
	95% CI of Mean	13.09, 17.37	11.11, 16.89	1.63, 4.84

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Baseline, 08:00 PM - 09:30 PM	n	78	42	40
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	154.38 (62.21)	155.44 (62.59)	146.78 (71.81)
	95% CI of Geometric Mean	135.70, 175.63	129.94, 185.94	119.42, 180.40
	Median	172.00	165.00	151.50
	Q25, Q75	117.00, 231.00	114.00, 231.00	111.00, 240.50
	Min, Max	23.0, 390.0	35.4, 380.0	25.4, 353.0
	Mean (SD)	176.46 (81.188)	179.12 (89.226)	173.72 (90.674)
	95% CI of Mean	158.15, 194.77	151.31, 206.93	144.71, 202.72

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 1, 08:00 PM - 09:30 PM	n	78	41	40
	Missing, n (%)	0	1 (2.4)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	144.49 (60.98)	149.13 (68.10)	82.57 (68.63)
	95% CI of Geometric Mean	127.28, 164.02	122.73, 181.21	67.69, 100.72
	Median	159.50	151.00	85.65
	Q25, Q75	104.00, 237.00	112.00, 252.00	51.25, 140.00
	Min, Max	28.2, 295.0	33.2, 380.0	19.2, 247.0
	Mean (SD)	164.81 (74.542)	175.40 (92.566)	97.61 (53.167)
	95% CI of Mean	148.00, 181.63	146.17, 204.62	80.60, 114.62

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 2, 08:00 PM - 09:30 PM	n	77	41	40
	Missing, n (%)	1 (1.3)	1 (2.4)	0
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	147.81 (56.09)	144.11 (71.07)	34.97 (76.33)
	95% CI of Geometric Mean	131.26, 166.44	117.77, 176.34	28.15, 43.43
	Median	162.00	155.00	39.45
	Q25, Q75	110.00, 227.00	99.50, 242.00	21.65, 61.40
	Min, Max	37.1, 320.0	27.2, 388.0	10.4, 161.0
	Mean (SD)	165.81 (70.637)	170.87 (90.855)	43.17 (29.082)
	95% CI of Mean	149.78, 181.85	142.18, 199.55	33.86, 52.47

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 3, 08:00 PM - 09:30 PM	n	77	41	39
	Missing, n (%)	1 (1.3)	1 (2.4)	1 (2.5)
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	154.76 (54.17)	139.07 (74.91)	15.92 (88.44)
	95% CI of Geometric Mean	137.93, 173.65	112.65, 171.69	12.44, 20.37
	Median	172.00	152.00	16.60
	Q25, Q75	125.00, 223.00	103.00, 229.00	10.40, 26.20
	Min, Max	34.1, 387.0	24.8, 390.0	3.7, 99.8
	Mean (SD)	172.33 (71.588)	167.43 (93.090)	21.00 (17.712)
	95% CI of Mean	156.08, 188.58	138.04, 196.82	15.25, 26.74

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 4, 08:00 PM - 09:30 PM	n	76	41	39
	Missing, n (%)	2 (2.6)	1 (2.4)	1 (2.5)
	BLOQ, n (%)	0	0	0
	Geometric Mean (CV%)	158.34 (54.56)	143.22 (77.43)	7.83 (101.82)
	95% CI of Geometric Mean	140.90, 177.93	115.35, 177.81	5.95, 10.30
	Median	179.50	161.00	7.81
	Q25, Q75	120.50, 219.00	114.00, 252.00	5.09, 12.90
	Min, Max	32.4, 377.0	27.8, 382.0	1.6, 70.6
	Mean (SD)	175.88 (69.692)	173.22 (94.312)	11.21 (11.993)
	95% CI of Mean	159.95, 191.81	143.45, 203.00	7.32, 15.10

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, 15 Min < T0	n	77	41	
	Missing, n (%)	1 (1.3)	1 (2.4)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	159.66 (53.38)	140.34 (75.39)	
	95% CI of Geometric Mean	142.50, 178.88	113.56, 173.44	
	Median	177.00	158.00	
	Q25, Q75	127.00, 228.00	107.00, 224.00	
	Min, Max	37.4, 360.0	25.5, 379.0	
	Mean (SD)	177.01 (70.364)	168.53 (91.279)	
	95% CI of Mean	161.04, 192.99	139.71, 197.35	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 2 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	169.09 (51.67)	144.25 (72.17)	
	95% CI of Geometric Mean	150.17, 190.39	115.86, 179.58	
	Median	182.00	158.00	
	Q25, Q75	146.00, 242.00	109.00, 229.00	
	Min, Max	37.3, 383.0	27.1, 353.0	
	Mean (SD)	186.23 (71.740)	170.88 (88.702)	
	95% CI of Mean	168.72, 203.73	140.87, 200.90	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 4 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	159.87 (51.95)	137.87 (73.63)	
	95% CI of Geometric Mean	141.90, 180.12	110.34, 172.27	
	Median	175.00	153.00	
	Q25, Q75	130.00, 225.00	102.00, 221.50	
	Min, Max	35.0, 341.0	25.1, 346.0	
	Mean (SD)	176.11 (67.233)	163.96 (85.351)	
	95% CI of Mean	159.70, 192.51	135.07, 192.84	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 6 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	165.63 (53.07)	142.07 (75.68)	
	95% CI of Geometric Mean	146.67, 187.03	113.14, 178.40	
	Median	182.00	160.00	
	Q25, Q75	136.00, 238.00	109.50, 230.00	
	Min, Max	35.1, 354.0	26.0, 359.0	
	Mean (SD)	183.13 (71.475)	170.14 (90.245)	
	95% CI of Mean	165.70, 200.57	139.60, 200.68	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 8 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	168.99 (52.49)	146.05 (75.52)	
	95% CI of Geometric Mean	149.83, 190.61	116.35, 183.32	
	Median	180.00	166.00	
	Q25, Q75	142.00, 242.00	117.00, 244.00	
	Min, Max	38.3, 360.0	27.9, 373.0	
	Mean (SD)	186.39 (71.351)	174.64 (91.686)	
	95% CI of Mean	168.98, 203.80	143.61, 205.67	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 10 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	174.46 (53.82)	150.00 (75.24)	
	95% CI of Geometric Mean	154.26, 197.30	119.58, 188.16	
	Median	192.00	172.50	
	Q25, Q75	158.00, 254.00	115.50, 240.50	
	Min, Max	34.8, 399.0	30.5, 386.0	
	Mean (SD)	193.12 (75.120)	179.28 (94.172)	
	95% CI of Mean	174.79, 211.45	147.41, 211.15	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 12 h	n	67	37	
	Missing, n (%)	11 (14.1)	5 (11.9)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	185.07 (54.60)	155.23 (76.98)	
	95% CI of Geometric Mean	163.38, 209.63	123.65, 194.87	
	Median	202.00	174.00	
	Q25, Q75	165.00, 268.00	116.00, 263.00	
	Min, Max	33.9, 418.0	29.5, 406.0	
	Mean (SD)	205.23 (79.878)	187.17 (101.433)	
	95% CI of Mean	185.74, 224.72	153.35, 221.00	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 14 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	179.31 (54.11)	153.51 (76.73)	
	95% CI of Geometric Mean	158.46, 202.91	121.93, 193.25	
	Median	192.00	177.50	
	Q25, Q75	159.00, 259.00	121.50, 255.00	
	Min, Max	32.5, 399.0	29.2, 427.0	
	Mean (SD)	198.32 (75.246)	184.55 (99.049)	
	95% CI of Mean	179.96, 216.68	151.03, 218.07	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, T0 + 16 h	n	67	36	
	Missing, n (%)	11 (14.1)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	191.43 (55.05)	160.72 (77.82)	
	95% CI of Geometric Mean	168.84, 217.03	127.33, 202.86	
	Median	205.00	194.00	
	Q25, Q75	168.00, 267.00	125.50, 251.00	
	Min, Max	34.3, 424.0	29.9, 411.0	
	Mean (SD)	212.50 (82.831)	193.36 (101.757)	
	95% CI of Mean	192.29, 232.71	158.92, 227.79	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5, 08:00 PM - 09:30 PM	n			39
	Missing, n (%)			1 (2.5)
	BLOQ, n (%)			4 (10.0)
	Geometric Mean (CV%)			3.41 (132.99)
	95% CI of Geometric Mean			2.45, 4.73
	Median			3.88
	Q25, Q75			1.95, 6.32
	Min, Max			0.5, 42.9
	Mean (SD)			5.59 (7.294)
	95% CI of Mean			3.22, 7.96

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 6/Discharge Confinement, T0 + 20 h	n	65	36	
	Missing, n (%)	13 (16.7)	6 (14.3)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	191.48 (52.79)	160.15 (74.30)	
	95% CI of Geometric Mean	169.34, 216.52	127.97, 200.43	
	Median	209.00	185.50	
	Q25, Q75	169.00, 267.00	126.50, 253.50	
	Min, Max	38.0, 428.0	29.3, 412.0	
	Mean (SD)	211.20 (80.432)	190.60 (98.236)	
	95% CI of Mean	191.27, 231.14	157.36, 223.84	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 6/Discharge Confinement, T0 + 24 h	n	44	31	
	Missing, n (%)	34 (43.6)	11 (26.2)	
	BLOQ, n (%)	0	0	
	Geometric Mean (CV%)	183.02 (51.35)	142.86 (77.89)	
	95% CI of Geometric Mean	157.98, 212.02	110.97, 183.91	
	Median	198.50	162.00	
	Q25, Q75	146.00, 259.50	97.70, 241.00	
	Min, Max	49.8, 316.0	28.5, 417.0	
	Mean (SD)	201.36 (76.625)	173.35 (98.018)	
	95% CI of Mean	178.06, 224.66	137.39, 209.30	

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 6/Discharge Confinement, 08:00 AM - 09:30 AM	n			39
	Missing, n (%)			1 (2.5)
	BLOQ, n (%)			6 (15.0)
	Geometric Mean (CV%)			2.91 (140.71)
	95% CI of Geometric Mean			2.07, 4.09
	Median			3.25
	Q25, Q75			1.86, 5.86
	Min, Max			0.5, 37.5
	Mean (SD)			4.94 (6.558)
	95% CI of Mean			2.81, 7.07

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 30, 10:00 AM - 11:30 AM	n	77	41	38
	Missing, n (%)	1 (1.3)	1 (2.4)	2 (5.0)
	BLOQ, n (%)	0	0	12 (30.0)
	Geometric Mean (CV%)	195.88 (66.71)	167.30 (80.91)	6.44 (1681.79)
	95% CI of Geometric Mean	170.68, 224.81	133.72, 209.31	2.94, 14.06
	Median	221.00	185.00	3.58
	Q25, Q75	155.00, 299.00	115.00, 280.00	0.50, 84.30
	Min, Max	37.6, 654.0	22.0, 552.0	0.5, 227.0
	Mean (SD)	228.62 (116.771)	205.85 (122.953)	47.68 (70.012)
	95% CI of Mean	202.12, 255.13	167.03, 244.66	24.66, 70.70

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 60, 10:00 AM - 11:30 AM	n	77	41	38
	Missing, n (%)	1 (1.3)	1 (2.4)	2 (5.0)
	BLOQ, n (%)	0	0	13 (32.5)
	Geometric Mean (CV%)	183.23 (69.12)	164.23 (79.55)	8.28 (2009.04)
	95% CI of Geometric Mean	159.00, 211.16	131.66, 204.85	3.69, 18.52
	Median	215.00	187.00	9.91
	Q25, Q75	144.00, 272.00	108.00, 277.00	0.50, 69.50
	Min, Max	26.7, 583.0	26.7, 439.0	0.5, 411.0
	Mean (SD)	214.58 (108.352)	199.66 (110.489)	57.13 (89.871)
	95% CI of Mean	189.99, 239.18	164.78, 234.54	27.58, 86.67

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Parameter (units): Cotinine (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 90, 10:00 AM - 12:30 PM	n	76	41	38
	Missing, n (%)	2 (2.6)	1 (2.4)	2 (5.0)
	BLOQ, n (%)	0	0	13 (32.5)
	Geometric Mean (CV%)	185.69 (64.68)	172.69 (78.74)	9.02 (2595.69)
	95% CI of Geometric Mean	162.22, 212.55	138.69, 215.02	3.89, 20.88
	Median	218.00	221.00	6.21
	Q25, Q75	151.00, 271.50	119.00, 299.00	0.50, 124.00
	Min, Max	39.3, 636.0	18.6, 389.0	0.5, 436.0
	Mean (SD)	215.34 (111.135)	207.89 (107.635)	66.16 (95.031)
	95% CI of Mean	189.94, 240.74	173.91, 241.87	34.92, 97.40

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

Note: T0 is the time of first product use on the Day

**Table 15.2.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter: Nicotine (ng/mL)**

Time point		Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Day 1	n		75	41	
	Geometric LS Mean (CV%)		9.79	10.47	93.43 (59.40)
	95% CI		8.62, 11.11	8.81, 12.45	75.47, 115.67
Day 2	n		76	41	
	Geometric LS Mean (CV%)		12.00	11.77	102.00 (42.37)
	95% CI		10.93, 13.18	10.36, 13.37	87.18, 119.33
Day 3	n		76	41	
	Geometric LS Mean (CV%)		14.48	12.56	115.29 (46.21)
	95% CI		13.09, 16.02	10.94, 14.42	97.28, 136.64
Day 4	n		76	41	
	Geometric LS Mean (CV%)		11.59	10.92	106.17 (50.22)
	95% CI		10.39, 12.92	9.40, 12.67	88.40, 127.51
Day 5	n		66	36	
	Geometric LS Mean (CV%)		14.00	12.69	110.37 (45.73)
	95% CI		12.54, 15.64	10.94, 14.71	92.09, 132.27

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

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.

**Table 15.2.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter: Nicotine (ng/mL)**

Time point		Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Day 30	n		74	41	
	Geometric LS Mean (CV%)		12.61	13.13	96.03 (50.98)
	95% CI		11.28, 14.11	11.29, 15.27	79.68, 115.74
Day 60	n		71	41	
	Geometric LS Mean (CV%)		12.68	12.33	102.81 (59.46)
	95% CI		11.12, 14.45	10.37, 14.66	82.87, 127.54
Day 90	n		69	41	
	Geometric LS Mean (CV%)		12.39	11.98	103.39 (61.69)
	95% CI		10.81, 14.20	10.02, 14.33	82.66, 129.30

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

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.

**Table 15.2.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter: Cotinine (ng/mL)**

Time point	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Day 1	n	76	41	
	Geometric LS Mean (CV%)	144.08	149.85	96.15 (17.87)
	95% CI	138.35, 150.04	141.78, 158.38	89.81, 102.93
Day 2	n	76	41	
	Geometric LS Mean (CV%)	146.93	145.53	100.96 (22.44)
	95% CI	139.66, 154.57	135.80, 155.96	92.71, 109.94
Day 3	n	76	41	
	Geometric LS Mean (CV%)	153.43	140.16	109.47 (26.17)
	95% CI	144.65, 162.74	129.34, 151.89	99.15, 120.85
Day 4	n	75	41	
	Geometric LS Mean (CV%)	157.18	144.85	108.51 (27.84)
	95% CI	147.60, 167.38	133.01, 157.75	97.66, 120.57
Day 5	n	66	36	
	Geometric LS Mean (CV%)	176.16	157.81	111.63 (27.52)
	95% CI	164.54, 188.61	144.06, 172.87	99.87, 124.77

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

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.

**Table 15.2.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set****Parameter: Cotinine (ng/mL)**

Time point		Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Day 30	n		74	41	
	Geometric LS Mean (CV%)		196.40	171.59	114.46 (44.87)
	95% CI		177.83, 216.92	150.11, 196.14	97.00, 135.05
Day 60	n		71	41	
	Geometric LS Mean (CV%)		182.83	171.80	106.42 (47.18)
	95% CI		164.38, 203.34	149.33, 197.63	89.37, 126.73
Day 90	n		69	41	
	Geometric LS Mean (CV%)		185.81	175.39	105.94 (43.82)
	95% CI		168.05, 205.44	153.87, 199.93	89.89, 124.84

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

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.

**Table 15.2.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter: Nicotine (ng/mL)**

Time point		Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Day 1	n		77	41	
	Geometric LS Mean (CV%)		9.70	10.47	92.67 (59.38)
	95% CI		8.55, 11.00	8.81, 12.44	74.94, 114.58
Day 2	n		77	41	
	Geometric LS Mean (CV%)		11.98	11.81	101.44 (42.44)
	95% CI		10.92, 13.15	10.39, 13.42	86.72, 118.67
Day 3	n		77	41	
	Geometric LS Mean (CV%)		14.59	12.61	115.67 (46.07)
	95% CI		13.19, 16.12	10.99, 14.47	97.67, 136.98
Day 4	n		77	41	
	Geometric LS Mean (CV%)		11.61	10.96	105.95 (50.01)
	95% CI		10.42, 12.93	9.45, 12.71	88.31, 127.11
Day 5	n		67	36	
	Geometric LS Mean (CV%)		13.96	12.73	109.66 (45.85)
	95% CI		12.51, 15.59	10.98, 14.77	91.49, 131.43

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

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.

**Table 15.2.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter: Nicotine (ng/mL)**

Time point		Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Day 30	n		77	41	
	Geometric LS Mean (CV%)		12.51	13.13	95.22 (50.73)
	95% CI		11.21, 13.95	11.30, 15.26	79.18, 114.51
Day 60	n		77	41	
	Geometric LS Mean (CV%)		12.86	12.23	105.14 (58.81)
	95% CI		11.36, 14.56	10.31, 14.51	85.21, 129.71
Day 90	n		76	41	
	Geometric LS Mean (CV%)		12.24	12.01	101.96 (62.64)
	95% CI		10.73, 13.97	10.02, 14.39	81.61, 127.37

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

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.

**Table 15.2.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter: Cotinine (ng/mL)**

Time point	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Day 1	n	78	41	
	Geometric LS Mean (CV%)	144.28	150.27	96.02 (17.82)
	95% CI	138.62, 150.18	142.20, 158.79	89.74, 102.74
Day 2	n	77	41	
	Geometric LS Mean (CV%)	147.89	146.60	100.88 (22.35)
	95% CI	140.65, 155.51	136.84, 157.06	92.69, 109.80
Day 3	n	77	41	
	Geometric LS Mean (CV%)	154.75	141.17	109.62 (26.07)
	95% CI	145.98, 164.05	130.31, 152.94	99.34, 120.95
Day 4	n	76	41	
	Geometric LS Mean (CV%)	158.46	145.91	108.60 (27.72)
	95% CI	148.90, 168.63	134.03, 158.85	97.81, 120.59
Day 5	n	67	36	
	Geometric LS Mean (CV%)	177.65	159.13	111.64 (27.38)
	95% CI	166.04, 190.06	145.32, 174.24	99.95, 124.68

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

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.

**Table 15.2.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS****Parameter: Cotinine (ng/mL)**

Time point		Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Day 30	n		77	41	
	Geometric LS Mean (CV%)		197.18	171.98	114.66 (44.23)
	95% CI		179.10, 217.09	150.72, 196.23	97.49, 134.84
Day 60	n		77	41	
	Geometric LS Mean (CV%)		185.34	169.72	109.21 (48.45)
	95% CI		166.96, 205.75	147.05, 195.87	91.57, 130.24
Day 90	n		76	41	
	Geometric LS Mean (CV%)		187.28	177.55	105.48 (45.57)
	95% CI		169.56, 206.84	155.03, 203.34	89.24, 124.66

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

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.

**Table 15.2.4.21.1 Descriptive Statistics of Plasma Nicotine and Cotinine PK Parameters on Day 5 - PP Set****Parameter: Nicotine (ng/mL)**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)
Average Conc (ng/mL)	n	76	41
	Geometric Mean (CV%)	11.20 (63.43)	8.72 (78.07)
	95% CI of Geometric Mean	9.81, 12.80	7.01, 10.85
	Median	11.81	9.91
	Q25, Q75	8.02, 16.94	6.29, 14.13
	Min, Max	1.4, 34.9	1.2, 22.7
	Mean (SD)	13.01 (6.994)	10.52 (5.741)
	95% CI of Mean	11.40, 14.61	8.70, 12.34
Max Conc (ng/mL)	n	76	41
	Geometric Mean (CV%)	20.70 (55.75)	15.67 (63.83)
	95% CI of Geometric Mean	18.38, 23.32	13.03, 18.86
	Median	22.10	17.80
	Q25, Q75	16.00, 28.95	11.30, 24.30
	Min, Max	2.8, 49.9	3.1, 41.4
	Mean (SD)	23.22 (10.358)	18.09 (8.982)
	95% CI of Mean	20.85, 25.60	15.25, 20.93
Time of C _{MAX} (h)	n	76	41
	Median	12.00	12.00
	Q25, Q75	10.00, 16.00	10.00, 14.00
	Min, Max	2.0, 16.0	4.0, 16.0

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

**Table 15.2.4.21.1 Descriptive Statistics of Plasma Nicotine and Cotinine PK Parameters on Day 5 - PP Set****Parameter: Cotinine (ng/mL)**

Variable	Statistic	THSm2.2 (N=76)	mCC (N=42)
Average Conc (ng/mL)	n	76	41
	Geometric Mean (CV%)	171.25 (53.06)	147.39 (77.41)
	95% CI of Geometric Mean	152.83, 191.90	118.72, 182.98
	Median	188.98	168.79
	Q25, Q75	141.67, 243.48	115.40, 243.42
	Min, Max	35.9, 322.5	28.3, 390.4
	Mean (SD)	189.28 (72.577)	178.08 (96.196)
	95% CI of Mean	172.69, 205.87	147.71, 208.45
Max Conc (ng/mL)	n	76	41
	Geometric Mean (CV%)	192.10 (52.85)	163.42 (77.07)
	95% CI of Geometric Mean	171.50, 215.18	131.73, 202.73
	Median	208.50	191.00
	Q25, Q75	163.00, 273.00	127.00, 268.00
	Min, Max	38.3, 372.0	30.5, 427.0
	Mean (SD)	212.08 (80.740)	197.22 (106.225)
	95% CI of Mean	193.62, 230.53	163.69, 230.76
Time of C _{MAX} (h)	n	76	41
	Median	16.00	16.00
	Q25, Q75	12.98, 20.00	12.00, 16.00
	Min, Max	0.0, 24.0	0.0, 24.1

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

**Table 15.2.4.21.2 Descriptive Statistics of Plasma Nicotine and Cotinine PK Parameters on Day 5 - FAS****Parameter: Nicotine (ng/mL)**

Variable		Statistic	THSm2.2 (N=78)	mCC (N=42)
Average Conc (ng/mL)	n		77	41
	Geometric Mean (CV%)		11.24 (63.03)	8.72 (78.07)
	95% CI of Geometric Mean		9.85, 12.82	7.01, 10.85
	Median		11.92	9.91
	Q25, Q75		8.18, 16.82	6.29, 14.13
	Min, Max		1.4, 34.9	1.2, 22.7
	Mean (SD)		13.03 (6.950)	10.52 (5.741)
	95% CI of Mean		11.44, 14.61	8.70, 12.34
Max Conc (ng/mL)	n		77	41
	Geometric Mean (CV%)		20.77 (55.44)	15.67 (63.83)
	95% CI of Geometric Mean		18.47, 23.37	13.03, 18.86
	Median		22.10	17.80
	Q25, Q75		16.40, 28.30	11.30, 24.30
	Min, Max		2.8, 49.9	3.1, 41.4
	Mean (SD)		23.27 (10.298)	18.09 (8.982)
	95% CI of Mean		20.93, 25.61	15.25, 20.93
Time of C _{MAX} (h)	n		77	41
	Median		12.00	12.00
	Q25, Q75		10.00, 16.00	10.00, 14.00
	Min, Max		2.0, 16.0	4.0, 16.0

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

**Table 15.2.4.21.2 Descriptive Statistics of Plasma Nicotine and Cotinine PK Parameters on Day 5 - FAS****Parameter: Cotinine (ng/mL)**

Variable		Statistic	THSm2.2 (N=78)	mCC (N=42)
Average Conc (ng/mL)	n		77	41
	Geometric Mean (CV%)		173.11 (53.74)	147.39 (77.41)
	95% CI of Geometric Mean		154.40, 194.08	118.72, 182.98
	Median		189.47	168.79
	Q25, Q75		141.68, 244.04	115.40, 243.42
	Min, Max		35.9, 392.5	28.3, 390.4
	Mean (SD)		191.92 (75.725)	178.08 (96.196)
	95% CI of Mean		174.72, 209.11	147.71, 208.45
Max Conc (ng/mL)	n		77	41
	Geometric Mean (CV%)		194.11 (53.47)	163.42 (77.07)
	95% CI of Geometric Mean		173.23, 217.51	131.73, 202.73
	Median		209.00	191.00
	Q25, Q75		168.00, 279.00	127.00, 268.00
	Min, Max		38.3, 428.0	30.5, 427.0
	Mean (SD)		214.88 (83.896)	197.22 (106.225)
	95% CI of Mean		195.83, 233.93	163.69, 230.76
Time of C _{MAX} (h)	n		77	41
	Median		16.00	16.00
	Q25, Q75		13.97, 20.00	12.00, 16.00
	Min, Max		0.0, 24.0	0.0, 24.1

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

**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 (ng/mL)				
Average Conc (ng/mL)	n	76	41	
	Geometric LS Mean (CV%)	11.08	8.73	126.96 (64.26)
	95% CI	9.69, 12.68	7.26, 10.49	101.27, 159.15
Max Conc (ng/mL)	n	76	41	
	Geometric LS Mean (CV%)	20.57	15.74	130.66 (55.86)
	95% CI	18.25, 23.18	13.38, 18.53	106.93, 159.64
Cotinine (ng/mL)				
Average Conc (ng/mL)	n	76	41	
	Geometric LS Mean (CV%)	168.65	145.97	115.54 (58.61)
	95% CI	148.94, 190.96	123.20, 172.94	93.75, 142.38
Max Conc (ng/mL)	n	76	41	
	Geometric LS Mean (CV%)	189.25	161.82	116.95 (58.71)
	95% CI	167.11, 214.33	136.55, 191.76	94.87, 144.17

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

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an mixed 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.

(1): For tpeak 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 Difference (h)
Nicotine (ng/mL)				
Time of C_{MAX} (h)	n	76	41	
	Median	12.0	12.0	-1.0
	95% CI	11.69, 13.29	10.83, 13.06	-2.00, 0.00
Cotinine (ng/mL)				
Time of C_{MAX} (h)	n	76	41	
	Median	16.0	16.0	-2.0
	95% CI	14.48, 17.13	11.96, 16.04	-4.00, 0.00

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

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an mixed 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.

(1): For tpeak 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 (ng/mL)				
Average Conc (ng/mL)	n	77	41	
	Geometric LS Mean (CV%)	11.08	8.73	126.93 (63.93)
	95% CI	9.70, 12.66	7.27, 10.48	101.40, 158.88
Max Conc (ng/mL)	n	77	41	
	Geometric LS Mean (CV%)	20.58	15.74	130.73 (55.58)
	95% CI	18.29, 23.16	13.39, 18.51	107.13, 159.52
Cotinine (ng/mL)				
Average Conc (ng/mL)	n	77	41	
	Geometric LS Mean (CV%)	169.85	145.95	116.37 (58.65)
	95% CI	150.10, 192.20	123.18, 172.93	94.46, 143.36
Max Conc (ng/mL)	n	77	41	
	Geometric LS Mean (CV%)	190.57	161.80	117.78 (58.73)
	95% CI	168.38, 215.67	136.53, 191.75	95.58, 145.13

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

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an mixed 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.

(1): For tpeak 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 Difference (h)
Nicotine (ng/mL)				
Time of C_{MAX} (h)	n	77	41	
	Median	12.0	12.0	-1.0
	95% CI	11.75, 13.33	10.83, 13.06	-2.00, 0.00
Cotinine (ng/mL)				
Time of C_{MAX} (h)	n	77	41	
	Median	16.0	16.0	-2.0
	95% CI	14.55, 17.18	11.96, 16.04	-4.00, 0.00

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

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an mixed 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.

(1): For tpeak 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**

Parameter: CYP1A2 Activity (%)
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	72.43 (31.86)		70.45 (28.96)		74.18 (36.55)	
	95% CI	67.46, 77.77		64.48, 76.97		66.13, 83.21	
	Median	70.53		69.07		82.41	
	Q25, Q75	58.35, 91.27		56.25, 83.11		57.30, 97.76	
	Min, Max	36.3, 142.1		35.8, 137.5		28.4, 142.3	
	Mean (SD)	75.96 (23.895)		73.31 (21.478)		78.49 (25.211)	
	95% CI of Mean	70.50, 81.43		66.61, 80.00		70.31, 86.67	
Day 5	n	76	76	42	42	39	39
	Geometric Mean (CV%)	55.62 (29.89)		75.84 (33.98)		55.34 (36.42)	
	95% CI	52.02, 59.47		68.41, 84.07		49.35, 62.05	
	Median	54.14	-21.79	78.28	6.53	61.12	-26.20
	Q25, Q75	46.29, 65.61	-32.86, -11.87	61.02, 95.62	-1.80, 14.95	45.17, 70.14	-34.98, -16.01
	Min, Max	20.8, 112.5	-52.1, 16.4	34.1, 144.7	-32.2, 114.2	19.9, 94.6	-46.8, 34.3
	Mean (SD)	58.02 (17.440)	-21.75 (15.250)	79.83 (25.226)	9.65 (23.145)	58.48 (18.322)	-23.81 (16.642)
	95% CI of Mean	54.03, 62.01	-25.24, -18.26	71.96, 87.69	2.43, 16.86	52.53, 64.42	-29.21, -18.41

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

Note: * % change from baseline, where baseline is Day 0.

**Table 15.2.4.23.1 Descriptive Statistics of CYP1A2 Activity (%) - PP Set****Parameter: CYP1A2 Activity (%)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	72.51 (31.68)		70.17 (29.22)		73.12 (36.95)	
	95% CI	67.35, 78.06		64.11, 76.81		64.89, 82.38	
	Median	70.53		68.40		76.38	
	Q25, Q75	58.85, 91.68		56.25, 83.11		57.30, 96.91	
	Min, Max	36.3, 142.1		35.8, 137.5		28.4, 142.3	
	Mean (SD)	76.00 (23.789)		73.08 (21.693)		77.49 (25.472)	
	95% CI of Mean	70.32, 81.67		66.23, 79.93		68.99, 85.99	
Day 90	n	70	70	41	41	37	37
	Geometric Mean (CV%)	54.57 (35.80)		77.67 (42.61)		59.51 (40.31)	
	95% CI	50.23, 59.28		68.27, 88.37		52.28, 67.74	
	Median	59.03	-20.70	83.20	8.23	62.07	-17.93
	Q25, Q75	46.19, 69.26	-38.59, -8.38	61.52, 100.75	-8.19, 28.59	45.04, 80.75	-31.27, -5.55
	Min, Max	20.5, 123.1	-75.3, 71.1	32.6, 179.8	-42.1, 196.7	24.5, 136.4	-63.1, 36.7
	Mean (SD)	57.63 (18.237)	-20.22 (26.983)	83.97 (32.986)	15.77 (39.676)	63.99 (25.199)	-15.82 (22.066)
	95% CI of Mean	53.27, 61.98	-26.66, -13.78	73.55, 94.39	3.24, 28.30	55.58, 72.39	-23.19, -8.46

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

Note: * % change from baseline, where baseline is Day 0.



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

Parameter: CYP1A2 Activity (%)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	72.43 (31.86)		70.45 (28.96)		74.18 (36.55)	
	95% CI	67.46, 77.77		64.48, 76.97		66.13, 83.21	
	Median	70.53		69.07		82.41	
	Q25, Q75	58.35, 91.27		56.25, 83.11		57.30, 97.76	
	Min, Max	36.3, 142.1		35.8, 137.5		28.4, 142.3	
	Mean (SD)	75.96 (23.895)		73.31 (21.478)		78.49 (25.211)	
	95% CI of Mean	70.50, 81.43		66.61, 80.00		70.31, 86.67	
Day 5	n	76	76	42	42	39	39
	Geometric Mean (CV%)	55.62 (29.89)		75.84 (33.98)		55.34 (36.42)	
	95% CI	52.02, 59.47		68.41, 84.07		49.35, 62.05	
	Median	54.14	-21.79	78.28	6.53	61.12	-26.20
	Q25, Q75	46.29, 65.61	-32.86, -11.87	61.02, 95.62	-1.80, 14.95	45.17, 70.14	-34.98, -16.01
	Min, Max	20.8, 112.5	-52.1, 16.4	34.1, 144.7	-32.2, 114.2	19.9, 94.6	-46.8, 34.3
	Mean (SD)	58.02 (17.440)	-21.75 (15.250)	79.83 (25.226)	9.65 (23.145)	58.48 (18.322)	-23.81 (16.642)
	95% CI of Mean	54.03, 62.01	-25.24, -18.26	71.96, 87.69	2.43, 16.86	52.53, 64.42	-29.21, -18.41

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

Note: * % change from baseline, where baseline is Day 0.

**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****Parameter: CYP1A2 Activity (%)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	72.51 (31.68)		70.17 (29.22)		73.12 (36.95)	
	95% CI	67.35, 78.06		64.11, 76.81		64.89, 82.38	
	Median	70.53		68.40		76.38	
	Q25, Q75	58.85, 91.68		56.25, 83.11		57.30, 96.91	
	Min, Max	36.3, 142.1		35.8, 137.5		28.4, 142.3	
	Mean (SD)	76.00 (23.789)		73.08 (21.693)		77.49 (25.472)	
	95% CI of Mean	70.32, 81.67		66.23, 79.93		68.99, 85.99	
Day 90	n	69	69	41	41	37	37
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0	0	0
	Geometric Mean (CV%)	54.35 (35.90)		77.67 (42.61)		59.51 (40.31)	
	95% CI	49.99, 59.10		68.27, 88.37		52.28, 67.74	
	Median	58.90	-20.44	83.20	8.23	62.07	-17.93
	Q25, Q75	46.19, 69.00	-38.59, -8.38	61.52, 100.75	-8.19, 28.59	45.04, 80.75	-31.27, -5.55
	Min, Max	20.5, 123.1	-75.3, 71.1	32.6, 179.8	-42.1, 196.7	24.5, 136.4	-63.1, 36.7
	Mean (SD)	57.42 (18.289)	-20.13 (27.172)	83.97 (32.986)	15.77 (39.676)	63.99 (25.199)	-15.82 (22.066)
	95% CI of Mean	53.02, 61.82	-26.67, -13.60	73.55, 94.39	3.24, 28.30	55.58, 72.39	-23.19, -8.46

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

Note: * % change from baseline, where baseline is Day 0.

**Table 15.2.4.23.2 Descriptive Statistics of CYP1A2 Activity (%) - FAS****Parameter: CYP1A2 Activity (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	72.64 (31.71)		70.45 (28.96)		73.76 (36.25)	
	95% CI	67.74, 77.90		64.48, 76.97		65.91, 82.53	
	Median	70.53		69.07		79.40	
	Q25, Q75	58.70, 91.68		56.25, 83.11		57.75, 97.34	
	Min, Max	36.3, 142.1		35.8, 137.5		28.4, 142.3	
	Mean (SD)	76.15 (23.789)		73.31 (21.478)		78.00 (25.076)	
	95% CI of Mean	70.78, 81.52		66.61, 80.00		69.98, 86.03	
Day 5	n	78	78	42	42	40	40
	Geometric Mean (CV%)	55.89 (29.66)		75.84 (33.98)		55.43 (35.94)	
	95% CI	52.35, 59.68		68.41, 84.07		49.58, 61.97	
	Median	54.58	-21.79	78.28	6.53	60.27	-25.52
	Q25, Q75	47.45, 67.05	-32.83, -11.58	61.02, 95.62	-1.80, 14.95	45.22, 69.77	-34.95, -15.08
	Min, Max	20.8, 112.5	-52.1, 16.4	34.1, 144.7	-32.2, 114.2	19.9, 94.6	-46.8, 34.3
	Mean (SD)	58.26 (17.278)	-21.59 (15.293)	79.83 (25.226)	9.65 (23.145)	58.49 (18.086)	-23.22 (16.853)
	95% CI of Mean	54.36, 62.16	-25.05, -18.14	71.96, 87.69	2.43, 16.86	52.70, 64.28	-28.61, -17.82

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

Note: * % change from baseline, where baseline is Day 0.

**Table 15.2.4.23.2 Descriptive Statistics of CYP1A2 Activity (%) - FAS****Parameter: CYP1A2 Activity (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	78	42	42	40	40
	Geometric Mean (CV%)	55.65 (34.82)		77.79 (42.06)		60.07 (39.00)	
	95% CI	51.56, 60.06		68.59, 88.22		53.26, 67.76	
	Median	59.44	-20.11	83.10	7.36	62.65	-18.33
	Q25, Q75	47.93, 69.28	-38.42, -5.65	61.52, 100.75	-8.19, 28.59	45.23, 81.04	-30.70, -4.96
	Min, Max	20.5, 123.1	-75.3, 71.1	32.6, 179.8	-42.1, 196.7	24.5, 136.4	-63.1, 36.7
	Mean (SD)	58.59 (17.903)	-18.96 (26.738)	83.94 (32.582)	15.39 (39.265)	64.30 (24.386)	-15.91 (21.486)
	95% CI of Mean	54.55, 62.63	-24.99, -12.93	73.78, 94.10	3.15, 27.63	56.49, 72.10	-22.78, -9.03

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

Note: * % change from baseline, where baseline is Day 0.

**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****Parameter: CYP1A2 Activity (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	72.64 (31.71)		70.45 (28.96)		73.76 (36.25)	
	95% CI	67.74, 77.90		64.48, 76.97		65.91, 82.53	
	Median	70.53		69.07		79.40	
	Q25, Q75	58.70, 91.68		56.25, 83.11		57.75, 97.34	
	Min, Max	36.3, 142.1		35.8, 137.5		28.4, 142.3	
	Mean (SD)	76.15 (23.789)		73.31 (21.478)		78.00 (25.076)	
	95% CI of Mean	70.78, 81.52		66.61, 80.00		69.98, 86.03	
Day 5	n	78	78	42	42	40	40
	Geometric Mean (CV%)	55.89 (29.66)		75.84 (33.98)		55.43 (35.94)	
	95% CI	52.35, 59.68		68.41, 84.07		49.58, 61.97	
	Median	54.58	-21.79	78.28	6.53	60.27	-25.52
	Q25, Q75	47.45, 67.05	-32.83, -11.58	61.02, 95.62	-1.80, 14.95	45.22, 69.77	-34.95, -15.08
	Min, Max	20.8, 112.5	-52.1, 16.4	34.1, 144.7	-32.2, 114.2	19.9, 94.6	-46.8, 34.3
	Mean (SD)	58.26 (17.278)	-21.59 (15.293)	79.83 (25.226)	9.65 (23.145)	58.49 (18.086)	-23.22 (16.853)
	95% CI of Mean	54.36, 62.16	-25.05, -18.14	71.96, 87.69	2.43, 16.86	52.70, 64.28	-28.61, -17.82

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

Note: * % change from baseline, where baseline is Day 0.

**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****Parameter: CYP1A2 Activity (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	77	77	42	42	40	40
	Missing, n(%)	1 (1.3)	1 (1.3)	0	0	0	0
	Geometric Mean (CV%)	55.46 (34.93)		77.79 (42.06)		60.07 (39.00)	
	95% CI	51.35, 59.91		68.59, 88.22		53.26, 67.76	
	Median	59.15	-19.78	83.10	7.36	62.65	-18.33
	Q25, Q75	47.93, 69.26	-38.42, -5.65	61.52, 100.75	-8.19, 28.59	45.23, 81.04	-30.70, -4.96
	Min, Max	20.5, 123.1	-75.3, 71.1	32.6, 179.8	-42.1, 196.7	24.5, 136.4	-63.1, 36.7
	Mean (SD)	58.42 (17.956)	-18.87 (26.901)	83.94 (32.582)	15.39 (39.265)	64.30 (24.386)	-15.91 (21.486)
	95% CI of Mean	54.34, 62.50	-24.98, -12.76	73.78, 94.10	3.15, 27.63	56.49, 72.10	-22.78, -9.03

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

Note: * % change from baseline, where baseline is Day 0.

**Table 15.2.4.24.1 Analysis of CYP1A2 Activity (%) - PP Set****Parameter: CYP1A2 Activity (%)**

Time Point		Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Day 5	n		76	42	39		
	Geometric LS Mean (CV%)		55.21	76.72	53.90	71.96 (18.46)	102.43 (18.46)
	95% CI		52.95, 57.56	72.52, 81.16	50.85, 57.13	67.12, 77.16	95.38, 110.00
	p-value (one-sided)					<.001	
Day 90	n		70	41	37		
	Geometric LS Mean (CV%)		53.94	78.07	58.33	69.09 (30.74)	92.48 (30.74)
	95% CI		50.23, 57.93	71.10, 85.73	52.88, 64.34	61.45, 77.68	81.95, 104.35
	p-value (one-sided)					<.001	

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

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: p-value for one-sided test is for comparison between THSm2.2 and mCC

**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****Parameter: CYP1A2 Activity (%)**

Time Point		Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Day 5	n		76	42	39		
	Geometric LS Mean (CV%)		55.21	76.72	53.90	71.96 (18.46)	102.43 (18.46)
	95% CI		52.95, 57.56	72.52, 81.16	50.85, 57.13	67.12, 77.16	95.38, 110.00
	p-value (one-sided)					<.001	
Day 90	n		69	41	37		
	Geometric LS Mean (CV%)		53.82	77.97	58.25	69.03 (30.85)	92.39 (30.85)
	95% CI		50.08, 57.84	70.98, 85.64	52.79, 64.28	61.36, 77.66	81.82, 104.33
	p-value (one-sided)					<.001	

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

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: p-value for one-sided test is for comparison between THSm2.2 and mCC

**Table 15.2.4.24.2 Analysis of CYP1A2 Activity (%) - FAS****Parameter: CYP1A2 Activity (%)**

Time Point		Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Day 5	n		78	42	40		
	Geometric LS Mean (CV%)		55.31	76.71	54.30	72.10 (18.51)	101.84 (18.51)
	95% CI		53.06, 57.64	72.50, 81.16	51.27, 57.52	67.26, 77.29	94.90, 109.29
	p-value (one-sided)					<.001	
Day 90	n		78	42	40		
	Geometric LS Mean (CV%)		55.03	78.21	58.91	70.37 (30.05)	93.41 (30.05)
	95% CI		51.50, 58.80	71.45, 85.61	53.73, 64.60	62.95, 78.66	83.42, 104.59
	p-value (one-sided)					<.001	

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

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: p-value for one-sided test is for comparison between THSm2.2 and mCC

**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****Parameter: CYP1A2 Activity (%)**

Time Point		Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Day 5	n		78	42	40		
	Geometric LS Mean (CV%)		55.31	76.71	54.30	72.10 (18.51)	101.84 (18.51)
	95% CI		53.06, 57.64	72.50, 81.16	51.27, 57.52	67.26, 77.29	94.90, 109.29
	p-value (one-sided)					<.001	
Day 90	n		77	42	40		
	Geometric LS Mean (CV%)		54.93	78.11	58.84	70.32 (30.15)	93.35 (30.15)
	95% CI		51.37, 58.72	71.34, 85.52	53.65, 64.54	62.87, 78.65	83.31, 104.58
	p-value (one-sided)					<.001	

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

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: p-value for one-sided test is for comparison between THSm2.2 and mCC

**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	76	42	39		
	Geometric LS Mean (CV%)	192.24	199.92	193.73	96.16 (19.63)	99.23 (19.63)
	95% CI of Geometric Mean	183.91, 200.95	188.33, 212.22	182.14, 206.06	89.30, 103.54	91.99, 107.04
Day 30						
	n	74	41	39		
	Geometric LS Mean (CV%)	199.77	218.67	211.39	91.36 (23.01)	94.51 (23.01)
	95% CI of Geometric Mean	189.57, 210.53	203.77, 234.66	196.69, 227.18	83.70, 99.71	86.47, 103.29
Day 60						
	n	71	41	38		
	Geometric LS Mean (CV%)	196.21	230.93	208.18	84.97 (26.48)	94.25 (26.48)
	95% CI of Geometric Mean	184.52, 208.64	212.98, 250.39	191.48, 226.34	76.80, 94.00	84.98, 104.53

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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	70	41	37		
	Geometric LS Mean (CV%)	193.56	221.74	208.62	87.29 (28.86)	92.78 (28.86)
	95% CI of Geometric Mean	181.00, 206.99	203.07, 242.12	190.24, 228.78	78.19, 97.45	82.80, 103.96
11-Dehydro-Thromboxane B2 (pg/mg creat)						
Day 5						
	n	76	42	39		
	Geometric LS Mean (CV%)	557.12	618.47	525.50	90.08 (21.86)	106.02 (21.86)
	95% CI of Geometric Mean	530.36, 585.23	578.66, 661.03	490.59, 562.90	82.94, 97.83	97.46, 115.33
Day 30						
	n	74	41	39		
	Geometric LS Mean (CV%)	470.62	565.15	499.99	83.27 (28.51)	94.12 (28.51)
	95% CI of Geometric Mean	441.19, 502.00	518.02, 616.56	457.45, 546.50	74.74, 92.78	84.37, 105.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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 60						
	n	71	41	38		
	Geometric LS Mean (CV%)	461.90	544.80	458.62	84.78 (32.54)	100.72 (32.54)
	95% CI of Geometric Mean	428.57, 497.83	493.46, 601.47	414.00, 508.04	74.92, 95.95	88.77, 114.27
Day 90						
	n	70	41	37		
	Geometric LS Mean (CV%)	500.52	549.90	443.37	91.02 (32.24)	112.89 (32.24)
	95% CI of Geometric Mean	464.53, 539.29	498.48, 606.63	399.99, 491.45	80.48, 102.94	99.47, 128.12
Intercellular Adhesion Molecule 1 (ng/mL)						
Day 6/Discharge Confinement						
	n	76	42	39		
	Geometric LS Mean (CV%)	204.22	212.19	199.86	96.25 (18.62)	102.18 (18.62)
	95% CI of Geometric Mean	195.79, 213.01	200.47, 224.60	188.50, 211.91	89.68, 103.29	95.09, 109.81

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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 30						
	n	74	41	39		
	Geometric LS Mean (CV%)	195.86	213.38	199.36	91.79 (24.85)	98.24 (24.85)
	95% CI of Geometric Mean	185.07, 207.28	197.71, 230.28	184.47, 215.46	83.48, 100.92	89.26, 108.13
Day 60						
	n	71	41	38		
	Geometric LS Mean (CV%)	174.19	180.61	174.12	96.45 (24.42)	100.04 (24.42)
	95% CI of Geometric Mean	164.54, 184.41	167.56, 194.68	161.16, 188.11	87.79, 105.95	90.89, 110.11
Day 90						
	n	70	41	37		
	Geometric LS Mean (CV%)	181.23	198.55	176.97	91.28 (18.16)	102.41 (18.16)
	95% CI of Geometric Mean	173.63, 189.17	187.71, 210.01	166.87, 187.68	85.06, 97.95	95.24, 110.12

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	74	41	39		
	Geometric LS Mean (CV%)	90.28	91.81	91.56	98.33 (6.45)	98.60 (6.45)
	95% CI of Geometric Mean	88.94, 91.63	89.99, 93.67	89.70, 93.45	95.92, 100.80	96.15, 101.12
Day 60						
	n	71	41	38		
	Geometric LS Mean (CV%)	89.81	92.19	88.12	97.42 (5.95)	101.92 (5.95)
	95% CI of Geometric Mean	88.56, 91.08	90.50, 93.91	86.45, 89.82	95.19, 99.69	99.54, 104.36
Day 91/Discharge Ambulatory						
	n	70	41	37		
	Geometric LS Mean (CV%)	89.82	90.75	87.38	98.98 (6.71)	102.80 (6.71)
	95% CI of Geometric Mean	88.40, 91.27	88.88, 92.67	85.49, 89.31	96.42, 101.60	100.06, 105.61

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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	74	41	39		
	Geometric LS Mean (CV%)	0.22	0.22	0.21	101.58 (124.69)	103.72 (124.69)
	95% CI of Geometric Mean	0.17, 0.28	0.16, 0.30	0.15, 0.29	69.91, 147.60	71.00, 151.51
Day 60						
	n	71	41	38		
	Geometric LS Mean (CV%)	0.20	0.21	0.23	95.99 (123.54)	88.59 (123.54)
	95% CI of Geometric Mean	0.16, 0.26	0.15, 0.29	0.16, 0.32	66.04, 139.54	60.40, 129.93
Day 90						
	n	70	41	37		
	Geometric LS Mean (CV%)	0.24	0.26	0.22	93.59 (141.19)	110.74 (141.19)
	95% CI of Geometric Mean	0.18, 0.32	0.18, 0.36	0.15, 0.31	62.23, 140.75	72.67, 168.76

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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 (%)
Homocysteine (umol/L)						
Day 30						
	n	74	41	39		
	Geometric LS Mean (CV%)	11.49	11.25	10.94	102.19 (17.70)	105.03 (17.70)
	95% CI of Geometric Mean	11.03, 11.98	10.65, 11.88	10.35, 11.58	95.49, 109.36	98.02, 112.54
Day 60						
	n	71	41	38		
	Geometric LS Mean (CV%)	10.85	10.38	10.96	104.48 (21.43)	98.94 (21.43)
	95% CI of Geometric Mean	10.31, 11.41	9.71, 11.09	10.23, 11.74	96.22, 113.44	90.92, 107.68
Day 90						
	n	70	41	37		
	Geometric LS Mean (CV%)	11.89	11.81	12.25	100.66 (19.53)	97.03 (19.53)
	95% CI of Geometric Mean	11.35, 12.45	11.12, 12.55	11.50, 13.05	93.35, 108.54	89.75, 104.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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 (%)
Fibrinogen (mg/dL)						
Day 30						
	n	74	41	39		
	Geometric LS Mean (CV%)	275.96	290.35	279.35	95.04 (14.53)	98.79 (14.53)
	95% CI of Geometric Mean	266.51, 285.75	277.40, 303.91	266.24, 293.10	89.79, 100.61	93.13, 104.78
Day 60						
	n	71	41	38		
	Geometric LS Mean (CV%)	272.43	280.35	280.65	97.17 (18.04)	97.07 (18.04)
	95% CI of Geometric Mean	260.58, 284.83	264.95, 296.64	264.25, 298.07	90.49, 104.35	90.12, 104.56
Day 90						
	n	70	41	37		
	Geometric LS Mean (CV%)	274.62	290.36	276.30	94.58 (18.63)	99.39 (18.63)
	95% CI of Geometric Mean	262.33, 287.50	273.91, 307.81	259.37, 294.34	87.87, 101.80	91.98, 107.40

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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 (%)
Platelets (GI/L)						
Day 6/Discharge Confinement						
	n	76	42	39		
	Geometric LS Mean (CV%)	236.33	227.97	220.98	103.67 (9.10)	106.94 (9.10)
	95% CI of Geometric Mean	231.48, 241.27	221.70, 234.41	214.67, 227.48	100.14, 107.32	103.20, 110.82
Day 30						
	n	74	41	39		
	Geometric LS Mean (CV%)	235.40	234.57	229.55	100.36 (10.30)	102.55 (10.30)
	95% CI of Geometric Mean	229.88, 241.06	227.20, 242.17	222.16, 237.19	96.46, 104.41	98.49, 106.78
Day 60						
	n	71	41	38		
	Geometric LS Mean (CV%)	245.86	237.74	239.26	103.41 (14.96)	102.76 (14.96)
	95% CI of Geometric Mean	237.37, 254.66	227.00, 248.99	228.03, 251.03	97.60, 109.57	96.82, 109.06

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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	70	41	37		
	Geometric LS Mean (CV%)	251.49	244.29	236.68	102.94 (13.72)	106.26 (13.72)
	95% CI of Geometric Mean	243.47, 259.77	234.15, 254.88	226.33, 247.50	97.61, 108.57	100.56, 112.28

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
Triglycerides (mg/dL)						
Day 30						
	n	74	41	39		
	LS Mean	141.48	139.09	145.75	2.39	-4.27
	95% CI	131.72, 151.24	126.03, 152.16	132.14, 159.35	-13.87, 18.64	-21.11, 12.58
Day 60						
	n	71	41	38		
	LS Mean	135.43	150.02	139.78	-14.60	-4.35
	95% CI	125.21, 145.65	136.63, 163.42	125.67, 153.88	-31.39, 2.19	-21.88, 13.18
Day 91/Discharge Ambulatory						
	n	70	41	37		
	LS Mean	130.07	136.32	148.77	-6.25	-18.69
	95% CI	120.96, 139.19	124.42, 148.23	136.06, 161.47	-21.20, 8.69	-34.39, -2.99

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
Cholesterol (mg/dL)						
Day 30						
	n	74	41	39		
	LS Mean	192.99	189.04	197.83	3.95	-4.84
	95% CI	188.76, 197.23	183.33, 194.76	191.94, 203.72	-3.12, 11.02	-12.09, 2.42
Day 60						
	n	71	41	38		
	LS Mean	193.79	191.56	201.81	2.22	-8.02
	95% CI	188.80, 198.77	184.99, 198.13	194.94, 208.68	-5.96, 10.41	-16.53, 0.48
Day 91/Discharge Ambulatory						
	n	70	41	37		
	LS Mean	189.61	187.62	197.91	2.00	-8.30
	95% CI	184.33, 194.90	180.67, 194.56	190.56, 205.27	-6.68, 10.67	-17.35, 0.75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
Hemoglobin A1C (%)						
Day 90						
	n	70	41	37		
	LS Mean	5.20	5.18	5.16	0.02	0.04
	95% CI	5.15, 5.25	5.11, 5.24	5.09, 5.23	-0.06, 0.10	-0.04, 0.12
HDL Cholesterol (mg/dL)						
Day 30						
	n	74	41	39		
	LS Mean	59.90	56.82	60.93	3.08	-1.03
	95% CI	58.13, 61.66	54.44, 59.20	58.51, 63.35	0.13, 6.03	-4.03, 1.96
Day 60						
	n	71	41	38		
	LS Mean	61.21	56.86	62.76	4.35	-1.55
	95% CI	59.27, 63.15	54.30, 59.43	60.12, 65.40	1.15, 7.55	-4.82, 1.72

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
HDL Cholesterol (mg/dL)						
Day 90						
	n	70	41	37		
	LS Mean	61.62	57.09	63.45	4.53	-1.83
	95% CI	59.58, 63.65	54.42, 59.77	60.66, 66.25	1.17, 7.88	-5.28, 1.61
LDL Cholesterol (mg/dL)						
Day 30						
	n	74	41	39		
	LS Mean	113.62	111.54	116.97	2.08	-3.35
	95% CI	110.00, 117.23	106.67, 116.41	111.96, 121.98	-3.95, 8.10	-9.53, 2.82
Day 60						
	n	71	41	38		
	LS Mean	113.88	111.63	118.54	2.25	-4.66
	95% CI	109.50, 118.26	105.86, 117.39	112.52, 124.55	-4.94, 9.44	-12.11, 2.79

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
LDL Cholesterol (mg/dL)						
Day 90						
n		70	41	37		
LS Mean		112.05	111.17	116.79	0.87	-4.74
95% CI		107.52, 116.58	105.24, 117.11	110.52, 123.06	-6.55, 8.30	-12.46, 2.99
Leukocytes (GI/L)						
Day 6/Discharge Confinement						
n		76	42	39		
LS Mean		6.26	6.28	5.62	-0.02	0.64
95% CI		6.04, 6.49	5.97, 6.58	5.31, 5.94	-0.39, 0.36	0.25, 1.02
Day 30						
n		74	41	39		
LS Mean		5.69	5.94	5.73	-0.25	-0.04
95% CI		5.45, 5.93	5.61, 6.27	5.39, 6.07	-0.65, 0.15	-0.46, 0.37

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
Leukocytes (GI/L)						
Day 60						
	n	71	41	38		
	LS Mean	5.68	5.95	5.74	-0.27	-0.05
	95% CI	5.38, 5.99	5.55, 6.36	5.32, 6.16	-0.77, 0.24	-0.58, 0.47
Day 91/Discharge						
Ambulatory						
	n	70	41	37		
	LS Mean	5.57	6.14	5.73	-0.57	-0.16
	95% CI	5.28, 5.86	5.76, 6.52	5.34, 6.13	-1.04, -0.10	-0.65, 0.33
Neutrophils (GI/L)						
Day 6/Discharge						
Confinement						
	n	76	42	39		
	LS Mean	3.43	3.68	3.29	-0.24	0.14
	95% CI	3.24, 3.62	3.42, 3.93	3.03, 3.56	-0.56, 0.07	-0.18, 0.46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Neutrophils (GI/L)						
Day 30						
	n	74	41	39		
	LS Mean	3.07	3.26	3.17	-0.19	-0.10
	95% CI	2.85, 3.29	2.97, 3.55	2.87, 3.47	-0.55, 0.17	-0.47, 0.27
Day 60						
	n	71	41	38		
	LS Mean	3.10	3.36	3.10	-0.27	0.00
	95% CI	2.82, 3.37	3.01, 3.72	2.73, 3.47	-0.71, 0.18	-0.46, 0.45
Day 91/Discharge						
Ambulatory						
	n	70	41	37		
	LS Mean	2.97	3.45	3.04	-0.48	-0.06
	95% CI	2.73, 3.22	3.13, 3.77	2.70, 3.38	-0.88, -0.08	-0.48, 0.35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
Lymphocytes (GI/L)						
Day 6/Discharge Confinement						
n		76	42	39		
LS Mean		2.33	2.08	1.92	0.25	0.41
95% CI		2.24, 2.42	1.95, 2.20	1.79, 2.05	0.10, 0.40	0.25, 0.56
Day 30						
n		74	41	39		
LS Mean		2.13	2.13	2.10	0.00	0.04
95% CI		2.04, 2.23	2.00, 2.26	1.97, 2.23	-0.15, 0.16	-0.13, 0.20
Day 60						
n		71	41	38		
LS Mean		2.12	2.04	2.17	0.08	-0.05
95% CI		2.02, 2.23	1.91, 2.18	2.03, 2.31	-0.09, 0.24	-0.22, 0.12

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
Lymphocytes (GI/L)						
Day 91/Discharge						
Ambulatory						
n		70	41	37		
LS Mean		2.13	2.10	2.23	0.03	-0.10
95% CI		2.03, 2.23	1.97, 2.23	2.09, 2.36	-0.14, 0.19	-0.27, 0.07
Monocytes (GI/L)						
Day 6/Discharge						
Confinement						
n		76	42	39		
LS Mean		0.32	0.31	0.26	0.00	0.06
95% CI		0.29, 0.34	0.28, 0.34	0.23, 0.29	-0.03, 0.04	0.02, 0.10
Day 30						
n		74	41	39		
LS Mean		0.29	0.31	0.29	-0.02	0.01
95% CI		0.27, 0.32	0.28, 0.34	0.25, 0.32	-0.06, 0.02	-0.03, 0.05

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Monocytes (GI/L)						
Day 60						
	n	71	41	38		
	LS Mean	0.28	0.32	0.26	-0.03	0.02
	95% CI	0.26, 0.31	0.28, 0.35	0.23, 0.29	-0.07, 0.01	-0.02, 0.06
Day 91/Discharge						
Ambulatory						
	n	70	41	37		
	LS Mean	0.30	0.35	0.28	-0.05	0.02
	95% CI	0.27, 0.33	0.32, 0.39	0.24, 0.32	-0.10, -0.01	-0.03, 0.06
Eosinophils (GI/L)						
Day 6/Discharge						
Confinement						
	n	76	42	39		
	LS Mean	0.12	0.14	0.12	-0.02	0.00
	95% CI	0.11, 0.14	0.12, 0.16	0.11, 0.14	-0.04, 0.00	-0.02, 0.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Eosinophils (GI/L)						
Day 30						
	n	74	41	39		
	LS Mean	0.14	0.17	0.16	-0.03	-0.02
	95% CI	0.12, 0.15	0.14, 0.19	0.13, 0.18	-0.06, 0.00	-0.05, 0.01
Day 60						
	n	71	41	38		
	LS Mean	0.13	0.16	0.19	-0.03	-0.06
	95% CI	0.09, 0.17	0.11, 0.21	0.14, 0.25	-0.09, 0.04	-0.13, 0.00
Day 91/Discharge						
Ambulatory						
	n	70	41	37		
	LS Mean	0.13	0.17	0.16	-0.04	-0.03
	95% CI	0.11, 0.16	0.14, 0.20	0.13, 0.19	-0.08, 0.00	-0.07, 0.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
Basophils (GI/L)						
Day 6/Discharge Confinement						
n		76	42	39		
LS Mean		0.06	0.06	0.05	0.00	0.01
95% CI		0.05, 0.07	0.05, 0.06	0.04, 0.06	-0.01, 0.01	0.00, 0.02
Day 30						
n		74	41	39		
LS Mean		0.05	0.05	0.05	0.00	0.00
95% CI		0.04, 0.06	0.04, 0.06	0.04, 0.06	-0.01, 0.01	-0.01, 0.01
Day 60						
n		71	41	38		
LS Mean		0.05	0.05	0.05	0.00	0.00
95% CI		0.04, 0.06	0.04, 0.06	0.04, 0.06	-0.01, 0.01	-0.01, 0.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
Basophils (GI/L)						
Day 91/Discharge						
Ambulatory						
n		70	41	37		
LS Mean		0.05	0.05	0.05	-0.01	0.00
95% CI		0.03, 0.06	0.04, 0.06	0.04, 0.06	-0.02, 0.01	-0.02, 0.01
Systolic Blood Pressure						
Day 6/Discharge						
Confinement						
n		76	42	39		
LS Mean		108.71	107.73	105.60	0.97	3.11
95% CI		106.97, 110.44	105.39, 110.07	103.10, 108.09	-1.91, 3.86	0.06, 6.16
Day 30						
n		74	41	39		
LS Mean		107.56	108.37	106.31	-0.81	1.25
95% CI		105.70, 109.42	105.86, 110.88	103.67, 108.96	-3.91, 2.29	-2.00, 4.49

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Systolic Blood Pressure						
Day 60						
	n	71	41	38		
	LS Mean	107.33	107.96	105.55	-0.63	1.78
	95% CI	105.51, 109.15	105.57, 110.36	102.99, 108.11	-3.61, 2.35	-1.37, 4.94
Day 91/Discharge						
Ambulatory						
	n	70	41	37		
	LS Mean	103.17	103.76	103.92	-0.59	-0.76
	95% CI	101.21, 105.12	101.19, 106.33	101.15, 106.69	-3.80, 2.62	-4.16, 2.65
Diastolic Blood Pressure						
Day 6/Discharge						
Confinement						
	n	76	42	39		
	LS Mean	69.94	67.79	66.36	2.15	3.58
	95% CI	68.69, 71.19	66.11, 69.48	64.59, 68.12	0.07, 4.23	1.42, 5.74

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Diastolic Blood Pressure						
Day 30						
	n	74	41	39		
	LS Mean	64.78	64.73	62.91	0.05	1.87
	95% CI	63.45, 66.11	62.93, 66.52	61.05, 64.77	-2.17, 2.27	-0.42, 4.15
Day 60						
	n	71	41	38		
	LS Mean	65.21	65.95	63.54	-0.74	1.66
	95% CI	63.73, 66.68	64.00, 67.89	61.51, 65.58	-3.16, 1.68	-0.85, 4.18
Day 91/Discharge						
Ambulatory						
	n	70	41	37		
	LS Mean	62.25	62.93	63.93	-0.68	-1.68
	95% CI	60.81, 63.69	61.04, 64.82	61.92, 65.94	-3.04, 1.69	-4.16, 0.79

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	THSm2.2 - SA
Weight						
Day 91/Discharge						
Ambulatory						
	n	70	41	37		
	LS Mean	62.55	62.64	63.79	-0.09	-1.24
	95% CI	62.15, 62.96	62.11, 63.17	63.24, 64.35	-0.75, 0.57	-1.92, -0.56
Waist Circumference						
Day 91/Discharge						
Ambulatory						
	n	70	41	37		
	LS Mean	81.04	79.44	80.96	1.60	0.08
	95% CI	78.63, 83.45	76.28, 82.60	77.64, 84.28	-2.36, 5.56	-4.00, 4.16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Day 5	n	76	42	39		
	Geometric LS Mean (CV%)	557.12	618.47	525.50	90.08 (21.86)	106.02 (21.86)
	95% CI of Geometric Mean	530.36, 585.23	578.66, 661.03	490.59, 562.90	82.94, 97.83	97.46, 115.33
Day 30	n	74	41	39		
	Geometric LS Mean (CV%)	470.62	565.15	499.99	83.27 (28.51)	94.12 (28.51)
	95% CI of Geometric Mean	441.19, 502.00	518.02, 616.56	457.45, 546.50	74.74, 92.78	84.37, 105.01
Day 60	n	71	41	38		
	Geometric LS Mean (CV%)	461.90	544.80	458.62	84.78 (32.54)	100.72 (32.54)
	95% CI of Geometric Mean	428.57, 497.83	493.46, 601.47	414.00, 508.04	74.92, 95.95	88.77, 114.27
Day 90	n	70	41	37		
	Geometric LS Mean (CV%)	500.52	549.90	443.37	91.02 (32.24)	112.89 (32.24)
	95% CI of Geometric Mean	464.53, 539.29	498.48, 606.63	399.99, 491.45	80.48, 102.94	99.47, 128.12

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

No concomitant medication impacting 11-DTX-B2 were recorded.

**Table 15.2.4.25.1.2 Analysis of FEV1 without Bronchodilator at Day 90 - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
FEV1 (%pred)						
	n	70	41	37		
	LS Mean	95.36	93.45	95.38	1.91	-0.02
	95% CI	94.11, 96.62	91.81, 95.09	93.66, 97.11	-0.14, 3.97	-2.15, 2.11

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = 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	78	42	40		
	Geometric LS Mean (CV%)	192.79	200.12	193.97	96.34 (19.45)	99.39 (19.45)
	95% CI of Geometric Mean	184.60, 201.34	188.62, 212.31	182.61, 206.03	89.56, 103.63	92.29, 107.04
Day 30						
	n	78	42	40		
	Geometric LS Mean (CV%)	199.44	217.71	211.17	91.61 (22.72)	94.45 (22.72)
	95% CI of Geometric Mean	189.62, 209.77	203.23, 233.23	196.85, 226.52	84.15, 99.72	86.64, 102.95
Day 60						
	n	78	42	40		
	Geometric LS Mean (CV%)	197.32	229.45	207.06	86.00 (26.05)	95.29 (26.05)
	95% CI of Geometric Mean	186.26, 209.04	212.09, 248.22	191.10, 224.35	78.05, 94.76	86.35, 105.16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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	78	42	40		
	Geometric LS Mean (CV%)	190.08	219.56	206.55	86.57 (28.49)	92.03 (28.49)
	95% CI of Geometric Mean	178.49, 202.42	201.52, 239.22	189.26, 225.42	77.89, 96.23	82.65, 102.46
11-Dehydro-Thromboxane B2 (pg/mg creat)						
Day 5						
	n	78	42	40		
	Geometric LS Mean (CV%)	559.24	620.52	529.07	90.12 (21.71)	105.70 (21.71)
	95% CI of Geometric Mean	532.84, 586.94	580.80, 662.95	494.59, 565.95	83.05, 97.79	97.32, 114.80
Day 30						
	n	78	42	40		
	Geometric LS Mean (CV%)	465.64	562.74	502.34	82.75 (28.71)	92.69 (28.71)
	95% CI of Geometric Mean	437.03, 496.12	515.98, 613.73	459.84, 548.76	74.34, 92.10	83.18, 103.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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 60						
	n	78	42	40		
	Geometric LS Mean (CV%)	462.67	539.69	461.56	85.73 (32.14)	100.24 (32.14)
	95% CI of Geometric Mean	431.11, 496.53	489.98, 594.45	418.28, 509.32	76.08, 96.59	88.85, 113.09
Day 90						
	n	78	42	40		
	Geometric LS Mean (CV%)	494.33	543.67	442.60	90.92 (32.10)	111.69 (32.10)
	95% CI of Geometric Mean	460.66, 530.46	493.66, 598.76	401.15, 488.34	80.71, 102.43	99.01, 125.98
Intercellular Adhesion Molecule 1 (ng/mL)						
Day 6/Discharge Confinement						
	n	78	42	40		
	Geometric LS Mean (CV%)	204.50	213.02	200.77	96.00 (18.74)	101.86 (18.74)
	95% CI of Geometric Mean	196.10, 213.27	201.17, 225.57	189.42, 212.79	89.44, 103.05	94.82, 109.42

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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 30						
n		78	42	40		
Geometric LS Mean (CV%)		193.23	214.16	199.80	90.23 (25.74)	96.71 (25.74)
95% CI of Geometric Mean		182.48, 204.60	198.09, 231.53	184.58, 216.29	81.92, 99.37	87.72, 106.62
Day 60						
n		78	42	40		
Geometric LS Mean (CV%)		173.20	181.53	175.75	95.41 (25.43)	98.55 (25.43)
95% CI of Geometric Mean		163.67, 183.27	168.06, 196.08	162.50, 190.07	86.72, 104.96	89.49, 108.52
Day 90						
n		78	42	40		
Geometric LS Mean (CV%)		180.12	199.74	179.59	90.17 (19.10)	100.30 (19.10)
95% CI of Geometric Mean		172.58, 187.99	188.43, 211.73	169.25, 190.55	83.90, 96.92	93.24, 107.88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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	78	42	40		
	Geometric LS Mean (CV%)	90.28	91.65	91.25	98.50 (6.41)	98.93 (6.41)
	95% CI of Geometric Mean	88.98, 91.59	89.86, 93.47	89.44, 93.10	96.14, 100.93	96.52, 101.40
Day 60						
	n	78	42	40		
	Geometric LS Mean (CV%)	89.72	91.88	87.78	97.65 (6.07)	102.21 (6.07)
	95% CI of Geometric Mean	88.50, 90.96	90.18, 93.61	86.13, 89.47	95.43, 99.92	99.85, 104.62
Day 91/Discharge Ambulatory						
	n	78	42	40		
	Geometric LS Mean (CV%)	89.85	90.50	87.14	99.28 (6.59)	103.11 (6.59)
	95% CI of Geometric Mean	88.52, 91.19	88.69, 92.35	85.36, 88.95	96.83, 101.79	100.53, 105.75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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	78	42	40		
	Geometric LS Mean (CV%)	0.22	0.21	0.21	101.62 (121.75)	103.23 (121.75)
	95% CI of Geometric Mean	0.17, 0.27	0.15, 0.29	0.15, 0.29	70.78, 145.88	71.54, 148.95
Day 60						
	n	78	42	40		
	Geometric LS Mean (CV%)	0.21	0.21	0.23	97.17 (118.68)	87.93 (118.68)
	95% CI of Geometric Mean	0.16, 0.26	0.15, 0.29	0.17, 0.32	68.09, 138.65	61.31, 126.10
Day 90						
	n	78	42	40		
	Geometric LS Mean (CV%)	0.26	0.25	0.22	102.61 (141.01)	119.43 (141.01)
	95% CI of Geometric Mean	0.20, 0.33	0.18, 0.36	0.15, 0.31	69.00, 152.59	79.87, 178.59

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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 (%)
Homocysteine (umol/L)						
Day 30						
	n	78	42	40		
	Geometric LS Mean (CV%)	11.58	11.28	10.99	102.60 (17.50)	105.37 (17.50)
	95% CI of Geometric Mean	11.12, 12.04	10.69, 11.90	10.40, 11.60	96.07, 109.58	98.55, 112.67
Day 60						
	n	78	42	40		
	Geometric LS Mean (CV%)	10.83	10.33	10.89	104.80 (20.87)	99.39 (20.87)
	95% CI of Geometric Mean	10.33, 11.35	9.69, 11.01	10.21, 11.63	96.92, 113.33	91.78, 107.63
Day 90						
	n	78	42	40		
	Geometric LS Mean (CV%)	11.85	11.73	12.08	101.02 (19.09)	98.10 (19.09)
	95% CI of Geometric Mean	11.35, 12.38	11.07, 12.44	11.38, 12.83	94.03, 108.52	91.19, 105.53

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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 (%)
Fibrinogen (mg/dL)						
Day 30						
	n	78	42	40		
	Geometric LS Mean (CV%)	274.56	289.64	278.96	94.79 (14.46)	98.42 (14.46)
	95% CI of Geometric Mean	265.39, 284.05	276.94, 302.92	266.13, 292.41	89.66, 100.22	92.91, 104.27
Day 60						
	n	78	42	40		
	Geometric LS Mean (CV%)	271.90	280.56	282.29	96.91 (17.65)	96.32 (17.65)
	95% CI of Geometric Mean	260.88, 283.38	265.66, 296.31	266.56, 298.95	90.56, 103.71	89.79, 103.32
Day 90						
	n	78	42	40		
	Geometric LS Mean (CV%)	275.31	289.76	276.82	95.01 (18.35)	99.46 (18.35)
	95% CI of Geometric Mean	263.73, 287.39	273.79, 306.66	260.81, 293.80	88.55, 101.95	92.46, 106.98

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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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 (%)
Platelets (GI/L)						
Day 6/Discharge Confinement						
	n	78	42	40		
	Geometric LS Mean (CV%)	236.15	227.72	220.79	103.70 (9.02)	106.96 (9.02)
	95% CI of Geometric Mean	231.40, 240.99	221.52, 234.10	214.61, 227.14	100.22, 107.30	103.29, 110.76
Day 30						
	n	78	42	40		
	Geometric LS Mean (CV%)	234.10	233.06	228.29	100.45 (10.26)	102.55 (10.26)
	95% CI of Geometric Mean	228.76, 239.56	225.85, 240.49	221.04, 235.77	96.63, 104.42	98.56, 106.70
Day 60						
	n	78	42	40		
	Geometric LS Mean (CV%)	244.76	236.72	238.08	103.39 (14.52)	102.81 (14.52)
	95% CI of Geometric Mean	236.91, 252.86	226.46, 247.45	227.48, 249.17	97.89, 109.21	97.21, 108.73

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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 91/Discharge						
Ambulatory						
	n	78	42	40		
	Geometric LS Mean (CV%)	251.23	242.80	237.00	103.47 (13.97)	106.00 (13.97)
	95% CI of Geometric Mean	243.48, 259.23	232.66, 253.38	226.84, 247.62	98.17, 109.07	100.44, 111.87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Triglycerides (mg/dL)						
Day 30						
	n	78	42	40		
	LS Mean	141.29	138.25	145.07	3.04	-3.79
	95% CI	131.94, 150.64	125.56, 150.94	131.87, 158.28	-12.67, 18.75	-20.08, 12.51
Day 60						
	n	78	42	40		
	LS Mean	134.92	148.81	139.48	-13.89	-4.57
	95% CI	125.29, 144.54	135.75, 161.87	125.90, 153.07	-30.06, 2.28	-21.34, 12.20
Day 91/Discharge Ambulatory						
	n	78	42	40		
	LS Mean	130.86	136.68	149.87	-5.81	-19.01
	95% CI	122.18, 139.55	124.89, 148.46	137.61, 162.14	-20.40, 8.78	-34.14, -3.87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Cholesterol (mg/dL)						
Day 30						
	n	78	42	40		
	LS Mean	193.19	188.79	197.11	4.39	-3.93
	95% CI	189.08, 197.29	183.19, 194.39	191.33, 202.89	-2.50, 11.28	-11.03, 3.17
Day 60						
	n	78	42	40		
	LS Mean	192.97	190.46	199.02	2.51	-6.05
	95% CI	188.24, 197.69	184.02, 196.90	192.37, 205.67	-5.42, 10.43	-14.22, 2.11
Day 91/Discharge						
Ambulatory						
	n	78	42	40		
	LS Mean	187.88	187.18	195.84	0.70	-7.96
	95% CI	182.84, 192.91	180.31, 194.05	188.75, 202.93	-7.75, 9.15	-16.67, 0.75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Hemoglobin A1C (%)						
Day 90						
	n	78	42	40		
	LS Mean	5.18	5.17	5.15	0.02	0.03
	95% CI	5.14, 5.23	5.10, 5.23	5.09, 5.21	-0.06, 0.10	-0.04, 0.11
HDL Cholesterol (mg/dL)						
Day 30						
	n	78	42	40		
	LS Mean	60.14	56.88	61.01	3.26	-0.87
	95% CI	58.43, 61.85	54.54, 59.22	58.63, 63.39	0.37, 6.14	-3.80, 2.06
Day 60						
	n	78	42	40		
	LS Mean	61.76	56.98	62.69	4.79	-0.92
	95% CI	59.93, 63.59	54.48, 59.48	60.14, 65.24	1.70, 7.88	-4.06, 2.21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

Study ID: ZRHM-REXA-07-JP

Program: t1502042502-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
HDL Cholesterol (mg/dL)						
Day 90						
	n	78	42	40		
	LS Mean	61.54	57.22	63.20	4.32	-1.67
	95% CI	59.57, 63.50	54.53, 59.91	60.46, 65.94	1.00, 7.64	-5.04, 1.70
LDL Cholesterol (mg/dL)						
Day 30						
	n	78	42	40		
	LS Mean	113.48	111.14	116.46	2.34	-2.98
	95% CI	109.95, 117.01	106.33, 115.95	111.51, 121.42	-3.58, 8.27	-9.07, 3.11
Day 60						
	n	78	42	40		
	LS Mean	112.70	110.36	116.89	2.34	-4.19
	95% CI	108.59, 116.82	104.76, 115.97	111.12, 122.66	-4.56, 9.24	-11.28, 2.90

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
LDL Cholesterol (mg/dL)						
Day 90						
	n	78	42	40		
	LS Mean	110.19	110.49	115.83	-0.30	-5.65
	95% CI	105.90, 114.48	104.64, 116.33	109.81, 121.85	-7.50, 6.90	-13.04, 1.75
Leukocytes (GI/L)						
Day 6/Discharge Confinement						
	n	78	42	40		
	LS Mean	6.27	6.29	5.68	-0.02	0.59
	95% CI	6.05, 6.50	5.98, 6.59	5.37, 6.00	-0.39, 0.36	0.20, 0.97
Day 30						
	n	78	42	40		
	LS Mean	5.70	5.94	5.79	-0.24	-0.09
	95% CI	5.46, 5.94	5.62, 6.26	5.46, 6.13	-0.64, 0.16	-0.50, 0.32

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Leukocytes (GI/L)						
Day 60						
	n	78	42	40		
	LS Mean	5.71	5.97	5.82	-0.26	-0.10
	95% CI	5.42, 6.00	5.57, 6.36	5.41, 6.22	-0.74, 0.23	-0.60, 0.39
Day 91/Discharge						
Ambulatory						
	n	78	42	40		
	LS Mean	5.69	6.15	5.81	-0.46	-0.12
	95% CI	5.41, 5.98	5.76, 6.54	5.41, 6.21	-0.93, 0.02	-0.61, 0.37
Neutrophils (GI/L)						
Day 6/Discharge						
Confinement						
	n	78	42	40		
	LS Mean	3.44	3.69	3.36	-0.25	0.08
	95% CI	3.25, 3.63	3.43, 3.95	3.10, 3.63	-0.56, 0.07	-0.25, 0.40

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Neutrophils (GI/L)						
Day 30						
	n	78	42	40		
	LS Mean	3.09	3.27	3.25	-0.19	-0.16
	95% CI	2.87, 3.30	2.98, 3.57	2.95, 3.55	-0.54, 0.17	-0.52, 0.21
Day 60						
	n	78	42	40		
	LS Mean	3.12	3.38	3.19	-0.26	-0.07
	95% CI	2.87, 3.38	3.03, 3.73	2.83, 3.55	-0.68, 0.17	-0.51, 0.37
Day 91/Discharge						
Ambulatory						
	n	78	42	40		
	LS Mean	3.09	3.46	3.14	-0.37	-0.05
	95% CI	2.84, 3.34	3.11, 3.80	2.78, 3.49	-0.79, 0.05	-0.48, 0.38

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Lymphocytes (GI/L)						
Day 6/Discharge Confinement						
n		78	42	40		
LS Mean		2.33	2.08	1.91	0.25	0.42
95% CI		2.24, 2.42	1.96, 2.20	1.78, 2.04	0.10, 0.40	0.27, 0.58
Day 30						
n		78	42	40		
LS Mean		2.13	2.12	2.09	0.01	0.04
95% CI		2.03, 2.22	1.99, 2.25	1.95, 2.22	-0.15, 0.17	-0.12, 0.20
Day 60						
n		78	42	40		
LS Mean		2.11	2.04	2.15	0.08	-0.03
95% CI		2.01, 2.21	1.90, 2.17	2.01, 2.29	-0.09, 0.24	-0.20, 0.14

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Lymphocytes (GI/L)						
Day 91/Discharge						
Ambulatory						
n		78	42	40		
LS Mean		2.12	2.10	2.20	0.02	-0.08
95% CI		2.02, 2.22	1.97, 2.24	2.07, 2.34	-0.14, 0.18	-0.25, 0.08
Monocytes (GI/L)						
Day 6/Discharge						
Confinement						
n		78	42	40		
LS Mean		0.32	0.31	0.26	0.00	0.06
95% CI		0.29, 0.34	0.28, 0.34	0.23, 0.29	-0.03, 0.04	0.02, 0.09
Day 30						
n		78	42	40		
LS Mean		0.29	0.31	0.29	-0.02	0.01
95% CI		0.27, 0.32	0.28, 0.34	0.26, 0.32	-0.05, 0.02	-0.03, 0.04

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Monocytes (GI/L)						
Day 60						
	n	78	42	40		
	LS Mean	0.28	0.32	0.27	-0.03	0.02
	95% CI	0.26, 0.31	0.29, 0.35	0.24, 0.30	-0.07, 0.00	-0.02, 0.05
Day 91/Discharge						
Ambulatory						
	n	78	42	40		
	LS Mean	0.30	0.35	0.28	-0.05	0.02
	95% CI	0.28, 0.33	0.32, 0.38	0.25, 0.32	-0.09, -0.01	-0.02, 0.06
Eosinophils (GI/L)						
Day 6/Discharge						
Confinement						
	n	78	42	40		
	LS Mean	0.12	0.14	0.12	-0.02	0.00
	95% CI	0.11, 0.13	0.12, 0.16	0.11, 0.14	-0.04, 0.00	-0.02, 0.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Eosinophils (GI/L)						
Day 30						
	n	78	42	40		
	LS Mean	0.14	0.17	0.16	-0.03	-0.02
	95% CI	0.12, 0.15	0.14, 0.19	0.13, 0.18	-0.06, 0.00	-0.05, 0.01
Day 60						
	n	78	42	40		
	LS Mean	0.14	0.16	0.19	-0.02	-0.05
	95% CI	0.10, 0.18	0.11, 0.21	0.14, 0.25	-0.08, 0.04	-0.12, 0.01
Day 91/Discharge Ambulatory						
	n	78	42	40		
	LS Mean	0.14	0.17	0.16	-0.03	-0.03
	95% CI	0.11, 0.16	0.14, 0.20	0.13, 0.19	-0.07, 0.00	-0.06, 0.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Basophils (GI/L)						
Day 6/Discharge Confinement						
n		78	42	40		
LS Mean		0.06	0.06	0.05	0.00	0.01
95% CI		0.05, 0.06	0.05, 0.06	0.04, 0.06	-0.01, 0.01	0.00, 0.02
Day 30						
n		78	42	40		
LS Mean		0.05	0.05	0.05	0.00	0.00
95% CI		0.04, 0.06	0.04, 0.06	0.04, 0.06	-0.01, 0.01	-0.01, 0.01
Day 60						
n		78	42	40		
LS Mean		0.05	0.05	0.05	0.00	0.00
95% CI		0.04, 0.06	0.04, 0.06	0.04, 0.06	-0.01, 0.01	-0.01, 0.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Basophils (GI/L)						
Day 91/Discharge						
Ambulatory						
n		78	42	40		
LS Mean		0.05	0.05	0.05	-0.01	0.00
95% CI		0.03, 0.06	0.04, 0.06	0.04, 0.06	-0.02, 0.01	-0.02, 0.01
Percent of predicted FEV1 value						
Day 91/Discharge						
Ambulatory						
n		77	41	39		
LS Mean		95.36	93.38	95.04	1.98	0.32
95% CI		94.15, 96.56	91.73, 95.03	93.35, 96.73	-0.05, 4.01	-1.75, 2.39
Systolic Blood Pressure						
Day 6/Discharge						
Confinement						
n		78	42	40		
LS Mean		108.78	107.68	105.81	1.11	2.97
95% CI		107.05, 110.52	105.30, 110.05	103.32, 108.30	-1.81, 4.02	-0.07, 6.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Systolic Blood Pressure						
Day 30						
	n	78	42	40		
	LS Mean	107.63	108.37	106.64	-0.75	0.99
	95% CI	105.81, 109.45	105.89, 110.86	104.03, 109.25	-3.80, 2.31	-2.20, 4.17
Day 60						
	n	78	42	40		
	LS Mean	107.36	107.93	105.94	-0.56	1.42
	95% CI	105.64, 109.09	105.57, 110.28	103.47, 108.42	-3.46, 2.34	-1.60, 4.44
Day 91/Discharge						
Ambulatory						
	n	78	42	40		
	LS Mean	103.41	103.87	104.52	-0.46	-1.12
	95% CI	101.55, 105.26	101.33, 106.41	101.86, 107.19	-3.59, 2.66	-4.37, 2.14

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Diastolic Blood Pressure						
Day 6/Discharge Confinement						
n		78	42	40		
LS Mean		70.05	67.71	66.10	2.33	3.94
95% CI		68.80, 71.29	66.01, 69.42	64.35, 67.86	0.23, 4.43	1.79, 6.09
Day 30						
n		78	42	40		
LS Mean		64.91	64.72	62.74	0.19	2.17
95% CI		63.58, 66.24	62.90, 66.53	60.87, 64.60	-2.04, 2.42	-0.11, 4.46
Day 60						
n		78	42	40		
LS Mean		65.22	65.87	63.42	-0.65	1.80
95% CI		63.81, 66.63	63.95, 67.80	61.44, 65.41	-3.03, 1.72	-0.64, 4.23

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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: 15.3.3.1, 15.3.6.10, 15.3.6.4, 15.3.6.5

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC	THSm2.2 - SA
Diastolic Blood Pressure						
Day 91/Discharge						
Ambulatory						
n		78	42	40		
LS Mean		62.53	62.90	63.62	-0.37	-1.09
95% CI		61.13, 63.93	60.98, 64.81	61.64, 65.59	-2.72, 1.99	-3.51, 1.33
Weight						
Day 91/Discharge						
Ambulatory						
n		78	42	40		
LS Mean		62.53	62.67	63.79	-0.14	-1.26
95% CI		62.15, 62.91	62.15, 63.19	63.26, 64.32	-0.78, 0.49	-1.91, -0.62
Waist Circumference						
Day 91/Discharge						
Ambulatory						
n		78	42	40		
LS Mean		81.31	79.22	80.56	2.09	0.74
95% CI		79.08, 83.54	76.18, 82.25	77.46, 83.67	-1.66, 5.84	-3.06, 4.55

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

**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****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Day 5	n	78	42	40		
	Geometric LS Mean (CV%)	559.24	620.52	529.07	90.12 (21.71)	105.70 (21.71)
	95% CI of Geometric Mean	532.84, 586.94	580.80, 662.95	494.59, 565.95	83.05, 97.79	97.32, 114.80
Day 30	n	78	42	40		
	Geometric LS Mean (CV%)	465.64	562.74	502.34	82.75 (28.71)	92.69 (28.71)
	95% CI of Geometric Mean	437.03, 496.12	515.98, 613.73	459.84, 548.76	74.34, 92.10	83.18, 103.30
Day 60	n	78	42	40		
	Geometric LS Mean (CV%)	462.67	539.69	461.56	85.73 (32.14)	100.24 (32.14)
	95% CI of Geometric Mean	431.11, 496.53	489.98, 594.45	418.28, 509.32	76.08, 96.59	88.85, 113.09
Day 90	n	78	42	40		
	Geometric LS Mean (CV%)	494.33	543.67	442.60	90.92 (32.10)	111.69 (32.10)
	95% CI of Geometric Mean	460.66, 530.46	493.66, 598.76	401.15, 488.34	80.71, 102.43	99.01, 125.98

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; 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.

No concomitant medication impacting 11-DTX-B2 were recorded.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	76		42		39	
	Mean (SD)	110.3 (11.17)		111.4 (10.05)		104.4 (7.61)	
	95% CI	107.7, 112.9		108.2, 114.5		101.8, 106.9	
	Median	110.0		112.0		103.0	
	Q25, Q75	102.0, 117.5		104.0, 118.0		100.0, 110.0	
	Min, Max	90, 136		94, 133		91, 125	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1							
	n	76	76	42	42	39	39
	Mean (SD)	106.5 (9.57)	-3.13 (7.473)	108.7 (11.91)	-2.21 (7.857)	102.3 (8.38)	-1.92 (5.648)
	95% CI	104.2, 108.7	-4.84, -1.41	105.0, 112.5	-4.66, 0.25	99.5, 105.0	-3.76, -0.09
	Median	106.0	-3.76	107.0	-1.78	101.0	-3.06
	Q25, Q75	99.5, 114.0	-7.77, 1.84	100.0, 116.0	-6.60, 2.78	95.0, 109.0	-5.26, 2.59
	Min, Max	87, 128	-21.4, 19.8	90, 135	-26.4, 13.3	90, 119	-15.2, 12.5

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2							
	n	76	76	41	41	39	39
	Mean (SD)	105.8 (10.37)	-3.75 (7.354)	107.6 (10.85)	-2.92 (7.482)	102.2 (8.65)	-1.90 (6.838)
	95% CI	103.4, 108.3	-5.43, -2.06	104.1, 111.1	-5.29, -0.56	99.4, 105.1	-4.12, 0.32
	Median	105.0	-4.25	105.0	-3.88	103.0	-2.78
	Q25, Q75	97.0, 113.0	-8.27, 1.61	99.0, 117.0	-7.63, 0.93	94.0, 109.0	-6.80, 2.11
	Min, Max	90, 140	-23.2, 14.4	90, 132	-14.4, 20.2	90, 121	-17.3, 16.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.7

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**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 3							
	n	76	76	41	41	39	39
	Mean (SD)	107.5 (10.48)	-2.28 (7.224)	109.1 (12.71)	-1.59 (8.827)	101.5 (7.17)	-2.49 (7.011)
	95% CI	105.0, 109.9	-3.94, -0.63	105.1, 113.2	-4.38, 1.21	99.1, 103.9	-4.77, -0.21
	Median	106.5	-3.00	107.0	-3.13	101.0	-3.03
	Q25, Q75	98.0, 115.0	-7.41, 2.90	100.0, 120.0	-6.84, 5.04	95.0, 106.0	-7.76, 2.68
	Min, Max	91, 130	-21.6, 16.8	88, 137	-18.4, 18.1	91, 121	-20.0, 12.7

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 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4							
	n	76	76	41	41	39	39
	Mean (SD)	106.3 (10.43)	-3.29 (8.353)	108.9 (11.69)	-1.81 (6.961)	101.2 (7.40)	-2.83 (6.389)
	95% CI	103.8, 108.7	-5.20, -1.38	105.2, 112.7	-4.01, 0.39	98.8, 103.7	-4.90, -0.75
	Median	105.5	-3.89	107.0	-3.39	101.0	-3.23
	Q25, Q75	97.5, 112.5	-8.41, 2.09	101.0, 115.0	-7.55, 3.70	94.0, 107.0	-8.33, 1.10
	Min, Max	90, 131	-22.4, 20.0	91, 136	-14.2, 11.5	90, 116	-12.0, 10.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5							
	n	76	76	41	41	39	39
	Mean (SD)	108.9 (10.66)	-0.98 (7.862)	108.7 (11.46)	-1.90 (7.688)	103.1 (9.77)	-0.96 (9.782)
	95% CI	106.4, 111.4	-2.78, 0.82	105.1, 112.4	-4.34, 0.53	99.9, 106.3	-4.13, 2.22
	Median	108.0	-1.30	105.0	-2.02	101.0	-2.73
	Q25, Q75	100.5, 115.5	-6.09, 2.60	100.0, 116.0	-7.22, 4.20	95.0, 112.0	-9.09, 1.08
	Min, Max	91, 133	-16.4, 20.9	90, 136	-15.4, 12.8	90, 139	-14.0, 39.0

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge Confinement							
	n	76	76	42	42	39	39
	Mean (SD)	109.5 (10.08)	-0.34 (8.630)	109.1 (10.65)	-1.80 (8.075)	103.1 (7.08)	-1.02 (6.178)
	95% CI	107.1, 111.8	-2.32, 1.64	105.7, 112.4	-4.32, 0.72	100.7, 105.4	-3.03, 0.99
	Median	109.0	-1.76	108.5	-3.98	102.0	-2.00
	Q25, Q75	103.0, 115.0	-6.24, 4.21	104.0, 118.0	-6.19, 2.91	98.0, 107.0	-5.56, 4.00
	Min, Max	90, 136	-14.4, 26.0	90, 131	-17.6, 22.9	90, 118	-9.9, 17.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	74		41		39	
	Mean (SD)	110.3 (11.30)		111.0 (9.94)		104.4 (7.61)	
	95% CI	107.6, 113.0		107.8, 114.2		101.8, 106.9	
	Median	110.0		112.0		103.0	
	Q25, Q75	102.0, 118.0		104.0, 117.0		100.0, 110.0	
	Min, Max	90, 136		94, 133		91, 125	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30							
	n	74	74	41	41	39	39
	Mean (SD)	108.7 (11.00)	-1.04 (9.004)	110.0 (11.82)	-0.82 (7.779)	104.1 (9.22)	-0.07 (7.576)
	95% CI	106.1, 111.3	-3.13, 1.05	106.2, 113.8	-3.28, 1.64	101.1, 107.2	-2.53, 2.39
	Median	109.0	-2.76	109.0	-2.61	104.0	0.00
	Q25, Q75	100.0, 116.0	-7.02, 5.41	100.0, 119.0	-5.88, 4.76	95.0, 111.0	-5.88, 4.31
	Min, Max	90, 134	-26.0, 17.9	90, 134	-17.1, 19.4	90, 126	-14.0, 26.0

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	71		41		38	
	Mean (SD)	110.6 (11.15)		111.0 (9.94)		104.4 (7.71)	
	95% CI	107.9, 113.3		107.8, 114.2		101.8, 107.0	
	Median	111.0		112.0		102.5	
	Q25, Q75	102.0, 118.0		104.0, 117.0		100.0, 110.0	
	Min, Max	90, 136		94, 133		91, 125	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60							
	n	71	71	41	41	38	38
	Mean (SD)	108.5 (10.82)	-1.46 (8.341)	109.4 (10.83)	-1.05 (10.290)	103.7 (8.36)	-0.46 (6.405)
	95% CI	105.9, 111.2	-3.44, 0.51	105.9, 112.8	-4.31, 2.20	100.9, 106.5	-2.57, 1.65
	Median	107.0	-2.56	111.0	-0.89	103.5	-2.01
	Q25, Q75	99.0, 118.0	-7.62, 3.88	102.0, 116.0	-10.24, 4.31	97.0, 108.0	-5.26, 3.19
	Min, Max	91, 132	-20.6, 26.3	92, 138	-20.3, 21.0	91, 127	-8.6, 20.0

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	70		41		37	
	Mean (SD)	110.2 (11.38)		111.0 (9.94)		104.7 (7.48)	
	95% CI	107.4, 112.9		107.8, 114.2		102.2, 107.3	
	Median	110.0		112.0		103.0	
	Q25, Q75	102.0, 118.0		104.0, 117.0		100.0, 110.0	
	Min, Max	90, 136		94, 133		93, 125	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Systolic blood Pressure (mmHg)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory							
	n	70	70	41	41	37	37
	Mean (SD)	104.2 (11.18)	-5.13 (7.825)	105.5 (13.01)	-4.71 (11.070)	102.2 (8.70)	-2.26 (7.059)
	95% CI	101.5, 106.9	-7.00, -3.26	101.3, 109.6	-8.21, -1.21	99.3, 105.2	-4.62, 0.10
	Median	104.0	-4.84	103.0	-6.73	100.0	-3.51
	Q25, Q75	95.0, 110.0	-10.66, -1.77	97.0, 115.0	-12.26, 0.84	95.0, 107.0	-6.45, 0.00
	Min, Max	85, 137	-20.6, 22.2	83, 142	-24.0, 35.0	87, 129	-11.4, 17.9

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****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	76		42		39	
	Mean (SD)	66.9 (8.93)		67.5 (7.08)		63.9 (5.85)	
	95% CI	64.8, 68.9		65.2, 69.7		62.0, 65.8	
	Median	67.0		66.5		63.0	
	Q25, Q75	59.0, 72.0		62.0, 73.0		60.0, 68.0	
	Min, Max	50, 88		56, 84		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****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1							
	n	76	76	42	42	39	39
	Mean (SD)	63.8 (7.36)	-3.91 (9.748)	64.8 (7.03)	-3.66 (7.647)	61.3 (6.40)	-3.81 (8.810)
	95% CI	62.0, 65.5	-6.14, -1.68	62.6, 67.1	-6.05, -1.27	59.2, 63.4	-6.67, -0.95
	Median	62.5	-4.64	64.0	-4.56	60.0	-4.92
	Q25, Q75	59.0, 69.0	-10.37, 2.88	60.0, 71.0	-8.82, 0.00	56.0, 65.0	-10.00, 0.00
	Min, Max	52, 83	-23.4, 20.0	52, 81	-18.2, 18.3	52, 80	-22.4, 23.6

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 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2							
	n	76	76	41	41	39	39
	Mean (SD)	63.0 (7.91)	-5.21 (9.136)	63.2 (8.13)	-6.22 (8.132)	59.7 (6.28)	-6.32 (9.024)
	95% CI	61.2, 64.9	-7.30, -3.11	60.6, 65.8	-8.79, -3.64	57.6, 61.8	-9.25, -3.39
	Median	62.0	-5.44	62.0	-6.78	59.0	-5.36
	Q25, Q75	56.5, 68.5	-10.29, 0.00	57.0, 67.0	-11.43, -1.52	55.0, 65.0	-11.67, 0.00
	Min, Max	50, 81	-29.2, 14.0	52, 83	-19.2, 24.6	45, 72	-26.2, 11.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 3							
	n	76	76	41	41	39	39
	Mean (SD)	65.2 (8.49)	-1.92 (10.512)	63.7 (8.80)	-5.43 (9.635)	59.8 (6.04)	-6.12 (8.527)
	95% CI	63.2, 67.2	-4.33, 0.48	60.9, 66.5	-8.48, -2.39	57.8, 61.8	-8.88, -3.35
	Median	64.0	-3.91	62.0	-4.62	60.0	-5.97
	Q25, Q75	59.0, 70.0	-8.26, 3.16	57.0, 66.0	-12.50, 1.25	55.0, 63.0	-12.70, 0.00
	Min, Max	51, 88	-25.0, 26.0	49, 89	-21.9, 17.1	51, 75	-22.9, 13.1

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

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**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4							
	n	76	76	41	41	39	39
	Mean (SD)	63.3 (7.54)	-4.55 (10.366)	64.8 (7.48)	-3.67 (9.107)	59.7 (5.89)	-6.15 (9.237)
	95% CI	61.6, 65.1	-6.92, -2.17	62.3, 67.2	-6.55, -0.79	57.8, 61.7	-9.15, -3.15
	Median	63.0	-5.59	63.0	-3.80	59.0	-5.97
	Q25, Q75	58.5, 66.5	-11.17, 0.77	59.0, 69.0	-7.46, 0.00	54.0, 64.0	-13.24, -1.43
	Min, Max	50, 90	-22.1, 30.6	54, 81	-21.4, 16.9	50, 71	-23.9, 12.7

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

Appendix: 15.3.6.7

Study ID:ZRHM-REXA-07-JP

Program: t1502042601-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5							
	n	76	76	41	41	39	39
	Mean (SD)	65.0 (7.61)	-2.11 (9.904)	64.6 (7.50)	-3.87 (10.291)	59.5 (6.50)	-6.31 (12.640)
	95% CI	63.2, 66.8	-4.38, 0.16	62.1, 67.0	-7.12, -0.61	57.3, 61.6	-10.41, -2.20
	Median	65.0	-2.21	65.0	-4.00	59.0	-8.20
	Q25, Q75	61.0, 70.0	-7.06, 3.36	59.0, 70.0	-10.71, 1.72	55.0, 62.0	-11.48, -1.69
	Min, Max	50, 83	-27.6, 34.0	50, 86	-27.6, 16.9	47, 84	-32.5, 42.4

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: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.7

Study ID:ZRHM-REXA-07-JP

Program: t1502042601-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge Confinement							
	n	76	76	42	42	39	39
	Mean (SD)	70.3 (7.59)	5.97 (10.591)	68.5 (7.32)	1.89 (9.062)	65.0 (5.56)	2.22 (9.110)
	95% CI	68.5, 72.1	3.55, 8.40	66.2, 70.9	-0.94, 4.72	63.2, 66.9	-0.73, 5.18
	Median	69.0	3.55	68.5	2.14	64.0	3.23
	Q25, Q75	64.0, 75.0	0.00, 12.00	65.0, 73.0	-4.00, 6.56	62.0, 68.0	-4.35, 9.09
	Min, Max	53, 88	-13.5, 35.1	51, 84	-17.1, 24.1	54, 80	-16.4, 19.6

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 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	74		41		39	
	Mean (SD)	66.9 (9.04)		67.5 (7.17)		63.9 (5.85)	
	95% CI	64.8, 69.0		65.2, 69.8		62.0, 65.8	
	Median	67.0		66.0		63.0	
	Q25, Q75	59.0, 72.0		62.0, 73.0		60.0, 68.0	
	Min, Max	50, 88		56, 84		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

Appendix: 15.3.6.7

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**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30							
	n	74	74	41	41	39	39
	Mean (SD)	65.3 (8.98)	-1.91 (10.199)	65.6 (7.80)	-2.63 (7.301)	61.3 (6.86)	-3.92 (7.958)
	95% CI	63.2, 67.4	-4.28, 0.46	63.1, 68.1	-4.94, -0.32	59.0, 63.6	-6.51, -1.34
	Median	64.5	-2.80	64.0	-2.86	61.0	-4.23
	Q25, Q75	58.0, 71.0	-8.00, 5.26	61.0, 70.0	-7.35, 2.99	56.0, 65.0	-10.45, 1.69
	Min, Max	48, 90	-28.8, 22.4	51, 88	-18.8, 14.5	51, 79	-17.9, 14.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.7

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**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	71		41		38	
	Mean (SD)	67.0 (8.95)		67.5 (7.17)		63.9 (5.92)	
	95% CI	64.9, 69.2		65.2, 69.8		62.0, 65.9	
	Median	67.0		66.0		63.0	
	Q25, Q75	59.0, 72.0		62.0, 73.0		60.0, 68.0	
	Min, Max	50, 88		56, 84		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

Appendix: 15.3.6.7

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**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60							
	n	71	71	41	41	38	38
	Mean (SD)	65.7 (8.60)	-1.47 (9.427)	66.7 (8.70)	-0.75 (10.520)	62.1 (6.37)	-2.43 (11.202)
	95% CI	63.7, 67.8	-3.71, 0.76	63.9, 69.5	-4.08, 2.57	59.9, 64.2	-6.12, 1.25
	Median	64.0	-3.33	64.0	0.00	61.5	-4.48
	Q25, Q75	59.0, 73.0	-7.81, 3.45	61.0, 72.0	-6.35, 5.71	58.0, 66.0	-9.84, 3.64
	Min, Max	52, 84	-21.3, 30.0	56, 95	-29.1, 22.6	49, 82	-26.9, 22.0

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.7

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**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	70		41		37	
	Mean (SD)	67.0 (9.20)		67.5 (7.17)		64.0 (6.00)	
	95% CI	64.8, 69.3		65.2, 69.8		62.0, 66.0	
	Median	67.0		66.0		63.0	
	Q25, Q75	59.0, 73.0		62.0, 73.0		60.0, 68.0	
	Min, Max	50, 88		56, 84		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****Parameter: Diastolic Blood Pressure (mmHg)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day							
91/Discharge							
Ambulatory							
	n	70	70	41	41	37	37
	Mean (SD)	62.8 (8.60)	-5.69 (10.231)	63.9 (9.05)	-5.03 (11.172)	62.7 (6.52)	-1.79 (8.153)
	95% CI	60.7, 64.9	-8.14, -3.25	61.0, 66.8	-8.56, -1.50	60.5, 64.9	-4.51, 0.94
	Median	62.0	-7.04	62.0	-7.02	63.0	-1.82
	Q25, Q75	56.0, 68.0	-11.63, 1.14	59.0, 68.0	-11.27, -1.33	58.0, 65.0	-7.14, 1.69
	Min, Max	48, 89	-27.5, 24.1	50, 91	-22.2, 32.3	54, 80	-16.4, 14.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Systolic blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	78		42		40	
	Mean (SD)	110.1 (11.12)		111.4 (10.05)		104.5 (7.55)	
	95% CI	107.6, 112.7		108.2, 114.5		102.0, 106.9	
	Median	110.0		112.0		103.0	
	Q25, Q75	102.0, 117.0		104.0, 118.0		100.0, 110.0	
	Min, Max	90, 136		94, 133		91, 125	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Systolic blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1							
	n	78	78	42	42	40	40
	Mean (SD)	106.5 (9.47)	-2.92 (7.606)	108.7 (11.91)	-2.21 (7.857)	102.2 (8.29)	-2.11 (5.692)
	95% CI	104.3, 108.6	-4.64, -1.21	105.0, 112.5	-4.66, 0.25	99.5, 104.9	-3.93, -0.28
	Median	106.0	-3.70	107.0	-1.78	101.0	-3.14
	Q25, Q75	100.0, 114.0	-7.69, 1.85	100.0, 116.0	-6.60, 2.78	95.5, 108.5	-5.41, 2.20
	Min, Max	87, 128	-21.4, 19.8	90, 135	-26.4, 13.3	90, 119	-15.2, 12.5

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Systolic blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2							
	n	77	77	41	41	40	40
	Mean (SD)	105.8 (10.31)	-3.72 (7.308)	107.6 (10.85)	-2.92 (7.482)	102.3 (8.54)	-1.97 (6.763)
	95% CI	103.4, 108.2	-5.39, -2.06	104.1, 111.1	-5.29, -0.56	99.5, 105.1	-4.13, 0.20
	Median	105.0	-4.08	105.0	-3.88	103.0	-2.89
	Q25, Q75	97.0, 112.0	-7.84, 1.57	99.0, 117.0	-7.63, 0.93	95.0, 108.5	-6.52, 2.11
	Min, Max	90, 140	-23.2, 14.4	90, 132	-14.4, 20.2	90, 121	-17.3, 16.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Systolic blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 3							
	n	77	77	41	41	40	40
	Mean (SD)	107.4 (10.44)	-2.33 (7.187)	109.1 (12.71)	-1.59 (8.827)	101.9 (7.44)	-2.27 (7.062)
	95% CI	105.0, 109.8	-3.96, -0.69	105.1, 113.2	-4.38, 1.21	99.4, 104.3	-4.53, -0.01
	Median	106.0	-3.03	107.0	-3.13	102.0	-2.88
	Q25, Q75	98.0, 115.0	-7.20, 2.86	100.0, 120.0	-6.84, 5.04	95.0, 106.0	-7.39, 2.84
	Min, Max	91, 130	-21.6, 16.8	88, 137	-18.4, 18.1	91, 121	-20.0, 12.7

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 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS****Parameter: Systolic blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4							
	n	77	77	41	41	39	39
	Mean (SD)	106.1 (10.43)	-3.37 (8.327)	108.9 (11.69)	-1.81 (6.961)	101.2 (7.40)	-2.83 (6.389)
	95% CI	103.7, 108.6	-5.26, -1.48	105.2, 112.7	-4.01, 0.39	98.8, 103.7	-4.90, -0.75
	Median	105.0	-4.00	107.0	-3.39	101.0	-3.23
	Q25, Q75	97.0, 112.0	-8.57, 1.98	101.0, 115.0	-7.55, 3.70	94.0, 107.0	-8.33, 1.10
	Min, Max	90, 131	-22.4, 20.0	91, 136	-14.2, 11.5	90, 116	-12.0, 10.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Systolic blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5							
	n	77	77	41	41	39	39
	Mean (SD)	108.8 (10.59)	-0.97 (7.811)	108.7 (11.46)	-1.90 (7.688)	103.1 (9.77)	-0.96 (9.782)
	95% CI	106.4, 111.3	-2.75, 0.81	105.1, 112.4	-4.34, 0.53	99.9, 106.3	-4.13, 2.22
	Median	108.0	-1.09	105.0	-2.02	101.0	-2.73
	Q25, Q75	101.0, 115.0	-5.98, 2.48	100.0, 116.0	-7.22, 4.20	95.0, 112.0	-9.09, 1.08
	Min, Max	91, 133	-16.4, 20.9	90, 136	-15.4, 12.8	90, 139	-14.0, 39.0

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Systolic blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day							
6/Discharge							
Confinement							
	n	78	78	42	42	40	40
	Mean (SD)	109.5 (10.05)	-0.10 (8.877)	109.1 (10.65)	-1.80 (8.075)	103.4 (7.28)	-0.83 (6.210)
	95% CI	107.2, 111.8	-2.11, 1.90	105.7, 112.4	-4.32, 0.72	101.0, 105.8	-2.83, 1.16
	Median	109.0	-1.76	108.5	-3.98	102.5	-1.86
	Q25, Q75	103.0, 115.0	-5.45, 4.26	104.0, 118.0	-6.19, 2.91	98.0, 107.5	-5.43, 4.11
	Min, Max	90, 136	-14.4, 26.0	90, 131	-17.6, 22.9	90, 118	-9.9, 17.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Systolic blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30							
	n	78	78	42	42	40	40
	Mean (SD)	108.7 (10.85)	-0.87 (9.165)	110.2 (11.78)	-0.90 (7.699)	104.4 (9.29)	0.09 (7.549)
	95% CI	106.2, 111.2	-2.95, 1.20	106.5, 113.9	-3.30, 1.51	101.4, 107.4	-2.33, 2.51
	Median	109.0	-2.76	109.0	-2.64	104.0	0.49
	Q25, Q75	100.0, 116.0	-7.02, 5.41	100.0, 120.0	-5.88, 4.76	95.5, 111.5	-5.72, 4.35
	Min, Max	90, 134	-26.0, 21.4	90, 134	-17.1, 19.4	90, 126	-14.0, 26.0

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Systolic blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60							
	n	78	78	42	42	40	40
	Mean (SD)	108.4 (10.58)	-1.16 (8.625)	109.6 (10.82)	-1.12 (10.174)	104.3 (8.49)	-0.06 (6.488)
	95% CI	106.0, 110.8	-3.11, 0.79	106.2, 113.0	-4.30, 2.05	101.5, 107.0	-2.14, 2.02
	Median	107.0	-2.75	111.0	-0.95	104.0	-1.97
	Q25, Q75	100.0, 118.0	-7.14, 3.88	102.0, 117.0	-10.24, 4.31	97.0, 109.5	-5.22, 4.15
	Min, Max	91, 132	-20.6, 26.3	92, 138	-20.3, 21.0	91, 127	-8.6, 20.0

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Systolic blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory	n	78	78	42	42	40	40
	Mean (SD)	104.6 (10.87)	-4.72 (8.177)	105.8 (13.04)	-4.69 (10.934)	102.6 (8.96)	-1.68 (7.137)
	95% CI	102.1, 107.1	-6.57, -2.87	101.7, 109.9	-8.10, -1.28	99.7, 105.5	-3.97, 0.60
	Median	104.0	-4.59	103.5	-6.31	100.5	-3.13
	Q25, Q75	97.0, 110.0	-10.09, -1.09	97.0, 115.0	-12.26, 0.84	95.0, 109.5	-6.41, 1.03
	Min, Max	85, 137	-20.6, 22.2	83, 142	-24.0, 35.0	87, 129	-11.4, 17.9

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 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS****Parameter: Diastolic Blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	78		42		40	
	Mean (SD)	66.6 (8.94)		67.5 (7.08)		63.9 (5.79)	
	95% CI	64.6, 68.7		65.2, 69.7		62.0, 65.7	
	Median	66.5		66.5		62.5	
	Q25, Q75	59.0, 72.0		62.0, 73.0		60.5, 68.0	
	Min, Max	50, 88		56, 84		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 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS****Parameter: Diastolic Blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1							
	n	78	78	42	42	40	40
	Mean (SD)	63.7 (7.29)	-3.64 (9.941)	64.8 (7.03)	-3.66 (7.647)	61.3 (6.32)	-3.80 (8.697)
	95% CI	62.0, 65.4	-5.89, -1.39	62.6, 67.1	-6.05, -1.27	59.2, 63.3	-6.58, -1.01
	Median	62.5	-4.60	64.0	-4.56	60.0	-4.28
	Q25, Q75	59.0, 69.0	-10.29, 2.99	60.0, 71.0	-8.82, 0.00	56.0, 64.5	-9.92, 0.00
	Min, Max	52, 83	-23.4, 20.0	52, 81	-18.2, 18.3	52, 80	-22.4, 23.6

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 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS****Parameter: Diastolic Blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2							
	n	77	77	41	41	40	40
	Mean (SD)	63.0 (7.87)	-5.16 (9.085)	63.2 (8.13)	-6.22 (8.132)	59.5 (6.29)	-6.52 (9.002)
	95% CI	61.1, 64.8	-7.23, -3.09	60.6, 65.8	-8.79, -3.64	57.4, 61.6	-9.41, -3.64
	Median	62.0	-5.08	62.0	-6.78	58.5	-5.54
	Q25, Q75	57.0, 68.0	-10.00, 0.00	57.0, 67.0	-11.43, -1.52	54.5, 64.5	-11.80, 0.00
	Min, Max	50, 81	-29.2, 14.0	52, 83	-19.2, 24.6	45, 72	-26.2, 11.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Diastolic Blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 3							
	n	77	77	41	41	40	40
	Mean (SD)	65.1 (8.44)	-1.90 (10.445)	63.7 (8.80)	-5.43 (9.635)	59.8 (5.96)	-6.08 (8.419)
	95% CI	63.2, 67.1	-4.27, 0.48	60.9, 66.5	-8.48, -2.39	57.8, 61.7	-8.78, -3.39
	Median	64.0	-3.70	62.0	-4.62	59.5	-5.71
	Q25, Q75	59.0, 70.0	-8.06, 2.99	57.0, 66.0	-12.50, 1.25	55.0, 62.5	-12.69, 0.00
	Min, Max	51, 88	-25.0, 26.0	49, 89	-21.9, 17.1	51, 75	-22.9, 13.1

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 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS****Parameter: Diastolic Blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4							
	n	77	77	41	41	39	39
	Mean (SD)	63.2 (7.54)	-4.59 (10.306)	64.8 (7.48)	-3.67 (9.107)	59.7 (5.89)	-6.15 (9.237)
	95% CI	61.5, 65.0	-6.94, -2.25	62.3, 67.2	-6.55, -0.79	57.8, 61.7	-9.15, -3.15
	Median	63.0	-5.63	63.0	-3.80	59.0	-5.97
	Q25, Q75	58.0, 66.0	-10.98, 0.00	59.0, 69.0	-7.46, 0.00	54.0, 64.0	-13.24, -1.43
	Min, Max	50, 90	-22.1, 30.6	54, 81	-21.4, 16.9	50, 71	-23.9, 12.7

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 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS****Parameter: Diastolic Blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5							
	n	77	77	41	41	39	39
	Mean (SD)	65.0 (7.57)	-2.06 (9.848)	64.6 (7.50)	-3.87 (10.291)	59.5 (6.50)	-6.31 (12.640)
	95% CI	63.2, 66.7	-4.30, 0.18	62.1, 67.0	-7.12, -0.61	57.3, 61.6	-10.41, -2.20
	Median	65.0	-1.75	65.0	-4.00	59.0	-8.20
	Q25, Q75	61.0, 70.0	-6.90, 3.33	59.0, 70.0	-10.71, 1.72	55.0, 62.0	-11.48, -1.69
	Min, Max	50, 83	-27.6, 34.0	50, 86	-27.6, 16.9	47, 84	-32.5, 42.4

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: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Diastolic Blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day							
6/Discharge							
Confinement							
	n	78	78	42	42	40	40
	Mean (SD)	70.4 (7.54)	6.50 (11.166)	68.5 (7.32)	1.89 (9.062)	64.9 (5.57)	2.05 (9.061)
	95% CI	68.6, 72.1	3.98, 9.02	66.2, 70.9	-0.94, 4.72	63.0, 66.7	-0.86, 4.95
	Median	69.0	4.37	68.5	2.14	64.0	3.11
	Q25, Q75	64.0, 75.0	0.00, 12.07	65.0, 73.0	-4.00, 6.56	61.5, 67.5	-4.55, 8.58
	Min, Max	53, 88	-13.5, 40.0	51, 84	-17.1, 24.1	54, 80	-16.4, 19.6

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 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS****Parameter: Diastolic Blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30							
	n	78	78	42	42	40	40
	Mean (SD)	65.3 (8.87)	-1.33 (11.063)	65.7 (7.75)	-2.47 (7.293)	61.3 (6.78)	-3.94 (7.857)
	95% CI	63.3, 67.4	-3.83, 1.17	63.3, 68.2	-4.74, -0.19	59.0, 63.5	-6.46, -1.43
	Median	64.5	-2.23	64.5	-2.26	60.5	-4.53
	Q25, Q75	58.0, 71.0	-7.58, 5.77	61.0, 70.0	-7.35, 3.23	56.0, 64.5	-10.37, 1.64
	Min, Max	48, 90	-28.8, 40.0	51, 88	-18.8, 14.5	51, 79	-17.9, 14.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Diastolic Blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60							
	n	78	78	42	42	40	40
	Mean (SD)	65.7 (8.56)	-0.92 (10.326)	66.8 (8.62)	-0.63 (10.421)	62.1 (6.28)	-2.23 (11.044)
	95% CI	63.7, 67.6	-3.26, 1.41	64.1, 69.6	-3.88, 2.62	60.0, 64.2	-5.77, 1.31
	Median	64.0	-3.05	64.5	0.00	61.5	-4.48
	Q25, Q75	59.0, 72.0	-7.35, 3.45	61.0, 72.0	-6.35, 5.71	58.5, 66.0	-9.08, 3.96
	Min, Max	52, 84	-21.3, 40.0	56, 95	-29.1, 22.6	49, 82	-26.9, 22.0

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Diastolic Blood Pressure (mmHg)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day							
91/Discharge							
Ambulatory							
	n	78	78	42	42	40	40
	Mean (SD)	63.1 (8.64)	-4.68 (11.244)	64.1 (9.00)	-4.80 (11.130)	62.5 (6.56)	-1.98 (8.326)
	95% CI	61.1, 65.1	-7.22, -2.14	61.2, 66.9	-8.28, -1.33	60.3, 64.6	-4.64, 0.69
	Median	62.0	-6.90	62.0	-6.63	63.0	-1.82
	Q25, Q75	58.0, 68.0	-10.45, 1.47	59.0, 70.0	-11.27, 0.00	57.5, 65.5	-7.74, 2.49
	Min, Max	48, 89	-27.5, 40.0	50, 91	-22.2, 32.3	52, 80	-16.4, 14.3

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: Glucose (mg/dL)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	84.6 (9.20)		85.4 (6.91)		84.9 (8.49)	
	95% CI of Geometric Mean	82.8, 86.4		83.5, 87.3		82.6, 87.3	
	Median	85.0		85.0		85.0	
	Q25, Q75	79.0, 89.0		81.0, 90.0		79.0, 90.0	
	Min, Max	70, 110		72, 101		74, 101	
	Mean (SD)	84.9 (7.88)		85.6 (5.87)		85.2 (7.37)	
	95% CI	83.1, 86.8		83.7, 87.5		82.8, 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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: Glucose (mg/dL)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		65	65	37	37	34	34
Confinement							
	Geometric Mean	83.3 (9.43)		84.9 (6.49)		82.1 (6.48)	
	(CV%)						
	95% CI of	81.3, 85.3		83.1, 86.8		80.2, 84.1	
	Geometric Mean						
	Median	85.0	-2.47	86.0	0.00	83.0	-0.58
	Q25, Q75	79.0, 88.0	-7.06, 2.60	83.0, 88.0	-4.26, 2.47	79.0, 86.0	-5.81, 2.53
	Min, Max	67, 103	-16.8, 21.1	67, 92	-23.9, 15.8	68, 90	-22.2, 14.3
	Mean (SD)	83.6 (7.84)	-1.36 (7.474)	85.1 (5.25)	0.23 (8.190)	82.3 (5.22)	-2.27 (7.991)
	95% CI	81.6, 85.6	-3.22, 0.50	83.3, 86.9	-2.51, 2.96	80.4, 84.2	-5.06, 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 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), and TC (mg/dL) - PP Set****Parameter: Glucose (mg/dL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	84.8 (9.20)		85.4 (6.99)		84.9 (8.49)	
	95% CI of Geometric Mean	83.0, 86.7		83.5, 87.3		82.6, 87.3	
	Median	85.0		85.0		85.0	
	Q25, Q75	79.0, 90.0		81.0, 90.0		79.0, 90.0	
	Min, Max	70, 110		72, 101		74, 101	
	Mean (SD)	85.1 (7.89)		85.6 (5.95)		85.2 (7.37)	
	95% CI	83.3, 87.0		83.7, 87.5		82.8, 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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: Glucose (mg/dL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	89.9 (7.69)		91.9 (8.37)		91.3 (10.32)	
	95% CI of Geometric Mean	88.3, 91.6		89.4, 94.4		88.3, 94.5	
	Median	90.0	5.95	92.0	6.17	88.0	7.59
	Q25, Q75	86.0, 92.0	1.18, 10.00	88.0, 95.0	3.53, 10.47	85.0, 99.0	2.41, 13.16
	Min, Max	77, 113	-7.4, 21.6	74, 126	-5.7, 48.2	77, 117	-16.0, 34.2
	Mean (SD)	90.2 (7.12)	6.28 (6.582)	92.2 (8.10)	7.88 (8.392)	91.8 (9.80)	7.95 (9.508)
	95% CI	88.5, 91.9	4.75, 7.81	89.6, 94.8	5.23, 10.54	88.6, 95.0	4.86, 11.04

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 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), and TC (mg/dL) - PP Set****Parameter: Glucose (mg/dL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	85.0 (9.06)		85.4 (6.99)		85.2 (8.40)	
	95% CI of Geometric Mean	83.1, 86.8		83.5, 87.3		82.8, 87.6	
	Median	85.0		85.0		85.0	
	Q25, Q75	79.0, 90.0		81.0, 90.0		79.0, 90.0	
	Min, Max	70, 110		72, 101		74, 101	
	Mean (SD)	85.3 (7.78)		85.6 (5.95)		85.5 (7.31)	
	95% CI	83.4, 87.2		83.7, 87.5		83.0, 87.9	

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set

Parameter: Glucose (mg/dL)

Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	89.8 (8.40)		92.4 (6.31)		88.2 (7.16)	
	95% CI of Geometric Mean	88.0, 91.6		90.6, 94.3		86.1, 90.3	
	Median	90.0	4.94	92.0	7.79	89.0	2.87
	Q25, Q75	85.0, 94.0	0.00, 10.59	88.0, 95.0	4.44, 10.84	83.0, 92.0	-2.17, 8.64
	Min, Max	70, 117	-10.5, 33.0	83, 108	0.0, 28.4	77, 108	-11.1, 27.1
	Mean (SD)	90.1 (7.69)	5.96 (7.473)	92.6 (5.90)	8.44 (6.546)	88.4 (6.42)	3.88 (8.487)
	95% CI	88.2, 92.0	4.18, 7.73	90.7, 94.5	6.37, 10.51	86.3, 90.6	1.08, 6.67

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 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), and TC (mg/dL) - PP Set****Parameter: Glucose (mg/dL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	84.9 (9.41)		85.4 (6.99)		85.3 (8.48)	
	95% CI of Geometric Mean	83.0, 86.9		83.5, 87.3		82.9, 87.8	
	Median	85.0		85.0		85.0	
	Q25, Q75	79.0, 92.0		81.0, 90.0		79.0, 90.0	
	Min, Max	70, 110		72, 101		74, 101	
	Mean (SD)	85.3 (8.06)		85.6 (5.95)		85.6 (7.37)	
	95% CI	83.3, 87.3		83.7, 87.5		83.1, 88.1	

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: Glucose (mg/dL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		70	70	41	41	37	37
	Geometric Mean (CV%)	89.8 (9.33)		91.1 (6.69)		87.6 (8.45)	
	95% CI of Geometric Mean	87.7, 91.8		89.1, 93.1		85.1, 90.1	
	Median	88.0	5.66	90.0	6.76	88.0	2.11
	Q25, Q75	85.0, 95.0	0.00, 10.59	88.0, 94.0	2.27, 12.22	85.0, 92.0	-1.30, 7.78
	Min, Max	76, 119	-9.5, 28.6	79, 106	-8.5, 24.7	72, 104	-13.3, 22.4
	Mean (SD)	90.2 (8.66)	6.03 (8.446)	91.3 (6.14)	6.89 (7.124)	87.9 (7.38)	2.99 (8.054)
	95% CI	88.0, 92.3	4.02, 8.05	89.3, 93.3	4.64, 9.14	85.4, 90.4	0.30, 5.68

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 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), and TC (mg/dL) - PP Set****Parameter: Triglycerides (mg/dL)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean	128.5 (47.07)		121.2 (40.93)		104.3 (37.45)	
	(CV%)						
	95% CI of	116.0, 142.4		107.1, 137.0		92.7, 117.3	
	Geometric Mean						
	Median	124.0		114.5		102.0	
	Q25, Q75	89.5, 169.5		96.0, 176.0		75.0, 128.0	
	Min, Max	54, 421		53, 236		54, 226	
	Mean (SD)	142.8 (73.67)		130.5 (50.88)		111.3 (41.79)	
	95% CI	125.9, 159.7		114.6, 146.4		97.7, 124.9	

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: Triglycerides (mg/dL)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		65	65	37	37	34	34
Confinement							
	Geometric Mean	124.4 (45.10)		125.5 (47.03)		102.0 (40.21)	
	(CV%)						
	95% CI of	111.8, 138.5		108.1, 145.8		89.0, 116.8	
	Geometric Mean						
	Median	124.0	-5.36	110.0	-1.73	101.0	-4.62
	Q25, Q75	91.0, 160.0	-18.60, 10.23	97.0, 191.0	-13.39, 27.49	79.0, 140.0	-16.83, 19.40
	Min, Max	56, 380	-41.3, 76.1	50, 254	-32.1, 58.3	53, 203	-56.6, 72.5
	Mean (SD)	137.0 (66.87)	-1.90 (23.534)	137.9 (59.75)	6.39 (25.839)	109.6 (42.41)	4.63 (33.089)
	95% CI	120.4, 153.6	-7.73, 3.94	117.9, 157.9	-2.23, 15.01	94.8, 124.5	-6.92, 16.18

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set**

Parameter: Triglycerides (mg/dL)
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	128.5 (47.76)		122.0 (41.19)		104.3 (37.45)	
	95% CI of Geometric Mean	115.6, 142.7		107.6, 138.3		92.7, 117.3	
	Median	124.0		117.0		102.0	
	Q25, Q75	88.0, 172.0		100.0, 176.0		75.0, 128.0	
	Min, Max	54, 421		53, 236		54, 226	
	Mean (SD)	143.1 (74.63)		131.5 (51.12)		111.3 (41.79)	
	95% CI	125.8, 160.5		115.3, 147.7		97.7, 124.9	

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set**

Parameter: Triglycerides (mg/dL)
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	134.9 (49.59)		130.8 (36.99)		117.1 (47.12)	
	95% CI of Geometric Mean	121.0, 150.5		116.8, 146.5		101.2, 135.4	
	Median	125.5	6.05	138.0	7.45	115.0	9.09
	Q25, Q75	94.0, 199.0	-14.29, 28.00	103.0, 172.0	-3.50, 24.62	87.0, 151.0	-11.88, 37.61
	Min, Max	50, 421	-46.5, 140.3	61, 229	-40.5, 80.5	44, 314	-42.4, 161.7
	Mean (SD)	151.0 (76.84)	9.11 (31.167)	138.9 (47.64)	9.49 (22.966)	129.3 (61.10)	18.35 (41.984)
	95% CI	133.1, 168.8	1.88, 16.33	123.8, 154.0	2.24, 16.75	109.4, 149.1	4.73, 31.96

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set**

Parameter: Triglycerides (mg/dL)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	129.1 (46.91)		122.0 (41.19)		104.2 (37.98)	
	95% CI of Geometric Mean	116.1, 143.6		107.6, 138.3		92.3, 117.6	
	Median	124.0		117.0		101.5	
	Q25, Q75	91.0, 167.0		100.0, 176.0		75.0, 128.0	
	Min, Max	54, 421		53, 236		54, 226	
	Mean (SD)	143.5 (74.59)		131.5 (51.12)		111.3 (42.35)	
	95% CI	125.8, 161.2		115.3, 147.7		97.3, 125.3	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set**

Parameter: Triglycerides (mg/dL)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	132.9 (41.31)		138.0 (43.68)		115.7 (43.25)	
	95% CI of Geometric Mean	120.9, 146.0		120.9, 157.6		101.0, 132.7	
	Median	126.0	1.96	141.0	13.51	121.5	8.68
	Q25, Q75	99.0, 178.0	-10.92, 23.70	98.0, 180.0	-7.69, 26.27	82.0, 158.0	-6.72, 40.83
	Min, Max	67, 368	-60.1, 81.0	52, 359	-53.0, 235.5	52, 267	-34.9, 128.2
	Mean (SD)	144.5 (66.11)	6.11 (26.029)	150.5 (66.22)	20.54 (49.395)	125.6 (51.63)	15.68 (34.485)
	95% CI	128.8, 160.2	-0.05, 12.28	129.5, 171.4	4.94, 36.13	108.6, 142.6	4.34, 27.02

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set**

Parameter: Triglycerides (mg/dL)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean	126.4 (45.87)		122.0 (41.19)		105.9 (36.88)	
	(CV%)						
	95% CI of	113.8, 140.3		107.6, 138.3		94.0, 119.4	
	Geometric Mean						
	Median	123.5		117.0		102.0	
	Q25, Q75	88.0, 167.0		100.0, 176.0		84.0, 128.0	
	Min, Max	54, 421		53, 236		54, 226	
	Mean (SD)	139.5 (68.77)		131.5 (51.12)		112.8 (41.90)	
	95% CI	123.1, 156.0		115.3, 147.7		98.8, 126.8	

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set**

Parameter: Triglycerides (mg/dL)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		70	70	41	41	37	37
	Geometric Mean (CV%)	122.6 (51.24)		129.6 (36.12)		118.5 (51.31)	
	95% CI of Geometric Mean	109.2, 137.6		116.0, 144.8		100.9, 139.3	
	Median	117.5	0.83	132.0	3.41	108.0	3.70
	Q25, Q75	87.0, 183.0	-20.00, 16.15	103.0, 177.0	-8.33, 26.89	75.0, 175.0	-4.11, 35.23
	Min, Max	49, 421	-50.8, 74.6	57, 236	-39.1, 93.9	53, 353	-26.3, 104.3
	Mean (SD)	138.5 (75.84)	0.57 (27.124)	137.2 (45.17)	9.88 (29.653)	133.1 (67.68)	15.67 (31.683)
	95% CI	120.4, 156.7	-5.90, 7.04	122.9, 151.5	0.52, 19.25	110.5, 155.7	5.10, 26.24

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: Cholesterol (mg/dL)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	194.6 (17.57)		196.1 (20.19)		181.7 (15.52)	
	95% CI of Geometric Mean	186.9, 202.5		184.2, 208.8		172.8, 191.1	
	Median	195.5		193.5		183.0	
	Q25, Q75	172.5, 214.0		173.0, 218.0		162.0, 208.0	
	Min, Max	131, 290		131, 343		131, 245	
	Mean (SD)	197.5 (34.90)		200.1 (42.06)		183.8 (28.24)	
	95% CI	189.5, 205.6		186.9, 213.2		174.6, 193.0	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: Cholesterol (mg/dL)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		65	65	37	37	34	34
Confinement							
	Geometric Mean	195.5 (17.39)		195.3 (17.78)		172.9 (16.89)	
	(CV%)						
	95% CI of	187.2, 204.1		184.1, 207.2		163.0, 183.3	
	Geometric Mean						
	Median	198.0	-0.59	204.0	1.03	177.0	-1.66
	Q25, Q75	177.0, 214.0	-5.82, 6.86	179.0, 217.0	-7.55, 4.98	162.0, 192.0	-10.20, 3.33
	Min, Max	130, 293	-21.0, 23.8	131, 276	-19.5, 31.5	125, 255	-23.2, 21.7
	Mean (SD)	198.3 (34.24)	0.21 (9.994)	198.2 (34.10)	0.20 (10.316)	175.2 (28.95)	-2.43 (11.295)
	95% CI	189.8, 206.9	-2.27, 2.69	186.8, 209.6	-3.24, 3.64	165.1, 185.4	-6.38, 1.51

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: Cholesterol (mg/dL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	194.3 (17.79)		197.6 (19.85)		181.7 (15.52)	
	95% CI of Geometric Mean	186.5, 202.5		185.6, 210.2		172.8, 191.1	
	Median	192.5		194.0		183.0	
	Q25, Q75	171.0, 214.0		173.0, 218.0		162.0, 208.0	
	Min, Max	131, 290		131, 343		131, 245	
	Mean (SD)	197.4 (35.35)		201.4 (41.66)		183.8 (28.24)	
	95% CI	189.1, 205.6		188.2, 214.6		174.6, 193.0	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: Cholesterol (mg/dL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	191.8 (17.06)		191.1 (17.13)		186.0 (17.84)	
	95% CI of Geometric Mean	184.4, 199.5		181.1, 201.7		175.6, 197.0	
	Median	190.0	-0.57	193.0	-5.00	183.0	4.67
	Q25, Q75	171.0, 214.0	-7.25, 4.60	175.0, 216.0	-10.06, 2.79	167.0, 214.0	-6.35, 9.74
	Min, Max	133, 291	-16.2, 19.1	121, 254	-27.4, 41.8	125, 256	-21.4, 20.7
	Mean (SD)	194.6 (33.62)	-0.95 (8.335)	193.8 (31.99)	-2.61 (11.818)	188.8 (33.57)	2.94 (10.815)
	95% CI	186.7, 202.4	-2.88, 0.99	183.6, 203.9	-6.34, 1.13	177.9, 199.8	-0.57, 6.46

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 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), and TC (mg/dL) - PP Set****Parameter: Cholesterol (mg/dL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	196.5 (17.10)		197.6 (19.85)		182.4 (15.55)	
	95% CI of Geometric Mean	188.7, 204.6		185.6, 210.2		173.3, 191.9	
	Median	198.0		194.0		183.5	
	Q25, Q75	175.0, 216.0		173.0, 218.0		162.0, 208.0	
	Min, Max	137, 290		131, 343		131, 245	
	Mean (SD)	199.4 (34.48)		201.4 (41.66)		184.5 (28.30)	
	95% CI	191.1, 207.6		188.2, 214.6		175.1, 193.8	

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: Cholesterol (mg/dL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	192.3 (18.89)		192.2 (17.62)		189.2 (17.34)	
	95% CI of Geometric Mean	183.9, 201.1		181.8, 203.2		178.7, 200.2	
	Median	191.0	-2.11	190.0	-0.88	190.5	2.56
	Q25, Q75	171.0, 212.0	-10.34, 6.91	171.0, 221.0	-7.78, 2.65	169.0, 212.0	-3.89, 11.31
	Min, Max	132, 311	-22.1, 28.2	130, 261	-30.0, 28.2	131, 263	-17.8, 38.5
	Mean (SD)	195.7 (37.85)	-1.55 (10.950)	195.1 (33.83)	-2.05 (11.489)	191.9 (32.62)	4.32 (11.344)
	95% CI	186.7, 204.7	-4.15, 1.05	184.3, 205.8	-5.68, 1.58	181.1, 202.7	0.59, 8.06

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 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), and TC (mg/dL) - PP Set****Parameter: Cholesterol (mg/dL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	194.4 (18.14)		197.6 (19.85)		182.2 (15.76)	
	95% CI of Geometric Mean	186.1, 202.9		185.6, 210.2		172.9, 192.0	
	Median	192.5		194.0		183.0	
	Q25, Q75	171.0, 216.0		173.0, 218.0		162.0, 208.0	
	Min, Max	131, 290		131, 343		131, 245	
	Mean (SD)	197.5 (36.06)		201.4 (41.66)		184.4 (28.68)	
	95% CI	188.9, 206.1		188.2, 214.6		174.8, 194.0	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: Cholesterol (mg/dL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		70	70	41	41	37	37
	Geometric Mean (CV%)	187.4 (19.84)		189.4 (16.87)		188.0 (14.88)	
	95% CI of Geometric Mean	178.8, 196.5		179.6, 199.7		178.9, 197.5	
	Median	189.5	-3.50	184.0	-5.56	193.0	0.89
	Q25, Q75	159.0, 214.0	-12.15, 4.71	169.0, 212.0	-9.57, 1.78	172.0, 207.0	-2.82, 9.27
	Min, Max	133, 311	-37.6, 32.8	125, 274	-34.7, 51.5	132, 252	-15.9, 27.5
	Mean (SD)	191.1 (38.45)	-2.85 (11.969)	192.0 (32.64)	-3.27 (13.789)	189.9 (27.24)	3.67 (10.649)
	95% CI	181.8, 200.3	-5.71, 0.01	181.6, 202.3	-7.63, 1.09	180.8, 199.1	0.12, 7.23

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 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), and TC (mg/dL) - PP Set****Parameter: C Reactive Protein (mg/L)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	0.203 (119.84)		0.174 (105.93)		0.222 (207.44)	
	95% CI of Geometric Mean	0.163, 0.253		0.132, 0.229		0.145, 0.338	
	Median	0.100		0.100		0.100	
	Q25, Q75	0.100, 0.420		0.100, 0.260		0.100, 0.500	
	Min, Max	0.10, 2.27		0.10, 1.54		0.10, 14.40	
	Mean (SD)	0.345 (0.4470)		0.280 (0.3560)		0.871 (2.5930)	
	95% CI	0.241, 0.449		0.167, 0.393		0.030, 1.711	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: C Reactive Protein (mg/L)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	0.226 (127.94)		0.208 (174.33)		0.228 (183.16)	
	95% CI of Geometric Mean	0.180, 0.285		0.142, 0.302		0.153, 0.338	
	Median	0.150	0.00	0.100	0.00	0.100	0.00
	Q25, Q75	0.100, 0.460	0.00, 23.33	0.100, 0.370	0.00, 46.38	0.100, 0.360	0.00, 100.00
	Min, Max	0.10, 11.00	-94.8, 10900.0	0.10, 21.40	-90.4, 4995.2	0.10, 9.40	-99.3, 1300.0
	Mean (SD)	0.472 (1.2910)	212.51 (1285.421)	0.874 (3.3810)	164.74 (782.179)	0.686 (1.7070)	87.96 (270.436)
	95% CI	0.173, 0.771	-85.30, 510.33	-0.193, 1.942	-82.15, 411.63	0.132, 1.240	0.29, 175.63

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: C Reactive Protein (mg/L)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	0.195 (112.40)		0.174 (105.93)		0.214 (206.69)	
	95% CI of Geometric Mean	0.157, 0.242		0.132, 0.229		0.140, 0.328	
	Median	0.100		0.100		0.100	
	Q25, Q75	0.100, 0.410		0.100, 0.260		0.100, 0.450	
	Min, Max	0.10, 2.27		0.10, 1.54		0.10, 14.40	
	Mean (SD)	0.319 (0.4090)		0.280 (0.3560)		0.871 (2.6280)	
	95% CI	0.222, 0.416		0.167, 0.393		0.007, 1.735	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: C Reactive Protein (mg/L)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	0.209 (170.38)		0.205 (140.02)		0.244 (119.39)	
	95% CI of Geometric Mean	0.158, 0.276		0.147, 0.286		0.179, 0.333	
	Median	0.100	0.00	0.100	0.00	0.220	0.00
	Q25, Q75	0.100, 0.350	-5.41, 0.00	0.100, 0.330	0.00, 110.00	0.100, 0.590	0.00, 120.00
	Min, Max	0.10, 42.10	-91.5, 5229.1	0.10, 3.93	-90.4, 1100.0	0.10, 1.31	-99.3, 950.0
	Mean (SD)	1.037 (5.1380)	168.68 (770.719)	0.432 (0.7910)	85.88 (225.552)	0.381 (0.3730)	100.00 (236.739)
	95% CI	-0.180, 2.253	-13.75, 351.11	0.182, 0.682	14.68, 157.08	0.257, 0.504	22.18, 177.82

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 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), and TC (mg/dL) - PP Set

Parameter: C Reactive Protein (mg/L)

Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	0.196 (116.34)		0.174 (105.93)		0.219 (210.49)	
	95% CI of Geometric Mean	0.157, 0.245		0.132, 0.229		0.141, 0.338	
	Median	0.100		0.100		0.100	
	Q25, Q75	0.100, 0.410		0.100, 0.260		0.100, 0.450	
	Min, Max	0.10, 2.27		0.10, 1.54		0.10, 14.40	
	Mean (SD)	0.329 (0.4280)		0.280 (0.3560)		0.892 (2.6610)	
	95% CI	0.226, 0.431		0.167, 0.393		0.004, 1.779	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: C Reactive Protein (mg/L)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	70	70	41	41	37	37
	Geometric Mean (CV%)	0.244 (153.18)		0.246 (192.43)		0.228 (142.45)	
	95% CI of Geometric Mean	0.187, 0.317		0.166, 0.365		0.160, 0.324	
	Median	0.100	0.00	0.100	0.00	0.100	0.00
	Q25, Q75	0.100, 0.500	0.00, 27.03	0.100, 0.480	-7.69, 130.00	0.100, 0.490	0.00, 85.00
	Min, Max	0.10, 8.49	-88.0, 8390.0	0.10, 9.25	-90.4, 9060.0	0.10, 4.62	-99.3, 1380.0
	Mean (SD)	0.583 (1.4080)	331.94 (1417.253)	0.788 (1.9980)	392.41 (1478.537)	0.452 (0.7920)	72.20 (241.913)
	95% CI	0.247, 0.919	-5.99, 669.88	0.157, 1.419	-74.28, 859.10	0.187, 0.716	-8.46, 152.86

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: HDL Cholesterol (mg/dL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	54.9 (25.08)		58.1 (25.95)		57.9 (24.30)	
	95% CI of Geometric Mean	51.8, 58.2		53.6, 63.1		53.5, 62.6	
	Median	56.5		56.0		58.0	
	Q25, Q75	44.0, 66.0		49.0, 73.0		49.0, 66.0	
	Min, Max	24, 88		36, 107		35, 97	
	Mean (SD)	56.5 (13.26)		60.0 (15.86)		59.5 (14.58)	
	95% CI	53.4, 59.6		55.0, 65.1		54.7, 64.3	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: HDL Cholesterol (mg/dL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	56.6 (25.98)		57.0 (21.64)		60.5 (23.25)	
	95% CI of Geometric Mean	53.3, 60.1		53.2, 61.1		56.1, 65.2	
	Median	57.0	3.50	55.0	-2.33	63.0	3.45
	Q25, Q75	46.0, 69.0	-2.70, 11.76	49.0, 67.0	-7.48, 3.57	51.0, 69.0	-3.77, 12.50
	Min, Max	32, 92	-25.4, 39.4	39, 99	-30.4, 36.4	35, 108	-23.9, 54.7
	Mean (SD)	58.4 (14.84)	3.84 (12.277)	58.3 (13.04)	-1.29 (11.483)	62.0 (14.35)	5.78 (17.247)
	95% CI	54.9, 61.9	0.99, 6.69	54.2, 62.5	-4.92, 2.33	57.3, 66.7	0.19, 11.38

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: HDL Cholesterol (mg/dL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	54.7 (25.04)		58.1 (25.95)		57.7 (24.59)	
	95% CI of Geometric Mean	51.6, 58.1		53.6, 63.1		53.3, 62.6	
	Median	56.0		56.0		58.0	
	Q25, Q75	44.0, 65.0		49.0, 73.0		49.0, 66.0	
	Min, Max	24, 88		36, 107		35, 97	
	Mean (SD)	56.3 (13.24)		60.0 (15.86)		59.4 (14.76)	
	95% CI	53.2, 59.5		55.0, 65.1		54.5, 64.3	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: HDL Cholesterol (mg/dL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	57.4 (26.60)		56.7 (24.50)		61.8 (25.71)	
	95% CI of Geometric Mean	53.9, 61.2		52.5, 61.2		56.8, 67.2	
	Median	57.0	6.35	57.0	-3.33	62.0	7.60
	Q25, Q75	46.0, 68.0	-4.88, 15.94	48.0, 66.0	-10.53, 5.63	53.0, 70.0	-1.49, 16.67
	Min, Max	31, 106	-32.3, 46.7	34, 104	-21.4, 31.8	38, 116	-22.7, 52.8
	Mean (SD)	59.4 (15.68)	6.09 (15.728)	58.3 (14.38)	-1.78 (12.491)	63.8 (16.71)	7.89 (14.142)
	95% CI	55.6, 63.2	2.36, 9.81	53.7, 62.9	-5.72, 2.17	58.2, 69.3	3.24, 12.55

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 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), and TC (mg/dL) - PP Set****Parameter: HDL Cholesterol (mg/dL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	55.4 (23.11)		58.1 (25.95)		56.9 (23.25)	
	95% CI of Geometric Mean	52.5, 58.6		53.6, 63.1		52.7, 61.5	
	Median	56.5		56.0		58.0	
	Q25, Q75	45.0, 65.0		49.0, 73.0		49.0, 65.0	
	Min, Max	34, 88		36, 107		35, 93	
	Mean (SD)	56.9 (12.79)		60.0 (15.86)		58.4 (13.55)	
	95% CI	53.8, 60.0		55.0, 65.1		53.8, 63.0	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: HDL Cholesterol (mg/dL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	70	70	41	41	37	37
	Geometric Mean (CV%)	58.3 (26.67)		56.7 (25.57)		61.8 (23.80)	
	95% CI of Geometric Mean	54.7, 62.1		52.3, 61.5		57.1, 66.9	
	Median	57.5	8.51	56.0	-3.66	61.0	9.38
	Q25, Q75	48.0, 72.0	-5.68, 16.22	46.0, 73.0	-10.20, 7.41	55.0, 70.0	-1.61, 17.78
	Min, Max	32, 100	-24.6, 47.2	36, 96	-26.7, 31.8	39, 106	-18.7, 58.5
	Mean (SD)	60.3 (15.93)	6.29 (15.574)	58.5 (14.98)	-1.63 (12.915)	63.5 (15.25)	9.70 (16.454)
	95% CI	56.5, 64.2	2.58, 10.01	53.7, 63.3	-5.72, 2.45	58.4, 68.6	4.21, 15.19

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: LDL Cholesterol (mg/dL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	116.2 (28.63)		118.4 (28.71)		107.2 (23.41)	
	95% CI of Geometric Mean	108.9, 124.1		108.3, 129.4		99.4, 115.6	
	Median	118.5		112.0		104.0	
	Q25, Q75	98.0, 137.0		96.0, 138.0		89.0, 130.0	
	Min, Max	58, 205		74, 241		63, 159	
	Mean (SD)	120.8 (34.06)		123.3 (37.76)		110.0 (25.24)	
	95% CI	112.9, 128.8		111.3, 135.2		101.7, 118.2	

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: LDL Cholesterol (mg/dL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	111.1 (28.17)		111.5 (27.09)		106.9 (24.63)	
	95% CI of Geometric Mean	104.2, 118.5		102.5, 121.4		98.8, 115.7	
	Median	111.5	-3.98	112.0	-5.56	102.0	0.00
	Q25, Q75	94.0, 135.0	-12.21, 5.05	89.0, 134.0	-12.26, 4.90	89.0, 123.0	-9.17, 10.23
	Min, Max	62, 215	-31.3, 23.5	65, 182	-31.0, 53.2	68, 173	-36.4, 37.3
	Mean (SD)	115.4 (32.66)	-3.74 (11.313)	115.4 (30.77)	-4.60 (15.582)	110.1 (27.20)	1.07 (16.225)
	95% CI	107.8, 123.0	-6.37, -1.11	105.7, 125.2	-9.53, 0.32	101.2, 118.9	-4.19, 6.34

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: LDL Cholesterol (mg/dL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	118.6 (27.35)		118.4 (28.71)		108.0 (23.15)	
	95% CI of Geometric Mean	111.2, 126.4		108.3, 129.4		100.2, 116.5	
	Median	120.0		112.0		105.5	
	Q25, Q75	99.0, 139.0		96.0, 138.0		89.0, 130.0	
	Min, Max	58, 205		74, 241		63, 159	
	Mean (SD)	122.8 (33.36)		123.3 (37.76)		110.8 (25.06)	
	95% CI	114.9, 130.8		111.3, 135.2		102.5, 119.1	

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: LDL Cholesterol (mg/dL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	111.0 (30.42)		109.8 (29.17)		107.1 (27.32)	
	95% CI of Geometric Mean	103.4, 119.2		100.3, 120.3		98.0, 117.0	
	Median	114.0	-7.41	109.0	-7.78	113.0	-0.79
	Q25, Q75	88.0, 127.0	-16.35, 5.80	89.0, 132.0	-13.89, -0.63	92.0, 125.0	-13.08, 9.63
	Min, Max	58, 224	-35.6, 46.5	49, 186	-46.7, 41.8	60, 171	-35.5, 52.6
	Mean (SD)	116.0 (35.77)	-5.08 (15.898)	114.1 (31.51)	-5.81 (16.532)	110.8 (28.48)	0.65 (17.971)
	95% CI	107.5, 124.5	-8.84, -1.31	104.2, 124.1	-11.03, -0.59	101.4, 120.2	-5.26, 6.56

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 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), and TC (mg/dL) - PP Set****Parameter: LDL Cholesterol (mg/dL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	116.6 (29.33)		118.4 (28.71)		108.3 (23.43)	
	95% CI of Geometric Mean	108.8, 124.9		108.3, 129.4		100.2, 117.0	
	Median	118.5		112.0		107.0	
	Q25, Q75	98.0, 139.0		96.0, 138.0		89.0, 130.0	
	Min, Max	58, 205		74, 241		63, 159	
	Mean (SD)	121.3 (34.85)		123.3 (37.76)		111.1 (25.32)	
	95% CI	113.0, 129.7		111.3, 135.2		102.6, 119.6	

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: LDL Cholesterol (mg/dL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	70	70	41	41	37	37
	Geometric Mean (CV%)	108.0 (32.30)		110.5 (26.03)		107.9 (22.72)	
	95% CI of Geometric Mean	100.1, 116.5		101.9, 119.8		100.0, 116.3	
	Median	113.5	-8.01	108.0	-8.49	109.0	0.00
	Q25, Q75	85.0, 134.0	-16.67, 3.02	92.0, 135.0	-15.50, 1.68	94.0, 124.0	-11.89, 7.69
	Min, Max	53, 237	-47.2, 45.9	67, 198	-36.1, 66.0	64, 168	-26.4, 50.8
	Mean (SD)	113.4 (36.35)	-5.94 (16.476)	114.1 (29.99)	-5.04 (19.084)	110.5 (24.42)	1.16 (18.660)
	95% CI	104.7, 122.1	-9.87, -2.00	104.6, 123.6	-11.07, 0.99	102.3, 118.7	-5.07, 7.39

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 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), and TC (mg/dL) - PP Set****Parameter: Homocysteine (umol/L)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	10.224 (48.21)		10.938 (51.41)		11.316 (58.90)	
	95% CI of Geometric Mean	9.196, 11.367		9.387, 12.745		9.481, 13.506	
	Median	9.540		10.580		9.780	
	Q25, Q75	7.400, 12.020		8.050, 12.540		7.900, 13.130	
	Min, Max	4.35, 69.65		4.99, 61.44		4.97, 57.13	
	Mean (SD)	11.728 (9.1340)		12.685 (9.7460)		13.586 (10.8280)	
	95% CI	9.612, 13.845		9.609, 15.762		10.076, 17.096	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: Homocysteine (umol/L)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	11.045 (46.02)		11.498 (56.61)		11.563 (60.26)	
	95% CI of Geometric Mean	9.978, 12.226		9.734, 13.580		9.653, 13.849	
	Median	10.250	6.36	11.040	3.35	10.320	2.33
	Q25, Q75	8.370, 12.910	-0.68, 15.28	8.050, 13.650	-7.94, 17.85	8.090, 12.780	-9.41, 14.10
	Min, Max	4.54, 61.77	-19.9, 98.6	4.44, 48.49	-46.0, 87.2	5.00, 60.38	-40.4, 44.9
	Mean (SD)	12.479 (8.6780)	9.39 (18.730)	13.478 (9.5070)	7.44 (23.229)	14.043 (11.8770)	3.70 (17.618)
	95% CI	10.468, 14.490	5.04, 13.73	10.477, 16.480	0.10, 14.77	10.193, 17.894	-2.02, 9.42

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 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), and TC (mg/dL) - PP Set****Parameter: Homocysteine (umol/L)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	10.432 (49.11)		10.938 (51.41)		11.298 (59.80)	
	95% CI of Geometric Mean	9.344, 11.646		9.387, 12.745		9.420, 13.550	
	Median	9.740		10.580		9.755	
	Q25, Q75	7.400, 12.580		8.050, 12.540		7.900, 13.130	
	Min, Max	4.35, 69.65		4.99, 61.44		4.97, 57.13	
	Mean (SD)	11.995 (9.2950)		12.685 (9.7460)		13.627 (10.9700)	
	95% CI	9.795, 14.196		9.609, 15.762		10.021, 17.233	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: Homocysteine (umol/L)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	10.693 (51.24)		10.656 (53.15)		11.514 (68.34)	
	95% CI of Geometric Mean	9.538, 11.988		9.104, 12.474		9.394, 14.113	
	Median	10.570	0.92	10.040	0.59	10.305	-0.28
	Q25, Q75	7.860, 13.160	-9.98, 15.79	8.260, 12.610	-12.80, 10.05	7.430, 14.740	-15.44, 18.94
	Min, Max	3.62, 84.11	-30.7, 78.7	3.57, 54.55	-52.2, 93.3	4.27, 62.64	-33.1, 76.7
	Mean (SD)	12.415 (10.3560)	4.29 (20.083)	12.330 (8.8660)	0.69 (27.040)	14.463 (12.7040)	5.44 (28.991)
	95% CI	9.964, 14.867	-0.47, 9.05	9.532, 15.129	-7.85, 9.23	10.288, 18.639	-4.09, 14.98

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 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - PP Set****Parameter: Homocysteine (umol/L)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	10.393 (49.07)		10.938 (51.41)		11.344 (60.69)	
	95% CI of Geometric Mean	9.303, 11.610		9.387, 12.745		9.412, 13.674	
	Median	9.775		10.580		9.780	
	Q25, Q75	7.560, 12.530		8.050, 12.540		7.900, 13.130	
	Min, Max	4.35, 69.65		4.99, 61.44		4.97, 57.13	
	Mean (SD)	11.959 (9.3410)		12.685 (9.7460)		13.733 (11.1020)	
	95% CI	9.731, 14.186		9.609, 15.762		10.031, 17.435	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - PP Set****Parameter: Homocysteine (umol/L)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	70	70	41	41	37	37
	Geometric Mean (CV%)	11.568 (48.04)		12.052 (52.37)		12.886 (58.83)	
	95% CI of Geometric Mean	10.377, 12.897		10.317, 14.079		10.744, 15.455	
	Median	11.010	13.57	11.230	13.36	11.680	14.06
	Q25, Q75	8.550, 14.000	0.68, 22.10	8.860, 15.170	-2.61, 26.66	9.070, 16.110	-1.87, 23.47
	Min, Max	5.24, 69.00	-29.2, 90.7	5.08, 61.87	-45.1, 77.0	5.32, 58.67	-39.4, 95.1
	Mean (SD)	13.151 (9.2560)	13.25 (21.884)	13.988 (10.3860)	12.35 (21.810)	15.391 (11.8500)	16.27 (25.780)
	95% CI	10.944, 15.358	8.03, 18.47	10.709, 17.266	5.46, 19.24	11.440, 19.342	7.67, 24.87

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 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), and TC (mg/dL) - FAS****Parameter: Glucose (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	84.8 (9.15)		85.4 (6.91)		84.8 (8.46)	
	95% CI of Geometric Mean	83.0, 86.6		83.5, 87.3		82.5, 87.1	
	Median	85.0		85.0		85.0	
	Q25, Q75	79.0, 90.0		81.0, 90.0		79.0, 90.0	
	Min, Max	70, 110		72, 101		74, 101	
	Mean (SD)	85.1 (7.84)		85.6 (5.87)		85.1 (7.34)	
	95% CI	83.3, 86.9		83.7, 87.5		82.7, 87.5	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - FAS****Parameter: Glucose (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		66	66	37	37	34	34
Confinement							
	Geometric Mean (CV%)	83.3 (9.38)		84.9 (6.49)		82.1 (6.48)	
	95% CI of Geometric Mean	81.4, 85.3		83.1, 86.8		80.2, 84.1	
	Median	85.0	-2.50	86.0	0.00	83.0	-0.58
	Q25, Q75	79.0, 88.0	-7.06, 2.60	83.0, 88.0	-4.26, 2.47	79.0, 86.0	-5.81, 2.53
	Min, Max	67, 103	-16.8, 21.1	67, 92	-23.9, 15.8	68, 90	-22.2, 14.3
	Mean (SD)	83.7 (7.80)	-1.41 (7.425)	85.1 (5.25)	0.23 (8.190)	82.3 (5.22)	-2.27 (7.991)
	95% CI	81.7, 85.7	-3.24, 0.42	83.3, 86.9	-2.51, 2.96	80.4, 84.2	-5.06, 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 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), and TC (mg/dL) - FAS****Parameter: Glucose (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	89.9 (7.57)		91.7 (8.33)		91.0 (10.44)	
	95% CI of Geometric Mean	88.4, 91.5		89.3, 94.2		88.0, 94.1	
	Median	90.0	5.95	92.0	6.10	88.0	7.29
	Q25, Q75	86.0, 92.0	1.18, 10.39	88.0, 95.0	3.26, 10.47	85.0, 97.0	1.20, 12.66
	Min, Max	77, 113	-7.4, 21.6	74, 126	-5.7, 48.2	77, 117	-16.0, 34.2
	Mean (SD)	90.2 (7.00)	6.33 (6.507)	92.0 (8.05)	7.72 (8.354)	91.5 (9.89)	7.75 (9.469)
	95% CI	88.6, 91.8	4.85, 7.80	89.5, 94.6	5.12, 10.33	88.3, 94.7	4.72, 10.78

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 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), and TC (mg/dL) - FAS****Parameter: Glucose (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	89.7 (8.35)		92.3 (6.33)		87.8 (7.31)	
	95% CI of Geometric Mean	88.0, 91.5		90.4, 94.2		85.7, 89.9	
	Median	90.0	5.41	92.0	7.70	88.0	2.87
	Q25, Q75	85.0, 94.0	0.00, 11.11	88.0, 95.0	3.61, 10.84	83.0, 92.0	-1.61, 8.22
	Min, Max	70, 117	-14.7, 33.0	83, 108	0.0, 28.4	77, 108	-11.1, 27.1
	Mean (SD)	90.0 (7.64)	6.16 (7.902)	92.5 (5.92)	8.27 (6.562)	88.0 (6.53)	3.85 (8.301)
	95% CI	88.3, 91.8	4.37, 7.94	90.6, 94.3	6.22, 10.32	85.9, 90.1	1.19, 6.51

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - FAS****Parameter: Glucose (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		78	78	42	42	40	40
	Geometric Mean (CV%)	89.8 (9.06)		90.9 (6.67)		87.1 (8.37)	
	95% CI of Geometric Mean	88.0, 91.7		89.0, 92.9		84.8, 89.5	
	Median	88.0	5.88	90.0	6.39	87.0	2.16
	Q25, Q75	85.0, 95.0	0.00, 11.39	88.0, 94.0	1.18, 12.22	82.0, 92.0	-1.23, 7.69
	Min, Max	76, 119	-9.5, 28.6	79, 106	-8.5, 24.7	72, 104	-13.3, 22.4
	Mean (SD)	90.2 (8.42)	6.32 (8.258)	91.1 (6.12)	6.75 (7.092)	87.4 (7.32)	3.06 (7.780)
	95% CI	88.3, 92.2	4.46, 8.19	89.2, 93.1	4.54, 8.97	85.0, 89.8	0.57, 5.55

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 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), and TC (mg/dL) - FAS****Parameter: Triglycerides (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	129.3 (46.69)		121.2 (40.93)		102.8 (38.24)	
	95% CI of Geometric Mean	117.0, 143.0		107.1, 137.0		91.3, 115.7	
	Median	124.5		114.5		101.5	
	Q25, Q75	91.0, 172.0		96.0, 176.0		74.5, 128.0	
	Min, Max	54, 421		53, 236		54, 226	
	Mean (SD)	143.4 (72.94)		130.5 (50.88)		109.9 (42.10)	
	95% CI	126.9, 159.9		114.6, 146.4		96.4, 123.4	

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: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - FAS****Parameter: Triglycerides (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		66	66	37	37	34	34
Confinement							
	Geometric Mean	124.6 (44.73)		125.5 (47.03)		102.0 (40.21)	
	(CV%)						
	95% CI of	112.1, 138.4		108.1, 145.8		89.0, 116.8	
	Geometric Mean						
	Median	124.5	-5.18	110.0	-1.73	101.0	-4.62
	Q25, Q75	91.0, 160.0	-18.60, 10.23	97.0, 191.0	-13.39, 27.49	79.0, 140.0	-16.83, 19.40
	Min, Max	56, 380	-41.3, 76.1	50, 254	-32.1, 58.3	53, 203	-56.6, 72.5
	Mean (SD)	137.0 (66.36)	-1.89 (23.352)	137.9 (59.75)	6.39 (25.839)	109.6 (42.41)	4.63 (33.089)
	95% CI	120.6, 153.3	-7.63, 3.86	117.9, 157.9	-2.23, 15.01	94.8, 124.5	-6.92, 16.18

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: Triglycerides (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	136.0 (48.41)		129.5 (37.12)		115.1 (48.05)	
	95% CI of Geometric Mean	122.6, 150.9		115.8, 144.9		99.4, 133.2	
	Median	131.5	6.27	138.0	7.04	113.5	7.88
	Q25, Q75	96.0, 194.0	-11.76, 27.78	101.0, 172.0	-4.40, 24.62	85.5, 151.0	-10.15, 37.44
	Min, Max	50, 421	-46.5, 140.3	61, 229	-40.5, 80.5	44, 314	-42.4, 161.7
	Mean (SD)	151.4 (75.01)	9.03 (30.373)	137.7 (47.73)	9.16 (22.785)	127.5 (61.36)	17.89 (41.544)
	95% CI	134.4, 168.3	2.17, 15.88	122.8, 152.6	2.06, 16.27	107.8, 147.2	4.60, 31.18

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: Triglycerides (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	132.6 (41.61)		136.5 (43.79)		114.5 (43.94)	
	95% CI of Geometric Mean	121.1, 145.2		119.8, 155.6		100.0, 131.0	
	Median	127.5	1.87	138.5	13.40	121.5	8.68
	Q25, Q75	99.0, 179.0	-10.64, 23.70	97.0, 180.0	-7.69, 26.27	81.5, 158.0	-5.44, 39.46
	Min, Max	66, 368	-60.1, 81.0	52, 359	-53.0, 235.5	52, 267	-34.9, 128.2
	Mean (SD)	144.2 (64.90)	5.73 (25.742)	149.0 (66.13)	19.94 (48.941)	124.5 (51.57)	15.84 (33.865)
	95% CI	129.5, 158.9	-0.08, 11.54	128.3, 169.6	4.69, 35.20	108.0, 141.1	5.00, 26.68

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 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), and TC (mg/dL) - FAS****Parameter: Triglycerides (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		78	78	42	42	40	40
	Geometric Mean (CV%)	125.1 (52.95)		128.4 (36.24)		114.9 (52.62)	
	95% CI of Geometric Mean	111.8, 140.0		115.0, 143.3		98.1, 134.6	
	Median	120.0	0.00	131.5	3.10	108.0	3.15
	Q25, Q75	87.0, 189.0	-20.69, 18.10	99.0, 177.0	-8.33, 26.89	73.5, 172.0	-3.62, 36.42
	Min, Max	49, 491	-50.8, 74.6	57, 236	-39.1, 93.9	53, 353	-26.3, 104.3
	Mean (SD)	142.7 (83.30)	0.21 (26.901)	136.0 (45.29)	9.54 (29.372)	129.7 (67.27)	15.39 (30.870)
	95% CI	123.8, 161.5	-5.86, 6.28	121.9, 150.2	0.38, 18.70	108.1, 151.3	5.51, 25.27

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	194.6 (17.64)		196.1 (20.19)		180.8 (15.67)	
	95% CI of Geometric Mean	187.0, 202.5		184.2, 208.8		171.9, 190.0	
	Median	195.5		193.5		182.0	
	Q25, Q75	171.0, 214.0		173.0, 218.0		161.5, 206.5	
	Min, Max	131, 290		131, 343		131, 245	
	Mean (SD)	197.6 (35.01)		200.1 (42.06)		182.9 (28.45)	
	95% CI	189.7, 205.5		186.9, 213.2		173.8, 192.0	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - FAS****Parameter: Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		66	66	37	37	34	34
Confinement							
	Geometric Mean (CV%)	195.2 (17.31)		195.3 (17.78)		172.9 (16.89)	
	95% CI of Geometric Mean	187.0, 203.6		184.1, 207.2		163.0, 183.3	
	Median	198.0	-0.02	204.0	1.03	177.0	-1.66
	Q25, Q75	177.0, 214.0	-5.82, 7.69	179.0, 217.0	-7.55, 4.98	162.0, 192.0	-10.20, 3.33
	Min, Max	130, 293	-21.0, 23.8	131, 276	-19.5, 31.5	125, 255	-23.2, 21.7
	Mean (SD)	198.0 (34.09)	0.35 (9.980)	198.2 (34.10)	0.20 (10.316)	175.2 (28.95)	-2.43 (11.295)
	95% CI	189.6, 206.4	-2.11, 2.81	186.8, 209.6	-3.24, 3.64	165.1, 185.4	-6.38, 1.51

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - FAS****Parameter: Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	192.6 (16.92)		190.1 (17.25)		184.9 (17.98)	
	95% CI of Geometric Mean	185.4, 200.1		180.2, 200.6		174.6, 195.8	
	Median	191.5	-0.51	192.5	-3.85	182.5	3.97
	Q25, Q75	173.0, 214.0	-6.91, 5.82	169.0, 216.0	-10.06, 3.36	167.0, 212.0	-5.65, 9.36
	Min, Max	133, 291	-16.2, 19.1	121, 254	-27.4, 41.8	125, 256	-21.4, 20.7
	Mean (SD)	195.3 (33.37)	-0.70 (8.305)	192.8 (32.19)	-2.40 (11.752)	187.8 (33.76)	2.87 (10.685)
	95% CI	187.7, 202.9	-2.58, 1.18	182.7, 202.9	-6.06, 1.27	177.0, 198.7	-0.55, 6.29

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	191.5 (18.65)		191.2 (17.75)		186.1 (18.54)	
	95% CI of Geometric Mean	183.6, 199.7		180.9, 202.0		175.4, 197.4	
	Median	188.0	-1.28	189.5	-0.82	189.0	2.16
	Q25, Q75	171.0, 211.0	-9.95, 6.91	165.0, 221.0	-7.78, 3.30	167.0, 209.5	-4.04, 11.04
	Min, Max	132, 311	-22.1, 28.2	130, 261	-30.0, 28.2	125, 263	-20.9, 38.5
	Mean (SD)	194.8 (37.19)	-1.04 (10.953)	194.1 (34.01)	-1.85 (11.419)	189.1 (34.15)	3.59 (11.761)
	95% CI	186.3, 203.2	-3.51, 1.44	183.4, 204.7	-5.42, 1.71	178.2, 200.1	-0.18, 7.35

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - FAS****Parameter: Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		78	78	42	42	40	40
	Geometric Mean (CV%)	186.4 (19.54)		188.4 (16.97)		184.9 (16.13)	
	95% CI of Geometric Mean	178.4, 194.7		178.7, 198.6		175.7, 194.7	
	Median	186.5	-4.59	183.5	-5.07	190.0	0.60
	Q25, Q75	159.0, 212.0	-13.30, 4.52	168.0, 212.0	-9.57, 2.99	168.5, 206.5	-3.55, 9.13
	Min, Max	133, 311	-37.6, 32.8	125, 274	-34.7, 51.5	125, 252	-20.9, 27.5
	Mean (SD)	189.9 (37.73)	-3.51 (12.021)	191.1 (32.76)	-3.04 (13.698)	187.2 (28.82)	2.87 (10.963)
	95% CI	181.3, 198.4	-6.23, -0.80	180.8, 201.3	-7.32, 1.23	177.9, 196.5	-0.64, 6.39

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 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), and TC (mg/dL) - FAS****Parameter: C Reactive Protein (mg/L)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	0.203 (116.24)		0.172 (104.83)		0.218 (204.02)	
	95% CI of Geometric Mean	0.164, 0.250		0.131, 0.225		0.144, 0.328	
	Median	0.100		0.100		0.100	
	Q25, Q75	0.100, 0.410		0.100, 0.260		0.100, 0.475	
	Min, Max	0.10, 2.27		0.10, 1.54		0.10, 14.40	
	Mean (SD)	0.338 (0.4370)		0.276 (0.3530)		0.851 (2.5620)	
	95% CI	0.240, 0.437		0.165, 0.386		0.031, 1.671	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - FAS****Parameter: C Reactive Protein (mg/L)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	0.224 (124.99)		0.204 (171.87)		0.223 (180.70)	
	95% CI of Geometric Mean	0.180, 0.279		0.141, 0.294		0.151, 0.329	
	Median	0.150	0.00	0.100	0.00	0.100	0.00
	Q25, Q75	0.100, 0.450	0.00, 23.33	0.100, 0.370	0.00, 46.38	0.100, 0.360	0.00, 90.00
	Min, Max	0.10, 11.00	-94.8, 10900.0	0.10, 21.40	-90.4, 4995.2	0.10, 9.40	-99.3, 1300.0
	Mean (SD)	0.459 (1.2580)	201.65 (1252.499)	0.856 (3.3420)	160.82 (773.000)	0.672 (1.6880)	85.77 (267.309)
	95% CI	0.175, 0.743	-80.75, 484.05	-0.186, 1.898	-80.07, 401.71	0.131, 1.212	0.27, 171.26

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 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), and TC (mg/dL) - FAS****Parameter: C Reactive Protein (mg/L)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	0.212 (160.55)		0.202 (138.53)		0.246 (120.97)	
	95% CI of Geometric Mean	0.164, 0.273		0.146, 0.279		0.181, 0.334	
	Median	0.100	0.00	0.100	0.00	0.220	0.00
	Q25, Q75	0.100, 0.350	-6.67, 0.00	0.100, 0.330	0.00, 110.00	0.100, 0.610	0.00, 120.00
	Min, Max	0.10, 42.10	-91.5, 5229.1	0.10, 3.93	-90.4, 1100.0	0.10, 1.31	-99.3, 950.0
	Mean (SD)	0.970 (4.9040)	154.31 (736.741)	0.424 (0.7830)	83.83 (223.178)	0.386 (0.3740)	95.00 (231.643)
	95% CI	-0.136, 2.076	-11.81, 320.42	0.180, 0.668	14.28, 153.39	0.265, 0.506	20.91, 169.09

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 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), and TC (mg/dL) - FAS****Parameter: C Reactive Protein (mg/L)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	78	42	42	40	40
	Geometric Mean (CV%)	0.265 (158.36)		0.241 (190.19)		0.226 (141.88)	
	95% CI of Geometric Mean	0.206, 0.342		0.163, 0.355		0.161, 0.317	
	Median	0.235	0.00	0.100	0.00	0.100	0.00
	Q25, Q75	0.100, 0.550	-1.96, 37.21	0.100, 0.480	-7.69, 130.00	0.100, 0.515	0.00, 81.50
	Min, Max	0.10, 8.49	-88.0, 8390.0	0.10, 9.25	-90.4, 9060.0	0.10, 4.62	-99.3, 1380.0
	Mean (SD)	0.621 (1.3860)	356.73 (1397.608)	0.772 (1.9760)	383.07 (1461.650)	0.445 (0.7680)	66.79 (233.219)
	95% CI	0.308, 0.934	41.61, 671.85	0.156, 1.388	-72.42, 838.55	0.199, 0.690	-7.80, 141.38

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: HDL Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	54.7 (25.01)		58.1 (25.63)		58.5 (24.88)	
	95% CI of Geometric Mean	51.7, 57.9		53.7, 62.9		54.0, 63.3	
	Median	56.5		56.0		59.0	
	Q25, Q75	44.0, 65.0		49.0, 73.0		49.0, 66.5	
	Min, Max	24, 88		36, 107		35, 97	
	Mean (SD)	56.3 (13.18)		60.0 (15.67)		60.2 (15.03)	
	95% CI	53.3, 59.3		55.0, 64.9		55.3, 65.1	

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: HDL Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	56.6 (26.12)		57.0 (21.37)		61.0 (23.69)	
	95% CI of Geometric Mean	53.4, 60.0		53.3, 61.0		56.6, 65.8	
	Median	58.5	3.50	56.0	-2.30	63.0	3.36
	Q25, Q75	46.0, 69.0	-2.38, 11.86	49.0, 67.0	-7.48, 3.57	51.0, 70.0	-3.45, 10.80
	Min, Max	32, 92	-25.4, 39.4	39, 99	-30.4, 36.4	35, 108	-23.9, 54.7
	Mean (SD)	58.5 (14.84)	4.21 (12.322)	58.3 (12.88)	-1.26 (11.344)	62.7 (14.71)	5.64 (17.049)
	95% CI	55.1, 61.9	1.42, 6.99	54.2, 62.4	-4.80, 2.28	57.9, 67.4	0.18, 11.10

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: HDL Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	57.8 (27.13)		56.7 (24.19)		62.3 (25.63)	
	95% CI of Geometric Mean	54.3, 61.4		52.6, 61.1		57.5, 67.6	
	Median	57.5	7.23	57.0	-3.07	62.5	6.85
	Q25, Q75	46.0, 70.0	-4.69, 17.14	48.0, 66.0	-10.53, 5.63	53.5, 70.0	-0.75, 15.94
	Min, Max	31, 106	-32.3, 46.7	34, 104	-21.4, 31.8	38, 116	-22.7, 52.8
	Mean (SD)	59.8 (15.89)	6.70 (15.326)	58.3 (14.20)	-1.73 (12.341)	64.3 (16.68)	7.50 (13.885)
	95% CI	56.2, 63.4	3.24, 10.16	53.8, 62.8	-5.58, 2.12	58.9, 69.7	3.05, 11.94

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 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), and TC (mg/dL) - FAS****Parameter: HDL Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	78	42	42	40	40
	Geometric Mean (CV%)	57.3 (29.40)		56.7 (25.25)		63.0 (24.34)	
	95% CI of Geometric Mean	53.6, 61.2		52.4, 61.3		58.3, 68.1	
	Median	56.0	7.48	56.0	-3.11	61.5	7.32
	Q25, Q75	48.0, 72.0	-5.88, 16.22	46.0, 73.0	-10.20, 7.41	55.0, 74.5	-2.98, 17.62
	Min, Max	22, 100	-29.0, 47.2	36, 96	-26.7, 31.8	39, 106	-18.7, 58.5
	Mean (SD)	59.6 (16.67)	5.91 (16.079)	58.5 (14.79)	-1.60 (12.759)	64.8 (15.75)	8.84 (16.113)
	95% CI	55.8, 63.4	2.28, 9.54	53.8, 63.1	-5.58, 2.39	59.7, 69.9	3.68, 14.00

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 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), and TC (mg/dL) - FAS****Parameter: LDL Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	116.7 (28.39)		117.2 (29.17)		105.6 (25.05)	
	95% CI of Geometric Mean	109.6, 124.3		107.1, 128.1		97.5, 114.3	
	Median	119.0		110.0		102.5	
	Q25, Q75	98.0, 137.0		94.0, 138.0		88.5, 130.0	
	Min, Max	58, 205		74, 241		59, 159	
	Mean (SD)	121.2 (33.86)		122.2 (37.98)		108.7 (26.19)	
	95% CI	113.6, 128.9		110.3, 134.0		100.3, 117.1	

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: LDL Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	111.7 (28.22)		110.6 (27.39)		105.4 (26.17)	
	95% CI of Geometric Mean	104.9, 118.9		101.6, 120.3		97.0, 114.4	
	Median	111.5	-3.61	109.5	-5.31	101.0	0.00
	Q25, Q75	94.0, 135.0	-12.21, 5.05	86.0, 134.0	-12.26, 4.90	89.0, 122.5	-8.38, 9.92
	Min, Max	62, 215	-31.3, 23.5	65, 182	-31.0, 53.2	59, 173	-36.4, 37.3
	Mean (SD)	116.0 (32.85)	-3.63 (11.485)	114.5 (30.97)	-4.49 (15.407)	108.8 (28.04)	1.05 (16.017)
	95% CI	108.6, 123.5	-6.23, -1.04	104.8, 124.2	-9.30, 0.31	99.8, 117.8	-4.08, 6.18

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: LDL Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	109.9 (30.51)		108.9 (29.36)		104.7 (28.72)	
	95% CI of Geometric Mean	102.7, 117.6		99.5, 119.2		95.7, 114.6	
	Median	112.5	-6.32	108.5	-7.53	112.5	0.00
	Q25, Q75	90.0, 126.0	-16.35, 6.49	89.0, 132.0	-13.89, 0.00	89.0, 124.5	-11.08, 9.14
	Min, Max	58, 224	-35.6, 46.5	49, 186	-46.7, 41.8	59, 171	-35.5, 52.6
	Mean (SD)	114.9 (35.63)	-4.59 (15.864)	113.3 (31.65)	-5.67 (16.354)	108.7 (29.32)	0.62 (17.505)
	95% CI	106.8, 123.0	-8.17, -1.01	103.4, 123.2	-10.77, -0.57	99.3, 118.1	-4.99, 6.22

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: LDL Cholesterol (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	78	42	42	40	40
	Geometric Mean (CV%)	106.9 (31.85)		109.5 (26.34)		105.4 (24.38)	
	95% CI of Geometric Mean	99.6, 114.7		101.0, 118.8		97.5, 113.8	
	Median	111.0	-9.18	106.0	-8.31	106.0	0.00
	Q25, Q75	85.0, 132.0	-18.28, 2.70	90.0, 135.0	-15.50, 1.68	90.0, 124.0	-11.64, 7.39
	Min, Max	53, 237	-47.2, 45.9	67, 198	-36.1, 66.0	59, 168	-26.4, 50.8
	Mean (SD)	112.2 (35.94)	-6.99 (16.632)	113.2 (30.17)	-4.92 (18.865)	108.3 (25.29)	1.25 (17.955)
	95% CI	104.0, 120.3	-10.75, -3.24	103.8, 122.7	-10.80, 0.96	100.2, 116.4	-4.50, 7.00

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 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), and TC (mg/dL) - FAS****Parameter: Homocysteine (umol/L)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	10.384 (51.60)		10.974 (50.76)		11.174 (58.76)	
	95% CI of Geometric Mean	9.306, 11.587		9.453, 12.740		9.387, 13.300	
	Median	9.540		10.680		9.755	
	Q25, Q75	7.370, 12.530		8.050, 12.560		7.900, 13.115	
	Min, Max	4.35, 69.65		4.99, 61.44		4.97, 57.13	
	Mean (SD)	12.129 (9.8560)		12.682 (9.6270)		13.417 (10.7420)	
	95% CI	9.906, 14.352		9.682, 15.683		9.981, 16.852	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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), and TC (mg/dL) - FAS****Parameter: Homocysteine (umol/L)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	11.233 (49.15)		11.522 (55.84)		11.411 (60.15)	
	95% CI of Geometric Mean	10.114, 12.476		9.795, 13.553		9.553, 13.631	
	Median	10.250	6.36	11.070	3.28	10.165	2.28
	Q25, Q75	8.370, 13.120	-0.46, 15.28	8.050, 13.650	-7.94, 17.85	7.815, 12.680	-6.99, 13.88
	Min, Max	4.54, 61.77	-19.9, 98.6	4.44, 48.49	-46.0, 87.2	5.00, 60.38	-40.4, 44.9
	Mean (SD)	12.894 (9.4180)	9.51 (18.556)	13.456 (9.3920)	7.26 (22.973)	13.863 (11.7800)	3.61 (17.400)
	95% CI	10.771, 15.018	5.32, 13.70	10.529, 16.383	0.10, 14.42	10.095, 17.630	-1.96, 9.18

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: Homocysteine (umol/L)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	10.663 (53.08)		10.698 (52.49)		11.377 (66.97)	
	95% CI of Geometric Mean	9.529, 11.931		9.173, 12.476		9.364, 13.822	
	Median	10.285	3.04	10.060	0.49	10.305	0.00
	Q25, Q75	7.860, 13.040	-9.68, 15.08	8.260, 12.610	-12.80, 10.05	7.125, 14.175	-15.33, 15.81
	Min, Max	3.62, 84.11	-30.7, 78.7	3.57, 54.55	-52.2, 93.3	4.27, 62.64	-33.1, 76.7
	Mean (SD)	12.537 (10.7560)	4.35 (19.355)	12.336 (8.7570)	0.67 (26.709)	14.212 (12.4370)	5.17 (28.264)
	95% CI	10.112, 14.963	-0.02, 8.71	9.606, 15.065	-7.65, 9.00	10.233, 18.190	-3.87, 14.21

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 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), and TC (mg/dL) - FAS****Parameter: Homocysteine (umol/L)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	78	42	42	40	40
	Geometric Mean (CV%)	11.586 (49.77)		12.064 (51.65)		12.572 (57.57)	
	95% CI of Geometric Mean	10.419, 12.882		10.367, 14.038		10.594, 14.919	
	Median	10.935	13.57	11.250	12.86	11.305	12.98
	Q25, Q75	8.630, 14.000	0.00, 23.31	8.860, 15.170	-2.61, 26.66	8.960, 15.980	-0.93, 22.33
	Min, Max	5.24, 69.00	-29.2, 90.7	5.08, 61.87	-45.1, 77.0	5.32, 58.67	-39.4, 95.1
	Mean (SD)	13.308 (9.7110)	13.46 (21.575)	13.954 (10.2610)	12.05 (21.626)	14.951 (11.5070)	15.05 (25.143)
	95% CI	11.118, 15.498	8.59, 18.33	10.756, 17.151	5.31, 18.80	11.270, 18.631	7.01, 23.10

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 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL) - PP Set****Parameter: Fibrinogen (mg/dL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	69		40		36	
	Geometric Mean (CV%)	278.73 (18.39)		276.16 (19.10)		285.65 (17.11)	
	95% CI of Geometric Mean	266.78, 291.21		259.93, 293.40		269.69, 302.56	
	Median	265.00		270.50		271.50	
	Q25, Q75	244.00, 330.00		235.00, 320.50		246.50, 326.50	
	Min, Max	192.0, 431.0		201.0, 414.0		213.0, 413.0	
	Mean (SD)	283.45 (53.878)		281.13 (55.027)		289.75 (50.516)	
	95% CI	270.50, 296.40		263.52, 298.73		272.65, 306.85	

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL) - PP Set****Parameter: Fibrinogen (mg/dL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	69	41	40	39	36
	Geometric Mean (CV%)	277.00 (16.93)		286.98 (19.27)		283.63 (19.03)	
	95% CI of Geometric Mean	266.42, 288.01		270.19, 304.82		266.81, 301.52	
	Median	271.50	-1.65	277.00	3.09	274.00	0.31
	Q25, Q75	246.00, 313.00	-10.46, 5.21	249.00, 322.00	-4.12, 12.18	244.00, 327.00	-10.34, 6.02
	Min, Max	196.0, 502.0	-29.2, 104.9	195.0, 484.0	-27.0, 53.5	220.0, 438.0	-43.6, 61.0
	Mean (SD)	281.03 (50.264)	-0.23 (17.889)	292.32 (59.276)	5.35 (16.176)	288.77 (57.590)	0.29 (18.997)
	95% CI	269.38, 292.68	-4.54, 4.07	273.60, 311.03	0.18, 10.53	270.10, 307.44	-6.14, 6.72

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Fibrinogen (mg/dL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	65		40		35	
	Geometric Mean (CV%)	277.32 (18.49)		276.16 (19.10)		283.06 (16.43)	
	95% CI of Geometric Mean	265.00, 290.21		259.93, 293.40		267.62, 299.38	
	Median	262.00		270.50		271.00	
	Q25, Q75	244.00, 330.00		235.00, 320.50		246.00, 325.00	
	Min, Max	192.0, 431.0		201.0, 414.0		213.0, 413.0	
	Mean (SD)	282.08 (54.198)		281.13 (55.027)		286.80 (48.005)	
	95% CI	268.64, 295.51		263.52, 298.73		270.30, 303.30	

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL) - PP Set****Parameter: Fibrinogen (mg/dL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	65	41	40	38	35
	Geometric Mean (CV%)	273.16 (21.35)		278.14 (18.05)		279.56 (19.36)	
	95% CI of Geometric Mean	259.84, 287.16		262.85, 294.32		262.48, 297.76	
	Median	268.00	-2.89	267.00	0.89	269.50	2.04
	Q25, Q75	244.00, 318.00	-16.39, 6.75	245.00, 316.00	-10.57, 9.52	244.00, 308.00	-12.76, 12.94
	Min, Max	154.0, 572.0	-41.5, 122.6	201.0, 451.0	-17.9, 55.2	209.0, 440.0	-42.9, 85.7
	Mean (SD)	279.46 (63.772)	-0.09 (24.011)	282.66 (53.215)	1.89 (15.582)	284.84 (58.527)	2.00 (23.839)
	95% CI	264.37, 294.56	-6.05, 5.86	265.86, 299.46	-3.10, 6.88	265.60, 304.08	-6.19, 10.20

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL) - PP Set****Parameter: Fibrinogen (mg/dL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	65		40		34	
	Geometric Mean (CV%)	279.19 (18.65)		276.16 (19.10)		284.47 (16.40)	
	95% CI of Geometric Mean	266.68, 292.28		259.93, 293.40		268.74, 301.12	
	Median	265.00		270.50		271.50	
	Q25, Q75	244.00, 331.00		235.00, 320.50		247.00, 325.00	
	Min, Max	192.0, 431.0		201.0, 414.0		213.0, 413.0	
	Mean (SD)	284.05 (54.697)		281.13 (55.027)		288.21 (47.990)	
	95% CI	270.49, 297.60		263.52, 298.73		271.46, 304.96	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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: Fibrinogen (mg/dL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	70	65	41	40	37	34
	Geometric Mean (CV%)	275.91 (21.33)		286.14 (21.76)		277.63 (17.19)	
	95% CI of Geometric Mean	262.37, 290.14		267.36, 306.24		262.27, 293.88	
	Median	267.50	-2.02	271.00	-1.80	265.00	-0.74
	Q25, Q75	240.00, 310.00	-12.29, 5.43	247.00, 311.00	-7.85, 20.08	250.00, 309.00	-9.60, 5.76
	Min, Max	189.0, 589.0	-39.9, 141.4	196.0, 511.0	-27.9, 107.7	207.0, 454.0	-46.7, 66.9
	Mean (SD)	282.44 (66.781)	0.21 (26.250)	293.15 (70.615)	6.07 (24.020)	281.76 (51.575)	-0.97 (19.448)
	95% CI	266.51, 298.37	-6.30, 6.72	270.85, 315.44	-1.62, 13.76	264.56, 298.96	-7.76, 5.82

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.28.2 Descriptive Statistics of Fibrinogen (mg/dL) - FAS****Parameter: Fibrinogen (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	72		41		37	
	Geometric Mean (CV%)	278.59 (18.22)		275.30 (18.97)		285.74 (16.87)	
	95% CI of Geometric Mean	267.00, 290.68		259.43, 292.13		270.21, 302.16	
	Median	267.50		267.00		272.00	
	Q25, Q75	244.00, 328.50		237.00, 307.00		247.00, 325.00	
	Min, Max	192.0, 431.0		201.0, 414.0		213.0, 413.0	
	Mean (SD)	283.22 (53.281)		280.20 (54.660)		289.73 (49.810)	
	95% CI	270.70, 295.75		262.94, 297.45		273.12, 306.34	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.3.2

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**Table 15.2.4.28.2 Descriptive Statistics of Fibrinogen (mg/dL) - FAS****Parameter: Fibrinogen (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	72	42	41	40	37
	Geometric Mean (CV%)	275.48 (16.79)		285.85 (19.21)		283.76 (18.78)	
	95% CI of Geometric Mean	265.32, 286.04		269.38, 303.32		267.36, 301.18	
	Median	269.50	-1.92	275.50	2.49	276.50	0.00
	Q25, Q75	245.00, 312.00	-11.08, 4.97	248.00, 322.00	-3.82, 11.59	245.00, 322.50	-10.00, 5.17
	Min, Max	196.0, 502.0	-29.2, 104.9	195.0, 484.0	-27.0, 53.5	220.0, 438.0	-43.6, 61.0
	Mean (SD)	279.44 (49.721)	-0.61 (17.759)	291.14 (59.041)	5.22 (15.994)	288.78 (56.847)	0.28 (18.731)
	95% CI	268.22, 290.65	-4.79, 3.56	272.74, 309.55	0.17, 10.28	270.59, 306.96	-5.97, 6.53

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.3.2

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**Table 15.2.4.28.2 Descriptive Statistics of Fibrinogen (mg/dL) - FAS****Parameter: Fibrinogen (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	72	42	41	40	37
	Geometric Mean (CV%)	272.74 (20.77)		277.25 (17.95)		282.19 (19.63)	
	95% CI of Geometric Mean	260.39, 285.68		262.28, 293.07		265.17, 300.30	
	Median	266.50	-3.26	265.50	0.58	273.00	0.00
	Q25, Q75	244.00, 318.00	-16.53, 6.80	245.00, 316.00	-10.56, 8.94	245.00, 311.00	-11.90, 11.72
	Min, Max	154.0, 572.0	-41.5, 122.6	201.0, 451.0	-17.9, 55.2	209.0, 440.0	-42.9, 85.7
	Mean (SD)	278.71 (61.841)	-0.75 (23.197)	281.71 (52.917)	1.84 (15.389)	287.65 (59.515)	1.89 (23.172)
	95% CI	264.76, 292.65	-6.20, 4.71	265.22, 298.21	-3.02, 6.70	268.61, 306.69	-5.84, 9.62

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.3.2

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**Table 15.2.4.28.2 Descriptive Statistics of Fibrinogen (mg/dL) - FAS****Parameter: Fibrinogen (mg/dL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	72	42	41	40	37
	Geometric Mean (CV%)	277.17 (20.93)		285.03 (21.64)		279.13 (17.66)	
	95% CI of Geometric Mean	264.52, 290.42		266.64, 304.68		263.91, 295.23	
	Median	271.00	-1.43	269.50	-1.58	269.50	-0.31
	Q25, Q75	242.00, 310.00	-13.14, 6.08	244.00, 311.00	-7.16, 19.63	249.00, 309.50	-8.04, 5.16
	Min, Max	189.0, 589.0	-39.9, 141.4	196.0, 511.0	-27.9, 107.7	207.0, 454.0	-46.7, 66.9
	Mean (SD)	283.47 (65.326)	0.51 (25.816)	291.95 (70.177)	5.92 (23.737)	283.53 (53.191)	-0.95 (18.622)
	95% CI	268.74, 298.21	-5.57, 6.58	270.08, 313.83	-1.58, 13.42	266.51, 300.54	-7.16, 5.27

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

Appendix: 15.3.3.2

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**Table 15.2.4.29.1 Descriptive Statistics of HbA1c (units) - PP Set**

Parameter: Hemoglobin A1C (%)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Mean (SD)	5.17 (0.288)		5.23 (0.279)		5.22 (0.277)	
	95% CI	5.10, 5.25		5.14, 5.32		5.13, 5.32	
	Median	5.15		5.20		5.20	
	Q25, Q75	5.00, 5.40		5.10, 5.40		5.10, 5.50	
	Min, Max	4.6, 5.9		4.7, 5.9		4.7, 5.8	

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 15.2.4.29.1 Descriptive Statistics of HbA1c (units) - PP Set****Parameter: Hemoglobin A1C (%)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	70	70	41	41	37	37
	Mean (SD)	5.17 (0.323)	0.03 (3.847)	5.20 (0.345)	-0.51 (3.942)	5.18 (0.274)	-0.84 (2.884)
	95% CI	5.09, 5.26	-0.89, 0.96	5.09, 5.32	-1.76, 0.74	5.08, 5.27	-1.80, 0.13
	Median	5.20	0.00	5.10	0.00	5.10	0.00
	Q25, Q75	5.00, 5.40	-1.96, 2.08	5.10, 5.40	-3.77, 1.82	5.00, 5.40	-1.96, 1.72
	Min, Max	4.5, 6.1	-10.9, 10.4	4.6, 6.2	-7.1, 11.5	4.6, 5.9	-7.4, 5.8

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 15.2.4.29.2 Descriptive Statistics of HbA1c (units) - FAS****Parameter: Hemoglobin A1C (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Mean (SD)	5.16 (0.320)		5.22 (0.288)		5.22 (0.294)	
	95% CI	5.08, 5.23		5.12, 5.31		5.12, 5.31	
	Median	5.10		5.20		5.20	
	Q25, Q75	5.00, 5.40		5.10, 5.40		5.00, 5.50	
	Min, Max	4.0, 5.9		4.7, 5.9		4.7, 5.8	

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 15.2.4.29.2 Descriptive Statistics of HbA1c (units) - FAS****Parameter: Hemoglobin A1C (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	78	42	42	40	40
	Mean (SD)	5.16 (0.337)	0.08 (3.839)	5.19 (0.350)	-0.50 (3.894)	5.18 (0.289)	-0.72 (2.813)
	95% CI	5.08, 5.24	-0.79, 0.95	5.08, 5.31	-1.72, 0.72	5.08, 5.27	-1.63, 0.18
	Median	5.20	0.00	5.10	0.00	5.10	0.00
	Q25, Q75	5.00, 5.40	-1.96, 2.08	5.00, 5.40	-3.77, 1.82	5.00, 5.40	-1.96, 1.77
	Min, Max	4.3, 6.1	-10.9, 10.4	4.6, 6.2	-7.1, 11.5	4.6, 5.9	-7.4, 5.8

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 15.2.4.30.1 Descriptive Statistics of sICAM (units) - PP Set****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	221.58 (35.93)		198.41 (49.66)		209.54 (51.88)	
	95% CI of Geometric Mean	204.61, 239.95		171.40, 229.68		178.87, 245.48	
	Median	214.75		200.65		222.00	
	Q25, Q75	180.80, 276.25		179.10, 265.50		181.90, 285.60	
	Min, Max	91.1, 544.9		53.7, 604.5		21.1, 347.9	
	Mean (SD)	235.58 (87.687)		219.54 (101.869)		227.18 (72.973)	
	95% CI	215.54, 255.62		187.79, 251.29		203.52, 250.84	

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 15.2.4.30.1 Descriptive Statistics of sICAM (units) - PP Set****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		76	76	42	42	39	39
Confinement							
	Geometric Mean	211.00 (33.74)		199.22 (44.16)		197.00 (52.80)	
	(CV%)						
	95% CI of	195.74, 227.44		174.66, 227.23		167.74, 231.36	
	Geometric Mean						
	Median	215.75	-1.19	206.80	3.96	206.40	-6.00
	Q25, Q75	178.65, 256.15	-12.51, 7.26	184.80, 242.90	-8.09, 12.39	176.60, 276.30	-10.80, 0.00
	Min, Max	89.8, 468.5	-48.0, 57.5	61.1, 651.7	-38.6, 49.9	21.1, 452.2	-40.3, 38.7
	Mean (SD)	222.21 (72.845)	-2.51 (20.413)	216.76 (96.212)	1.86 (16.838)	214.95 (76.026)	-4.95 (14.058)
	95% CI	205.56, 238.86	-7.18, 2.16	186.77, 246.74	-3.39, 7.11	190.30, 239.60	-9.51, -0.39

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (units) - PP Set****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	221.65 (35.41)		198.70 (50.34)		209.54 (51.88)	
	95% CI of Geometric Mean	204.68, 240.02		171.01, 230.86		178.87, 245.48	
	Median	214.75		200.70		222.00	
	Q25, Q75	181.60, 276.10		179.10, 265.50		181.90, 285.60	
	Min, Max	91.1, 544.9		53.7, 604.5		21.1, 347.9	
	Mean (SD)	235.29 (86.891)		220.33 (103.003)		227.18 (72.973)	
	95% CI	215.16, 255.43		187.81, 252.85		203.52, 250.84	

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 15.2.4.30.1 Descriptive Statistics of sICAM (units) - PP Set****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	199.34 (35.60)		197.99 (51.24)		194.43 (52.25)	
	95% CI of Geometric Mean	184.01, 215.96		170.00, 230.59		165.80, 228.00	
	Median	196.95	-10.03	203.70	-3.19	198.30	-7.64
	Q25, Q75	168.30, 234.40	-22.55, -1.44	177.40, 259.20	-11.78, 8.47	173.50, 269.20	-22.35, 11.21
	Min, Max	75.5, 514.1	-50.9, 104.1	52.9, 655.7	-37.2, 111.1	21.1, 470.7	-51.6, 91.2
	Mean (SD)	211.47 (76.567)	-6.04 (29.737)	220.17 (105.172)	2.60 (27.672)	212.29 (78.111)	-2.55 (32.698)
	95% CI	193.73, 229.22	-12.94, 0.85	186.97, 253.37	-6.14, 11.34	186.97, 237.62	-13.15, 8.06

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (units) - PP Set****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	223.11 (36.46)		198.70 (50.34)		207.55 (52.22)	
	95% CI of Geometric Mean	205.21, 242.58		171.01, 230.86		176.61, 243.91	
	Median	212.20		200.70		221.15	
	Q25, Q75	181.60, 276.80		179.10, 265.50		181.90, 280.10	
	Min, Max	91.1, 544.9		53.7, 604.5		21.1, 347.9	
	Mean (SD)	237.58 (89.453)		220.33 (103.003)		225.23 (72.921)	
	95% CI	216.40, 258.76		187.81, 252.85		201.26, 249.21	

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 15.2.4.30.1 Descriptive Statistics of sICAM (units) - PP Set****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	182.66 (34.06)		174.14 (48.84)		172.54 (46.05)	
	95% CI of Geometric Mean	168.88, 197.56		150.48, 201.51		149.38, 199.30	
	Median	179.70	-16.12	184.30	-9.10	175.50	-14.50
	Q25, Q75	159.60, 219.60	-29.41, -7.67	153.40, 210.70	-23.90, -0.25	156.20, 228.00	-29.57, 1.48
	Min, Max	76.8, 388.5	-61.8, 49.7	52.7, 841.9	-46.0, 53.0	21.1, 302.7	-58.3, 42.9
	Mean (SD)	192.37 (61.659)	-14.98 (23.613)	194.90 (118.869)	-9.76 (22.642)	184.56 (56.246)	-13.55 (23.937)
	95% CI	177.77, 206.97	-20.58, -9.39	157.38, 232.43	-16.91, -2.61	166.07, 203.06	-21.42, -5.67

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (units) - PP Set****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	222.92 (36.03)		198.70 (50.34)		207.89 (53.02)	
	95% CI of Geometric Mean	205.10, 242.28		171.01, 230.86		176.09, 245.42	
	Median	214.75		200.70		222.00	
	Q25, Q75	181.60, 276.40		179.10, 265.50		181.90, 280.10	
	Min, Max	91.1, 544.9		53.7, 604.5		21.1, 347.9	
	Mean (SD)	237.05 (88.583)		220.33 (103.003)		226.04 (73.757)	
	95% CI	215.93, 258.18		187.81, 252.85		201.44, 250.63	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (units) - PP Set****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	70	70	41	41	37	37
	Geometric Mean (CV%)	188.43 (28.88)		188.40 (46.83)		174.07 (48.46)	
	95% CI of Geometric Mean	176.13, 201.59		163.69, 216.83		149.35, 202.88	
	Median	183.25	-11.98	196.80	-1.78	183.80	-12.04
	Q25, Q75	159.60, 217.50	-22.11, -4.77	175.80, 240.30	-9.37, 3.39	160.30, 208.80	-27.96, -2.19
	Min, Max	81.9, 444.2	-52.0, 25.5	55.0, 559.0	-45.4, 21.1	21.1, 362.1	-53.1, 48.5
	Mean (SD)	196.16 (58.854)	-13.92 (15.583)	205.81 (86.827)	-4.02 (14.208)	187.58 (61.511)	-14.06 (19.736)
	95% CI	182.12, 210.20	-17.64, -10.20	178.40, 233.22	-8.51, 0.47	167.07, 208.09	-20.65, -7.48

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 15.2.4.30.2 Descriptive Statistics of sICAM (units) - FAS****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	223.95 (36.23)		198.41 (49.66)		209.24 (51.14)	
	95% CI of Geometric Mean	206.90, 242.41		171.40, 229.68		179.34, 244.11	
	Median	217.65		200.65		221.15	
	Q25, Q75	181.60, 276.80		179.10, 265.50		182.00, 282.85	
	Min, Max	91.1, 544.9		53.7, 604.5		21.1, 347.9	
	Mean (SD)	238.25 (88.551)		219.54 (101.869)		226.44 (72.183)	
	95% CI	218.28, 258.22		187.79, 251.29		203.35, 249.53	

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.30.2 Descriptive Statistics of sICAM (units) - FAS****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		78	78	42	42	40	40
Confinement							
	Geometric Mean	212.01 (33.48)		199.22 (44.16)		196.90 (52.03)	
	(CV%)						
	95% CI of	196.99, 228.19		174.66, 227.23		168.36, 230.27	
	Geometric Mean						
	Median	215.90		206.80		205.70	
		-1.19		3.96		-5.71	
	Q25, Q75	178.80, 258.10		184.80, 242.90		177.90, 264.55	
		-12.66, 6.60		-8.09, 12.39		-10.39, -0.18	
	Min, Max	89.8, 468.5		61.1, 651.7		21.1, 452.2	
		-48.0, 57.5		-38.6, 49.9		-40.3, 38.7	
	Mean (SD)	223.08 (72.252)		216.76 (96.212)		214.41 (75.124)	
		-2.99 (20.651)		1.86 (16.838)		-4.88 (13.883)	
	95% CI	206.79, 239.38		186.77, 246.74		190.37, 238.44	
		-7.65, 1.67		-3.39, 7.11		-9.33, -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 10 AM on Day 1 in the SA arm

**Table 15.2.4.30.2 Descriptive Statistics of sICAM (units) - FAS****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	197.15 (36.91)		197.72 (50.54)		194.40 (51.49)	
	95% CI of Geometric Mean	181.88, 213.70		170.41, 229.41		166.46, 227.02	
	Median	194.95	-10.49	202.65	-2.78	197.55	-7.41
	Q25, Q75	167.50, 234.40	-24.13, -1.44	177.40, 259.20	-11.78, 8.47	175.05, 264.60	-22.29, 7.90
	Min, Max	74.8, 514.1	-59.0, 104.1	52.9, 655.7	-37.2, 111.1	21.1, 470.7	-51.6, 91.2
	Mean (SD)	209.79 (76.848)	-7.65 (30.204)	219.38 (104.008)	2.54 (27.336)	211.82 (77.163)	-2.54 (32.276)
	95% CI	192.46, 227.12	-14.46, -0.83	186.97, 251.80	-5.99, 11.06	187.13, 236.50	-12.87, 7.79

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 15.2.4.30.2 Descriptive Statistics of sICAM (units) - FAS****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	181.35 (35.66)		174.43 (48.19)		174.48 (45.15)	
	95% CI of Geometric Mean	167.73, 196.06		151.28, 201.13		152.02, 200.25	
	Median	179.20	-16.31	184.90	-9.08	177.85	-14.50
	Q25, Q75	159.60, 219.60	-32.85, -7.67	153.40, 210.70	-23.90, -0.09	158.05, 229.50	-28.82, 1.45
	Min, Max	72.4, 388.5	-61.8, 69.4	52.7, 841.9	-46.0, 53.0	21.1, 302.7	-58.3, 42.9
	Mean (SD)	191.77 (63.107)	-15.38 (25.673)	194.72 (117.417)	-9.53 (22.415)	186.18 (55.510)	-13.43 (23.408)
	95% CI	177.54, 206.01	-21.18, -9.59	158.12, 231.31	-16.52, -2.54	168.42, 203.94	-20.92, -5.94

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.30.2 Descriptive Statistics of sICAM (units) - FAS****Parameter: Intercellular Adhesion Molecule 1 (ng/mL)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	78	42	42	40	40
	Geometric Mean (CV%)	187.22 (31.76)		188.36 (46.19)		176.76 (46.84)	
	95% CI of Geometric Mean	174.58, 200.78		164.24, 216.03		153.29, 203.82	
	Median	183.70	-11.98	196.70	-1.41	184.90	-11.07
	Q25, Q75	159.60, 219.60	-22.68, -4.77	175.80, 240.30	-9.37, 3.39	162.05, 210.65	-26.77, -1.81
	Min, Max	61.2, 444.2	-54.2, 25.5	55.0, 559.0	-45.4, 21.1	21.1, 362.1	-53.1, 48.5
	Mean (SD)	196.01 (60.367)	-14.61 (16.554)	205.36 (85.810)	-3.92 (14.047)	189.60 (59.783)	-13.38 (19.369)
	95% CI	182.40, 209.63	-18.35, -10.88	178.61, 232.10	-8.31, 0.46	170.48, 208.72	-19.58, -7.19

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Leukocytes (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	5.777 (21.93)		5.612 (23.91)		6.221 (29.87)	
	95% CI of Geometric Mean	5.497, 6.071		5.214, 6.040		5.658, 6.840	
	Median	5.905		5.660		6.260	
	Q25, Q75	5.215, 6.645		4.920, 6.630		4.850, 7.410	
	Min, Max	3.10, 8.68		2.99, 9.52		3.34, 12.40	
	Mean (SD)	5.905 (1.1930)		5.763 (1.3370)		6.488 (1.9510)	
	95% CI	5.632, 6.178		5.346, 6.180		5.855, 7.120	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Leukocytes (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		76	76	42	42	39	39
Confinement							
	Geometric Mean (CV%)	6.056 (21.20)		5.947 (23.72)		5.742 (27.12)	
	95% CI of Geometric Mean	5.772, 6.354		5.528, 6.397		5.266, 6.260	
	Median	6.170	6.75	6.215	7.30	5.740	-6.93
	Q25, Q75	5.360, 7.080	-4.57, 15.02	5.300, 6.940	-3.73, 16.05	4.810, 6.670	-25.15, 8.95
	Min, Max	2.96, 9.04	-41.8, 53.0	3.47, 9.92	-18.2, 35.8	2.50, 10.30	-35.7, 71.1
	Mean (SD)	6.184 (1.2340)	6.34 (17.949)	6.101 (1.3620)	6.79 (13.401)	5.942 (1.6070)	-5.49 (21.572)
	95% CI	5.901, 6.466	2.23, 10.45	5.677, 6.526	2.61, 10.97	5.421, 6.463	-12.49, 1.51

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Leukocytes (GI/L)

Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	5.765 (22.09)		5.613 (24.21)		6.221 (29.87)	
	95% CI of Geometric Mean	5.480, 6.065		5.205, 6.052		5.658, 6.840	
	Median	5.905		5.680		6.260	
	Q25, Q75	5.140, 6.640		4.920, 6.630		4.850, 7.410	
	Min, Max	3.10, 8.68		2.99, 9.52		3.34, 12.40	
	Mean (SD)	5.895 (1.2000)		5.767 (1.3530)		6.488 (1.9510)	
	95% CI	5.617, 6.173		5.340, 6.195		5.855, 7.120	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Leukocytes (GI/L)

Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	5.504 (21.51)		5.628 (25.54)		5.824 (24.52)	
	95% CI of Geometric Mean	5.239, 5.782		5.199, 6.094		5.385, 6.299	
	Median	5.535	-1.95	5.810	-0.14	5.700	-2.11
	Q25, Q75	4.850, 6.390	-14.38, 9.40	5.020, 6.750	-7.11, 9.50	4.770, 6.700	-21.72, 12.50
	Min, Max	3.07, 8.00	-43.4, 29.4	2.85, 9.88	-22.3, 33.0	3.90, 10.04	-61.1, 53.4
	Mean (SD)	5.625 (1.1620)	-3.20 (15.678)	5.796 (1.3820)	1.16 (13.627)	5.996 (1.5130)	-3.41 (23.164)
	95% CI	5.355, 5.895	-6.84, 0.44	5.360, 6.233	-3.15, 5.46	5.505, 6.487	-10.93, 4.10

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

Appendix: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Leukocytes (GI/L)

Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	5.754 (22.55)		5.613 (24.21)		6.148 (29.27)	
	95% CI of Geometric Mean	5.458, 6.066		5.205, 6.052		5.594, 6.756	
	Median	5.900		5.680		6.200	
	Q25, Q75	5.100, 6.650		4.920, 6.630		4.850, 7.300	
	Min, Max	3.10, 8.68		2.99, 9.52		3.34, 12.40	
	Mean (SD)	5.889 (1.2250)		5.767 (1.3530)		6.402 (1.9010)	
	95% CI	5.599, 6.180		5.340, 6.195		5.777, 7.027	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Leukocytes (GI/L)

Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	5.480 (24.12)		5.627 (28.35)		5.773 (25.86)	
	95% CI of Geometric Mean	5.179, 5.798		5.154, 6.144		5.310, 6.277	
	Median	5.580	-3.59	5.690	-2.35	5.890	-0.83
	Q25, Q75	4.710, 6.240	-14.58, 9.03	4.990, 6.570	-10.15, 15.18	4.770, 6.920	-17.41, 11.61
	Min, Max	2.88, 11.78	-62.2, 63.7	2.75, 10.84	-30.4, 95.3	3.16, 11.05	-54.1, 45.6
	Mean (SD)	5.635 (1.3850)	-2.57 (20.450)	5.837 (1.5970)	2.24 (22.030)	5.961 (1.5800)	-3.06 (23.664)
	95% CI	5.307, 5.963	-7.41, 2.28	5.333, 6.341	-4.72, 9.19	5.442, 6.481	-10.84, 4.73

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Leukocytes (GI/L)

Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	5.760 (22.61)		5.613 (24.21)		6.137 (29.66)	
	95% CI of Geometric Mean	5.461, 6.075		5.205, 6.052		5.570, 6.761	
	Median	5.905		5.680		6.140	
	Q25, Q75	5.100, 6.650		4.920, 6.630		4.850, 7.300	
	Min, Max	3.10, 8.68		2.99, 9.52		3.34, 12.40	
	Mean (SD)	5.895 (1.2270)		5.767 (1.3530)		6.397 (1.9270)	
	95% CI	5.603, 6.188		5.340, 6.195		5.754, 7.040	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Leukocytes (GI/L)

Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		70	70	41	41	37	37
	Geometric Mean (CV%)	5.403 (23.14)		5.848 (26.83)		5.759 (26.37)	
	95% CI of Geometric Mean	5.116, 5.706		5.381, 6.356		5.281, 6.279	
	Median	5.545	-5.85	5.680	1.85	6.040	-5.27
	Q25, Q75	4.890, 6.190	-14.41, 5.57	5.360, 6.540	-5.49, 14.05	4.760, 6.810	-22.02, 12.32
	Min, Max	2.75, 9.38	-61.6, 44.6	2.83, 10.23	-24.3, 64.7	3.01, 10.11	-62.3, 95.3
	Mean (SD)	5.538 (1.2150)	-4.42 (18.000)	6.044 (1.5680)	5.97 (20.452)	5.943 (1.4830)	-2.05 (29.403)
	95% CI	5.248, 5.828	-8.72, -0.12	5.549, 6.540	-0.49, 12.43	5.448, 6.438	-11.85, 7.76

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Neutrophils (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	3.206 (35.13)		3.099 (29.62)		3.504 (45.31)	
	95% CI of Geometric Mean	2.965, 3.466		2.831, 3.393		3.045, 4.031	
	Median	3.310		3.035		3.600	
	Q25, Q75	2.610, 4.070		2.740, 3.600		2.570, 4.640	
	Min, Max	1.17, 6.20		1.47, 5.63		1.37, 9.73	
	Mean (SD)	3.380 (1.0420)		3.226 (0.9340)		3.838 (1.7230)	
	95% CI	3.141, 3.618		2.935, 3.518		3.279, 4.397	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Neutrophils (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		76	76	42	42	39	39
Confinement							
	Geometric Mean	3.246 (30.37)		3.377 (31.66)		3.285 (40.73)	
	(CV%)						
	95% CI of	3.032, 3.474		3.066, 3.719		2.893, 3.730	
	Geometric Mean						
	Median	3.420	2.54	3.545	10.46	3.260	-5.86
	Q25, Q75	2.735, 4.040	-10.49, 15.41	2.850, 4.260	0.66, 22.28	2.530, 4.140	-23.43, 11.93
	Min, Max	1.47, 5.74	-62.2, 93.9	1.64, 6.09	-33.0, 61.4	1.05, 7.98	-52.4, 97.5
	Mean (SD)	3.383 (0.9490)	4.71 (27.187)	3.531 (1.0350)	11.01 (21.295)	3.541 (1.4590)	-2.16 (30.034)
	95% CI	3.166, 3.601	-1.51, 10.92	3.208, 3.854	4.37, 17.65	3.067, 4.014	-11.90, 7.59

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Neutrophils (GI/L)
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	3.197 (35.48)		3.106 (29.96)		3.504 (45.31)	
	95% CI of Geometric Mean	2.951, 3.463		2.831, 3.408		3.045, 4.031	
	Median	3.310		3.040		3.600	
	Q25, Q75	2.600, 4.070		2.740, 3.600		2.570, 4.640	
	Min, Max	1.17, 6.20		1.47, 5.63		1.37, 9.73	
	Mean (SD)	3.374 (1.0510)		3.236 (0.9430)		3.838 (1.7230)	
	95% CI	3.130, 3.618		2.938, 3.534		3.279, 4.397	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Neutrophils (GI/L)
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	2.864 (35.03)		2.989 (34.30)		3.135 (36.04)	
	95% CI of Geometric Mean	2.646, 3.099		2.690, 3.321		2.798, 3.511	
	Median	2.940	-6.46	2.980	-3.17	3.000	-10.05
	Q25, Q75	2.320, 3.680	-23.04, 3.75	2.400, 3.940	-16.38, 7.89	2.390, 3.840	-29.13, 15.35
	Min, Max	1.19, 5.51	-78.6, 66.1	1.21, 5.20	-34.3, 72.8	1.94, 7.79	-75.1, 118.8
	Mean (SD)	3.024 (0.9780)	-6.83 (24.897)	3.146 (0.9870)	-1.44 (23.197)	3.340 (1.3090)	-3.62 (37.464)
	95% CI	2.797, 3.251	-12.60, -1.05	2.834, 3.458	-8.77, 5.88	2.915, 3.764	-15.77, 8.53

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 10 AM on Day 1 in the SA arm

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Neutrophils (GI/L)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	3.174 (35.92)		3.106 (29.96)		3.453 (44.86)	
	95% CI of Geometric Mean	2.922, 3.447		2.831, 3.408		3.000, 3.976	
	Median	3.300		3.040		3.580	
	Q25, Q75	2.550, 4.070		2.740, 3.600		2.570, 4.570	
	Min, Max	1.17, 6.20		1.47, 5.63		1.37, 9.73	
	Mean (SD)	3.354 (1.0620)		3.236 (0.9430)		3.779 (1.7050)	
	95% CI	3.102, 3.606		2.938, 3.534		3.218, 4.340	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Neutrophils (GI/L)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	2.868 (37.23)		3.065 (38.35)		3.055 (36.49)	
	95% CI of Geometric Mean	2.633, 3.124		2.726, 3.446		2.720, 3.432	
	Median	2.960	-5.25	3.030	-5.12	2.965	-9.09
	Q25, Q75	2.380, 3.510	-25.73, 3.79	2.550, 3.990	-14.93, 6.33	2.440, 3.710	-32.52, 14.13
	Min, Max	1.01, 9.46	-81.8, 120.0	1.10, 8.07	-42.8, 139.5	1.40, 7.63	-71.1, 104.6
	Mean (SD)	3.063 (1.2400)	-4.43 (33.371)	3.273 (1.2520)	2.53 (32.162)	3.253 (1.2420)	-5.32 (34.748)
	95% CI	2.769, 3.357	-12.33, 3.48	2.878, 3.669	-7.62, 12.69	2.844, 3.661	-16.75, 6.11

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Neutrophils (GI/L)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	3.208 (35.59)		3.106 (29.96)		3.454 (45.54)	
	95% CI of Geometric Mean	2.954, 3.484		2.831, 3.408		2.988, 3.992	
	Median	3.310		3.040		3.600	
	Q25, Q75	2.600, 4.070		2.740, 3.600		2.570, 4.570	
	Min, Max	1.17, 6.20		1.47, 5.63		1.37, 9.73	
	Mean (SD)	3.387 (1.0600)		3.236 (0.9430)		3.788 (1.7280)	
	95% CI	3.134, 3.640		2.938, 3.534		3.212, 4.365	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Neutrophils (GI/L)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		70	70	41	41	37	37
	Geometric Mean (CV%)	2.796 (34.66)		3.161 (36.82)		2.965 (40.04)	
	95% CI of Geometric Mean	2.579, 3.030		2.824, 3.538		2.607, 3.372	
	Median	2.895	-12.22	2.930	1.74	3.210	-14.60
	Q25, Q75	2.170, 3.530	-22.95, 3.85	2.610, 3.730	-17.11, 14.01	2.430, 3.740	-30.85, 12.18
	Min, Max	1.32, 7.42	-75.0, 97.0	1.17, 6.72	-38.7, 121.9	1.17, 6.84	-76.4, 179.9
	Mean (SD)	2.954 (1.0150)	-9.36 (25.732)	3.366 (1.2650)	5.92 (33.229)	3.175 (1.1760)	-4.92 (48.098)
	95% CI	2.712, 3.197	-15.51, -3.22	2.966, 3.766	-4.57, 16.42	2.783, 3.568	-20.96, 11.12

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Lymphocytes (GI/L)
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	2.003 (25.67)		1.957 (26.79)		2.093 (23.00)	
	95% CI of Geometric Mean	1.890, 2.123		1.803, 2.125		1.944, 2.254	
	Median	2.040		1.895		2.080	
	Q25, Q75	1.755, 2.350		1.670, 2.290		1.790, 2.440	
	Min, Max	1.01, 3.39		1.24, 3.40		1.36, 3.14	
	Mean (SD)	2.065 (0.5070)		2.026 (0.5560)		2.147 (0.4930)	
	95% CI	1.949, 2.181		1.852, 2.200		1.986, 2.307	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Lymphocytes (GI/L)
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		76	76	42	42	39	39
Confinement							
	Geometric Mean	2.258 (23.68)		1.986 (24.12)		1.920 (21.32)	
	(CV%)						
	95% CI of	2.140, 2.382		1.844, 2.140		1.793, 2.057	
	Geometric Mean						
	Median	2.255	11.35	1.945	0.74	1.900	-6.06
	Q25, Q75	1.935, 2.650	-0.45, 29.08	1.710, 2.270	-5.10, 10.90	1.710, 2.230	-28.69, 14.29
	Min, Max	1.24, 3.94	-38.1, 85.0	1.28, 3.21	-23.5, 29.4	1.09, 2.76	-41.2, 57.3
	Mean (SD)	2.319 (0.5470)	14.81 (22.308)	2.042 (0.4930)	2.24 (12.585)	1.961 (0.4020)	-4.59 (27.120)
	95% CI	2.194, 2.444	9.71, 19.91	1.888, 2.196	-1.69, 6.16	1.831, 2.092	-13.38, 4.21

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 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Lymphocytes (GI/L)
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	1.999 (25.96)		1.950 (27.01)		2.093 (23.00)	
	95% CI of Geometric Mean	1.884, 2.121		1.793, 2.121		1.944, 2.254	
	Median	2.040		1.890		2.080	
	Q25, Q75	1.720, 2.350		1.670, 2.230		1.790, 2.440	
	Min, Max	1.01, 3.39		1.24, 3.40		1.36, 3.14	
	Mean (SD)	2.063 (0.5130)		2.020 (0.5620)		2.147 (0.4930)	
	95% CI	1.943, 2.182		1.842, 2.197		1.986, 2.307	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Lymphocytes (GI/L)
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	2.073 (25.80)		2.002 (32.00)		2.120 (18.48)	
	95% CI of Geometric Mean	1.954, 2.199		1.814, 2.210		1.997, 2.250	
	Median	2.080	4.04	2.010	0.68	2.140	4.71
	Q25, Q75	1.760, 2.450	-6.21, 18.66	1.640, 2.440	-11.11, 11.64	1.850, 2.420	-15.95, 17.83
	Min, Max	0.70, 3.38	-38.6, 55.8	1.09, 4.38	-34.5, 67.0	1.32, 3.05	-46.0, 82.8
	Mean (SD)	2.135 (0.5040)	5.50 (19.497)	2.101 (0.6860)	4.60 (21.235)	2.154 (0.3880)	4.34 (26.556)
	95% CI	2.018, 2.253	0.98, 10.02	1.884, 2.318	-2.11, 11.31	2.028, 2.280	-4.27, 12.95

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Lymphocytes (GI/L)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	2.017 (25.51)		1.950 (27.01)		2.079 (22.90)	
	95% CI of Geometric Mean	1.900, 2.141		1.793, 2.121		1.930, 2.240	
	Median	2.060		1.890		2.065	
	Q25, Q75	1.720, 2.350		1.670, 2.230		1.790, 2.420	
	Min, Max	1.01, 3.39		1.24, 3.40		1.36, 3.14	
	Mean (SD)	2.079 (0.5110)		2.020 (0.5620)		2.132 (0.4910)	
	95% CI	1.958, 2.201		1.842, 2.197		1.970, 2.294	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Lymphocytes (GI/L)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	2.052 (26.55)		1.943 (26.85)		2.149 (22.06)	
	95% CI of Geometric Mean	1.928, 2.183		1.787, 2.112		2.000, 2.310	
	Median	2.050	3.33	1.920	1.99	2.205	3.11
	Q25, Q75	1.690, 2.480	-13.78, 18.40	1.680, 2.310	-11.11, 12.17	1.790, 2.550	-15.28, 20.62
	Min, Max	0.83, 3.46	-50.5, 54.5	1.08, 3.43	-50.0, 63.1	1.49, 3.18	-38.3, 83.1
	Mean (SD)	2.119 (0.5330)	3.81 (20.731)	2.009 (0.5240)	1.78 (20.873)	2.199 (0.4780)	6.53 (27.280)
	95% CI	1.993, 2.246	-1.10, 8.72	1.843, 2.175	-4.81, 8.37	2.042, 2.357	-2.45, 15.50

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Lymphocytes (GI/L)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	1.984 (26.13)		1.950 (27.01)		2.064 (22.76)	
	95% CI of Geometric Mean	1.866, 2.110		1.793, 2.121		1.915, 2.225	
	Median	2.020		1.890		2.050	
	Q25, Q75	1.710, 2.350		1.670, 2.230		1.790, 2.420	
	Min, Max	1.01, 3.39		1.24, 3.40		1.36, 3.14	
	Mean (SD)	2.048 (0.5130)		2.020 (0.5620)		2.116 (0.4880)	
	95% CI	1.926, 2.171		1.842, 2.197		1.953, 2.279	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Lymphocytes (GI/L)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		70	70	41	41	37	37
	Geometric Mean (CV%)	2.054 (26.86)		2.003 (29.39)		2.223 (20.23)	
	95% CI of Geometric Mean	1.929, 2.188		1.828, 2.194		2.079, 2.377	
	Median	2.075	5.61	2.030	2.36	2.110	7.33
	Q25, Q75	1.730, 2.530	-8.95, 19.30	1.690, 2.410	-5.11, 16.99	1.930, 2.490	-6.22, 28.93
	Min, Max	0.91, 3.32	-38.2, 67.7	1.09, 3.44	-29.5, 69.0	1.58, 3.42	-25.2, 79.1
	Mean (SD)	2.123 (0.5360)	5.88 (22.586)	2.082 (0.5730)	4.60 (20.536)	2.268 (0.4710)	10.04 (23.497)
	95% CI	1.995, 2.252	0.49, 11.27	1.901, 2.263	-1.89, 11.08	2.111, 2.425	2.20, 17.88

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Monocytes (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	0.277 (29.35)		0.276 (30.21)		0.306 (35.38)	
	95% CI of Geometric Mean	0.259, 0.296		0.252, 0.304		0.273, 0.342	
	Median	0.290		0.275		0.300	
	Q25, Q75	0.220, 0.340		0.230, 0.330		0.240, 0.380	
	Min, Max	0.12, 0.51		0.14, 0.55		0.16, 0.68	
	Mean (SD)	0.288 (0.0790)		0.289 (0.0880)		0.324 (0.1210)	
	95% CI	0.269, 0.306		0.261, 0.316		0.285, 0.364	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Monocytes (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		76	76	42	42	39	39
Confinement							
	Geometric Mean	0.296 (35.15)		0.300 (26.02)		0.260 (33.93)	
	(CV%)						
	95% CI of	0.273, 0.320		0.276, 0.325		0.233, 0.290	
	Geometric Mean						
	Median	0.300	6.78	0.300	9.84	0.270	-12.82
	Q25, Q75	0.250, 0.365	-13.90, 33.63	0.260, 0.360	-12.90, 30.00	0.210, 0.340	-29.69, 4.35
	Min, Max	0.14, 0.67	-55.6, 109.4	0.13, 0.57	-35.0, 103.6	0.09, 0.45	-50.0, 45.0
	Mean (SD)	0.313 (0.1110)	12.07 (34.640)	0.309 (0.0790)	12.08 (29.754)	0.273 (0.0790)	-12.29 (21.727)
	95% CI	0.287, 0.339	4.15, 20.00	0.284, 0.334	2.80, 21.35	0.247, 0.298	-19.34, -5.24

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 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Monocytes (GI/L)

Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	0.277 (29.72)		0.275 (30.46)		0.306 (35.38)	
	95% CI of Geometric Mean	0.258, 0.296		0.250, 0.303		0.273, 0.342	
	Median	0.290		0.270		0.300	
	Q25, Q75	0.220, 0.340		0.230, 0.320		0.240, 0.380	
	Min, Max	0.12, 0.51		0.14, 0.55		0.16, 0.68	
	Mean (SD)	0.288 (0.0800)		0.288 (0.0890)		0.324 (0.1210)	
	95% CI	0.269, 0.307		0.259, 0.316		0.285, 0.364	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Monocytes (GI/L)

Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	0.274 (35.15)		0.288 (39.42)		0.289 (33.74)	
	95% CI of Geometric Mean	0.253, 0.297		0.255, 0.325		0.259, 0.322	
	Median	0.285	-1.32	0.280	5.00	0.290	-3.70
	Q25, Q75	0.220, 0.350	-18.42, 23.08	0.240, 0.380	-9.68, 17.39	0.220, 0.380	-17.39, 3.33
	Min, Max	0.10, 0.52	-50.0, 73.9	0.10, 0.55	-56.5, 130.0	0.13, 0.72	-54.7, 75.0
	Mean (SD)	0.290 (0.0950)	3.12 (29.524)	0.308 (0.1120)	8.05 (29.153)	0.304 (0.1060)	-1.81 (27.394)
	95% CI	0.267, 0.312	-3.73, 9.97	0.272, 0.344	-1.15, 17.26	0.270, 0.339	-10.70, 7.07

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Monocytes (GI/L)

Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	0.276 (29.46)		0.275 (30.46)		0.299 (33.00)	
	95% CI of Geometric Mean	0.257, 0.296		0.250, 0.303		0.269, 0.333	
	Median	0.290		0.270		0.295	
	Q25, Q75	0.220, 0.340		0.230, 0.320		0.240, 0.350	
	Min, Max	0.12, 0.51		0.14, 0.55		0.16, 0.64	
	Mean (SD)	0.287 (0.0790)		0.288 (0.0890)		0.315 (0.1070)	
	95% CI	0.267, 0.306		0.259, 0.316		0.280, 0.350	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Monocytes (GI/L)

Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	0.267 (32.89)		0.295 (35.00)		0.263 (27.69)	
	95% CI of Geometric Mean	0.247, 0.288		0.265, 0.329		0.240, 0.288	
	Median	0.270	-11.76	0.290	5.88	0.260	-9.60
	Q25, Q75	0.210, 0.330	-20.83, 18.18	0.240, 0.340	-6.45, 28.57	0.220, 0.310	-33.33, 7.14
	Min, Max	0.11, 0.64	-44.4, 80.8	0.16, 0.76	-35.0, 60.0	0.14, 0.55	-59.4, 243.8
	Mean (SD)	0.281 (0.0940)	0.37 (28.371)	0.314 (0.1240)	10.12 (24.956)	0.273 (0.0770)	-4.60 (48.845)
	95% CI	0.258, 0.303	-6.35, 7.09	0.274, 0.354	2.24, 18.00	0.247, 0.299	-20.66, 11.46

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Monocytes (GI/L)

Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	0.279 (29.85)		0.275 (30.46)		0.304 (31.93)	
	95% CI of Geometric Mean	0.259, 0.299		0.250, 0.303		0.273, 0.338	
	Median	0.290		0.270		0.300	
	Q25, Q75	0.220, 0.340		0.230, 0.320		0.250, 0.350	
	Min, Max	0.12, 0.51		0.14, 0.55		0.16, 0.64	
	Mean (SD)	0.290 (0.0810)		0.288 (0.0890)		0.319 (0.1060)	
	95% CI	0.270, 0.310		0.259, 0.316		0.283, 0.354	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Monocytes (GI/L)

Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		70	70	41	41	37	37
	Geometric Mean (CV%)	0.280 (34.04)		0.322 (40.70)		0.279 (35.19)	
	95% CI of Geometric Mean	0.258, 0.303		0.284, 0.365		0.249, 0.314	
	Median	0.290	2.27	0.320	16.13	0.280	-3.85
	Q25, Q75	0.220, 0.330	-17.65, 18.75	0.250, 0.420	-9.68, 40.74	0.220, 0.370	-26.42, 20.00
	Min, Max	0.10, 0.63	-44.7, 96.9	0.12, 0.77	-25.0, 92.9	0.12, 0.48	-65.6, 100.0
	Mean (SD)	0.295 (0.0990)	3.89 (28.169)	0.347 (0.1380)	21.49 (34.404)	0.295 (0.0930)	-0.08 (40.954)
	95% CI	0.271, 0.319	-2.83, 10.61	0.303, 0.391	10.62, 32.35	0.263, 0.326	-13.74, 13.58

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Eosinophils (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	0.108 (57.89)		0.143 (65.57)		0.114 (59.23)	
	95% CI of Geometric Mean	0.095, 0.123		0.119, 0.173		0.095, 0.137	
	Median	0.100		0.160		0.120	
	Q25, Q75	0.080, 0.170		0.080, 0.250		0.070, 0.160	
	Min, Max	0.04, 0.37		0.04, 0.38		0.03, 0.28	
	Mean (SD)	0.125 (0.0710)		0.169 (0.0940)		0.131 (0.0680)	
	95% CI	0.109, 0.142		0.139, 0.198		0.109, 0.153	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Eosinophils (GI/L)
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		76	76	42	42	39	39
Confinement							
	Geometric Mean (CV%)	0.100 (54.74)		0.144 (55.33)		0.107 (55.07)	
	95% CI of Geometric Mean	0.088, 0.112		0.122, 0.170		0.090, 0.127	
	Median	0.100	-7.92	0.145	2.63	0.110	-3.70
	Q25, Q75	0.070, 0.140	-22.47, 12.50	0.110, 0.230	-25.00, 25.00	0.070, 0.160	-25.00, 22.22
	Min, Max	0.04, 0.32	-65.5, 72.7	0.05, 0.33	-51.4, 75.0	0.03, 0.29	-53.8, 133.3
	Mean (SD)	0.113 (0.0600)	-3.89 (28.935)	0.163 (0.0780)	5.50 (31.995)	0.121 (0.0600)	0.23 (38.434)
	95% CI	0.099, 0.127	-10.51, 2.73	0.138, 0.188	-4.48, 15.47	0.101, 0.141	-12.23, 12.69

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Eosinophils (GI/L)

Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	0.107 (57.78)		0.146 (65.59)		0.114 (59.23)	
	95% CI of Geometric Mean	0.094, 0.121		0.120, 0.176		0.095, 0.137	
	Median	0.100		0.160		0.120	
	Q25, Q75	0.080, 0.160		0.090, 0.250		0.070, 0.160	
	Min, Max	0.04, 0.37		0.04, 0.38		0.03, 0.28	
	Mean (SD)	0.123 (0.0710)		0.171 (0.0940)		0.131 (0.0680)	
	95% CI	0.107, 0.140		0.141, 0.201		0.109, 0.153	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Eosinophils (GI/L)
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	0.111 (54.20)		0.172 (52.79)		0.130 (63.38)	
	95% CI of Geometric Mean	0.099, 0.126		0.147, 0.202		0.107, 0.157	
	Median	0.115	2.27	0.190	10.71	0.130	8.33
	Q25, Q75	0.080, 0.160	-11.11, 27.27	0.120, 0.270	-2.94, 42.11	0.090, 0.200	-8.33, 50.00
	Min, Max	0.04, 0.33	-72.2, 144.4	0.06, 0.36	-31.6, 175.0	0.03, 0.53	-69.2, 430.0
	Mean (SD)	0.126 (0.0630)	12.90 (44.752)	0.192 (0.0840)	24.53 (44.828)	0.153 (0.0960)	25.55 (75.055)
	95% CI	0.111, 0.141	2.53, 23.27	0.165, 0.219	10.37, 38.68	0.121, 0.184	1.22, 49.89

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Eosinophils (GI/L)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	0.106 (54.81)		0.146 (65.59)		0.113 (59.66)	
	95% CI of Geometric Mean	0.093, 0.120		0.120, 0.176		0.094, 0.136	
	Median	0.100		0.160		0.115	
	Q25, Q75	0.080, 0.160		0.090, 0.250		0.070, 0.160	
	Min, Max	0.04, 0.37		0.04, 0.38		0.03, 0.28	
	Mean (SD)	0.121 (0.0660)		0.171 (0.0940)		0.130 (0.0690)	
	95% CI	0.105, 0.137		0.141, 0.201		0.107, 0.153	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Eosinophils (GI/L)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	0.110 (56.27)		0.165 (60.84)		0.133 (84.98)	
	95% CI of Geometric Mean	0.096, 0.124		0.138, 0.198		0.104, 0.169	
	Median	0.120	0.00	0.170	10.71	0.130	5.21
	Q25, Q75	0.070, 0.170	-25.00, 44.44	0.110, 0.240	0.00, 40.00	0.080, 0.210	-16.67, 66.67
	Min, Max	0.03, 0.26	-58.3, 300.0	0.05, 0.42	-45.9, 137.5	0.03, 1.84	-59.1, 1740.0
	Mean (SD)	0.124 (0.0590)	14.41 (57.739)	0.191 (0.1040)	19.25 (38.912)	0.191 (0.2880)	62.89 (283.219)
	95% CI	0.110, 0.138	0.74, 28.08	0.158, 0.224	6.96, 31.54	0.096, 0.286	-30.21, 155.99

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

Program: T1502043101_ZRHM_REXA_07_JP_V4.sas

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Eosinophils (GI/L)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	0.106 (58.96)		0.146 (65.59)		0.113 (60.56)	
	95% CI of Geometric Mean	0.092, 0.121		0.120, 0.176		0.093, 0.136	
	Median	0.100		0.160		0.110	
	Q25, Q75	0.080, 0.160		0.090, 0.250		0.070, 0.160	
	Min, Max	0.04, 0.37		0.04, 0.38		0.03, 0.28	
	Mean (SD)	0.123 (0.0720)		0.171 (0.0940)		0.130 (0.0700)	
	95% CI	0.105, 0.141		0.141, 0.201		0.106, 0.154	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

Program: T1502043101_ZRHM_REXA_07_JP_V4.sas

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Eosinophils (GI/L)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		70	70	41	41	37	37
	Geometric Mean (CV%)	0.107 (54.65)		0.169 (64.10)		0.120 (79.75)	
	95% CI of Geometric Mean	0.094, 0.121		0.140, 0.204		0.095, 0.152	
	Median	0.110	2.27	0.170	16.67	0.120	0.00
	Q25, Q75	0.080, 0.150	-25.00, 30.00	0.110, 0.250	-6.90, 37.50	0.080, 0.200	-25.00, 30.77
	Min, Max	0.03, 0.36	-68.4, 150.0	0.05, 0.52	-40.0, 120.0	0.03, 0.90	-76.9, 800.0
	Mean (SD)	0.121 (0.0630)	8.89 (43.042)	0.198 (0.1130)	21.40 (36.806)	0.155 (0.1450)	38.97 (152.486)
	95% CI	0.106, 0.136	-1.38, 19.16	0.162, 0.234	9.77, 33.02	0.106, 0.204	-11.88, 89.82

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Basophils (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	0.045 (38.86)		0.048 (53.16)		0.043 (60.48)	
	95% CI of Geometric Mean	0.041, 0.049		0.040, 0.056		0.036, 0.053	
	Median	0.050		0.050		0.050	
	Q25, Q75	0.040, 0.055		0.040, 0.070		0.030, 0.060	
	Min, Max	0.02, 0.11		0.00, 0.10		0.00, 0.10	
	Mean (SD)	0.048 (0.0190)		0.051 (0.0230)		0.048 (0.0260)	
	95% CI	0.043, 0.053		0.044, 0.059		0.040, 0.057	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

Program: T1502043101_ZRHM_REXA_07_JP_V4.sas

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Basophils (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		76	76	42	42	39	39
Confinement							
	Geometric Mean (CV%)	0.052 (39.78)		0.051 (46.55)		0.043 (40.31)	
	95% CI of Geometric Mean	0.047, 0.057		0.044, 0.060		0.037, 0.049	
	Median	0.050	25.00	0.050	0.00	0.040	0.00
	Q25, Q75	0.040, 0.070	-4.55, 40.00	0.040, 0.070	0.00, 33.33	0.030, 0.060	-22.22, 20.00
	Min, Max	0.02, 0.12	-50.0, 250.0	0.01, 0.10	-60.0, 300.0	0.00, 0.09	-60.0, 200.0
	Mean (SD)	0.056 (0.0220)	21.69 (43.039)	0.056 (0.0220)	15.16 (53.954)	0.045 (0.0190)	9.26 (55.657)
	95% CI	0.050, 0.061	11.85, 31.53	0.049, 0.063	-1.65, 31.98	0.038, 0.051	-8.79, 27.31

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: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Basophils (GI/L)

Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	0.044 (38.72)		0.047 (53.76)		0.043 (60.48)	
	95% CI of Geometric Mean	0.040, 0.049		0.040, 0.056		0.036, 0.053	
	Median	0.045		0.050		0.050	
	Q25, Q75	0.040, 0.050		0.040, 0.070		0.030, 0.060	
	Min, Max	0.02, 0.11		0.00, 0.10		0.00, 0.10	
	Mean (SD)	0.048 (0.0190)		0.051 (0.0240)		0.048 (0.0260)	
	95% CI	0.043, 0.052		0.043, 0.059		0.040, 0.057	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Basophils (GI/L)

Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	0.047 (39.84)		0.046 (52.34)		0.046 (42.00)	
	95% CI of Geometric Mean	0.042, 0.052		0.039, 0.054		0.040, 0.053	
	Median	0.050	0.00	0.040	0.00	0.050	-11.11
	Q25, Q75	0.040, 0.060	0.00, 25.00	0.040, 0.070	-22.22, 20.00	0.030, 0.060	-28.57, 50.00
	Min, Max	0.01, 0.13	-50.0, 160.0	0.01, 0.14	-57.1, 100.0	0.00, 0.09	-50.0, 400.0
	Mean (SD)	0.050 (0.0190)	11.55 (39.507)	0.051 (0.0250)	0.67 (35.474)	0.048 (0.0200)	25.80 (95.833)
	95% CI	0.045, 0.055	2.39, 20.70	0.043, 0.060	-10.53, 11.87	0.041, 0.055	-5.27, 56.87

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Basophils (GI/L)

Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	0.045 (38.53)		0.047 (53.76)		0.042 (59.19)	
	95% CI of Geometric Mean	0.041, 0.050		0.040, 0.056		0.035, 0.051	
	Median	0.050		0.050		0.045	
	Q25, Q75	0.040, 0.060		0.040, 0.070		0.030, 0.060	
	Min, Max	0.02, 0.11		0.00, 0.10		0.00, 0.10	
	Mean (SD)	0.049 (0.0190)		0.051 (0.0240)		0.047 (0.0240)	
	95% CI	0.044, 0.053		0.043, 0.059		0.038, 0.055	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Basophils (GI/L)

Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	0.045 (35.48)		0.045 (50.74)		0.041 (53.21)	
	95% CI of Geometric Mean	0.041, 0.049		0.038, 0.053		0.035, 0.049	
	Median	0.050	0.00	0.040	0.00	0.040	0.00
	Q25, Q75	0.040, 0.060	-20.00, 20.00	0.030, 0.070	-22.22, 16.67	0.030, 0.060	-25.00, 20.00
	Min, Max	0.02, 0.09	-60.0, 100.0	0.01, 0.16	-66.7, 100.0	0.02, 0.14	-60.0, 600.0
	Mean (SD)	0.048 (0.0170)	3.75 (31.213)	0.050 (0.0250)	-1.92 (31.555)	0.047 (0.0260)	17.95 (107.519)
	95% CI	0.043, 0.052	-3.64, 11.14	0.042, 0.059	-11.88, 8.05	0.038, 0.056	-17.40, 53.29

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

Appendix: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Basophils (GI/L)

Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	0.044 (39.49)		0.047 (53.76)		0.041 (57.69)	
	95% CI of Geometric Mean	0.040, 0.049		0.040, 0.056		0.034, 0.050	
	Median	0.040		0.050		0.040	
	Q25, Q75	0.040, 0.060		0.040, 0.070		0.030, 0.060	
	Min, Max	0.02, 0.11		0.00, 0.10		0.00, 0.09	
	Mean (SD)	0.048 (0.0190)		0.051 (0.0240)		0.045 (0.0230)	
	95% CI	0.043, 0.053		0.043, 0.059		0.037, 0.053	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Basophils (GI/L)

Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		70	70	41	41	37	37
	Geometric Mean (CV%)	0.043 (34.41)		0.046 (48.30)		0.045 (45.23)	
	95% CI of Geometric Mean	0.039, 0.047		0.039, 0.054		0.039, 0.053	
	Median	0.040	0.00	0.050	0.00	0.040	0.00
	Q25, Q75	0.030, 0.050	-25.00, 25.00	0.030, 0.060	-25.00, 20.00	0.030, 0.060	-22.22, 33.33
	Min, Max	0.02, 0.09	-44.4, 100.0	0.02, 0.27	-70.0, 200.0	0.00, 0.11	-33.3, 450.0
	Mean (SD)	0.045 (0.0160)	1.07 (34.708)	0.052 (0.0390)	1.48 (45.625)	0.048 (0.0230)	21.96 (81.912)
	95% CI	0.041, 0.049	-7.21, 9.35	0.040, 0.065	-12.92, 15.89	0.040, 0.056	-5.35, 49.28

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: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Platelets (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	221.2 (22.19)		222.9 (21.97)		233.9 (18.80)	
	95% CI of Geometric Mean	210.3, 232.6		208.2, 238.5		220.1, 248.5	
	Median	222.5		220.0		230.0	
	Q25, Q75	190.0, 256.5		196.0, 257.0		206.0, 277.0	
	Min, Max	140, 448		147, 363		167, 335	
	Mean (SD)	226.7 (53.90)		228.0 (50.05)		237.9 (44.75)	
	95% CI	214.4, 239.1		212.4, 243.7		223.3, 252.5	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Platelets (GI/L)

Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		76	76	42	42	39	39
Confinement							
	Geometric Mean	233.3 (21.78)		226.6 (20.55)		229.4 (20.94)	
	(CV%)						
	95% CI of	222.0, 245.1		212.6, 241.5		214.5, 245.4	
	Geometric Mean						
	Median	232.5	6.29	234.5	2.79	226.0	-2.17
	Q25, Q75	208.0, 264.0	-0.19, 10.77	189.0, 263.0	-5.23, 8.28	201.0, 263.0	-7.38, 3.86
	Min, Max	141, 465	-13.5, 33.3	144, 344	-15.8, 22.6	146, 386	-22.8, 32.4
	Mean (SD)	238.8 (53.80)	5.86 (9.340)	231.1 (45.99)	2.13 (9.625)	234.4 (50.45)	-1.40 (10.303)
	95% CI	226.4, 251.1	3.72, 8.00	216.8, 245.5	-0.87, 5.14	218.0, 250.8	-4.75, 1.94

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Platelets (GI/L)

Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	222.2 (22.10)		224.8 (21.50)		233.9 (18.80)	
	95% CI of Geometric Mean	211.2, 233.8		210.1, 240.4		220.1, 248.5	
	Median	222.5		226.0		230.0	
	Q25, Q75	191.0, 260.0		202.0, 257.0		206.0, 277.0	
	Min, Max	140, 448		147, 363		167, 335	
	Mean (SD)	227.7 (54.00)		229.8 (49.38)		237.9 (44.75)	
	95% CI	215.2, 240.3		214.1, 245.4		223.3, 252.5	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

Program: T1502043101_ZRHM_REXA_07_JP_V4.sas

Status: Final v4.0/17FEB2016

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Platelets (GI/L)

Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	232.2 (21.03)		233.5 (21.71)		236.5 (18.64)	
	95% CI of Geometric Mean	221.3, 243.8		218.1, 249.9		222.7, 251.1	
	Median	230.0	4.16	231.0	3.20	227.0	0.82
	Q25, Q75	207.0, 266.0	-3.42, 11.48	209.0, 263.0	-3.03, 11.97	217.0, 265.0	-4.39, 6.15
	Min, Max	149, 402	-22.7, 58.5	153, 335	-20.6, 24.9	161, 365	-21.7, 32.3
	Mean (SD)	237.3 (50.12)	5.21 (12.544)	238.7 (50.46)	4.47 (11.217)	240.5 (46.24)	1.50 (9.053)
	95% CI	225.6, 248.9	2.30, 8.12	222.7, 254.7	0.92, 8.01	225.5, 255.6	-1.44, 4.44

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

Program: T1502043101_ZRHM_REXA_07_JP_V4.sas

Status: Final v4.0/17FEB2016

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Platelets (GI/L)

Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	220.7 (22.77)		224.8 (21.50)		233.8 (19.06)	
	95% CI of Geometric Mean	209.2, 232.8		210.1, 240.4		219.7, 248.9	
	Median	221.0		226.0		229.0	
	Q25, Q75	189.0, 261.0		202.0, 257.0		206.0, 277.0	
	Min, Max	140, 448		147, 363		167, 335	
	Mean (SD)	226.5 (55.42)		229.8 (49.38)		237.9 (45.35)	
	95% CI	213.3, 239.7		214.1, 245.4		223.0, 252.9	

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

Appendix: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

Program: T1502043101_ZRHM_REXA_07_JP_V4.sas

Status: Final v4.0/17FEB2016

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Platelets (GI/L)

Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	241.9 (23.36)		236.9 (21.83)		245.7 (18.88)	
	95% CI of Geometric Mean	229.0, 255.6		221.2, 253.6		231.0, 261.3	
	Median	234.0	8.02	250.0	2.40	245.0	2.73
	Q25, Q75	205.0, 281.0	-2.30, 21.99	205.0, 279.0	-5.63, 16.82	222.0, 276.0	-5.04, 13.58
	Min, Max	129, 448	-19.2, 65.9	146, 353	-21.2, 54.4	164, 357	-17.1, 48.8
	Mean (SD)	248.5 (60.64)	11.11 (18.883)	242.1 (50.15)	6.85 (18.429)	249.9 (46.46)	6.06 (15.137)
	95% CI	234.1, 263.0	6.64, 15.59	226.3, 258.0	1.03, 12.67	234.6, 265.2	1.08, 11.04

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 10 AM on Day 1 in the SA arm

Appendix: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

Program: T1502043101_ZRHM_REXA_07_JP_V4.sas

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Platelets (GI/L)

Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	222.5 (22.43)		224.8 (21.50)		233.7 (19.32)	
	95% CI of Geometric Mean	211.0, 234.6		210.1, 240.4		219.2, 249.1	
	Median	222.5		226.0		228.0	
	Q25, Q75	191.0, 261.0		202.0, 257.0		206.0, 277.0	
	Min, Max	140, 448		147, 363		167, 335	
	Mean (SD)	228.1 (54.95)		229.8 (49.38)		237.9 (45.98)	
	95% CI	215.0, 241.3		214.1, 245.4		222.5, 253.3	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.5

Study ID: ZRHM-REXA-07-JP

Program: T1502043101_ZRHM_REXA_07_JP_V4.sas

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Table 15.2.4.31.1 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - PP Set

Parameter: Platelets (GI/L)

Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		70	70	41	41	37	37
	Geometric Mean (CV%)	247.9 (22.11)		242.1 (20.94)		241.0 (16.48)	
	95% CI of Geometric Mean	235.3, 261.2		226.7, 258.5		228.2, 254.6	
	Median	238.5	10.04	252.0	7.04	241.0	2.61
	Q25, Q75	215.0, 280.0	0.00, 23.39	212.0, 275.0	-6.19, 23.67	222.0, 261.0	-5.75, 14.93
	Min, Max	135, 459	-24.9, 62.1	145, 361	-19.0, 40.5	162, 347	-21.2, 37.7
	Mean (SD)	253.9 (58.36)	12.81 (18.042)	247.0 (48.22)	9.12 (17.788)	244.1 (39.72)	4.11 (14.548)
	95% CI	240.0, 267.9	8.50, 17.11	231.7, 262.2	3.50, 14.74	230.8, 257.4	-0.75, 8.96

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Leukocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	5.792 (21.72)		5.612 (23.91)		6.239 (29.53)	
	95% CI of Geometric Mean	5.518, 6.080		5.214, 6.040		5.688, 6.844	
	Median	5.950		5.660		6.360	
	Q25, Q75	5.290, 6.650		4.920, 6.630		4.850, 7.355	
	Min, Max	3.10, 8.68		2.99, 9.52		3.34, 12.40	
	Mean (SD)	5.918 (1.1810)		5.763 (1.3370)		6.501 (1.9270)	
	95% CI	5.652, 6.185		5.346, 6.180		5.884, 7.117	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Leukocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		78	78	42	42	40	40
Confinement							
	Geometric Mean	6.066 (20.98)		5.947 (23.72)		5.799 (27.53)	
	(CV%)						
	95% CI of	5.789, 6.357		5.528, 6.397		5.318, 6.323	
	Geometric Mean						
	Median	6.170	6.75	6.215	7.30	5.805	-6.41
	Q25, Q75	5.370, 7.060	-4.63, 14.85	5.300, 6.940	-3.73, 16.05	4.850, 6.670	-22.45, 10.28
	Min, Max	2.96, 9.04	-41.8, 53.0	3.47, 9.92	-18.2, 35.8	2.50, 10.30	-35.7, 71.1
	Mean (SD)	6.191 (1.2220)	6.22 (17.826)	6.101 (1.3620)	6.79 (13.401)	6.006 (1.6370)	-4.82 (21.714)
	95% CI	5.916, 6.467	2.19, 10.24	5.677, 6.526	2.61, 10.97	5.482, 6.530	-11.77, 2.13

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 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Leukocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	5.524 (21.13)		5.624 (25.23)		5.879 (24.97)	
	95% CI of Geometric Mean	5.269, 5.791		5.205, 6.077		5.434, 6.361	
	Median	5.565	-2.30	5.810	-0.29	5.745	-1.68
	Q25, Q75	4.910, 6.390	-14.38, 9.40	5.020, 6.750	-7.11, 9.50	4.795, 6.800	-18.16, 12.85
	Min, Max	3.07, 8.00	-43.4, 29.4	2.85, 9.88	-22.3, 33.0	3.90, 10.04	-61.1, 53.4
	Mean (SD)	5.641 (1.1430)	-3.34 (15.524)	5.788 (1.3660)	1.08 (13.470)	6.059 (1.5460)	-2.79 (23.199)
	95% CI	5.383, 5.899	-6.84, 0.17	5.362, 6.214	-3.13, 5.28	5.564, 6.553	-10.22, 4.63

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Leukocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	5.509 (23.26)		5.623 (27.99)		5.877 (26.46)	
	95% CI of Geometric Mean	5.230, 5.802		5.161, 6.126		5.408, 6.388	
	Median	5.695	-3.76	5.615	-2.34	6.105	-0.83
	Q25, Q75	4.750, 6.240	-14.12, 8.63	4.990, 6.570	-10.15, 15.18	4.785, 7.095	-17.64, 11.91
	Min, Max	2.88, 11.78	-62.2, 63.7	2.75, 10.84	-30.4, 95.3	3.16, 11.05	-54.1, 45.6
	Mean (SD)	5.654 (1.3350)	-2.83 (19.811)	5.828 (1.5780)	2.13 (21.771)	6.076 (1.6210)	-2.81 (23.498)
	95% CI	5.352, 5.955	-7.31, 1.64	5.335, 6.320	-4.66, 8.92	5.557, 6.595	-10.33, 4.71

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Leukocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge		78	78	42	42	40	40
Ambulatory							
	Geometric Mean (CV%)	5.499 (24.02)		5.838 (26.51)		5.859 (26.62)	
	95% CI of Geometric Mean	5.213, 5.801		5.382, 6.333		5.388, 6.371	
	Median	5.625	-5.85	5.675	1.38	6.045	-5.67
	Q25, Q75	4.890, 6.270	-14.41, 6.34	5.360, 6.540	-5.49, 14.05	4.875, 6.910	-21.20, 13.63
	Min, Max	2.75, 9.38	-61.6, 80.9	2.83, 10.23	-24.3, 64.7	3.01, 10.11	-62.3, 95.3
	Mean (SD)	5.650 (1.3160)	-3.03 (20.195)	6.030 (1.5510)	5.77 (20.242)	6.050 (1.5160)	-2.18 (28.685)
	95% CI	5.353, 5.947	-7.59, 1.53	5.547, 6.514	-0.54, 12.08	5.565, 6.535	-11.36, 7.00

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Neutrophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	3.220 (34.77)		3.099 (29.62)		3.519 (44.77)	
	95% CI of Geometric Mean	2.983, 3.475		2.831, 3.393		3.069, 4.035	
	Median	3.360		3.035		3.640	
	Q25, Q75	2.620, 4.070		2.740, 3.600		2.665, 4.605	
	Min, Max	1.17, 6.20		1.47, 5.63		1.37, 9.73	
	Mean (SD)	3.391 (1.0310)		3.226 (0.9340)		3.846 (1.7010)	
	95% CI	3.158, 3.623		2.935, 3.518		3.302, 4.391	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Neutrophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		78	78	42	42	40	40
Confinement							
	Geometric Mean	3.253 (30.07)		3.377 (31.66)		3.341 (41.78)	
	(CV%)						
	95% CI of	3.044, 3.477		3.066, 3.719		2.938, 3.798	
	Geometric Mean						
	Median	3.420	2.54	3.545	10.46	3.330	-5.56
	Q25, Q75	2.740, 4.030	-10.98, 14.75	2.850, 4.260	0.66, 22.28	2.545, 4.185	-23.40, 13.57
	Min, Max	1.47, 5.74	-62.2, 93.9	1.64, 6.09	-33.0, 61.4	1.05, 7.98	-52.4, 97.5
	Mean (SD)	3.388 (0.9400)	4.42 (26.945)	3.531 (1.0350)	11.01 (21.295)	3.613 (1.5110)	-0.74 (30.973)
	95% CI	3.176, 3.601	-1.66, 10.50	3.208, 3.854	4.37, 17.65	3.129, 4.096	-10.65, 9.17

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 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Neutrophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	2.886 (34.40)		2.992 (33.86)		3.191 (37.55)	
	95% CI of Geometric Mean	2.676, 3.113		2.700, 3.316		2.841, 3.585	
	Median	3.000	-6.46	3.005	-2.70	3.010	-8.53
	Q25, Q75	2.330, 3.680	-22.01, 3.75	2.400, 3.940	-16.38, 11.35	2.390, 3.970	-27.22, 16.51
	Min, Max	1.19, 5.51	-78.6, 66.1	1.21, 5.20	-34.3, 72.8	1.94, 7.79	-75.1, 118.8
	Mean (SD)	3.042 (0.9610)	-6.91 (24.336)	3.146 (0.9750)	-1.14 (22.997)	3.417 (1.3820)	-2.17 (38.108)
	95% CI	2.825, 3.259	-12.41, -1.42	2.842, 3.450	-8.31, 6.03	2.975, 3.859	-14.36, 10.02

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Neutrophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	2.907 (36.01)		3.067 (37.85)		3.146 (38.28)	
	95% CI of Geometric Mean	2.686, 3.145		2.736, 3.438		2.795, 3.542	
	Median	3.025	-5.38	3.085	-4.46	3.085	-9.09
	Q25, Q75	2.440, 3.510	-24.40, 2.55	2.550, 3.990	-14.93, 9.78	2.445, 4.115	-29.62, 14.57
	Min, Max	1.01, 9.46	-81.8, 120.0	1.10, 8.07	-42.8, 139.5	1.40, 7.63	-71.1, 104.6
	Mean (SD)	3.090 (1.1950)	-4.94 (31.998)	3.270 (1.2370)	2.74 (31.796)	3.369 (1.3280)	-4.25 (35.269)
	95% CI	2.820, 3.360	-12.16, 2.28	2.884, 3.656	-7.17, 12.66	2.944, 3.794	-15.54, 7.03

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Neutrophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory		78	78	42	42	40	40
	Geometric Mean (CV%)	2.879 (36.50)		3.160 (36.34)		3.056 (41.26)	
	95% CI of Geometric Mean	2.658, 3.118		2.831, 3.528		2.691, 3.470	
	Median	2.975	-12.22	2.985	1.78	3.220	-15.56
	Q25, Q75	2.230, 3.620	-21.53, 4.07	2.610, 3.730	-17.11, 14.01	2.470, 3.845	-30.81, 12.19
	Min, Max	1.32, 7.42	-75.0, 248.0	1.17, 6.72	-38.7, 121.9	1.17, 6.84	-76.4, 179.9
	Mean (SD)	3.064 (1.1450)	-5.29 (39.137)	3.360 (1.2500)	6.05 (32.832)	3.288 (1.2640)	-4.16 (47.297)
	95% CI	2.806, 3.323	-14.12, 3.54	2.971, 3.750	-4.18, 16.29	2.883, 3.692	-19.29, 10.97

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Lymphocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	2.008 (25.41)		1.957 (26.79)		2.096 (22.71)	
	95% CI of Geometric Mean	1.897, 2.125		1.803, 2.125		1.950, 2.252	
	Median	2.040		1.895		2.090	
	Q25, Q75	1.790, 2.350		1.670, 2.290		1.810, 2.430	
	Min, Max	1.01, 3.39		1.24, 3.40		1.36, 3.14	
	Mean (SD)	2.069 (0.5020)		2.026 (0.5560)		2.148 (0.4870)	
	95% CI	1.955, 2.183		1.852, 2.200		1.992, 2.304	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Lymphocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		78	78	42	42	40	40
Confinement							
	Geometric Mean	2.263 (23.41)		1.986 (24.12)		1.908 (21.43)	
	(CV%)						
	95% CI of	2.147, 2.384		1.844, 2.140		1.783, 2.043	
	Geometric Mean						
	Median	2.260	11.35	1.945	0.74	1.885	-6.58
	Q25, Q75	1.950, 2.650	-0.91, 28.34	1.710, 2.270	-5.10, 10.90	1.705, 2.200	-29.46, 13.66
	Min, Max	1.24, 3.94	-38.1, 85.0	1.28, 3.21	-23.5, 29.4	1.09, 2.76	-41.2, 57.3
	Mean (SD)	2.323 (0.5400)	14.75 (22.138)	2.042 (0.4930)	2.24 (12.585)	1.949 (0.4030)	-5.29 (27.133)
	95% CI	2.200, 2.445	9.75, 19.75	1.888, 2.196	-1.69, 6.16	1.820, 2.079	-13.97, 3.39

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Lymphocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	2.071 (25.42)		1.997 (31.63)		2.101 (19.10)	
	95% CI of Geometric Mean	1.957, 2.192		1.814, 2.200		1.977, 2.233	
	Median	2.080	2.04	1.980	0.34	2.130	4.55
	Q25, Q75	1.760, 2.450	-6.91, 18.66	1.640, 2.440	-11.19, 11.64	1.835, 2.410	-16.89, 17.04
	Min, Max	0.70, 3.38	-38.6, 55.8	1.09, 4.38	-34.5, 67.0	1.32, 3.05	-46.0, 82.8
	Mean (SD)	2.132 (0.4970)	5.00 (19.672)	2.094 (0.6780)	4.00 (21.330)	2.138 (0.3970)	3.42 (26.855)
	95% CI	2.019, 2.245	0.56, 9.44	1.883, 2.306	-2.65, 10.65	2.010, 2.265	-5.18, 12.01

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Lymphocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	2.037 (26.46)		1.940 (26.53)		2.134 (22.31)	
	95% CI of Geometric Mean	1.921, 2.161		1.788, 2.105		1.988, 2.290	
	Median	2.035	3.12	1.910	-0.14	2.205	0.89
	Q25, Q75	1.660, 2.480	-14.13, 18.87	1.680, 2.310	-11.97, 12.17	1.785, 2.530	-15.92, 19.64
	Min, Max	0.83, 3.46	-50.5, 54.5	1.08, 3.43	-50.0, 63.1	1.49, 3.18	-38.3, 83.1
	Mean (SD)	2.104 (0.5300)	3.80 (21.820)	2.005 (0.5180)	1.25 (20.902)	2.185 (0.4790)	5.02 (27.469)
	95% CI	1.985, 2.224	-1.13, 8.72	1.843, 2.166	-5.27, 7.77	2.031, 2.338	-3.77, 13.81

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 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Lymphocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge		78	78	42	42	40	40
Ambulatory							
	Geometric Mean (CV%)	2.051 (26.34)		1.998 (29.05)		2.207 (20.51)	
	95% CI of Geometric Mean	1.934, 2.174		1.828, 2.184		2.068, 2.355	
	Median	2.065	2.52	2.010	2.24	2.165	3.27
	Q25, Q75	1.730, 2.530	-9.69, 18.13	1.690, 2.410	-7.94, 16.99	1.930, 2.485	-10.29, 27.92
	Min, Max	0.91, 3.32	-43.0, 67.7	1.09, 3.44	-29.5, 69.0	1.49, 3.42	-32.6, 79.1
	Mean (SD)	2.117 (0.5250)	4.55 (22.699)	2.076 (0.5680)	4.00 (20.651)	2.252 (0.4690)	7.79 (24.080)
	95% CI	1.998, 2.236	-0.57, 9.67	1.899, 2.253	-2.44, 10.44	2.102, 2.403	0.08, 15.50

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Monocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	0.275 (30.37)		0.276 (30.21)		0.305 (34.89)	
	95% CI of Geometric Mean	0.256, 0.294		0.252, 0.304		0.274, 0.341	
	Median	0.290		0.275		0.300	
	Q25, Q75	0.220, 0.340		0.230, 0.330		0.245, 0.365	
	Min, Max	0.12, 0.51		0.14, 0.55		0.16, 0.68	
	Mean (SD)	0.286 (0.0810)		0.289 (0.0880)		0.324 (0.1190)	
	95% CI	0.268, 0.305		0.261, 0.316		0.285, 0.362	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Monocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		78	78	42	42	40	40
Confinement							
	Geometric Mean	0.296 (34.92)		0.300 (26.02)		0.262 (33.70)	
	(CV%)						
	95% CI of	0.273, 0.320		0.276, 0.325		0.235, 0.291	
	Geometric Mean						
	Median	0.300		0.300		0.275	
	Q25, Q75	0.250, 0.370		0.260, 0.360		0.220, 0.335	
	Min, Max	0.14, 0.67		0.13, 0.57		0.09, 0.45	
	Mean (SD)	0.313 (0.1100)		0.309 (0.0790)		0.274 (0.0780)	
	95% CI	0.288, 0.338		0.284, 0.334		0.249, 0.299	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Monocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	0.274 (34.48)		0.290 (39.12)		0.290 (33.36)	
	95% CI of Geometric Mean	0.254, 0.296		0.257, 0.326		0.261, 0.322	
	Median	0.280	0.00	0.280	5.73	0.290	-3.37
	Q25, Q75	0.220, 0.350	-18.42, 23.08	0.240, 0.380	-9.68, 17.39	0.235, 0.360	-16.39, 6.01
	Min, Max	0.10, 0.52	-50.0, 76.9	0.10, 0.55	-56.5, 130.0	0.13, 0.72	-54.7, 75.0
	Mean (SD)	0.289 (0.0940)	3.97 (30.032)	0.309 (0.1110)	8.15 (28.802)	0.305 (0.1050)	-1.52 (27.105)
	95% CI	0.268, 0.311	-2.81, 10.75	0.274, 0.344	-0.83, 17.13	0.271, 0.339	-10.19, 7.16

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 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Monocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	0.267 (31.81)		0.297 (34.74)		0.271 (30.84)	
	95% CI of Geometric Mean	0.248, 0.287		0.267, 0.330		0.245, 0.299	
	Median	0.270	-11.60	0.290	6.51	0.270	-8.93
	Q25, Q75	0.220, 0.330	-20.00, 15.79	0.240, 0.350	-6.45, 28.57	0.220, 0.310	-32.18, 8.57
	Min, Max	0.11, 0.64	-44.4, 80.8	0.16, 0.76	-35.0, 60.0	0.14, 0.64	-59.4, 243.8
	Mean (SD)	0.280 (0.0910)	0.78 (28.744)	0.315 (0.1230)	10.17 (24.652)	0.284 (0.0950)	-4.26 (47.633)
	95% CI	0.259, 0.301	-5.70, 7.27	0.276, 0.354	2.48, 17.86	0.253, 0.314	-19.50, 10.98

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 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Monocytes (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge		78	78	42	42	40	40
Ambulatory							
	Geometric Mean (CV%)	0.283 (33.47)		0.323 (40.23)		0.282 (38.15)	
	95% CI of Geometric Mean	0.262, 0.305		0.286, 0.365		0.250, 0.318	
	Median	0.290	4.65	0.320	14.73	0.290	-4.86
	Q25, Q75	0.230, 0.330	-15.79, 23.33	0.250, 0.420	-9.68, 40.74	0.220, 0.370	-24.97, 17.89
	Min, Max	0.10, 0.63	-44.7, 96.9	0.12, 0.77	-25.0, 92.9	0.12, 0.64	-65.6, 100.0
	Mean (SD)	0.298 (0.0990)	6.94 (30.078)	0.347 (0.1370)	21.26 (34.013)	0.301 (0.1080)	-0.27 (39.435)
	95% CI	0.275, 0.320	0.15, 13.73	0.304, 0.390	10.66, 31.87	0.266, 0.335	-12.88, 12.35

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Eosinophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	0.108 (57.46)		0.143 (65.57)		0.117 (60.10)	
	95% CI of Geometric Mean	0.096, 0.123		0.119, 0.173		0.097, 0.140	
	Median	0.100		0.160		0.120	
	Q25, Q75	0.080, 0.170		0.080, 0.250		0.075, 0.165	
	Min, Max	0.04, 0.37		0.04, 0.38		0.03, 0.28	
	Mean (SD)	0.125 (0.0700)		0.169 (0.0940)		0.134 (0.0700)	
	95% CI	0.109, 0.141		0.139, 0.198		0.111, 0.157	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Eosinophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		78	78	42	42	40	40
Confinement							
	Geometric Mean	0.099 (54.06)		0.144 (55.33)		0.108 (55.06)	
	(CV%)						
	95% CI of	0.088, 0.112		0.122, 0.170		0.092, 0.128	
	Geometric Mean						
	Median	0.100	-7.92	0.145	2.63	0.115	-4.12
	Q25, Q75	0.070, 0.140	-22.22, 12.50	0.110, 0.230	-25.00, 25.00	0.070, 0.165	-26.14, 21.83
	Min, Max	0.04, 0.32	-65.5, 72.7	0.05, 0.33	-51.4, 75.0	0.03, 0.29	-53.8, 133.3
	Mean (SD)	0.113 (0.0590)	-3.86 (28.691)	0.163 (0.0780)	5.50 (31.995)	0.123 (0.0600)	-0.47 (38.200)
	95% CI	0.099, 0.127	-10.34, 2.61	0.138, 0.188	-4.48, 15.47	0.103, 0.142	-12.70, 11.75

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Eosinophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	0.113 (53.81)		0.168 (55.23)		0.131 (62.72)	
	95% CI of Geometric Mean	0.100, 0.127		0.142, 0.198		0.108, 0.158	
	Median	0.120	2.27	0.185	10.62	0.130	7.29
	Q25, Q75	0.080, 0.160	-11.11, 25.00	0.120, 0.270	-3.85, 42.11	0.090, 0.190	-8.33, 47.22
	Min, Max	0.04, 0.33	-72.2, 144.4	0.06, 0.36	-31.6, 175.0	0.03, 0.53	-69.2, 430.0
	Mean (SD)	0.127 (0.0620)	12.42 (43.720)	0.189 (0.0850)	23.35 (44.932)	0.154 (0.0950)	24.22 (74.569)
	95% CI	0.113, 0.142	2.56, 22.28	0.162, 0.216	9.34, 37.36	0.123, 0.184	0.36, 48.07

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Eosinophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	0.112 (61.33)		0.161 (62.71)		0.136 (83.91)	
	95% CI of Geometric Mean	0.098, 0.128		0.134, 0.193		0.107, 0.173	
	Median	0.120	0.00	0.165	10.62	0.130	5.21
	Q25, Q75	0.070, 0.170	-25.00, 44.44	0.110, 0.240	0.00, 40.00	0.085, 0.210	-17.42, 66.67
	Min, Max	0.03, 0.53	-58.3, 300.0	0.05, 0.42	-45.9, 137.5	0.03, 1.84	-59.1, 1740.0
	Mean (SD)	0.131 (0.0800)	14.44 (56.201)	0.188 (0.1040)	18.20 (39.036)	0.193 (0.2810)	60.81 (276.240)
	95% CI	0.113, 0.150	1.76, 27.11	0.155, 0.221	6.03, 30.37	0.103, 0.283	-27.54, 149.16

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 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Eosinophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge		78	78	42	42	40	40
Ambulatory							
	Geometric Mean (CV%)	0.111 (55.60)		0.165 (65.97)		0.124 (78.22)	
	95% CI of Geometric Mean	0.098, 0.125		0.136, 0.199		0.099, 0.155	
	Median	0.110	5.21	0.170	16.67	0.120	-1.79
	Q25, Q75	0.080, 0.160	-25.00, 30.00	0.110, 0.250	-7.14, 37.50	0.080, 0.200	-25.00, 36.81
	Min, Max	0.03, 0.36	-68.4, 233.3	0.05, 0.52	-40.0, 120.0	0.03, 0.90	-76.9, 800.0
	Mean (SD)	0.126 (0.0660)	11.74 (49.295)	0.195 (0.1130)	20.29 (37.053)	0.158 (0.1410)	36.92 (147.158)
	95% CI	0.111, 0.142	0.62, 22.86	0.159, 0.230	8.74, 31.84	0.113, 0.204	-10.15, 83.99

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Basophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	0.045 (38.37)		0.048 (53.16)		0.044 (60.64)	
	95% CI of Geometric Mean	0.041, 0.049		0.040, 0.056		0.036, 0.053	
	Median	0.050		0.050		0.050	
	Q25, Q75	0.040, 0.050		0.040, 0.070		0.030, 0.060	
	Min, Max	0.02, 0.11		0.00, 0.10		0.00, 0.10	
	Mean (SD)	0.048 (0.0180)		0.051 (0.0230)		0.049 (0.0260)	
	95% CI	0.043, 0.053		0.044, 0.059		0.040, 0.058	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Basophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		78	78	42	42	40	40
Confinement							
	Geometric Mean	0.051 (40.90)		0.051 (46.55)		0.043 (40.15)	
	(CV%)						
	95% CI of	0.046, 0.056		0.044, 0.060		0.038, 0.050	
	Geometric Mean						
	Median	0.050	25.00	0.050	0.00	0.045	0.00
	Q25, Q75	0.040, 0.070	-9.09, 40.00	0.040, 0.070	0.00, 33.33	0.030, 0.060	-23.61, 20.00
	Min, Max	0.02, 0.12	-50.0, 250.0	0.01, 0.10	-60.0, 300.0	0.00, 0.09	-60.0, 200.0
	Mean (SD)	0.055 (0.0220)	20.49 (43.308)	0.056 (0.0220)	15.16 (53.954)	0.045 (0.0190)	8.40 (55.205)
	95% CI	0.050, 0.060	10.72, 30.26	0.049, 0.063	-1.65, 31.98	0.039, 0.052	-9.26, 26.07

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Basophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	0.047 (39.70)		0.046 (51.83)		0.046 (41.67)	
	95% CI of Geometric Mean	0.043, 0.052		0.039, 0.054		0.040, 0.053	
	Median	0.050	0.00	0.045	0.00	0.050	-12.70
	Q25, Q75	0.040, 0.060	0.00, 25.00	0.040, 0.070	-22.22, 20.00	0.035, 0.060	-26.79, 37.50
	Min, Max	0.01, 0.13	-50.0, 160.0	0.01, 0.14	-57.1, 100.0	0.00, 0.09	-50.0, 400.0
	Mean (SD)	0.050 (0.0190)	10.38 (38.885)	0.052 (0.0250)	0.65 (35.039)	0.048 (0.0190)	24.53 (94.936)
	95% CI	0.046, 0.055	1.61, 19.15	0.043, 0.060	-10.27, 11.58	0.042, 0.055	-5.84, 54.89

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Basophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	0.044 (35.26)		0.045 (50.28)		0.042 (52.18)	
	95% CI of Geometric Mean	0.041, 0.049		0.039, 0.053		0.035, 0.050	
	Median	0.040	0.00	0.045	0.00	0.040	0.00
	Q25, Q75	0.040, 0.060	-20.00, 20.00	0.030, 0.070	-22.22, 16.67	0.030, 0.060	-26.79, 20.00
	Min, Max	0.02, 0.09	-60.0, 100.0	0.01, 0.16	-66.7, 100.0	0.02, 0.14	-60.0, 600.0
	Mean (SD)	0.047 (0.0160)	3.50 (30.977)	0.050 (0.0250)	-1.87 (31.169)	0.047 (0.0260)	15.17 (105.476)
	95% CI	0.043, 0.051	-3.49, 10.49	0.042, 0.059	-11.59, 7.85	0.039, 0.056	-18.56, 48.91

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Basophils (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge		78	78	42	42	40	40
Ambulatory							
	Geometric Mean (CV%)	0.043 (34.18)		0.046 (47.86)		0.046 (44.19)	
	95% CI of Geometric Mean	0.039, 0.046		0.040, 0.054		0.040, 0.053	
	Median	0.040	0.00	0.050	0.00	0.050	0.00
	Q25, Q75	0.030, 0.050	-25.00, 20.00	0.030, 0.060	-25.00, 20.00	0.030, 0.065	-23.61, 29.17
	Min, Max	0.02, 0.09	-44.4, 100.0	0.02, 0.27	-70.0, 200.0	0.00, 0.11	-50.0, 450.0
	Mean (SD)	0.045 (0.0160)	0.31 (34.645)	0.052 (0.0380)	1.45 (45.066)	0.049 (0.0230)	17.69 (80.208)
	95% CI	0.041, 0.049	-7.51, 8.12	0.040, 0.065	-12.60, 15.50	0.041, 0.057	-7.96, 43.35

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Platelets (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	220.0 (22.20)		222.9 (21.97)		235.2 (18.91)	
	95% CI of Geometric Mean	209.4, 231.2		208.2, 238.5		221.5, 249.8	
	Median	221.5		220.0		233.0	
	Q25, Q75	189.0, 253.0		196.0, 257.0		206.5, 277.5	
	Min, Max	140, 448		147, 363		167, 335	
	Mean (SD)	225.5 (53.76)		228.0 (50.05)		239.3 (45.06)	
	95% CI	213.4, 237.7		212.4, 243.7		224.8, 253.8	

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 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Platelets (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge n		78	78	42	42	40	40
Confinement							
	Geometric Mean	232.3 (21.73)		226.6 (20.55)		230.5 (20.91)	
	(CV%)						
	95% CI of	221.3, 243.9		212.6, 241.5		215.7, 246.4	
	Geometric Mean						
	Median	231.5	6.51	234.5	2.79	227.0	-2.20
	Q25, Q75	208.0, 263.0	0.00, 10.93	189.0, 263.0	-5.23, 8.28	201.0, 263.5	-7.38, 3.49
	Min, Max	141, 465	-13.5, 33.3	144, 344	-15.8, 22.6	146, 386	-22.8, 32.4
	Mean (SD)	237.7 (53.58)	5.96 (9.244)	231.1 (45.99)	2.13 (9.625)	235.5 (50.30)	-1.50 (10.187)
	95% CI	225.6, 249.9	3.87, 8.05	216.8, 245.5	-0.87, 5.14	219.3, 251.6	-4.76, 1.77

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 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Platelets (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	230.2 (21.08)		231.5 (22.13)		237.5 (18.59)	
	95% CI of Geometric Mean	219.6, 241.3		216.2, 247.9		223.8, 251.9	
	Median	227.5	4.16	230.5	4.15	227.5	0.77
	Q25, Q75	207.0, 264.0	-3.42, 11.52	206.0, 263.0	-3.03, 11.97	217.0, 270.5	-4.58, 6.11
	Min, Max	149, 402	-22.7, 58.5	153, 335	-20.6, 24.9	161, 365	-21.7, 32.3
	Mean (SD)	235.2 (49.93)	5.33 (12.579)	236.9 (51.12)	4.48 (11.080)	241.5 (46.05)	1.33 (8.997)
	95% CI	223.9, 246.5	2.49, 8.17	220.9, 252.9	1.03, 7.94	226.7, 256.3	-1.55, 4.21

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 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Platelets (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	240.8 (22.55)		234.8 (22.30)		246.1 (18.52)	
	95% CI of Geometric Mean	228.9, 253.2		219.2, 251.6		232.0, 261.0	
	Median	234.5	8.33	245.0	2.93	245.0	2.50
	Q25, Q75	206.0, 277.0	-1.62, 19.40	204.0, 279.0	-5.63, 16.82	223.5, 277.5	-5.07, 13.13
	Min, Max	129, 448	-19.2, 65.9	146, 353	-21.2, 54.4	164, 357	-17.1, 48.8
	Mean (SD)	246.9 (58.50)	10.78 (18.106)	240.3 (50.95)	6.81 (18.205)	250.2 (45.59)	5.58 (14.901)
	95% CI	233.7, 260.1	6.69, 14.87	224.4, 256.2	1.13, 12.49	235.5, 264.8	0.81, 10.35

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm



Table 15.2.4.31.2 Descriptive Statistics of Total WBC Count (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Count (GI/L) - FAS

Parameter: Platelets (GI/L)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge		78	78	42	42	40	40
Ambulatory							
	Geometric Mean (CV%)	246.5 (21.64)		239.9 (21.54)		243.5 (16.73)	
	95% CI of Geometric Mean	234.9, 258.7		224.4, 256.4		230.8, 256.8	
	Median	238.0	10.66	250.5	6.98	243.0	2.03
	Q25, Q75	216.0, 280.0	0.00, 23.39	210.0, 275.0	-6.19, 23.67	222.0, 274.0	-5.58, 15.68
	Min, Max	135, 459	-24.9, 79.5	145, 361	-19.0, 40.5	162, 347	-21.2, 37.7
	Mean (SD)	252.3 (56.66)	13.53 (19.144)	245.0 (49.28)	9.02 (17.581)	246.8 (40.75)	4.53 (14.995)
	95% CI	239.4, 265.1	9.20, 17.85	229.6, 260.4	3.54, 14.51	233.7, 259.8	-0.27, 9.33

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 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: Prostaglandin F2 Alpha (pg/mg creat)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	199.56 (34.64)		201.65 (32.30)		197.64 (34.91)	
	95% CI of Geometric Mean	184.78, 215.52		182.79, 222.45		177.06, 220.61	
	Median	198.39		190.48		193.58	
	Q25, Q75	158.66, 243.97		165.20, 243.46		151.76, 255.24	
	Min, Max	99.2, 480.9		110.7, 463.7		108.8, 399.7	
	Mean (SD)	211.31 (75.493)		212.17 (73.280)		209.18 (73.256)	
	95% CI	194.05, 228.56		189.33, 235.01		185.43, 232.93	

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: Prostaglandin F2 Alpha (pg/mg creat)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	42	42	39	39
	Geometric Mean (CV%)	192.01 (28.73)		200.83 (27.29)		192.23 (37.16)	
	95% CI of Geometric Mean	180.04, 204.78		184.73, 218.32		171.08, 216.00	
	Median	193.09	-2.68	203.55	2.73	204.13	-4.38
	Q25, Q75	162.15, 239.51	-16.01, 6.65	164.66, 241.61	-10.03, 13.93	145.22, 252.21	-14.75, 4.21
	Min, Max	103.0, 324.0	-39.1, 219.5	105.7, 336.4	-45.0, 60.0	95.0, 442.4	-38.8, 126.5
	Mean (SD)	199.47 (54.540)	-0.92 (30.756)	207.84 (54.550)	1.44 (19.184)	204.41 (72.630)	0.18 (28.316)
	95% CI	187.00, 211.94	-7.96, 6.11	190.84, 224.85	-4.54, 7.43	180.86, 227.96	-9.00, 9.37

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: Prostaglandin F2 Alpha (pg/mg creat)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	199.57 (34.99)		202.65 (32.54)		197.64 (34.91)	
	95% CI of Geometric Mean	184.45, 215.92		183.33, 224.00		177.06, 220.61	
	Median	198.39		190.96		193.58	
	Q25, Q75	157.53, 245.65		169.25, 243.46		151.76, 255.24	
	Min, Max	99.2, 480.9		110.7, 463.7		108.8, 399.7	
	Mean (SD)	211.54 (76.264)		213.33 (73.800)		209.18 (73.256)	
	95% CI	193.87, 229.22		190.03, 236.63		185.43, 232.93	

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: Prostaglandin F2 Alpha (pg/mg creat)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	199.96 (29.15)		220.64 (29.87)		210.25 (38.76)	
	95% CI of Geometric Mean	187.15, 213.64		201.19, 241.97		186.24, 237.36	
	Median	190.43	0.72	219.35	16.37	204.13	7.78
	Q25, Q75	162.63, 239.86	-13.03, 17.19	179.01, 270.90	-5.65, 25.37	156.13, 259.35	-6.90, 21.68
	Min, Max	111.9, 431.8	-66.4, 122.3	110.1, 381.4	-44.7, 55.8	105.7, 453.1	-42.5, 73.3
	Mean (SD)	208.60 (65.271)	4.10 (29.723)	229.85 (66.235)	11.00 (20.991)	225.60 (90.318)	9.83 (27.960)
	95% CI	193.47, 223.73	-2.80, 10.99	208.94, 250.76	4.37, 17.63	196.32, 254.88	0.76, 18.90

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: Prostaglandin F2 Alpha (pg/mg creat)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	200.87 (35.46)		202.65 (32.54)		197.08 (35.36)	
	95% CI of Geometric Mean	185.15, 217.92		183.33, 224.00		176.05, 220.61	
	Median	200.00		190.96		190.45	
	Q25, Q75	159.78, 246.31		169.25, 243.46		151.76, 255.24	
	Min, Max	99.2, 480.9		110.7, 463.7		108.8, 399.7	
	Mean (SD)	213.17 (77.258)		213.33 (73.800)		208.89 (74.216)	
	95% CI	194.88, 231.46		190.03, 236.63		184.49, 233.29	

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 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: Prostaglandin F2 Alpha (pg/mg creat)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	196.87 (35.06)		232.97 (37.14)		205.75 (40.37)	
	95% CI of Geometric Mean	181.62, 213.40		207.97, 260.96		181.08, 233.79	
	Median	186.96	-1.92	235.52	12.73	211.85	10.92
	Q25, Q75	160.00, 242.83	-16.87, 14.15	180.71, 310.48	-5.48, 34.13	147.52, 276.19	-16.15, 32.29
	Min, Max	89.4, 566.5	-45.4, 93.6	111.0, 536.9	-37.2, 122.4	92.1, 450.1	-56.1, 80.4
	Mean (SD)	209.08 (79.796)	1.00 (25.759)	248.37 (93.249)	19.84 (35.705)	221.10 (84.911)	8.77 (30.102)
	95% CI	190.18, 227.97	-5.10, 7.10	218.93, 277.81	8.56, 31.11	193.18, 249.01	-1.13, 18.67

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: Prostaglandin F2 Alpha (pg/mg creat)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	201.95 (34.82)		202.65 (32.54)		198.47 (35.57)	
	95% CI of Geometric Mean	186.30, 218.92		183.33, 224.00		176.89, 222.68	
	Median	201.39		190.96		193.58	
	Q25, Q75	157.53, 246.31		169.25, 243.46		153.30, 255.24	
	Min, Max	104.0, 480.9		110.7, 463.7		108.8, 399.7	
	Mean (SD)	213.99 (77.020)		213.33 (73.800)		210.43 (74.619)	
	95% CI	195.62, 232.36		190.03, 236.63		185.55, 235.32	

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 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: Prostaglandin F2 Alpha (pg/mg creat)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	70	70	41	41	37	37
	Geometric Mean (CV%)	194.40 (38.28)		222.48 (29.53)		206.59 (45.85)	
	95% CI of Geometric Mean	177.99, 212.32		203.07, 243.75		178.59, 238.98	
	Median	184.36	-2.26	220.99	11.31	216.94	7.04
	Q25, Q75	156.46, 239.30	-17.66, 12.89	191.29, 258.99	-4.21, 23.59	154.49, 276.57	-16.16, 26.82
	Min, Max	87.7, 587.3	-50.3, 87.9	113.6, 471.9	-51.4, 77.7	56.5, 431.3	-79.0, 176.2
	Mean (SD)	209.14 (90.796)	-0.82 (24.862)	231.97 (71.146)	13.37 (28.738)	224.76 (88.685)	12.87 (46.247)
	95% CI	187.48, 230.79	-6.76, 5.11	209.50, 254.43	4.29, 22.44	195.19, 254.34	-2.55, 28.30

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	571.09 (38.44)		525.88 (30.13)		594.06 (35.89)	
	95% CI of Geometric Mean	524.64, 621.66		479.72, 576.48		530.67, 665.02	
	Median	583.86		535.42		568.99	
	Q25, Q75	445.15, 726.58		453.21, 640.63		479.82, 719.54	
	Min, Max	121.3, 1440.8		214.0, 921.9		286.3, 1538.7	
	Mean (SD)	608.97 (220.309)		547.44 (152.047)		631.43 (240.454)	
	95% CI	558.62, 659.32		500.05, 594.82		553.48, 709.38	

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 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	42	42	39	39
	Geometric Mean (CV%)	558.30 (33.76)		584.24 (29.39)		540.80 (36.19)	
	95% CI of Geometric Mean	517.92, 601.82		534.11, 639.07		482.66, 605.94	
	Median	570.01	-1.42	584.02	9.86	538.46	-7.12
	Q25, Q75	428.44, 706.54	-16.89, 10.93	467.29, 724.10	-0.09, 18.51	422.95, 678.10	-17.39, -0.81
	Min, Max	224.9, 1103.8	-52.9, 85.3	300.0, 1071.4	-13.1, 105.9	292.9, 1741.7	-71.0, 103.3
	Mean (SD)	587.70 (186.290)	0.87 (26.145)	608.14 (175.177)	12.99 (23.619)	578.35 (252.682)	-5.50 (26.268)
	95% CI	545.12, 630.27	-5.11, 6.85	553.55, 662.74	5.62, 20.35	496.43, 660.26	-14.02, 3.02

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	572.37 (38.34)		533.13 (29.05)		594.06 (35.89)	
	95% CI of Geometric Mean	525.31, 623.65		487.32, 583.24		530.67, 665.02	
	Median	583.86		537.65		568.99	
	Q25, Q75	452.74, 724.77		459.23, 640.63		479.82, 719.54	
	Min, Max	121.3, 1440.8		214.0, 921.9		286.3, 1538.7	
	Mean (SD)	610.10 (220.395)		553.47 (148.755)		631.43 (240.454)	
	95% CI	559.03, 661.17		506.51, 600.43		553.48, 709.38	

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 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set**

Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	470.24 (38.06)		533.11 (35.21)		513.17 (46.23)	
	95% CI of Geometric Mean	431.82, 512.07		478.57, 593.86		444.94, 591.86	
	Median	463.62	-20.34	545.54	-4.32	536.61	-15.69
	Q25, Q75	362.28, 604.45	-32.55, -4.06	419.35, 715.74	-10.50, 14.28	365.16, 700.39	-27.01, 6.05
	Min, Max	177.0, 1222.1	-60.6, 213.9	248.8, 953.3	-50.5, 176.3	184.1, 1970.8	-58.7, 130.1
	Mean (SD)	502.36 (188.338)	-13.54 (34.317)	563.25 (184.396)	4.51 (36.963)	566.69 (294.737)	-9.15 (32.300)
	95% CI	458.73, 546.00	-21.50, -5.58	505.04, 621.46	-7.17, 16.18	471.15, 662.24	-19.62, 1.33

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 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	577.16 (38.60)		533.13 (29.05)		604.80 (34.36)	
	95% CI of Geometric Mean	528.43, 630.39		487.32, 583.24		541.91, 674.98	
	Median	586.72		537.65		579.31	
	Q25, Q75	452.74, 728.40		459.23, 640.63		480.00, 719.54	
	Min, Max	121.3, 1440.8		214.0, 921.9		286.3, 1538.7	
	Mean (SD)	615.51 (222.488)		553.47 (148.755)		640.14 (237.374)	
	95% CI	562.84, 668.18		506.51, 600.43		562.11, 718.16	

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 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	458.84 (41.50)		513.62 (42.92)		468.25 (33.36)	
	95% CI of Geometric Mean	417.52, 504.24		451.09, 584.80		420.83, 521.03	
	Median	467.76	-20.06	524.19	-5.94	458.32	-20.05
	Q25, Q75	382.43, 587.32	-33.38, 0.03	413.33, 634.53	-15.59, 13.22	399.44, 545.74	-33.66, -4.60
	Min, Max	142.7, 1476.4	-71.1, 465.1	213.0, 1903.5	-60.4, 148.1	143.7, 905.5	-72.0, 66.9
	Mean (SD)	495.04 (202.765)	-12.21 (61.851)	563.42 (295.451)	1.13 (34.241)	491.26 (151.366)	-19.02 (24.300)
	95% CI	447.04, 543.04	-26.85, 2.44	470.16, 656.68	-9.68, 11.94	441.50, 541.01	-27.01, -11.03

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	580.41 (38.57)		533.13 (29.05)		604.77 (34.86)	
	95% CI of Geometric Mean	531.09, 634.32		487.32, 583.24		540.20, 677.06	
	Median	586.21		537.65		568.99	
	Q25, Q75	456.02, 728.40		459.23, 640.63		480.00, 719.54	
	Min, Max	121.3, 1440.8		214.0, 921.9		286.3, 1538.7	
	Mean (SD)	618.70 (222.107)		553.47 (148.755)		641.07 (240.578)	
	95% CI	565.73, 671.66		506.51, 600.43		560.85, 721.29	

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 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	70	70	41	41	37	37
	Geometric Mean (CV%)	498.22 (47.35)		515.18 (31.88)		450.76 (38.57)	
	95% CI of Geometric Mean	447.54, 554.63		466.99, 568.35		398.12, 510.37	
	Median	500.31	-18.90	498.06	-5.36	454.65	-22.28
	Q25, Q75	357.78, 628.04	-33.71, -0.81	427.50, 653.67	-15.41, 4.57	361.58, 609.00	-31.43, -11.13
	Min, Max	182.1, 1778.2	-62.3, 582.8	254.9, 1015.3	-27.4, 49.2	215.8, 892.6	-75.4, 14.7
	Mean (SD)	552.88 (281.142)	-1.82 (81.587)	540.07 (170.343)	-1.71 (19.069)	481.59 (176.721)	-22.97 (18.085)
	95% CI	485.84, 619.92	-21.28, 17.64	486.30, 593.85	-7.73, 4.31	422.67, 540.52	-29.01, -16.94

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 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**

Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	571.09 (38.44)		525.88 (30.13)		594.06 (35.89)	
	95% CI of Geometric Mean	524.64, 621.66		479.72, 576.48		530.67, 665.02	
	Median	583.86		535.42		568.99	
	Q25, Q75	445.15, 726.58		453.21, 640.63		479.82, 719.54	
	Min, Max	121.3, 1440.8		214.0, 921.9		286.3, 1538.7	
	Mean (SD)	608.97 (220.309)		547.44 (152.047)		631.43 (240.454)	
	95% CI	558.62, 659.32		500.05, 594.82		553.48, 709.38	

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 15.2.4.32.1.1 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**

Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	42	42	39	39
	Geometric Mean (CV%)	558.30 (33.76)		584.24 (29.39)		540.80 (36.19)	
	95% CI of Geometric Mean	517.92, 601.82		534.11, 639.07		482.66, 605.94	
	Median	570.01	-1.42	584.02	9.86	538.46	-7.12
	Q25, Q75	428.44, 706.54	-16.89, 10.93	467.29, 724.10	-0.09, 18.51	422.95, 678.10	-17.39, -0.81
	Min, Max	224.9, 1103.8	-52.9, 85.3	300.0, 1071.4	-13.1, 105.9	292.9, 1741.7	-71.0, 103.3
	Mean (SD)	587.70 (186.290)	0.87 (26.145)	608.14 (175.177)	12.99 (23.619)	578.35 (252.682)	-5.50 (26.268)
	95% CI	545.12, 630.27	-5.11, 6.85	553.55, 662.74	5.62, 20.35	496.43, 660.26	-14.02, 3.02

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)**
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Geometric Mean (CV%)	572.37 (38.34)		533.13 (29.05)		594.06 (35.89)	
	95% CI of Geometric Mean	525.31, 623.65		487.32, 583.24		530.67, 665.02	
	Median	583.86		537.65		568.99	
	Q25, Q75	452.74, 724.77		459.23, 640.63		479.82, 719.54	
	Min, Max	121.3, 1440.8		214.0, 921.9		286.3, 1538.7	
	Mean (SD)	610.10 (220.395)		553.47 (148.755)		631.43 (240.454)	
	95% CI	559.03, 661.17		506.51, 600.43		553.48, 709.38	

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 15.2.4.32.1.1 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

Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	39	39
	Geometric Mean (CV%)	470.24 (38.06)		533.11 (35.21)		513.17 (46.23)	
	95% CI of Geometric Mean	431.82, 512.07		478.57, 593.86		444.94, 591.86	
	Median	463.62	-20.34	545.54	-4.32	536.61	-15.69
	Q25, Q75	362.28, 604.45	-32.55, -4.06	419.35, 715.74	-10.50, 14.28	365.16, 700.39	-27.01, 6.05
	Min, Max	177.0, 1222.1	-60.6, 213.9	248.8, 953.3	-50.5, 176.3	184.1, 1970.8	-58.7, 130.1
	Mean (SD)	502.36 (188.338)	-13.54 (34.317)	563.25 (184.396)	4.51 (36.963)	566.69 (294.737)	-9.15 (32.300)
	95% CI	458.73, 546.00	-21.50, -5.58	505.04, 621.46	-7.17, 16.18	471.15, 662.24	-19.62, 1.33

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

Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Geometric Mean (CV%)	577.16 (38.60)		533.13 (29.05)		604.80 (34.36)	
	95% CI of Geometric Mean	528.43, 630.39		487.32, 583.24		541.91, 674.98	
	Median	586.72		537.65		579.31	
	Q25, Q75	452.74, 728.40		459.23, 640.63		480.00, 719.54	
	Min, Max	121.3, 1440.8		214.0, 921.9		286.3, 1538.7	
	Mean (SD)	615.51 (222.488)		553.47 (148.755)		640.14 (237.374)	
	95% CI	562.84, 668.18		506.51, 600.43		562.11, 718.16	

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 15.2.4.32.1.1 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

Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Geometric Mean (CV%)	458.84 (41.50)		513.62 (42.92)		468.25 (33.36)	
	95% CI of Geometric Mean	417.52, 504.24		451.09, 584.80		420.83, 521.03	
	Median	467.76	-20.06	524.19	-5.94	458.32	-20.05
	Q25, Q75	382.43, 587.32	-33.38, 0.03	413.33, 634.53	-15.59, 13.22	399.44, 545.74	-33.66, -4.60
	Min, Max	142.7, 1476.4	-71.1, 465.1	213.0, 1903.5	-60.4, 148.1	143.7, 905.5	-72.0, 66.9
	Mean (SD)	495.04 (202.765)	-12.21 (61.851)	563.42 (295.451)	1.13 (34.241)	491.26 (151.366)	-19.02 (24.300)
	95% CI	447.04, 543.04	-26.85, 2.44	470.16, 656.68	-9.68, 11.94	441.50, 541.01	-27.01, -11.03

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 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

Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	580.41 (38.57)		533.13 (29.05)		604.77 (34.86)	
	95% CI of Geometric Mean	531.09, 634.32		487.32, 583.24		540.20, 677.06	
	Median	586.21		537.65		568.99	
	Q25, Q75	456.02, 728.40		459.23, 640.63		480.00, 719.54	
	Min, Max	121.3, 1440.8		214.0, 921.9		286.3, 1538.7	
	Mean (SD)	618.70 (222.107)		553.47 (148.755)		641.07 (240.578)	
	95% CI	565.73, 671.66		506.51, 600.43		560.85, 721.29	

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 15.2.4.32.1.1 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****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)**
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	70	70	41	41	37	37
	Geometric Mean (CV%)	498.22 (47.35)		515.18 (31.88)		450.76 (38.57)	
	95% CI of Geometric Mean	447.54, 554.63		466.99, 568.35		398.12, 510.37	
	Median	500.31	-18.90	498.06	-5.36	454.65	-22.28
	Q25, Q75	357.78, 628.04	-33.71, -0.81	427.50, 653.67	-15.41, 4.57	361.58, 609.00	-31.43, -11.13
	Min, Max	182.1, 1778.2	-62.3, 582.8	254.9, 1015.3	-27.4, 49.2	215.8, 892.6	-75.4, 14.7
	Mean (SD)	552.88 (281.142)	-1.82 (81.587)	540.07 (170.343)	-1.71 (19.069)	481.59 (176.721)	-22.97 (18.085)
	95% CI	485.84, 619.92	-21.28, 17.64	486.30, 593.85	-7.73, 4.31	422.67, 540.52	-29.01, -16.94

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS****Parameter: Prostaglandin F2 Alpha (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	200.58 (34.51)		201.65 (32.30)		197.06 (34.49)	
	95% CI of Geometric Mean	185.97, 216.35		182.79, 222.45		177.02, 219.37	
	Median	199.09		190.48		190.45	
	Q25, Q75	159.78, 245.65		165.20, 243.46		152.53, 252.40	
	Min, Max	99.2, 480.9		110.7, 463.7		108.8, 399.7	
	Mean (SD)	212.28 (75.200)		212.17 (73.280)		208.35 (72.503)	
	95% CI	195.32, 229.24		189.33, 235.01		185.16, 231.54	

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-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS****Parameter: Prostaglandin F2 Alpha (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	78	78	42	42	40	40
	Geometric Mean (CV%)	193.03 (28.69)		200.83 (27.29)		191.80 (36.68)	
	95% CI of Geometric Mean	181.16, 205.67		184.73, 218.32		171.20, 214.89	
	Median	196.40	-2.68	203.55	2.73	204.04	-4.26
	Q25, Q75	162.36, 240.43	-15.59, 6.62	164.66, 241.61	-10.03, 13.93	148.25, 248.27	-14.61, 3.59
	Min, Max	103.0, 324.0	-39.1, 219.5	105.7, 336.4	-45.0, 60.0	95.0, 442.4	-38.8, 126.5
	Mean (SD)	200.49 (54.602)	-0.99 (30.361)	207.84 (54.550)	1.44 (19.184)	203.70 (71.835)	0.18 (27.950)
	95% CI	188.17, 212.80	-7.84, 5.86	190.84, 224.85	-4.54, 7.43	180.72, 226.68	-8.77, 9.12

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS****Parameter: Prostaglandin F2 Alpha (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	200.23 (28.48)		219.11 (29.86)		209.31 (38.34)	
	95% CI of Geometric Mean	188.00, 213.25		200.03, 240.01		185.93, 235.64	
	Median	195.14	0.41	219.21	15.98	203.04	6.94
	Q25, Q75	162.96, 239.86	-13.03, 16.48	177.17, 270.90	-5.65, 25.37	157.69, 254.67	-6.18, 21.48
	Min, Max	111.9, 431.8	-66.4, 122.3	110.1, 381.4	-44.7, 55.8	105.7, 453.1	-42.5, 73.3
	Mean (SD)	208.50 (63.780)	3.59 (29.187)	228.30 (66.191)	10.73 (20.803)	224.35 (89.500)	9.58 (27.643)
	95% CI	194.12, 222.89	-2.99, 10.18	207.67, 248.93	4.25, 17.22	195.73, 252.98	0.74, 18.43

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS****Parameter: Prostaglandin F2 Alpha (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	197.95 (34.38)		231.05 (37.10)		204.91 (39.33)	
	95% CI of Geometric Mean	183.57, 213.44		206.58, 258.41		181.49, 231.34	
	Median	188.96	-1.03	234.36	12.53	205.43	8.19
	Q25, Q75	163.52, 242.42	-16.31, 14.15	172.58, 310.48	-5.48, 34.13	148.34, 268.16	-16.12, 31.05
	Min, Max	89.4, 566.5	-45.4, 93.6	111.0, 536.9	-37.2, 122.4	92.1, 450.1	-56.1, 80.4
	Mean (SD)	209.79 (78.620)	1.63 (25.543)	246.37 (93.006)	19.37 (35.400)	219.54 (83.052)	8.15 (29.459)
	95% CI	192.06, 227.52	-4.14, 7.39	217.39, 275.36	8.33, 30.40	192.98, 246.11	-1.28, 17.58

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS****Parameter: Prostaglandin F2 Alpha (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	78	42	42	40	40
	Geometric Mean (CV%)	190.98 (37.15)		220.90 (29.55)		204.56 (44.13)	
	95% CI of Geometric Mean	176.11, 207.12		201.84, 241.74		178.74, 234.11	
	Median	184.11	-2.26	220.69	9.90	210.39	6.91
	Q25, Q75	156.20, 231.37	-18.39, 11.05	180.46, 258.99	-4.21, 23.59	160.09, 276.32	-15.31, 26.58
	Min, Max	87.7, 587.3	-50.3, 87.9	113.6, 471.9	-51.4, 77.7	56.5, 431.3	-79.0, 176.2
	Mean (SD)	204.76 (87.459)	-1.77 (25.089)	230.36 (71.037)	13.05 (28.461)	221.55 (86.089)	11.95 (44.592)
	95% CI	185.04, 224.49	-7.44, 3.89	208.22, 252.51	4.18, 21.92	194.01, 249.08	-2.31, 26.22

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 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	574.63 (38.15)		525.88 (30.13)		597.59 (35.62)	
	95% CI of Geometric Mean	528.80, 624.42		479.72, 576.48		535.05, 667.44	
	Median	586.21		535.42		579.31	
	Q25, Q75	452.74, 728.40		453.21, 640.63		479.91, 721.20	
	Min, Max	121.3, 1440.8		214.0, 921.9		286.3, 1538.7	
	Mean (SD)	612.03 (218.414)		547.44 (152.047)		634.47 (238.129)	
	95% CI	562.78, 661.28		500.05, 594.82		558.31, 710.64	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	78	78	42	42	40	40
	Geometric Mean (CV%)	560.32 (33.39)		584.24 (29.39)		545.29 (36.13)	
	95% CI of Geometric Mean	520.72, 602.94		534.11, 639.07		487.51, 609.93	
	Median	571.94	-1.42	584.02	9.86	542.51	-7.01
	Q25, Q75	428.57, 705.56	-17.70, 10.63	467.29, 724.10	-0.09, 18.51	427.77, 678.28	-17.21, -0.40
	Min, Max	224.9, 1103.8	-52.9, 85.3	300.0, 1071.4	-13.1, 105.9	292.9, 1741.7	-71.0, 103.3
	Mean (SD)	589.14 (184.148)	0.57 (25.929)	608.14 (175.177)	12.99 (23.619)	582.71 (250.947)	-5.36 (25.944)
	95% CI	547.62, 630.66	-5.28, 6.42	553.55, 662.74	5.62, 20.35	502.45, 662.98	-13.67, 2.94

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	466.29 (38.51)		525.86 (36.01)		518.11 (46.06)	
	95% CI of Geometric Mean	428.79, 507.08		471.64, 586.31		450.30, 596.14	
	Median	459.67	-21.08	527.25	-4.04	547.32	-15.50
	Q25, Q75	362.28, 604.45	-32.93, -4.06	410.92, 715.74	-10.50, 14.28	376.28, 700.54	-25.04, 4.85
	Min, Max	177.0, 1222.1	-60.6, 213.9	248.8, 953.3	-50.5, 176.3	184.1, 1970.8	-58.7, 130.1
	Mean (SD)	498.74 (187.811)	-14.54 (33.980)	556.98 (186.608)	4.40 (36.516)	571.35 (292.423)	-8.92 (31.916)
	95% CI	456.39, 541.09	-22.21, -6.88	498.83, 615.14	-6.99, 15.78	477.83, 664.88	-19.13, 1.30

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	460.32 (40.99)		507.08 (43.30)		470.84 (33.70)	
	95% CI of Geometric Mean	421.18, 503.09		445.63, 577.01		423.96, 522.91	
	Median	468.98	-20.18	522.00	-3.96	458.32	-17.75
	Q25, Q75	389.32, 587.32	-33.38, 0.03	410.60, 634.53	-15.59, 13.22	399.02, 556.48	-32.05, -3.33
	Min, Max	142.7, 1476.4	-71.1, 465.1	213.0, 1903.5	-60.4, 148.1	143.7, 905.5	-72.0, 66.9
	Mean (SD)	495.70 (199.038)	-12.07 (59.365)	557.15 (294.643)	1.10 (33.821)	494.60 (154.611)	-17.55 (24.653)
	95% CI	450.82, 540.58	-25.46, 1.32	465.32, 648.97	-9.44, 11.65	445.15, 544.05	-25.44, -9.66

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 10 AM on Day 1 in the SA arm

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2a (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS****Parameter: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	78	42	42	40	40
	Geometric Mean (CV%)	490.70 (46.23)		508.59 (32.67)		451.83 (38.32)	
	95% CI of Geometric Mean	444.34, 541.90		460.54, 561.66		401.38, 508.63	
	Median	500.31	-18.04	494.73	-5.04	443.18	-22.12
	Q25, Q75	348.04, 627.58	-33.71, -0.81	400.23, 653.67	-15.41, 4.57	362.32, 637.54	-31.93, -8.19
	Min, Max	182.1, 1778.2	-62.3, 582.8	254.9, 1015.3	-27.4, 49.2	215.8, 892.6	-75.4, 20.7
	Mean (SD)	542.46 (271.730)	-3.13 (77.684)	534.36 (172.282)	-1.67 (18.837)	482.58 (177.218)	-21.71 (19.224)
	95% CI	481.19, 603.73	-20.65, 14.39	480.67, 588.05	-7.54, 4.21	425.90, 539.27	-27.87, -15.56

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 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: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	78		42		40	
	Geometric Mean (CV%)	574.63 (38.15)		525.88 (30.13)		597.59 (35.62)	
	95% CI of Geometric Mean	528.80, 624.42		479.72, 576.48		535.05, 667.44	
	Median	586.21		535.42		579.31	
	Q25, Q75	452.74, 728.40		453.21, 640.63		479.91, 721.20	
	Min, Max	121.3, 1440.8		214.0, 921.9		286.3, 1538.7	
	Mean (SD)	612.03 (218.414)		547.44 (152.047)		634.47 (238.129)	
	95% CI	562.78, 661.28		500.05, 594.82		558.31, 710.64	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: no assessment was excluded because of concomitant medication affecting 11-DTX-B2.

**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: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	78	78	42	42	40	40
	Geometric Mean (CV%)	560.32 (33.39)		584.24 (29.39)		545.29 (36.13)	
	95% CI of Geometric Mean	520.72, 602.94		534.11, 639.07		487.51, 609.93	
	Median	571.94	-1.42	584.02	9.86	542.51	-7.01
	Q25, Q75	428.57, 705.56	-17.70, 10.63	467.29, 724.10	-0.09, 18.51	427.77, 678.28	-17.21, -0.40
	Min, Max	224.9, 1103.8	-52.9, 85.3	300.0, 1071.4	-13.1, 105.9	292.9, 1741.7	-71.0, 103.3
	Mean (SD)	589.14 (184.148)	0.57 (25.929)	608.14 (175.177)	12.99 (23.619)	582.71 (250.947)	-5.36 (25.944)
	95% CI	547.62, 630.66	-5.28, 6.42	553.55, 662.74	5.62, 20.35	502.45, 662.98	-13.67, 2.94

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 10 AM on Day 1 in the SA arm.

Note: no assessment was excluded because of concomitant medication affecting 11-DTX-B2.

**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: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	78	78	42	42	40	40
	Geometric Mean (CV%)	466.29 (38.51)		525.86 (36.01)		518.11 (46.06)	
	95% CI of Geometric Mean	428.79, 507.08		471.64, 586.31		450.30, 596.14	
	Median	459.67	-21.08	527.25	-4.04	547.32	-15.50
	Q25, Q75	362.28, 604.45	-32.93, -4.06	410.92, 715.74	-10.50, 14.28	376.28, 700.54	-25.04, 4.85
	Min, Max	177.0, 1222.1	-60.6, 213.9	248.8, 953.3	-50.5, 176.3	184.1, 1970.8	-58.7, 130.1
	Mean (SD)	498.74 (187.811)	-14.54 (33.980)	556.98 (186.608)	4.40 (36.516)	571.35 (292.423)	-8.92 (31.916)
	95% CI	456.39, 541.09	-22.21, -6.88	498.83, 615.14	-6.99, 15.78	477.83, 664.88	-19.13, 1.30

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 10 AM on Day 1 in the SA arm.

Note: no assessment was excluded because of concomitant medication affecting 11-DTX-B2.

**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: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	78	78	42	42	40	40
	Geometric Mean (CV%)	460.32 (40.99)		507.08 (43.30)		470.84 (33.70)	
	95% CI of Geometric Mean	421.18, 503.09		445.63, 577.01		423.96, 522.91	
	Median	468.98	-20.18	522.00	-3.96	458.32	-17.75
	Q25, Q75	389.32, 587.32	-33.38, 0.03	410.60, 634.53	-15.59, 13.22	399.02, 556.48	-32.05, -3.33
	Min, Max	142.7, 1476.4	-71.1, 465.1	213.0, 1903.5	-60.4, 148.1	143.7, 905.5	-72.0, 66.9
	Mean (SD)	495.70 (199.038)	-12.07 (59.365)	557.15 (294.643)	1.10 (33.821)	494.60 (154.611)	-17.55 (24.653)
	95% CI	450.82, 540.58	-25.46, 1.32	465.32, 648.97	-9.44, 11.65	445.15, 544.05	-25.44, -9.66

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 10 AM on Day 1 in the SA arm.

Note: no assessment was excluded because of concomitant medication affecting 11-DTX-B2.

**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: 11-Dehydro-Thromboxane B2 (pg/mg creat)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	78	78	42	42	40	40
	Geometric Mean (CV%)	490.70 (46.23)		508.59 (32.67)		451.83 (38.32)	
	95% CI of Geometric Mean	444.34, 541.90		460.54, 561.66		401.38, 508.63	
	Median	500.31	-18.04	494.73	-5.04	443.18	-22.12
	Q25, Q75	348.04, 627.58	-33.71, -0.81	400.23, 653.67	-15.41, 4.57	362.32, 637.54	-31.93, -8.19
	Min, Max	182.1, 1778.2	-62.3, 582.8	254.9, 1015.3	-27.4, 49.2	215.8, 892.6	-75.4, 20.7
	Mean (SD)	542.46 (271.730)	-3.13 (77.684)	534.36 (172.282)	-1.67 (18.837)	482.58 (177.218)	-21.71 (19.224)
	95% CI	481.19, 603.73	-20.65, 14.39	480.67, 588.05	-7.54, 4.21	425.90, 539.27	-27.87, -15.56

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 10 AM on Day 1 in the SA arm.

Note: no assessment was excluded because of concomitant medication affecting 11-DTX-B2.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Parameter: Weight (kg)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	61.73 (16.98)		61.16 (16.81)		60.76 (17.57)	
	95% CI	59.39, 64.15		58.06, 64.43		57.42, 64.29	
	Median	61.55		63.80		61.00	
	Q25, Q75	55.20, 69.55		51.90, 67.40		53.30, 69.20	
	Min, Max	45.1, 97.8		43.4, 84.4		43.7, 91.8	
	Mean (SD)	62.61 (10.835)		61.99 (10.228)		61.68 (11.044)	
	95% CI of Mean	60.13, 65.09		58.80, 65.18		58.09, 65.26	
Day 6/Discharge Confinement	n	76	76	42	42	39	39
	Geometric Mean (CV%)	61.16 (16.71)		61.08 (16.32)		60.68 (17.02)	
	95% CI	58.88, 63.53		58.07, 64.25		57.44, 64.11	
	Median	60.85	-0.86	63.30	-0.18	61.20	0.00
	Q25, Q75	55.05, 68.75	-1.67, -0.08	52.60, 67.10	-1.19, 0.61	53.00, 69.10	-1.42, 0.82
	Min, Max	44.8, 94.5	-4.3, 2.6	44.2, 84.4	-2.3, 3.1	43.4, 88.4	-3.7, 2.5
	Mean (SD)	62.01 (10.505)	-0.91 (1.306)	61.87 (9.959)	-0.12 (1.358)	61.54 (10.569)	-0.11 (1.470)
	95% CI of Mean	59.60, 64.41	-1.21, -0.60	58.76, 64.98	-0.55, 0.31	58.11, 64.97	-0.59, 0.37

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: NC= Not Calculated

Appendix: 15.3.6.7

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Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set
Parameter: Weight (kg)
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	74		41		39	
	Geometric Mean (CV%)	61.71 (17.21)		61.17 (17.02)		60.76 (17.57)	
	95% CI	59.31, 64.21		57.98, 64.52		57.42, 64.29	
	Median	61.55		63.90		61.00	
	Q25, Q75	55.20, 70.30		51.90, 67.40		53.30, 69.20	
	Min, Max	45.1, 97.8		43.4, 84.4		43.7, 91.8	
	Mean (SD)	62.62 (10.981)		62.01 (10.354)		61.68 (11.044)	
	95% CI of Mean	60.07, 65.17		58.74, 65.29		58.09, 65.26	
Day 30							
	n	74	74	41	41	38	38
	Geometric Mean (CV%)	62.09 (17.34)		61.69 (17.15)		62.05 (17.92)	
	95% CI	59.66, 64.63		58.45, 65.10		58.52, 65.78	
	Median	62.00	0.66	63.00	0.78	62.55	2.08
	Q25, Q75	54.80, 72.00	-0.68, 2.09	52.70, 68.40	-0.51, 2.20	54.30, 71.20	0.88, 3.53
	Min, Max	45.1, 95.6	-2.8, 4.8	44.2, 84.9	-2.2, 4.2	44.6, 88.9	-3.2, 6.7
	Mean (SD)	63.01 (11.011)	0.63 (1.817)	62.55 (10.500)	0.86 (1.705)	63.01 (11.243)	1.92 (2.171)
	95% CI of Mean	60.46, 65.57	0.21, 1.06	59.23, 65.87	0.32, 1.41	59.31, 66.71	1.21, 2.64

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: NC= Not Calculated

Appendix: 15.3.6.7

Study ID:ZRHM-REXA-07-JP

Program: t1502043301-ZRHM-REXA-07-JP-v3.0.sas

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Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set
Parameter: Weight (kg)
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	71		41		38	
	Geometric Mean (CV%)	61.78 (17.00)		61.17 (17.02)		60.89 (17.75)	
	95% CI	59.36, 64.31		57.98, 64.52		57.46, 64.52	
	Median	62.10		63.90		61.20	
	Q25, Q75	55.20, 70.30		51.90, 67.40		53.30, 69.20	
	Min, Max	45.1, 97.8		43.4, 84.4		43.7, 91.8	
	Mean (SD)	62.67 (10.863)		62.01 (10.354)		61.83 (11.152)	
	95% CI of Mean	60.09, 65.25		58.74, 65.29		58.16, 65.50	
Day 60							
	n	71	71	41	41	38	38
	Geometric Mean (CV%)	62.17 (17.00)		61.85 (17.07)		62.52 (17.55)	
	95% CI	59.74, 64.71		58.62, 65.25		59.04, 66.21	
	Median	62.00	0.50	64.40	0.92	63.05	2.70
	Q25, Q75	55.00, 71.00	-0.81, 2.20	52.30, 69.50	0.34, 1.55	55.10, 71.60	1.70, 4.63
	Min, Max	45.6, 96.6	-4.9, 6.2	43.8, 84.9	-3.5, 7.2	45.1, 89.0	-4.5, 7.8
	Mean (SD)	63.06 (10.811)	0.66 (2.260)	62.71 (10.467)	1.13 (1.995)	63.45 (11.096)	2.72 (2.703)
	95% CI of Mean	60.50, 65.62	0.12, 1.20	59.40, 66.02	0.50, 1.77	59.80, 67.10	1.83, 3.61

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 10 AM on Day 1 in the SA arm

Note: NC= Not Calculated

Appendix: 15.3.6.7

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Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set
Parameter: Weight (kg)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	70		41		37	
	Geometric Mean (CV%)	61.43 (17.39)		61.17 (17.02)		61.33 (17.41)	
	95% CI	58.95, 64.02		57.98, 64.52		57.89, 64.97	
	Median	61.55		63.90		61.40	
	Q25, Q75	54.10, 68.80		51.90, 67.40		53.90, 69.20	
	Min, Max	45.1, 97.8		43.4, 84.4		43.7, 91.8	
	Mean (SD)	62.35 (11.097)		62.01 (10.354)		62.24 (11.013)	
	95% CI of Mean	59.70, 65.01		58.74, 65.29		58.56, 65.91	
Day 91/Discharge Ambulatory							
	n	70	70	41	41	37	37
	Geometric Mean (CV%)	61.73 (17.56)		61.56 (17.02)		62.84 (17.69)	
	95% CI	59.21, 64.35		58.36, 64.93		59.27, 66.63	
	Median	61.25	0.23	63.40	0.78	62.60	2.41
	Q25, Q75	54.00, 70.90	-1.50, 2.14	52.60, 69.10	-0.65, 2.40	55.40, 72.20	0.94, 4.38
	Min, Max	45.4, 96.2	-5.7, 7.7	44.5, 84.8	-6.0, 5.7	44.7, 88.3	-4.1, 10.1
	Mean (SD)	62.67 (11.188)	0.52 (2.758)	62.41 (10.422)	0.67 (2.319)	63.79 (11.195)	2.52 (2.993)
	95% CI of Mean	60.00, 65.34	-0.14, 1.19	59.12, 65.71	-0.07, 1.40	60.05, 67.53	1.51, 3.52

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: NC= Not Calculated

Appendix: 15.3.6.7



Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set
Parameter: Waist Circumference (cm)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	84.53 (22.93)		87.42 (27.04)		83.47 (22.99)	
	95% CI	80.09, 89.22		80.39, 95.07		77.38, 90.04	
	Median	80.00		80.00		79.00	
	Q25, Q75	73.00, 90.00		75.00, 88.00		75.00, 87.00	
	Min, Max	65.0, 174.0		64.0, 172.0		66.0, 167.0	
	Mean (SD)	87.06 (25.030)		91.00 (30.442)		85.97 (25.089)	
	95% CI of Mean	81.08, 93.03		81.39, 100.61		77.60, 94.34	
	Day 91/Discharge Ambulatory	n	70	69	41	41	37
Geometric Mean (CV%)		80.13 (14.41)		79.90 (9.00)		80.20 (11.99)	
95% CI		77.43, 82.91		77.67, 82.21		77.06, 83.46	
Median		77.50	-1.05	80.00	-1.28	78.00	1.23
Q25, Q75		73.00, 87.00	-3.49, 1.37	75.00, 85.00	-3.41, 1.39	73.00, 88.00	-3.03, 2.94
Min, Max		66.0, 172.0	-55.4, 9.0	67.0, 95.0	-56.7, 8.5	64.0, 105.0	-53.9, 16.0
Mean (SD)		81.04 (14.185)	-4.01 (12.925)	80.22 (7.238)	-6.49 (16.987)	80.76 (9.743)	-2.65 (13.661)
95% CI of Mean		77.66, 84.43	-7.12, -0.90	77.93, 82.51	-11.85, -1.12	77.50, 84.01	-7.21, 1.91

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: NC= Not Calculated

Appendix: 15.3.6.7

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Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS
Parameter: Weight (kg)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	78		42		40	
	Geometric Mean (CV%)	61.97 (17.14)		61.16 (16.81)		60.43 (17.69)	
	95% CI	59.63, 64.39		58.06, 64.43		57.12, 63.92	
	Median	61.55		63.80		59.95	
	Q25, Q75	55.20, 70.30		51.90, 67.40		53.15, 69.05	
	Min, Max	45.1, 97.8		43.4, 84.4		43.7, 91.8	
	Mean (SD)	62.87 (10.976)		61.99 (10.228)		61.36 (11.090)	
	95% CI of Mean	60.39, 65.35		58.80, 65.18		57.80, 64.91	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: NC= Not Calculated

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Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS
Parameter: Weight (kg)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge Confinement	n	78	78	42	42	40	40
	Geometric Mean (CV%)	61.41 (16.87)		61.08 (16.32)		60.39 (17.09)	
	95% CI	59.13, 63.78		58.07, 64.25		57.20, 63.76	
	Median	61.40	-0.86	63.30	-0.18	60.20	0.00
	Q25, Q75	55.30, 69.20	-1.66, 0.00	52.60, 67.10	-1.19, 0.61	52.80, 68.45	-1.09, 0.84
	Min, Max	44.8, 94.5	-4.3, 2.6	44.2, 84.4	-2.3, 3.1	43.4, 88.4	-3.7, 2.5
	Mean (SD)	62.27 (10.650)	-0.89 (1.299)	61.87 (9.959)	-0.12 (1.358)	61.25 (10.591)	-0.05 (1.507)
	95% CI of Mean	59.87, 64.68	-1.19, -0.59	58.76, 64.98	-0.55, 0.31	57.86, 64.64	-0.53, 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 10 AM on Day 1 in the SA arm

Note: NC= Not Calculated

Appendix: 15.3.6.7

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Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS
Parameter: Weight (kg)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30							
	n	77	77	41	41	38	38
	Geometric Mean (CV%)	62.10 (17.00)		61.69 (17.15)		62.05 (17.92)	
	95% CI	59.76, 64.52		58.45, 65.10		58.52, 65.78	
	Median	62.00	0.65	63.00	0.78	62.55	2.08
	Q25, Q75	55.00, 69.80	-0.59, 1.96	52.70, 68.40	-0.51, 2.20	54.30, 71.20	0.88, 3.53
	Min, Max	45.1, 95.6	-2.8, 4.8	44.2, 84.9	-2.2, 4.2	44.6, 88.9	-3.2, 6.7
	Mean (SD)	62.98 (10.795)	0.63 (1.784)	62.55 (10.500)	0.86 (1.705)	63.01 (11.243)	1.92 (2.171)
	95% CI of Mean	60.53, 65.44	0.22, 1.04	59.23, 65.87	0.32, 1.41	59.31, 66.71	1.21, 2.64

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: NC= Not Calculated

Appendix: 15.3.6.7

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Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS
Parameter: Weight (kg)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60							
	n	77	77	41	41	39	39
	Geometric Mean (CV%)	62.12 (17.03)		61.85 (17.07)		62.34 (17.41)	
	95% CI	59.77, 64.55		58.62, 65.25		58.94, 65.94	
	Median	61.90	0.50	64.40	0.92	62.60	2.68
	Q25, Q75	55.40, 70.70	-0.81, 2.20	52.30, 69.50	0.34, 1.55	55.10, 71.60	1.11, 4.63
	Min, Max	45.6, 96.6	-4.9, 6.2	43.8, 84.9	-3.5, 7.2	45.1, 89.0	-4.5, 7.8
	Mean (SD)	63.00 (10.828)	0.67 (2.269)	62.71 (10.467)	1.13 (1.995)	63.26 (11.015)	2.64 (2.707)
	95% CI of Mean	60.54, 65.47	0.15, 1.19	59.40, 66.02	0.50, 1.77	59.68, 66.83	1.76, 3.53

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 10 AM on Day 1 in the SA arm

Note: NC= Not Calculated

Appendix: 15.3.6.7

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Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS
Parameter: Weight (kg)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory	n	78	78	42	42	40	40
	Geometric Mean (CV%)	62.22 (17.20)		61.55 (16.81)		61.92 (17.88)	
	95% CI	59.86, 64.66		58.43, 64.84		58.50, 65.54	
	Median	61.50	0.30	63.40	0.70	62.05	2.44
	Q25, Q75	56.00, 71.20	-1.50, 2.12	52.60, 69.10	-0.65, 2.40	54.35, 72.15	0.94, 4.44
	Min, Max	45.4, 96.2	-5.7, 7.7	44.5, 84.8	-6.0, 5.7	44.7, 88.3	-4.1, 10.1
	Mean (SD)	63.13 (10.994)	0.44 (2.719)	62.39 (10.296)	0.66 (2.291)	62.88 (11.263)	2.51 (2.938)
	95% CI of Mean	60.64, 65.61	-0.18, 1.06	59.17, 65.60	-0.06, 1.38	59.27, 66.49	1.57, 3.46

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 10 AM on Day 1 in the SA arm

Note: NC= Not Calculated

Appendix: 15.3.6.7

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Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS
Parameter: Waist Circumference (cm)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	78		42		40	
	Geometric Mean (CV%)	84.55 (21.83)		87.10 (26.81)		82.69 (22.34)	
	95% CI	80.53, 88.77		80.23, 94.56		77.05, 88.74	
	Median	81.50		79.50		77.50	
	Q25, Q75	74.00, 90.00		75.00, 88.00		75.00, 86.50	
	Min, Max	65.0, 174.0		64.0, 172.0		66.0, 167.0	
	Mean (SD)	86.85 (23.808)		90.62 (30.170)		85.05 (24.329)	
	95% CI of Mean	81.47, 92.22		81.21, 100.03		77.26, 92.84	

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

Note: NC= Not Calculated

Appendix: 15.3.6.7

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Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS
Parameter: Waist Circumference (cm)

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 91/Discharge Ambulatory	n	78	76	42	41	40	38
	Geometric Mean (CV%)	80.57 (13.99)		79.78 (8.95)		79.71 (11.72)	
	95% CI	78.08, 83.14		77.59, 82.04		76.79, 82.75	
	Median	78.50	-1.05	79.50	-1.28	77.50	1.23
	Q25, Q75	73.00, 87.00	-3.13, 1.33	75.00, 85.00	-3.41, 1.39	73.00, 87.50	-3.03, 2.94
	Min, Max	66.0, 172.0	-55.4, 9.0	67.0, 95.0	-56.7, 8.5	64.0, 105.0	-53.9, 16.0
	Mean (SD)	81.44 (13.678)	-3.66 (12.370)	80.10 (7.194)	-6.49 (16.987)	80.25 (9.535)	-2.55 (13.492)
	95% CI of Mean	78.35, 84.52	-6.49, -0.83	77.85, 82.34	-11.85, -1.12	77.20, 83.30	-6.99, 1.89

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 10 AM on Day 1 in the SA arm

Note: NC= Not Calculated

Appendix: 15.3.6.7

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**Table 15.2.4.34.1 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence Results - PP Set****Parameter: Fagerstrom score****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	Change/ Shift(1)	Raw value	Change/ Shift(1)	Raw value	Change/ Shift(1)
Baseline	n	70		41		36	
	Missing, n(%)	0		0		1 (2.7)	
	Mean (SD)	4.3 (1.78)		4.3 (1.82)		4.7 (2.13)	
	Median	4.0		4.0		5.0	
	Q25, Q75	3.0, 6.0		3.0, 5.0		4.0, 6.0	
	Min, Max	1, 8		1, 8		0, 9	
	Mild (0 – 3) , n(%)	26 (37.1)		17 (41.5)		8 (21.6)	
	Moderate (4 – 6) , n(%)	38 (54.3)		17 (41.5)		21 (56.8)	
	Severe (7 – 10) , n(%)	6 (8.6)		7 (17.1)		7 (18.9)	

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.

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**Table 15.2.4.34.1 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence Results - PP Set****Parameter: Fagerstrom score****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	Change/ Shift(1)	Raw value	Change/ Shift(1)	Raw value	Change/ Shift(1)
Day 90	n	69	69	41	41	37	36
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0	0	1 (2.7)
	Mean (SD)	4.1 (2.10)	-0.2 (1.78)	3.6 (1.71)	-0.7 (1.44)	3.2 (2.52)	-1.6 (2.34)
	Median	4.0	0.0	4.0	-1.0	3.0	-1.0
	Q25, Q75	3.0, 6.0	-1.0, 1.0	2.0, 4.0	-2.0, 0.0	1.0, 5.0	-3.0, 0.0
	Min, Max	0, 9	-7, 3	0, 7	-4, 2	0, 8	-6, 2
	Mild (0 – 3) , n(%)	28 (40.0)		17 (41.5)		20 (54.1)	
	Mild to Mild, n(%)		18 (25.7)		12 (29.3)		7 (18.9)
	Moderate to Mild, n(%)		9 (12.9)		4 (9.8)		11 (29.7)
	Severe to Mild, n(%)		1 (1.4)		1 (2.4)		2 (5.4)
	Moderate (4 – 6) , n(%)	33 (47.1)		22 (53.7)		14 (37.8)	
	Mild to Moderate, n(%)		8 (11.4)		5 (12.2)		1 (2.7)
	Moderate to Moderate, n(%)		25 (35.7)		13 (31.7)		9 (24.3)
	Severe to Moderate, n(%)		0		4 (9.8)		4 (10.8)
	Severe (7 – 10) , n(%)	8 (11.4)		2 (4.9)		3 (8.1)	
	Moderate to Severe, n(%)		3 (4.3)		0		1 (2.7)
	Severe to Severe, n(%)		5 (7.1)		2 (4.9)		1 (2.7)

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.

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Study ID:ZRHM-REXA-07-JP

Program: t1502043401-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.34.2 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence Results - FAS****Parameter: Fagerstrom score**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	Change/Shift(1)	Raw value	Change/Shift(1)	Raw value	Change/Shift(1)
Baseline	n	78		42		39	
	Missing, n(%)	0		0		1 (2.5)	
	Mean (SD)	4.3 (1.78)		4.3 (1.81)		4.7 (2.08)	
	Median	4.0		4.0		5.0	
	Q25, Q75	3.0, 6.0		3.0, 5.0		4.0, 6.0	
	Min, Max	1, 9		1, 8		0, 9	
	Mild (0 – 3) , n(%)	27 (34.6)		17 (40.5)		8 (20.0)	
	Moderate (4 – 6) , n(%)	44 (56.4)		18 (42.9)		23 (57.5)	
	Severe (7 – 10) , n(%)	7 (9.0)		7 (16.7)		8 (20.0)	

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.

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Study ID:ZRHM-REXA-07-JP

Program: t1502043402-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.34.2 Descriptive Statistics of Fagestrom Test for Nicotine Dependence Results - FAS****Parameter: Fagerstrom score**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	Change/Shift(1)	Raw value	Change/Shift(1)	Raw value	Change/Shift(1)
Day 90	n	76	76	41	41	38	37
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	2 (5.0)	3 (7.5)
	Mean (SD)	4.2 (2.23)	-0.2 (1.83)	3.6 (1.71)	-0.7 (1.44)	3.1 (2.54)	-1.8 (2.47)
	Median	4.0	0.0	4.0	-1.0	3.0	-1.0
	Q25, Q75	3.0, 6.0	-1.0, 1.0	2.0, 4.0	-2.0, 0.0	1.0, 5.0	-3.0, 0.0
	Min, Max	0, 10	-7, 3	0, 7	-4, 2	0, 8	-7, 2
	Mild (0 – 3) , n(%)	32 (41.0)		17 (40.5)		21 (52.5)	
	Mild to Mild, n(%)		19 (24.4)		12 (28.6)		7 (17.5)
	Moderate to Mild, n(%)		12 (15.4)		4 (9.5)		11 (27.5)
	Severe to Mild, n(%)		1 (1.3)		1 (2.4)		3 (7.5)
	Moderate (4 – 6) , n(%)	33 (42.3)		22 (52.4)		14 (35.0)	
	Mild to Moderate, n(%)		8 (10.3)		5 (11.9)		1 (2.5)
	Moderate to Moderate, n(%)		25 (32.1)		13 (31.0)		9 (22.5)
	Severe to Moderate, n(%)		0		4 (9.5)		4 (10.0)
	Severe (7 – 10) , n(%)	11 (14.1)		2 (4.8)		3 (7.5)	
	Moderate to Severe, n(%)		5 (6.4)		0		1 (2.5)
	Severe to Severe, n(%)		6 (7.7)		2 (4.8)		1 (2.5)

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.

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**Table 15.2.4.34.3 Descriptive Statistics of Fagestrom Test for Nicotine Dependence Results - Compliant Population****Parameter: Fagerstrom score**

Time Point	Statistic	THSm2.2 (N=65)		mCC (N=41)		SA (N=37)	
		Raw value	Change/Shift(1)	Raw value	Change/Shift(1)	Raw value	Change/Shift(1)
Baseline	n	65		41		36	
	Missing, n(%)	0		0		1 (2.7)	
	Mean (SD)	4.3 (1.80)		4.3 (1.82)		4.7 (2.13)	
	Median	4.0		4.0		5.0	
	Q25, Q75	3.0, 6.0		3.0, 5.0		4.0, 6.0	
	Min, Max	1, 8		1, 8		0, 9	
	Mild (0 – 3) , n(%)	24 (36.9)		17 (41.5)		8 (21.6)	
	Moderate (4 – 6) , n(%)	35 (53.8)		17 (41.5)		21 (56.8)	
	Severe (7 – 10) , n(%)	6 (9.2)		7 (17.1)		7 (18.9)	

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.

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**Table 15.2.4.34.3 Descriptive Statistics of Fagestrom Test for Nicotine Dependence Results - Compliant Population****Parameter: Fagerstrom score**

Time Point	Statistic	THSm2.2 (N=65)		mCC (N=41)		SA (N=37)	
		Raw value	Change/Shift(1)	Raw value	Change/Shift(1)	Raw value	Change/Shift(1)
Day 90	n	64	64	41	41	37	36
	Missing, n(%)	1 (1.5)	1 (1.5)	0	0	0	1 (2.7)
	Mean (SD)	4.2 (2.08)	-0.1 (1.74)	3.6 (1.71)	-0.7 (1.44)	3.2 (2.52)	-1.6 (2.34)
	Median	4.0	0.0	4.0	-1.0	3.0	-1.0
	Q25, Q75	3.0, 6.0	-1.0, 1.0	2.0, 4.0	-2.0, 0.0	1.0, 5.0	-3.0, 0.0
	Min, Max	0, 9	-7, 3	0, 7	-4, 2	0, 8	-6, 2
	Mild (0 – 3) , n(%)	25 (38.5)		17 (41.5)		20 (54.1)	
	Mild to Mild, n(%)		16 (24.6)		12 (29.3)		7 (18.9)
	Moderate to Mild, n(%)		8 (12.3)		4 (9.8)		11 (29.7)
	Severe to Mild, n(%)		1 (1.5)		1 (2.4)		2 (5.4)
	Moderate (4 – 6) , n(%)	31 (47.7)		22 (53.7)		14 (37.8)	
	Mild to Moderate, n(%)		8 (12.3)		5 (12.2)		1 (2.7)
	Moderate to Moderate, n(%)		23 (35.4)		13 (31.7)		9 (24.3)
	Severe to Moderate, n(%)		0		4 (9.8)		4 (10.8)
	Severe (7 – 10) , n(%)	8 (12.3)		2 (4.9)		3 (8.1)	
	Moderate to Severe, n(%)		3 (4.6)		0		1 (2.7)
	Severe to Severe, n(%)		5 (7.7)		2 (4.9)		1 (2.7)

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.

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**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set**

Parameter: Factor 1 - Reward
Product Use Time Period: Period 1

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	75		42		39	
	Missing, n(%)	1 (1.3)		0		0	
	Median	4.60		3.70		4.20	
	Q25, Q75	3.00, 5.20		2.40, 5.20		2.60, 5.20	
	Min, Max	1.0, 7.0		1.0, 7.0		1.0, 7.0	
	Mean (SD)	4.22 (1.580)		3.72 (1.670)		4.20 (1.731)	
	95% CI of Mean	3.86, 4.59		3.19, 4.24		3.63, 4.77	

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	4.00	0.00	3.40	-10.71	5.60	31.82
	Q25, Q75	2.60, 5.20	-21.88, 15.00	2.60, 4.20	-26.92, 23.08	4.40, 6.40	0.00, 93.75
	Min, Max	1.0, 7.0	-77.4, 300.0	1.0, 6.0	-61.5, 128.6	2.2, 7.0	-39.4, 191.7
	Mean (SD)	3.90 (1.642)	0.55 (49.866)	3.40 (1.314)	2.65 (43.272)	5.37 (1.272)	45.79 (54.436)
	95% CI of Mean	3.52, 4.29	-10.93, 12.03	2.98, 3.82	-11.02, 16.31	4.96, 5.79	28.13, 63.44

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	3.80	-12.50	3.40	-9.09	5.40	22.73
	Q25, Q75	2.20, 5.20	-25.00, 8.00	2.40, 4.40	-25.81, 0.00	4.00, 6.40	-2.86, 80.00
	Min, Max	1.0, 7.0	-83.9, 333.3	1.0, 6.0	-57.7, 242.9	1.8, 7.0	-42.4, 230.0
	Mean (SD)	3.73 (1.556)	-3.28 (53.019)	3.31 (1.369)	-2.02 (46.551)	5.13 (1.438)	37.50 (54.299)
	95% CI of Mean	3.37, 4.09	-15.49, 8.92	2.88, 3.75	-16.72, 12.67	4.66, 5.60	19.90, 55.11

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	3.60	-12.50	3.00	-12.50	5.60	26.09
	Q25, Q75	2.00, 5.00	-30.77, 5.56	2.20, 4.40	-24.24, 8.33	4.00, 6.20	0.00, 70.00
	Min, Max	1.0, 7.0	-83.9, 175.0	1.0, 6.0	-53.8, 100.0	2.0, 7.0	-69.7, 300.0
	Mean (SD)	3.59 (1.613)	-8.42 (44.138)	3.20 (1.339)	-6.48 (32.795)	5.10 (1.475)	42.55 (72.452)
	95% CI of Mean	3.21, 3.97	-18.58, 1.74	2.78, 3.63	-16.83, 3.88	4.62, 5.59	19.06, 66.04

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	3.60	-14.29	3.00	-15.00	5.20	30.00
	Q25, Q75	2.00, 4.80	-37.50, 7.41	2.00, 4.20	-35.29, 20.00	3.80, 6.40	-9.38, 77.78
	Min, Max	1.0, 7.0	-78.3, 287.5	1.0, 6.0	-61.5, 214.3	1.4, 7.0	-42.1, 250.0
	Mean (SD)	3.62 (1.655)	-6.22 (55.633)	3.21 (1.456)	-3.05 (51.450)	5.09 (1.575)	38.28 (63.179)
	95% CI of Mean	3.24, 4.01	-19.03, 6.58	2.75, 3.67	-19.29, 13.20	4.57, 5.60	17.79, 58.76

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	3.80	-13.33	2.80	-7.69	5.20	16.00
	Q25, Q75	2.20, 4.80	-28.00, 0.00	2.20, 4.20	-30.77, 8.33	3.20, 6.60	-9.38, 52.63
	Min, Max	1.0, 7.0	-83.9, 200.0	1.0, 6.0	-57.7, 257.1	1.0, 7.0	-53.6, 250.0
	Mean (SD)	3.53 (1.527)	-10.00 (42.832)	3.20 (1.318)	-2.07 (52.140)	4.87 (1.806)	28.82 (61.202)
	95% CI of Mean	3.17, 3.88	-19.86, -0.14	2.77, 3.62	-18.54, 14.39	4.28, 5.46	8.97, 48.66

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 2**

		THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Median	4.60		3.60		4.20	
	Q25, Q75	3.00, 5.20		2.40, 5.20		2.60, 5.20	
	Min, Max	1.0, 7.0		1.0, 7.0		1.0, 7.0	
	Mean (SD)	4.22 (1.590)		3.66 (1.644)		4.20 (1.731)	
	95% CI of Mean	3.84, 4.59		3.13, 4.18		3.63, 4.77	

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 2**

		THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	38	38
	Missing, n(%)	0	0	0	0	1 (2.6)	1 (2.6)
	Median	3.80	-8.29	3.20	-6.25	2.40	-26.68
	Q25, Q75	2.60, 4.80	-33.33, 25.00	2.60, 4.20	-25.00, 16.67	1.60, 4.00	-52.94, 0.00
	Min, Max	1.0, 7.0	-80.0, 185.7	1.0, 7.0	-61.5, 185.7	1.0, 7.0	-80.8, 116.7
	Mean (SD)	3.76 (1.523)	0.16 (51.726)	3.43 (1.300)	6.37 (51.700)	2.99 (1.759)	-20.65 (44.188)
	95% CI of Mean	3.40, 4.12	-11.83, 12.15	3.01, 3.84	-9.95, 22.70	2.41, 3.58	-35.18, -6.12

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 3**

		THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Median	4.60		3.60		4.10	
	Q25, Q75	3.00, 5.20		2.40, 5.20		2.60, 5.00	
	Min, Max	1.0, 7.0		1.0, 7.0		1.0, 7.0	
	Mean (SD)	4.23 (1.594)		3.66 (1.644)		4.14 (1.708)	
	95% CI of Mean	3.85, 4.61		3.13, 4.18		3.57, 4.70	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 3**

		THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Median	3.80	-10.00	3.40	-5.56	2.00	-36.57
	Q25, Q75	2.80, 5.00	-34.78, 13.04	2.40, 4.40	-17.65, 20.00	1.60, 3.60	-62.50, 0.00
	Min, Max	1.0, 7.0	-82.9, 216.7	1.2, 5.8	-61.5, 271.4	1.0, 7.0	-80.8, 108.3
	Mean (SD)	3.72 (1.555)	0.36 (58.683)	3.43 (1.305)	7.87 (56.848)	2.74 (1.725)	-28.17 (41.226)
	95% CI of Mean	3.35, 4.09	-13.54, 14.25	3.01, 3.85	-10.08, 25.81	2.16, 3.31	-41.73, -14.61

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 4**

		THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Median	4.60		3.60		4.00	
	Q25, Q75	3.00, 5.20		2.40, 5.20		2.60, 5.00	
	Min, Max	1.0, 7.0		1.0, 7.0		1.0, 7.0	
	Mean (SD)	4.22 (1.604)		3.66 (1.644)		4.11 (1.725)	
	95% CI of Mean	3.83, 4.61		3.13, 4.18		3.53, 4.69	

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 4**

		THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	69	41	41	37	37
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0	0	0
	Median	4.00	-4.35	3.20	-7.69	1.80	-52.17
	Q25, Q75	2.80, 4.80	-26.09, 17.39	2.40, 4.60	-33.33, 16.67	1.00, 2.80	-68.75, -9.09
	Min, Max	1.0, 7.0	-78.3, 266.7	1.2, 6.2	-65.4, 228.6	1.0, 7.0	-83.3, 75.0
	Mean (SD)	3.94 (1.513)	8.02 (65.470)	3.35 (1.308)	7.80 (65.466)	2.40 (1.813)	-36.85 (39.859)
	95% CI of Mean	3.57, 4.31	-7.72, 23.75	2.93, 3.76	-12.87, 28.47	1.79, 3.01	-50.14, -23.55

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	75		42		39	
	Missing, n(%)	1 (1.3)		0		0	
	Median	2.80		2.40		3.00	
	Q25, Q75	1.60, 4.20		1.60, 3.60		1.60, 4.00	
	Min, Max	1.0, 6.8		1.0, 6.2		1.0, 6.0	
	Mean (SD)	2.98 (1.553)		2.73 (1.404)		3.10 (1.457)	
	95% CI of Mean	2.62, 3.34		2.29, 3.17		2.63, 3.58	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	2.40	0.00	2.20	-12.50	4.80	41.67
	Q25, Q75	1.60, 3.80	-20.00, 11.11	1.40, 3.00	-25.00, 11.11	3.40, 6.20	13.79, 100.00
	Min, Max	1.0, 6.6	-70.6, 266.7	1.0, 5.0	-60.0, 66.7	1.2, 7.0	-40.0, 350.0
	Mean (SD)	2.78 (1.494)	2.28 (49.082)	2.37 (1.056)	-6.82 (25.999)	4.65 (1.779)	68.52 (82.309)
	95% CI of Mean	2.43, 3.13	-9.02, 13.58	2.03, 2.71	-15.03, 1.40	4.07, 5.23	41.83, 95.21

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	2.20	-9.09	1.80	-22.22	5.00	29.41
	Q25, Q75	1.40, 3.80	-26.32, 0.00	1.20, 3.00	-30.00, 0.00	2.60, 5.80	6.90, 100.00
	Min, Max	1.0, 6.2	-78.3, 120.0	1.0, 5.6	-54.5, 100.0	1.2, 7.0	-35.7, 316.7
	Mean (SD)	2.64 (1.440)	-5.09 (36.943)	2.28 (1.261)	-12.47 (32.285)	4.46 (1.788)	61.79 (80.436)
	95% CI of Mean	2.31, 2.98	-13.60, 3.41	1.88, 2.68	-22.67, -2.28	3.87, 5.04	35.71, 87.87

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	2.40	-14.29	2.00	-10.00	4.20	23.08
	Q25, Q75	1.40, 3.60	-28.57, 5.88	1.20, 3.00	-39.13, 0.00	2.60, 6.20	0.00, 80.00
	Min, Max	1.0, 6.2	-78.3, 140.0	1.0, 5.8	-56.0, 55.6	1.0, 7.0	-57.1, 366.7
	Mean (SD)	2.54 (1.329)	-7.49 (37.188)	2.28 (1.256)	-12.42 (28.869)	4.26 (1.997)	51.98 (85.228)
	95% CI of Mean	2.23, 2.85	-16.05, 1.07	1.88, 2.68	-21.54, -3.31	3.61, 4.91	24.35, 79.62

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	2.20	-11.11	2.00	-11.11	4.00	21.43
	Q25, Q75	1.20, 3.60	-25.93, 0.00	1.40, 3.00	-28.57, 11.11	2.40, 6.00	0.00, 68.42
	Min, Max	1.0, 6.4	-73.9, 260.0	1.0, 5.0	-64.7, 66.7	1.0, 7.0	-50.0, 328.6
	Mean (SD)	2.54 (1.336)	-5.12 (48.948)	2.37 (1.207)	-6.39 (33.101)	4.04 (1.963)	41.17 (72.460)
	95% CI of Mean	2.23, 2.85	-16.38, 6.15	1.98, 2.76	-16.84, 4.07	3.39, 4.68	17.67, 64.66

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	2.20	-14.29	2.00	-12.90	4.00	16.67
	Q25, Q75	1.20, 3.40	-31.82, 0.00	1.20, 2.40	-47.83, 5.56	2.20, 6.00	0.00, 76.47
	Min, Max	1.0, 6.0	-79.2, 200.0	1.0, 5.4	-60.0, 133.3	1.0, 7.0	-45.0, 342.9
	Mean (SD)	2.48 (1.324)	-7.96 (45.902)	2.22 (1.265)	-12.18 (38.026)	4.07 (2.028)	41.21 (75.112)
	95% CI of Mean	2.17, 2.79	-18.52, 2.61	1.82, 2.62	-24.18, -0.17	3.40, 4.73	16.86, 65.57

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 2**

		THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Median	2.70		2.40		3.00	
	Q25, Q75	1.60, 4.20		1.60, 3.60		1.60, 4.00	
	Min, Max	1.0, 6.8		1.0, 6.2		1.0, 6.0	
	Mean (SD)	2.96 (1.559)		2.74 (1.419)		3.10 (1.457)	
	95% CI of Mean	2.60, 3.33		2.29, 3.19		2.63, 3.58	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 2**

		THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	38	38
	Missing, n(%)	0	0	0	0	1 (2.6)	1 (2.6)
	Median	2.30	-7.68	2.00	-14.29	1.80	-27.88
	Q25, Q75	1.20, 3.40	-40.00, 4.76	1.40, 2.80	-45.00, 11.11	1.20, 2.80	-51.72, 6.67
	Min, Max	1.0, 6.2	-75.0, 300.0	1.0, 6.2	-66.7, 220.0	1.0, 7.0	-79.2, 63.2
	Mean (SD)	2.46 (1.330)	-6.22 (52.722)	2.26 (1.222)	-4.69 (56.242)	2.34 (1.690)	-18.75 (41.698)
	95% CI of Mean	2.15, 2.78	-18.44, 6.00	1.87, 2.65	-22.45, 13.07	1.78, 2.90	-32.46, -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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 3**

		THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Median	2.60		2.40		3.10	
	Q25, Q75	1.60, 4.20		1.60, 3.60		1.60, 4.00	
	Min, Max	1.0, 6.8		1.0, 6.2		1.0, 6.0	
	Mean (SD)	2.95 (1.534)		2.74 (1.419)		3.11 (1.476)	
	95% CI of Mean	2.59, 3.32		2.29, 3.19		2.62, 3.60	

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 3**

		THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Median	2.40	-10.00	2.00	-10.00	1.40	-37.17
	Q25, Q75	1.20, 3.40	-37.50, 13.79	1.40, 2.80	-40.00, 11.11	1.00, 2.60	-61.54, 0.00
	Min, Max	1.0, 6.6	-85.3, 300.0	1.0, 5.8	-68.0, 120.0	1.0, 7.0	-80.0, 116.7
	Mean (SD)	2.51 (1.375)	-1.78 (62.279)	2.29 (1.261)	-7.39 (43.052)	2.18 (1.706)	-24.03 (46.456)
	95% CI of Mean	2.18, 2.84	-16.53, 12.96	1.89, 2.69	-20.98, 6.21	1.62, 2.75	-39.30, -8.75

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 4**

		THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Median	2.70		2.40		3.00	
	Q25, Q75	1.60, 4.20		1.60, 3.60		1.60, 4.00	
	Min, Max	1.0, 6.8		1.0, 6.2		1.0, 6.0	
	Mean (SD)	2.98 (1.586)		2.74 (1.419)		3.09 (1.489)	
	95% CI of Mean	2.60, 3.36		2.29, 3.19		2.59, 3.59	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 4**

		THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	69	41	41	37	37
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0	0	0
	Median	2.60	-16.00	1.80	-16.67	1.20	-44.44
	Q25, Q75	1.60, 3.20	-35.00, 10.53	1.20, 3.00	-40.00, 11.11	1.00, 2.00	-62.50, 0.00
	Min, Max	1.0, 6.8	-73.9, 180.0	1.0, 5.8	-68.0, 150.0	1.0, 7.0	-82.8, 83.3
	Mean (SD)	2.56 (1.265)	-1.07 (53.138)	2.31 (1.280)	-5.78 (48.098)	1.98 (1.741)	-30.10 (44.429)
	95% CI of Mean	2.25, 2.87	-13.84, 11.70	1.90, 2.72	-20.97, 9.40	1.39, 2.56	-44.91, -15.28

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: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	75		42		39	
	Missing, n(%)	1 (1.3)		0		0	
	Median	3.50		3.15		3.70	
	Q25, Q75	2.40, 4.80		1.90, 4.40		2.20, 4.80	
	Min, Max	1.0, 6.9		1.0, 6.3		1.0, 6.5	
	Mean (SD)	3.60 (1.502)		3.22 (1.478)		3.65 (1.537)	
	95% CI of Mean	3.25, 3.95		2.76, 3.69		3.15, 4.15	

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	3.30	-4.44	2.80	-12.28	5.30	43.24
	Q25, Q75	2.00, 4.50	-19.44, 15.79	2.00, 3.80	-25.71, 17.65	4.00, 6.40	8.33, 81.82
	Min, Max	1.0, 6.6	-74.1, 227.3	1.0, 5.3	-44.4, 92.3	2.0, 7.0	-15.6, 222.2
	Mean (SD)	3.34 (1.474)	0.53 (45.139)	2.89 (1.102)	-1.81 (33.340)	5.01 (1.462)	52.19 (52.987)
	95% CI of Mean	3.00, 3.69	-9.86, 10.92	2.53, 3.24	-12.34, 8.72	4.53, 5.49	35.01, 69.37

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	2.90	-10.45	2.70	-11.11	5.00	33.33
	Q25, Q75	2.00, 4.30	-20.45, 7.32	1.80, 3.60	-28.57, 1.75	3.50, 6.20	5.26, 66.67
	Min, Max	1.0, 6.4	-81.5, 236.4	1.0, 5.8	-54.5, 176.9	1.5, 7.0	-40.4, 241.2
	Mean (SD)	3.19 (1.424)	-4.67 (42.282)	2.80 (1.236)	-6.42 (37.496)	4.79 (1.554)	45.17 (55.736)
	95% CI of Mean	2.85, 3.52	-14.40, 5.07	2.40, 3.19	-18.26, 5.42	4.28, 5.30	27.10, 63.24

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	3.00	-12.28	2.60	-12.96	4.60	24.07
	Q25, Q75	1.80, 4.10	-27.78, 3.85	1.90, 3.80	-28.57, 0.00	3.50, 6.40	4.62, 80.56
	Min, Max	1.0, 6.5	-81.5, 107.7	1.0, 5.9	-51.8, 78.3	1.6, 6.8	-66.0, 252.9
	Mean (SD)	3.07 (1.385)	-8.82 (36.595)	2.74 (1.231)	-9.38 (28.476)	4.68 (1.671)	43.68 (62.284)
	95% CI of Mean	2.74, 3.39	-17.25, -0.40	2.35, 3.13	-18.37, -0.38	4.14, 5.23	23.49, 63.88

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	3.00	-13.56	2.70	-11.76	4.50	18.92
	Q25, Q75	1.90, 4.00	-32.20, 5.77	1.80, 3.80	-32.50, 8.33	3.20, 6.30	0.00, 72.50
	Min, Max	1.0, 6.6	-75.0, 176.9	1.0, 5.2	-59.1, 138.5	1.2, 7.0	-37.5, 282.4
	Mean (SD)	3.08 (1.389)	-6.84 (45.147)	2.79 (1.245)	-5.24 (39.844)	4.56 (1.692)	38.08 (61.400)
	95% CI of Mean	2.76, 3.41	-17.23, 3.56	2.39, 3.19	-17.82, 7.34	4.01, 5.11	18.17, 57.98

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

		THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	3.00	-13.04	2.40	-12.28	4.60	16.36
	Q25, Q75	1.80, 4.10	-27.45, 0.00	1.70, 3.60	-31.43, 4.55	2.80, 6.00	-9.30, 63.89
	Min, Max	1.0, 6.4	-81.5, 200.0	1.0, 5.7	-54.2, 200.0	1.0, 7.0	-50.0, 288.2
	Mean (SD)	3.00 (1.330)	-9.55 (42.523)	2.71 (1.221)	-7.07 (42.991)	4.47 (1.839)	33.06 (63.346)
	95% CI of Mean	2.69, 3.31	-19.34, 0.24	2.32, 3.10	-20.65, 6.50	3.87, 5.07	12.52, 53.60

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 2**

		THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41		39	
	Median	3.45		3.10		3.70	
	Q25, Q75	2.40, 4.80		1.90, 4.40		2.20, 4.80	
	Min, Max	1.0, 6.9		1.0, 6.3		1.0, 6.5	
	Mean (SD)	3.59 (1.509)		3.20 (1.489)		3.65 (1.537)	
	95% CI of Mean	3.24, 3.95		2.73, 3.67		3.15, 4.15	

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 2**

		THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41	38	38
	Missing, n(%)	0	0	0	0	1 (2.6)	1 (2.6)
	Median	3.00	-7.85	2.60	-11.36	2.35	-35.01
	Q25, Q75	2.00, 3.80	-34.29, 15.38	2.00, 3.40	-27.50, 15.79	1.50, 3.50	-50.00, 13.33
	Min, Max	1.0, 6.6	-74.4, 233.3	1.0, 6.6	-61.4, 161.5	1.0, 7.0	-76.2, 94.4
	Mean (SD)	3.11 (1.344)	-3.12 (48.417)	2.85 (1.160)	0.43 (46.329)	2.67 (1.675)	-20.67 (41.187)
	95% CI of Mean	2.80, 3.43	-14.34, 8.11	2.48, 3.22	-14.20, 15.06	2.11, 3.22	-34.21, -7.12

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 3**

		THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Median	3.50		3.10		3.65	
	Q25, Q75	2.40, 4.80		1.90, 4.40		2.20, 4.80	
	Min, Max	1.0, 6.9		1.0, 6.3		1.0, 6.5	
	Mean (SD)	3.59 (1.498)		3.20 (1.489)		3.62 (1.547)	
	95% CI of Mean	3.23, 3.95		2.73, 3.67		3.11, 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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 3**

		THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41	38	38
	Median	3.10	-9.76	2.60	-4.76	1.75	-32.15
	Q25, Q75	2.10, 4.00	-31.25, 15.15	2.00, 3.50	-29.63, 22.58	1.30, 3.10	-61.29, 0.00
	Min, Max	1.0, 6.8	-84.1, 233.3	1.1, 5.8	-59.1, 200.0	1.0, 7.0	-76.2, 111.1
	Mean (SD)	3.12 (1.389)	-1.14 (56.328)	2.86 (1.207)	0.41 (45.551)	2.46 (1.690)	-27.64 (41.082)
	95% CI of Mean	2.78, 3.45	-14.48, 12.20	2.47, 3.24	-13.97, 14.79	1.90, 3.02	-41.15, -14.13

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 4**

		THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Median	3.50		3.10		3.60	
	Q25, Q75	2.40, 4.80		1.90, 4.40		2.20, 4.80	
	Min, Max	1.0, 6.9		1.0, 6.3		1.0, 6.5	
	Mean (SD)	3.60 (1.531)		3.20 (1.489)		3.60 (1.562)	
	95% CI of Mean	3.23, 3.97		2.73, 3.67		3.07, 4.13	

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 4**

		THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	69	41	41	37	37
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0	0	0
	Median	3.30	-10.00	2.50	-14.29	1.40	-44.19
	Q25, Q75	2.50, 4.00	-31.43, 14.29	1.80, 3.70	-31.48, 5.26	1.00, 2.40	-62.50, -8.33
	Min, Max	1.0, 6.9	-70.4, 180.0	1.2, 6.0	-63.6, 192.3	1.0, 7.0	-81.8, 77.8
	Mean (SD)	3.25 (1.279)	3.54 (55.344)	2.83 (1.221)	0.67 (52.824)	2.19 (1.759)	-34.90 (40.745)
	95% CI of Mean	2.94, 3.56	-9.76, 16.84	2.44, 3.22	-16.01, 17.34	1.60, 2.78	-48.49, -21.31

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: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	77		42		40	
	Missing, n(%)	1 (1.3)		0		0	
	Median	4.60		3.70		4.10	
	Q25, Q75	3.00, 5.00		2.40, 5.20		2.50, 5.10	
	Min, Max	1.0, 7.0		1.0, 7.0		1.0, 7.0	
	Mean (SD)	4.21 (1.566)		3.72 (1.670)		4.13 (1.773)	
	95% CI of Mean	3.85, 4.57		3.19, 4.24		3.55, 4.70	

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).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	77	77	41	41	40	40
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	3.80	0.00	3.40	-10.71	5.60	32.58
	Q25, Q75	2.80, 5.00	-21.88, 13.33	2.60, 4.20	-26.92, 23.08	4.30, 6.30	1.52, 93.93
	Min, Max	1.0, 7.0	-77.4, 300.0	1.0, 6.0	-61.5, 128.6	2.2, 7.0	-39.4, 200.0
	Mean (SD)	3.89 (1.624)	0.26 (49.393)	3.40 (1.314)	2.65 (43.272)	5.33 (1.287)	49.64 (59.007)
	95% CI of Mean	3.51, 4.26	-10.96, 11.47	2.98, 3.82	-11.02, 16.31	4.91, 5.75	30.76, 68.52

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	76	76	41	41	40	40
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	0	0
	Median	3.80	-11.96	3.40	-9.09	5.30	23.86
	Q25, Q75	2.20, 5.10	-24.50, 9.00	2.40, 4.40	-25.81, 0.00	3.90, 6.30	-1.43, 81.67
	Min, Max	1.0, 7.0	-83.9, 333.3	1.0, 6.0	-57.7, 242.9	1.8, 7.0	-42.4, 230.0
	Mean (SD)	3.74 (1.547)	-2.71 (52.898)	3.31 (1.369)	-2.02 (46.551)	5.10 (1.435)	41.98 (60.624)
	95% CI of Mean	3.38, 4.10	-14.81, 9.38	2.88, 3.75	-16.72, 12.67	4.63, 5.56	22.59, 61.38

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	3.70	-11.96	3.00	-12.50	5.60	26.09
	Q25, Q75	2.10, 5.00	-29.67, 6.78	2.20, 4.40	-24.24, 8.33	4.00, 6.20	0.00, 70.00
	Min, Max	1.0, 7.0	-83.9, 175.0	1.0, 6.0	-53.8, 100.0	2.0, 7.0	-69.7, 300.0
	Mean (SD)	3.61 (1.616)	-7.25 (45.000)	3.20 (1.339)	-6.48 (32.795)	5.10 (1.475)	42.55 (72.452)
	95% CI of Mean	3.24, 3.99	-17.54, 3.03	2.78, 3.63	-16.83, 3.88	4.62, 5.59	19.06, 66.04

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	3.60	-14.29	3.00	-15.00	5.20	30.00
	Q25, Q75	2.00, 4.80	-36.25, 8.70	2.00, 4.20	-35.29, 20.00	3.80, 6.40	-9.38, 77.78
	Min, Max	1.0, 7.0	-78.3, 287.5	1.0, 6.0	-61.5, 214.3	1.4, 7.0	-42.1, 250.0
	Mean (SD)	3.63 (1.644)	-5.70 (55.446)	3.21 (1.456)	-3.05 (51.450)	5.09 (1.575)	38.28 (63.179)
	95% CI of Mean	3.25, 4.01	-18.38, 6.97	2.75, 3.67	-19.29, 13.20	4.57, 5.60	17.79, 58.76

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	3.80	-13.33	2.80	-7.69	5.20	16.00
	Q25, Q75	2.20, 4.70	-27.46, 0.00	2.20, 4.20	-30.77, 8.33	3.20, 6.60	-9.38, 52.63
	Min, Max	1.0, 7.0	-83.9, 200.0	1.0, 6.0	-57.7, 257.1	1.0, 7.0	-53.6, 250.0
	Mean (SD)	3.52 (1.518)	-9.87 (42.561)	3.20 (1.318)	-2.07 (52.140)	4.87 (1.806)	28.82 (61.202)
	95% CI of Mean	3.17, 3.87	-19.60, -0.14	2.77, 3.62	-18.54, 14.39	4.28, 5.46	8.97, 48.66

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	77	76	41	41	38	38
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	3.80	-7.23	3.20	-6.25	2.40	-26.68
	Q25, Q75	2.80, 4.80	-31.88, 25.83	2.60, 4.20	-25.00, 16.67	1.60, 4.00	-52.94, 0.00
	Min, Max	1.0, 7.0	-80.0, 185.7	1.0, 7.0	-61.5, 185.7	1.0, 7.0	-80.8, 116.7
	Mean (SD)	3.81 (1.528)	0.68 (51.236)	3.43 (1.300)	6.37 (51.700)	2.99 (1.759)	-20.65 (44.188)
	95% CI of Mean	3.46, 4.16	-11.03, 12.39	3.01, 3.84	-9.95, 22.70	2.41, 3.58	-35.18, -6.12

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	77	76	41	41	38	38
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	3.80	-10.00	3.40	-5.56	2.00	-36.57
	Q25, Q75	2.80, 4.80	-34.06, 11.52	2.40, 4.40	-17.65, 20.00	1.60, 3.60	-62.50, 0.00
	Min, Max	1.0, 7.0	-82.9, 216.7	1.2, 5.8	-61.5, 271.4	1.0, 7.0	-80.8, 108.3
	Mean (SD)	3.69 (1.533)	-0.83 (57.417)	3.43 (1.305)	7.87 (56.848)	2.74 (1.725)	-28.17 (41.226)
	95% CI of Mean	3.34, 4.04	-13.96, 12.29	3.01, 3.85	-10.08, 25.81	2.16, 3.31	-41.73, -14.61

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	76	75	41	41	38	38
	Missing, n(%)	2 (2.6)	3 (3.8)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	4.00	-8.33	3.20	-7.69	1.80	-52.28
	Q25, Q75	2.80, 4.80	-30.00, 16.67	2.40, 4.60	-33.33, 16.67	1.00, 2.80	-68.75, -9.09
	Min, Max	1.0, 7.0	-78.3, 266.7	1.2, 6.2	-65.4, 228.6	1.0, 7.0	-83.3, 75.0
	Mean (SD)	3.91 (1.516)	6.01 (63.682)	3.35 (1.308)	7.80 (65.466)	2.39 (1.789)	-37.35 (39.439)
	95% CI of Mean	3.56, 4.26	-8.64, 20.67	2.93, 3.76	-12.87, 28.47	1.80, 2.99	-50.32, -24.38

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	77		42		40	
	Missing, n(%)	1 (1.3)		0		0	
	Median	2.60		2.40		3.00	
	Q25, Q75	1.60, 4.20		1.60, 3.60		1.60, 4.00	
	Min, Max	1.0, 6.8		1.0, 6.2		1.0, 6.0	
	Mean (SD)	2.94 (1.553)		2.73 (1.404)		3.05 (1.476)	
	95% CI of Mean	2.58, 3.30		2.29, 3.17		2.57, 3.53	

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	77	77	41	41	40	40
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	2.40	0.00	2.20	-12.50	4.80	40.83
	Q25, Q75	1.60, 3.80	-20.00, 11.11	1.40, 3.00	-25.00, 11.11	3.10, 6.10	15.23, 100.00
	Min, Max	1.0, 6.6	-70.6, 266.7	1.0, 5.0	-60.0, 66.7	1.2, 7.0	-40.0, 350.0
	Mean (SD)	2.76 (1.481)	3.78 (50.985)	2.37 (1.056)	-6.82 (25.999)	4.57 (1.829)	67.81 (81.372)
	95% CI of Mean	2.42, 3.10	-7.80, 15.35	2.03, 2.71	-15.03, 1.40	3.98, 5.16	41.78, 93.84

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	76	76	41	41	40	40
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	0	0
	Median	2.20	-9.09	1.80	-22.22	4.80	29.29
	Q25, Q75	1.40, 3.80	-25.66, 0.00	1.20, 3.00	-30.00, 0.00	2.50, 5.80	8.71, 96.67
	Min, Max	1.0, 6.2	-78.3, 120.0	1.0, 5.6	-54.5, 100.0	1.2, 7.0	-35.7, 316.7
	Mean (SD)	2.64 (1.431)	-4.90 (36.736)	2.28 (1.261)	-12.47 (32.285)	4.38 (1.838)	60.75 (79.672)
	95% CI of Mean	2.30, 2.97	-13.30, 3.50	1.88, 2.68	-22.67, -2.28	3.78, 4.97	35.26, 86.23

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	2.40	-14.29	2.00	-10.00	4.20	23.08
	Q25, Q75	1.40, 3.60	-28.57, 5.72	1.20, 3.00	-39.13, 0.00	2.60, 6.20	0.00, 80.00
	Min, Max	1.0, 6.2	-78.3, 140.0	1.0, 5.8	-56.0, 55.6	1.0, 7.0	-57.1, 366.7
	Mean (SD)	2.54 (1.322)	-7.39 (36.950)	2.28 (1.256)	-12.42 (28.869)	4.26 (1.997)	51.98 (85.228)
	95% CI of Mean	2.23, 2.84	-15.84, 1.06	1.88, 2.68	-21.54, -3.31	3.61, 4.91	24.35, 79.62

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	2.20	-10.56	2.00	-11.11	4.00	21.43
	Q25, Q75	1.30, 3.60	-24.33, 2.78	1.40, 3.00	-28.57, 11.11	2.40, 6.00	0.00, 68.42
	Min, Max	1.0, 6.4	-73.9, 260.0	1.0, 5.0	-64.7, 66.7	1.0, 7.0	-50.0, 328.6
	Mean (SD)	2.54 (1.328)	-4.52 (48.896)	2.37 (1.207)	-6.39 (33.101)	4.04 (1.963)	41.17 (72.460)
	95% CI of Mean	2.23, 2.85	-15.70, 6.66	1.98, 2.76	-16.84, 4.07	3.39, 4.68	17.67, 64.66

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	2.20	-13.81	2.00	-12.90	4.00	16.67
	Q25, Q75	1.20, 3.40	-31.13, 0.00	1.20, 2.40	-47.83, 5.56	2.20, 6.00	0.00, 76.47
	Min, Max	1.0, 6.0	-79.2, 200.0	1.0, 5.4	-60.0, 133.3	1.0, 7.0	-45.0, 342.9
	Mean (SD)	2.48 (1.315)	-7.72 (45.641)	2.22 (1.265)	-12.18 (38.026)	4.07 (2.028)	41.21 (75.112)
	95% CI of Mean	2.17, 2.78	-18.16, 2.71	1.82, 2.62	-24.18, -0.17	3.40, 4.73	16.86, 65.57

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	77	76	41	41	38	38
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	2.20	-7.68	2.00	-14.29	1.80	-27.88
	Q25, Q75	1.20, 3.20	-40.00, 2.38	1.40, 2.80	-45.00, 11.11	1.20, 2.80	-51.72, 6.67
	Min, Max	1.0, 6.2	-75.0, 300.0	1.0, 6.2	-66.7, 220.0	1.0, 7.0	-79.2, 63.2
	Mean (SD)	2.46 (1.311)	-6.32 (52.043)	2.26 (1.222)	-4.69 (56.242)	2.34 (1.690)	-18.75 (41.698)
	95% CI of Mean	2.15, 2.76	-18.22, 5.58	1.87, 2.65	-22.45, 13.07	1.78, 2.90	-32.46, -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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	77	76	41	41	38	38
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	2.20	-10.00	2.00	-10.00	1.40	-37.17
	Q25, Q75	1.40, 3.20	-36.93, 2.50	1.40, 2.80	-40.00, 11.11	1.00, 2.60	-61.54, 0.00
	Min, Max	1.0, 6.6	-85.3, 300.0	1.0, 5.8	-68.0, 120.0	1.0, 7.0	-80.0, 116.7
	Mean (SD)	2.48 (1.357)	-3.07 (60.687)	2.29 (1.261)	-7.39 (43.052)	2.18 (1.706)	-24.03 (46.456)
	95% CI of Mean	2.16, 2.79	-16.94, 10.81	1.89, 2.69	-20.98, 6.21	1.62, 2.75	-39.30, -8.75

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	76	75	41	41	38	38
	Missing, n(%)	2 (2.6)	3 (3.8)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	2.50	-16.00	1.80	-16.67	1.20	-45.91
	Q25, Q75	1.60, 3.30	-37.50, 10.53	1.20, 3.00	-40.00, 11.11	1.00, 2.00	-62.50, 0.00
	Min, Max	1.0, 6.8	-73.9, 180.0	1.0, 5.8	-68.0, 150.0	1.0, 7.0	-82.8, 83.3
	Mean (SD)	2.54 (1.233)	-2.32 (51.672)	2.31 (1.280)	-5.78 (48.098)	1.97 (1.719)	-30.88 (44.093)
	95% CI of Mean	2.25, 2.82	-14.22, 9.57	1.90, 2.72	-20.97, 9.40	1.40, 2.54	-45.38, -16.39

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	77		42		40	
	Missing, n(%)	1 (1.3)		0		0	
	Median	3.40		3.15		3.65	
	Q25, Q75	2.40, 4.60		1.90, 4.40		2.20, 4.75	
	Min, Max	1.0, 6.9		1.0, 6.3		1.0, 6.5	
	Mean (SD)	3.58 (1.490)		3.22 (1.478)		3.59 (1.569)	
	95% CI of Mean	3.23, 3.92		2.76, 3.69		3.08, 4.09	

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	77	77	41	41	40	40
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	3.20	-4.00	2.80	-12.28	5.25	45.95
	Q25, Q75	2.00, 4.50	-19.40, 14.58	2.00, 3.80	-25.71, 17.65	3.90, 6.30	8.82, 82.58
	Min, Max	1.0, 6.6	-74.1, 227.3	1.0, 5.3	-44.4, 92.3	2.0, 7.0	-15.6, 222.2
	Mean (SD)	3.32 (1.460)	0.47 (44.544)	2.89 (1.102)	-1.81 (33.340)	4.95 (1.497)	54.07 (53.633)
	95% CI of Mean	2.99, 3.66	-9.64, 10.59	2.53, 3.24	-12.34, 8.72	4.47, 5.43	36.91, 71.23

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	76	76	41	41	40	40
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	0	0
	Median	2.90	-10.14	2.70	-11.11	4.95	33.33
	Q25, Q75	2.00, 4.25	-20.40, 7.36	1.80, 3.60	-28.57, 1.75	3.40, 6.10	6.12, 70.83
	Min, Max	1.0, 6.4	-81.5, 236.4	1.0, 5.8	-54.5, 176.9	1.5, 7.0	-40.4, 241.2
	Mean (SD)	3.19 (1.414)	-4.24 (42.166)	2.80 (1.236)	-6.42 (37.496)	4.73 (1.576)	47.22 (56.528)
	95% CI of Mean	2.86, 3.51	-13.88, 5.40	2.40, 3.19	-18.26, 5.42	4.23, 5.24	29.14, 65.31

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: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	3.00	-12.20	2.60	-12.96	4.60	24.07
	Q25, Q75	1.85, 4.10	-27.53, 4.34	1.90, 3.80	-28.57, 0.00	3.50, 6.40	4.62, 80.56
	Min, Max	1.0, 6.5	-81.5, 107.7	1.0, 5.9	-51.8, 78.3	1.6, 6.8	-66.0, 252.9
	Mean (SD)	3.08 (1.377)	-8.08 (36.930)	2.74 (1.231)	-9.38 (28.476)	4.68 (1.671)	43.68 (62.284)
	95% CI of Mean	2.76, 3.39	-16.52, 0.37	2.35, 3.13	-18.37, -0.38	4.14, 5.23	23.49, 63.88

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	3.05	-13.50	2.70	-11.76	4.50	18.92
	Q25, Q75	1.90, 4.00	-32.01, 6.01	1.80, 3.80	-32.50, 8.33	3.20, 6.30	0.00, 72.50
	Min, Max	1.0, 6.6	-75.0, 176.9	1.0, 5.2	-59.1, 138.5	1.2, 7.0	-37.5, 282.4
	Mean (SD)	3.09 (1.380)	-6.27 (45.113)	2.79 (1.245)	-5.24 (39.844)	4.56 (1.692)	38.08 (61.400)
	95% CI of Mean	2.77, 3.41	-16.59, 4.04	2.39, 3.19	-17.82, 7.34	4.01, 5.11	18.17, 57.98

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	3.00	-12.77	2.40	-12.28	4.60	16.36
	Q25, Q75	1.85, 4.05	-26.44, 0.00	1.70, 3.60	-31.43, 4.55	2.80, 6.00	-9.30, 63.89
	Min, Max	1.0, 6.4	-81.5, 200.0	1.0, 5.7	-54.2, 200.0	1.0, 7.0	-50.0, 288.2
	Mean (SD)	3.00 (1.322)	-9.37 (42.267)	2.71 (1.221)	-7.07 (42.991)	4.47 (1.839)	33.06 (63.346)
	95% CI of Mean	2.69, 3.31	-19.03, 0.29	2.32, 3.10	-20.65, 6.50	3.87, 5.07	12.52, 53.60

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	77	76	41	41	38	38
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	3.10	-7.85	2.60	-11.36	2.35	-35.01
	Q25, Q75	2.10, 3.90	-33.81, 16.39	2.00, 3.40	-27.50, 15.79	1.50, 3.50	-50.00, 13.33
	Min, Max	1.0, 6.6	-74.4, 233.3	1.0, 6.6	-61.4, 161.5	1.0, 7.0	-76.2, 94.4
	Mean (SD)	3.14 (1.325)	-2.84 (47.874)	2.85 (1.160)	0.43 (46.329)	2.67 (1.675)	-20.67 (41.187)
	95% CI of Mean	2.83, 3.44	-13.78, 8.11	2.48, 3.22	-14.20, 15.06	2.11, 3.22	-34.21, -7.12

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	77	76	41	41	38	38
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	3.00	-9.80	2.60	-4.76	1.75	-32.15
	Q25, Q75	2.10, 4.00	-32.29, 12.41	2.00, 3.50	-29.63, 22.58	1.30, 3.10	-61.29, 0.00
	Min, Max	1.0, 6.8	-84.1, 233.3	1.1, 5.8	-59.1, 200.0	1.0, 7.0	-76.2, 111.1
	Mean (SD)	3.08 (1.366)	-2.39 (55.040)	2.86 (1.207)	0.41 (45.551)	2.46 (1.690)	-27.64 (41.082)
	95% CI of Mean	2.77, 3.40	-14.97, 10.19	2.47, 3.24	-13.97, 14.79	1.90, 3.02	-41.15, -14.13

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

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.35.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

		THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	76	75	41	41	38	38
	Missing, n(%)	2 (2.6)	3 (3.8)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	3.25	-10.53	2.50	-14.29	1.45	-47.81
	Q25, Q75	2.45, 4.00	-33.33, 14.29	1.80, 3.70	-31.48, 5.26	1.00, 2.40	-62.50, -8.33
	Min, Max	1.0, 6.9	-70.4, 180.0	1.2, 6.0	-63.6, 192.3	1.0, 7.0	-81.8, 77.8
	Mean (SD)	3.23 (1.263)	1.86 (53.964)	2.83 (1.221)	0.67 (52.824)	2.18 (1.736)	-35.51 (40.362)
	95% CI of Mean	2.93, 3.52	-10.56, 14.28	2.44, 3.22	-16.01, 17.34	1.61, 2.76	-48.78, -22.23

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 10 AM on Day 1 in the SA arm

Note: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 1	n	75	41	39		
	LS Mean	3.83	3.61	5.31	0.21	-1.48
	95% CI	3.55, 4.10	3.24, 3.99	4.92, 5.69	-0.25, 0.68	-1.95, -1.01
Day 2	n	75	41	39		
	LS Mean	3.66	3.55	5.06	0.11	-1.41
	95% CI	3.38, 3.93	3.18, 3.92	4.69, 5.44	-0.35, 0.57	-1.87, -0.95
Day 3	n	75	41	39		
	LS Mean	3.50	3.39	5.02	0.11	-1.53
	95% CI	3.20, 3.79	2.98, 3.79	4.61, 5.43	-0.39, 0.61	-2.03, -1.02
Day 4	n	75	41	39		
	LS Mean	3.51	3.37	4.99	0.14	-1.48
	95% CI	3.19, 3.83	2.94, 3.80	4.55, 5.43	-0.39, 0.68	-2.02, -0.94

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 5	n	75	41	39		
	LS Mean	3.45	3.41	4.80	0.04	-1.35
	95% CI	3.14, 3.75	2.99, 3.82	4.38, 5.22	-0.47, 0.55	-1.87, -0.84
Day 30	n	74	41	38		
	LS Mean	3.68	3.58	2.95	0.10	0.73
	95% CI	3.36, 4.00	3.15, 4.01	2.50, 3.39	-0.44, 0.63	0.19, 1.28
Day 60	n	71	41	38		
	LS Mean	3.64	3.58	2.70	0.07	0.95
	95% CI	3.31, 3.98	3.13, 4.02	2.24, 3.15	-0.49, 0.62	0.39, 1.51
Day 90	n	69	41	37		
	LS Mean	3.85	3.47	2.35	0.37	1.50
	95% CI	3.50, 4.19	3.03, 3.92	1.88, 2.81	-0.19, 0.94	0.92, 2.07

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 1	n	75	41	39		
	LS Mean	2.77	2.51	4.55	0.26	-1.78
	95% CI	2.52, 3.02	2.18, 2.85	4.21, 4.90	-0.16, 0.67	-2.20, -1.36
Day 2	n	75	41	39		
	LS Mean	2.63	2.44	4.35	0.19	-1.72
	95% CI	2.40, 2.86	2.12, 2.75	4.03, 4.67	-0.20, 0.58	-2.11, -1.32
Day 3	n	75	41	39		
	LS Mean	2.52	2.42	4.15	0.10	-1.63
	95% CI	2.27, 2.77	2.09, 2.76	3.80, 4.49	-0.32, 0.51	-2.05, -1.21
Day 4	n	75	41	39		
	LS Mean	2.51	2.50	3.92	0.01	-1.41
	95% CI	2.25, 2.77	2.16, 2.85	3.57, 4.28	-0.42, 0.43	-1.85, -0.98

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 5	n	75	41	39		
	LS Mean	2.47	2.37	3.97	0.10	-1.50
	95% CI	2.20, 2.73	2.01, 2.73	3.60, 4.33	-0.34, 0.54	-1.95, -1.05
Day 30	n	74	41	38		
	LS Mean	2.46	2.37	2.25	0.08	0.21
	95% CI	2.19, 2.73	2.01, 2.74	1.87, 2.62	-0.37, 0.53	-0.25, 0.67
Day 60	n	71	41	38		
	LS Mean	2.50	2.39	2.10	0.11	0.40
	95% CI	2.20, 2.79	2.00, 2.78	1.69, 2.50	-0.38, 0.59	-0.09, 0.89
Day 90	n	69	41	37		
	LS Mean	2.53	2.41	1.89	0.12	0.63
	95% CI	2.24, 2.81	2.04, 2.77	1.51, 2.28	-0.34, 0.58	0.16, 1.10

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 1	n	75	41	39		
	LS Mean	3.29	3.07	4.93	0.22	-1.64
	95% CI	3.05, 3.53	2.75, 3.40	4.60, 5.26	-0.18, 0.62	-2.04, -1.23
Day 2	n	75	41	39		
	LS Mean	3.14	3.00	4.71	0.13	-1.57
	95% CI	2.90, 3.37	2.68, 3.32	4.38, 5.03	-0.26, 0.53	-1.97, -1.17
Day 3	n	75	41	39		
	LS Mean	3.00	2.92	4.58	0.08	-1.58
	95% CI	2.75, 3.25	2.58, 3.26	4.23, 4.93	-0.34, 0.50	-2.01, -1.16
Day 4	n	75	41	39		
	LS Mean	3.00	2.95	4.46	0.06	-1.45
	95% CI	2.74, 3.27	2.59, 3.31	4.09, 4.82	-0.38, 0.50	-1.90, -1.01

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.1 Analysis of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 5	n	75	41	39		
	LS Mean	2.95	2.90	4.38	0.06	-1.43
	95% CI	2.69, 3.22	2.54, 3.25	4.02, 4.75	-0.39, 0.50	-1.88, -0.98
Day 30	n	74	41	38		
	LS Mean	3.06	2.99	2.60	0.08	0.47
	95% CI	2.79, 3.34	2.61, 3.36	2.21, 2.98	-0.38, 0.54	0.00, 0.94
Day 60	n	71	41	38		
	LS Mean	3.07	2.99	2.40	0.08	0.67
	95% CI	2.76, 3.37	2.59, 3.39	1.99, 2.81	-0.42, 0.57	0.16, 1.17
Day 90	n	69	41	37		
	LS Mean	3.18	2.94	2.12	0.24	1.06
	95% CI	2.88, 3.48	2.56, 3.33	1.72, 2.53	-0.25, 0.72	0.56, 1.55

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 1	n	77	41	40		
	LS Mean	3.80	3.60	5.29	0.20	-1.48
	95% CI	3.53, 4.08	3.23, 3.98	4.91, 5.66	-0.26, 0.66	-1.94, -1.02
Day 2	n	76	41	40		
	LS Mean	3.66	3.53	5.05	0.13	-1.39
	95% CI	3.39, 3.93	3.16, 3.90	4.68, 5.42	-0.33, 0.59	-1.85, -0.94
Day 3	n	76	41	39		
	LS Mean	3.52	3.38	5.02	0.14	-1.49
	95% CI	3.23, 3.82	2.97, 3.79	4.60, 5.43	-0.36, 0.65	-2.00, -0.99
Day 4	n	76	41	39		
	LS Mean	3.52	3.37	4.99	0.16	-1.47
	95% CI	3.21, 3.84	2.94, 3.80	4.55, 5.43	-0.38, 0.69	-2.00, -0.93

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 1 - Reward**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 5	n	76	41	39		
	LS Mean	3.44	3.40	4.79	0.04	-1.35
	95% CI	3.14, 3.75	2.99, 3.81	4.38, 5.21	-0.47, 0.55	-1.86, -0.84
Day 30	n	76	41	38		
	LS Mean	3.71	3.58	2.95	0.13	0.76
	95% CI	3.39, 4.02	3.15, 4.01	2.50, 3.39	-0.41, 0.66	0.22, 1.30
Day 60	n	76	41	38		
	LS Mean	3.60	3.57	2.69	0.04	0.92
	95% CI	3.28, 3.93	3.13, 4.01	2.24, 3.14	-0.51, 0.58	0.36, 1.47
Day 90	n	75	41	38		
	LS Mean	3.79	3.47	2.34	0.32	1.45
	95% CI	3.47, 4.12	3.03, 3.91	1.89, 2.79	-0.22, 0.87	0.90, 2.00

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 1	n	77	41	40		
	LS Mean	2.76	2.49	4.48	0.27	-1.72
	95% CI	2.51, 3.00	2.15, 2.83	4.14, 4.82	-0.15, 0.68	-2.14, -1.31
Day 2	n	76	41	40		
	LS Mean	2.62	2.42	4.29	0.19	-1.67
	95% CI	2.39, 2.85	2.11, 2.74	3.97, 4.61	-0.19, 0.58	-2.06, -1.28
Day 3	n	76	41	39		
	LS Mean	2.51	2.42	4.14	0.10	-1.63
	95% CI	2.27, 2.76	2.08, 2.75	3.80, 4.48	-0.31, 0.51	-2.04, -1.21
Day 4	n	76	41	39		
	LS Mean	2.52	2.50	3.92	0.02	-1.40
	95% CI	2.26, 2.77	2.15, 2.85	3.57, 4.27	-0.41, 0.44	-1.84, -0.97

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter: Factor 2 - Relief**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 5	n	76	41	39		
	LS Mean	2.47	2.36	3.96	0.10	-1.49
	95% CI	2.21, 2.73	2.01, 2.72	3.60, 4.33	-0.33, 0.54	-1.94, -1.05
Day 30	n	76	41	38		
	LS Mean	2.46	2.38	2.25	0.09	0.21
	95% CI	2.19, 2.73	2.01, 2.74	1.87, 2.62	-0.36, 0.53	-0.24, 0.67
Day 60	n	76	41	38		
	LS Mean	2.47	2.39	2.10	0.08	0.37
	95% CI	2.19, 2.75	2.00, 2.77	1.70, 2.49	-0.39, 0.55	-0.11, 0.86
Day 90	n	75	41	38		
	LS Mean	2.51	2.40	1.87	0.11	0.64
	95% CI	2.24, 2.78	2.04, 2.76	1.50, 2.25	-0.34, 0.55	0.18, 1.09

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 1	n	77	41	40		
	LS Mean	3.27	3.06	4.88	0.22	-1.61
	95% CI	3.04, 3.51	2.73, 3.38	4.56, 5.21	-0.18, 0.61	-2.01, -1.21
Day 2	n	76	41	40		
	LS Mean	3.13	2.99	4.67	0.14	-1.54
	95% CI	2.90, 3.37	2.67, 3.31	4.35, 4.99	-0.25, 0.54	-1.93, -1.15
Day 3	n	76	41	39		
	LS Mean	3.01	2.91	4.58	0.10	-1.57
	95% CI	2.76, 3.26	2.57, 3.25	4.23, 4.93	-0.32, 0.52	-1.99, -1.14
Day 4	n	76	41	39		
	LS Mean	3.01	2.94	4.45	0.07	-1.44
	95% CI	2.75, 3.27	2.59, 3.30	4.09, 4.82	-0.37, 0.51	-1.88, -1.00

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.36.2 Analysis of QSU-brief Factors and Total Scores - FAS****Parameter: Total Score**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 5	n	76	41	39		
	LS Mean	2.95	2.89	4.38	0.06	-1.43
	95% CI	2.69, 3.22	2.53, 3.25	4.01, 4.74	-0.38, 0.50	-1.87, -0.98
Day 30	n	76	41	38		
	LS Mean	3.08	2.98	2.60	0.09	0.48
	95% CI	2.81, 3.35	2.61, 3.36	2.21, 2.98	-0.36, 0.55	0.02, 0.95
Day 60	n	76	41	38		
	LS Mean	3.03	2.98	2.39	0.05	0.64
	95% CI	2.74, 3.32	2.59, 3.38	1.99, 2.80	-0.44, 0.54	0.14, 1.14
Day 90	n	75	41	38		
	LS Mean	3.15	2.94	2.11	0.20	1.04
	95% CI	2.86, 3.43	2.56, 3.32	1.72, 2.50	-0.27, 0.67	0.56, 1.51

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

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: QSU-brief scores reported on a 7-point scale. Higher scores indicate greater intensity of urge.

**Table 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set**

Parameter: Aversion Subscale
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	75		42	
	Missing, n(%)	1 (1.3)		0	
	Median	1.00		1.00	
	Q25, Q75	1.00, 2.00		1.00, 2.00	
	Min, Max	1.0, 5.5		1.0, 4.0	
	Mean (SD)	1.66 (1.041)		1.57 (0.831)	
	95% CI of Mean	1.42, 1.90		1.31, 1.84	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	1.50	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	0.00, 33.33	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 4.5	-66.7, 300.0	1.0, 4.0	-57.1, 300.0
	Mean (SD)	1.67 (0.852)	16.26 (67.034)	1.57 (0.834)	7.77 (57.409)
	95% CI of Mean	1.47, 1.87	0.83, 31.69	1.31, 1.84	-10.35, 25.90

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	-25.00, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 5.5	-75.0, 300.0	1.0, 7.0	-71.4, 600.0
	Mean (SD)	1.57 (0.900)	8.62 (63.579)	1.63 (1.163)	15.05 (101.248)
	95% CI of Mean	1.36, 1.79	-6.02, 23.25	1.26, 2.01	-16.92, 47.01

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	-25.00, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 3.5	-72.7, 200.0	1.0, 4.5	-71.4, 300.0
	Mean (SD)	1.51 (0.700)	3.12 (48.196)	1.55 (0.907)	6.59 (56.930)
	95% CI of Mean	1.34, 1.67	-7.98, 14.21	1.26, 1.84	-11.38, 24.57

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	-25.00, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 4.5	-66.7, 350.0	1.0, 7.0	-71.4, 600.0
	Mean (SD)	1.51 (0.847)	5.15 (66.887)	1.67 (1.192)	19.60 (103.160)
	95% CI of Mean	1.31, 1.71	-10.25, 20.54	1.29, 2.05	-12.97, 52.17

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	-33.33, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 4.5	-75.0, 350.0	1.0, 4.0	-71.4, 300.0
	Mean (SD)	1.57 (0.836)	10.89 (68.994)	1.48 (0.799)	3.56 (56.273)
	95% CI of Mean	1.37, 1.76	-4.99, 26.77	1.22, 1.73	-14.20, 21.33

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41	
	Median	1.00		1.00	
	Q25, Q75	1.00, 2.00		1.00, 2.00	
	Min, Max	1.0, 5.5		1.0, 4.0	
	Mean (SD)	1.67 (1.045)		1.59 (0.836)	
	95% CI of Mean	1.42, 1.92		1.32, 1.85	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41
	Median	1.00	0.00	1.50	0.00
	Q25, Q75	1.00, 2.00	-33.33, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 5.0	-66.7, 350.0	1.0, 4.0	-71.4, 250.0
	Mean (SD)	1.59 (0.867)	11.14 (66.477)	1.60 (0.808)	12.69 (55.613)
	95% CI of Mean	1.39, 1.80	-4.26, 26.55	1.34, 1.86	-4.87, 30.25

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41	
	Median	1.00		1.00	
	Q25, Q75	1.00, 2.00		1.00, 2.00	
	Min, Max	1.0, 5.5		1.0, 4.0	
	Mean (SD)	1.58 (0.948)		1.59 (0.836)	
	95% CI of Mean	1.35, 1.81		1.32, 1.85	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41
	Median	1.00	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	-25.00, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 3.5	-66.7, 200.0	1.0, 3.5	-50.0, 200.0
	Mean (SD)	1.46 (0.614)	4.24 (44.192)	1.46 (0.637)	2.94 (46.569)
	95% CI of Mean	1.31, 1.61	-6.23, 14.70	1.26, 1.67	-11.77, 17.64

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41	
	Median	1.25		1.00	
	Q25, Q75	1.00, 2.00		1.00, 2.00	
	Min, Max	1.0, 5.5		1.0, 4.0	
	Mean (SD)	1.68 (1.054)		1.59 (0.836)	
	95% CI of Mean	1.42, 1.93		1.32, 1.85	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	69	41	41
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0
	Median	1.00	0.00	1.50	0.00
	Q25, Q75	1.00, 2.00	-33.33, 0.00	1.00, 1.50	0.00, 50.00
	Min, Max	1.0, 5.0	-63.6, 233.3	1.0, 6.0	-66.7, 300.0
	Mean (SD)	1.57 (0.820)	6.06 (53.269)	1.67 (1.111)	13.63 (58.938)
	95% CI of Mean	1.37, 1.77	-6.74, 18.86	1.32, 2.03	-4.98, 32.24

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	75		42	
	Missing, n(%)	1 (1.3)		0	
	Median	4.0		5.0	
	Q25, Q75	3.0, 5.0		3.0, 5.0	
	Min, Max	1, 7		1, 7	
	Mean (SD)	4.3 (1.42)		4.5 (1.46)	
	95% CI of Mean	3.9, 4.6		3.9, 5.0	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	-20.00	4.0	0.00
	Q25, Q75	3.0, 4.0	-40.00, 0.00	3.0, 5.0	-20.00, 0.00
	Min, Max	1, 7	-75.0, 200.0	1, 7	-60.0, 200.0
	Mean (SD)	3.6 (1.47)	-8.49 (43.292)	4.3 (1.55)	0.49 (41.679)
	95% CI of Mean	3.2, 4.0	-18.46, 1.47	3.7, 4.8	-12.67, 13.65

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	-20.00	4.0	0.00
	Q25, Q75	3.0, 4.0	-40.00, 0.00	3.0, 5.0	-20.00, 0.00
	Min, Max	1, 7	-75.0, 500.0	1, 7	-50.0, 200.0
	Mean (SD)	3.5 (1.35)	-3.98 (77.359)	4.2 (1.58)	-1.23 (42.308)
	95% CI of Mean	3.2, 3.9	-21.78, 13.83	3.7, 4.8	-14.59, 12.13

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	-20.00	4.0	-14.29
	Q25, Q75	3.0, 4.0	-40.00, 0.00	3.0, 5.0	-20.00, 0.00
	Min, Max	1, 7	-80.0, 500.0	2, 7	-57.1, 200.0
	Mean (SD)	3.5 (1.36)	-4.08 (77.167)	3.9 (1.23)	-5.83 (41.021)
	95% CI of Mean	3.2, 3.9	-21.84, 13.68	3.5, 4.3	-18.78, 7.12

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	-16.67	4.0	-14.29
	Q25, Q75	3.0, 4.0	-40.00, 0.00	3.0, 5.0	-25.00, 0.00
	Min, Max	1, 7	-85.7, 400.0	1, 7	-75.0, 200.0
	Mean (SD)	3.5 (1.31)	-8.67 (66.363)	4.1 (1.56)	-3.89 (44.121)
	95% CI of Mean	3.1, 3.8	-23.94, 6.61	3.5, 4.6	-17.82, 10.04

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	-16.67	4.0	-14.29
	Q25, Q75	3.0, 5.0	-40.00, 0.00	3.0, 5.0	-33.33, 0.00
	Min, Max	1, 7	-80.0, 500.0	1, 7	-83.3, 200.0
	Mean (SD)	3.6 (1.50)	-4.44 (73.296)	3.8 (1.42)	-9.80 (43.211)
	95% CI of Mean	3.2, 4.0	-21.31, 12.43	3.3, 4.3	-23.45, 3.84

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41	
	Median	4.0		5.0	
	Q25, Q75	3.0, 5.0		4.0, 5.0	
	Min, Max	1, 7		1, 7	
	Mean (SD)	4.3 (1.43)		4.5 (1.46)	
	95% CI of Mean	3.9, 4.6		4.0, 5.0	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41
	Median	4.0	0.00	4.0	0.00
	Q25, Q75	3.0, 5.0	-25.00, 20.00	4.0, 5.0	-20.00, 20.00
	Min, Max	1, 7	-66.7, 400.0	1, 6	-57.1, 300.0
	Mean (SD)	4.2 (1.39)	8.05 (60.231)	4.4 (1.28)	8.27 (58.799)
	95% CI of Mean	3.8, 4.5	-5.91, 22.01	3.9, 4.8	-10.29, 26.83

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41	
	Median	4.0		5.0	
	Q25, Q75	3.0, 5.0		4.0, 5.0	
	Min, Max	1, 7		1, 7	
	Mean (SD)	4.3 (1.45)		4.5 (1.46)	
	95% CI of Mean	3.9, 4.7		4.0, 5.0	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41
	Median	4.0	0.00	4.0	0.00
	Q25, Q75	3.0, 5.0	-25.00, 25.00	3.0, 5.0	-25.00, 20.00
	Min, Max	1, 7	-57.1, 600.0	1, 7	-50.0, 200.0
	Mean (SD)	4.2 (1.41)	15.88 (99.469)	4.1 (1.41)	-2.24 (41.278)
	95% CI of Mean	3.8, 4.6	-7.67, 39.43	3.7, 4.6	-15.28, 10.79

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41	
	Median	4.0		5.0	
	Q25, Q75	3.0, 5.0		4.0, 5.0	
	Min, Max	1, 7		1, 7	
	Mean (SD)	4.3 (1.44)		4.5 (1.46)	
	95% CI of Mean	3.9, 4.7		4.0, 5.0	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	69	41	41
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0
	Median	4.0	0.00	4.0	0.00
	Q25, Q75	3.0, 5.0	-25.00, 20.00	3.0, 5.0	-20.00, 0.00
	Min, Max	1, 7	-57.1, 500.0	1, 7	-50.0, 200.0
	Mean (SD)	4.0 (1.23)	11.90 (87.371)	4.3 (1.41)	2.10 (45.251)
	95% CI of Mean	3.7, 4.4	-9.09, 32.90	3.8, 4.8	-12.19, 16.39

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set**

Parameter: Enjoyment of Respiratory Tract Sensation Subscale
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	75		42	
	Missing, n(%)	1 (1.3)		0	
	Median	4.0		3.0	
	Q25, Q75	2.0, 5.0		2.0, 4.0	
	Min, Max	1, 7		1, 7	
	Mean (SD)	3.7 (1.58)		3.5 (1.68)	
	95% CI of Mean	3.3, 4.1		3.0, 4.1	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set**

Parameter: Enjoyment of Respiratory Tract Sensation Subscale
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	0.00	4.0	0.00
	Q25, Q75	2.0, 4.0	-33.33, 0.00	3.0, 4.0	0.00, 0.00
	Min, Max	1, 6	-75.0, 300.0	1, 7	-33.3, 100.0
	Mean (SD)	3.1 (1.32)	-3.41 (56.495)	3.5 (1.33)	10.78 (37.652)
	95% CI of Mean	2.7, 3.4	-16.41, 9.60	3.0, 4.0	-1.11, 22.67

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	0.00	4.0	0.00
	Q25, Q75	2.0, 4.0	-25.00, 0.00	2.0, 5.0	0.00, 0.00
	Min, Max	1, 6	-75.0, 300.0	1, 7	-50.0, 200.0
	Mean (SD)	3.1 (1.19)	-1.49 (55.454)	3.6 (1.68)	13.62 (56.482)
	95% CI of Mean	2.8, 3.4	-14.26, 11.27	3.0, 4.2	-4.21, 31.45

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set**

Parameter: Enjoyment of Respiratory Tract Sensation Subscale
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	0.00	4.0	0.00
	Q25, Q75	2.0, 4.0	-25.00, 0.00	2.0, 4.0	-25.00, 0.00
	Min, Max	1, 6	-75.0, 300.0	1, 7	-50.0, 150.0
	Mean (SD)	3.3 (1.34)	1.21 (56.567)	3.3 (1.58)	3.73 (50.839)
	95% CI of Mean	2.9, 3.6	-11.81, 14.23	2.8, 3.9	-12.32, 19.78

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set**

Parameter: Enjoyment of Respiratory Tract Sensation Subscale
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	0.00	4.0	0.00
	Q25, Q75	2.0, 4.0	-25.00, 0.00	2.0, 4.0	-25.00, 0.00
	Min, Max	1, 6	-75.0, 300.0	1, 7	-66.7, 200.0
	Mean (SD)	3.3 (1.33)	2.04 (58.532)	3.5 (1.57)	11.74 (57.666)
	95% CI of Mean	2.9, 3.6	-11.43, 15.51	2.9, 4.0	-6.46, 29.95

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set**

Parameter: Enjoyment of Respiratory Tract Sensation Subscale
Product Use Time Period: Period 1

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	0.00	3.0	0.00
	Q25, Q75	3.0, 4.0	-25.00, 0.00	2.0, 4.0	-33.33, 0.00
	Min, Max	1, 6	-75.0, 300.0	1, 7	-50.0, 200.0
	Mean (SD)	3.3 (1.26)	5.25 (62.730)	3.3 (1.51)	8.12 (62.685)
	95% CI of Mean	3.0, 3.6	-9.18, 19.69	2.8, 3.8	-11.67, 27.91

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set**

Parameter: Enjoyment of Respiratory Tract Sensation Subscale
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41	
	Median	4.0		3.0	
	Q25, Q75	2.0, 5.0		2.0, 4.0	
	Min, Max	1, 7		1, 7	
	Mean (SD)	3.7 (1.59)		3.5 (1.65)	
	95% CI of Mean	3.2, 4.1		2.9, 4.0	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set**

Parameter: Enjoyment of Respiratory Tract Sensation Subscale
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41
	Median	4.0	0.00	4.0	0.00
	Q25, Q75	3.0, 5.0	-20.00, 40.00	3.0, 5.0	0.00, 33.33
	Min, Max	1, 7	-75.0, 500.0	1, 6	-66.7, 300.0
	Mean (SD)	3.9 (1.40)	27.49 (84.950)	3.7 (1.28)	27.40 (80.543)
	95% CI of Mean	3.5, 4.3	7.80, 47.17	3.2, 4.1	1.97, 52.83

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41	
	Median	4.0		3.0	
	Q25, Q75	2.0, 5.0		2.0, 4.0	
	Min, Max	1, 7		1, 7	
	Mean (SD)	3.6 (1.59)		3.5 (1.65)	
	95% CI of Mean	3.2, 4.0		2.9, 4.0	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41
	Median	4.0	0.00	4.0	0.00
	Q25, Q75	3.0, 5.0	-20.00, 33.33	3.0, 5.0	-25.00, 50.00
	Min, Max	1, 6	-60.0, 500.0	1, 6	-57.1, 200.0
	Mean (SD)	3.9 (1.38)	30.32 (87.625)	3.6 (1.43)	21.60 (67.861)
	95% CI of Mean	3.5, 4.2	9.57, 51.06	3.1, 4.1	0.18, 43.03

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41	
	Median	4.0		3.0	
	Q25, Q75	2.0, 5.0		2.0, 4.0	
	Min, Max	1, 7		1, 7	
	Mean (SD)	3.6 (1.59)		3.5 (1.65)	
	95% CI of Mean	3.2, 4.1		2.9, 4.0	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set**

Parameter: Enjoyment of Respiratory Tract Sensation Subscale
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	69	41	41
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0
	Median	4.0	0.00	3.0	0.00
	Q25, Q75	3.0, 5.0	-20.00, 33.33	3.0, 4.0	-25.00, 33.33
	Min, Max	1, 7	-75.0, 600.0	1, 6	-66.7, 200.0
	Mean (SD)	3.8 (1.44)	26.34 (93.312)	3.4 (1.15)	19.20 (66.944)
	95% CI of Mean	3.4, 4.2	3.92, 48.76	3.0, 3.8	-1.93, 40.34

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	75		42	
	Missing, n(%)	1 (1.3)		0	
	Median	3.40		2.90	
	Q25, Q75	2.60, 4.20		2.00, 4.00	
	Min, Max	1.0, 6.6		1.4, 6.4	
	Mean (SD)	3.46 (1.197)		3.21 (1.350)	
	95% CI of Mean	3.18, 3.74		2.78, 3.63	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	2.80	-17.65	2.80	-6.25
	Q25, Q75	2.00, 3.20	-33.33, -4.76	2.00, 3.60	-16.67, 11.11
	Min, Max	1.0, 6.2	-78.3, 120.0	1.2, 6.6	-40.0, 71.4
	Mean (SD)	2.74 (1.013)	-15.77 (32.269)	2.98 (1.240)	-3.32 (22.560)
	95% CI of Mean	2.50, 2.97	-23.20, -8.34	2.58, 3.37	-10.44, 3.81

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	2.80	-16.67	2.60	0.00
	Q25, Q75	2.20, 3.60	-33.33, 0.00	2.00, 3.80	-23.53, 0.00
	Min, Max	1.0, 6.2	-78.3, 120.0	1.0, 7.0	-44.4, 40.0
	Mean (SD)	2.80 (0.996)	-13.92 (32.480)	2.96 (1.434)	-6.34 (21.030)
	95% CI of Mean	2.57, 3.03	-21.40, -6.44	2.50, 3.41	-12.98, 0.31

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	2.80	-18.52	2.80	-10.00
	Q25, Q75	2.20, 3.20	-31.58, 0.00	2.00, 4.00	-26.32, 11.11
	Min, Max	1.0, 5.6	-78.3, 260.0	1.0, 5.4	-58.3, 75.0
	Mean (SD)	2.78 (1.021)	-13.87 (41.342)	2.87 (1.293)	-6.91 (29.919)
	95% CI of Mean	2.54, 3.02	-23.39, -4.36	2.46, 3.29	-16.36, 2.54

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	2.80	-16.67	2.60	-7.69
	Q25, Q75	2.20, 3.60	-36.84, 0.00	1.80, 3.80	-28.57, 0.00
	Min, Max	1.0, 5.6	-78.3, 140.0	1.0, 6.2	-50.0, 50.0
	Mean (SD)	2.81 (1.085)	-14.01 (34.973)	2.85 (1.380)	-9.50 (24.419)
	95% CI of Mean	2.56, 3.07	-22.06, -5.95	2.41, 3.29	-17.21, -1.78

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	2.80	-18.52	2.60	-10.00
	Q25, Q75	2.20, 3.40	-33.33, 0.00	2.00, 3.60	-28.57, 3.70
	Min, Max	1.0, 6.0	-78.3, 100.0	1.0, 5.6	-50.0, 75.0
	Mean (SD)	2.79 (1.039)	-15.48 (29.055)	2.81 (1.237)	-8.75 (27.996)
	95% CI of Mean	2.54, 3.03	-22.17, -8.79	2.42, 3.21	-17.59, 0.10

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41	
	Median	3.40		2.80	
	Q25, Q75	2.60, 4.20		2.00, 4.00	
	Min, Max	1.0, 6.6		1.4, 6.4	
	Mean (SD)	3.45 (1.204)		3.18 (1.348)	
	95% CI of Mean	3.17, 3.74		2.75, 3.61	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41
	Median	3.20	-14.55	3.00	0.00
	Q25, Q75	2.40, 3.60	-26.32, 11.11	2.20, 3.80	-17.86, 11.11
	Min, Max	1.0, 6.0	-58.3, 112.5	1.2, 6.0	-50.0, 57.1
	Mean (SD)	3.10 (0.995)	-4.79 (31.381)	3.08 (1.173)	1.63 (25.461)
	95% CI of Mean	2.86, 3.34	-12.06, 2.49	2.70, 3.45	-6.41, 9.67

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41	
	Median	3.40		2.80	
	Q25, Q75	2.60, 4.20		2.00, 4.00	
	Min, Max	1.0, 6.6		1.4, 6.4	
	Mean (SD)	3.40 (1.174)		3.18 (1.348)	
	95% CI of Mean	3.12, 3.68		2.75, 3.61	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41
	Median	3.00	-7.69	2.80	0.00
	Q25, Q75	2.20, 3.80	-27.27, 10.53	2.00, 3.80	-17.65, 10.00
	Min, Max	1.0, 6.8	-73.7, 480.0	1.0, 5.6	-58.3, 55.6
	Mean (SD)	3.14 (1.146)	2.22 (66.751)	2.96 (1.239)	-4.22 (25.190)
	95% CI of Mean	2.86, 3.41	-13.59, 18.02	2.56, 3.36	-12.18, 3.74

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41	
	Median	3.40		2.80	
	Q25, Q75	2.60, 4.20		2.00, 4.00	
	Min, Max	1.0, 6.6		1.4, 6.4	
	Mean (SD)	3.41 (1.221)		3.18 (1.348)	
	95% CI of Mean	3.11, 3.70		2.75, 3.61	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	69	41	41
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0
	Median	3.20	-13.04	2.80	-10.00
	Q25, Q75	2.40, 3.80	-33.33, 6.25	2.00, 4.00	-28.57, 20.00
	Min, Max	1.0, 5.8	-58.3, 420.0	1.0, 5.8	-50.0, 66.7
	Mean (SD)	3.06 (1.075)	-1.48 (61.072)	2.92 (1.296)	-5.20 (30.904)
	95% CI of Mean	2.79, 3.32	-16.16, 13.19	2.50, 3.33	-14.96, 4.56

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	75		42	
	Missing, n(%)	1 (1.3)		0	
	Median	4.30		4.00	
	Q25, Q75	3.70, 5.30		3.00, 5.00	
	Min, Max	1.0, 7.0		2.0, 7.0	
	Mean (SD)	4.37 (1.245)		4.12 (1.226)	
	95% CI of Mean	4.08, 4.66		3.73, 4.51	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.00	-25.00	4.00	-6.98
	Q25, Q75	2.30, 4.00	-43.33, -6.98	3.00, 4.70	-18.92, 10.00
	Min, Max	1.0, 6.7	-80.0, 70.0	1.7, 7.0	-38.6, 48.1
	Mean (SD)	3.16 (1.142)	-23.76 (28.564)	3.90 (1.203)	-3.08 (21.747)
	95% CI of Mean	2.89, 3.42	-30.33, -17.18	3.51, 4.28	-9.95, 3.79

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.30	-23.33	3.70	0.00
	Q25, Q75	2.70, 4.00	-37.74, -5.66	3.00, 4.70	-14.81, 11.67
	Min, Max	1.0, 6.3	-80.0, 130.0	2.3, 7.0	-30.2, 74.1
	Mean (SD)	3.31 (1.078)	-19.75 (30.702)	4.02 (1.214)	0.63 (23.296)
	95% CI of Mean	3.06, 3.56	-26.82, -12.68	3.64, 4.41	-6.73, 7.99

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.30	-23.33	3.30	0.00
	Q25, Q75	2.70, 4.00	-36.51, 0.00	2.70, 5.00	-23.26, 7.50
	Min, Max	1.0, 6.7	-80.0, 370.0	2.0, 7.0	-43.4, 60.6
	Mean (SD)	3.45 (1.207)	-14.97 (51.548)	3.83 (1.250)	-4.46 (22.624)
	95% CI of Mean	3.16, 3.73	-26.83, -3.10	3.43, 4.23	-11.61, 2.68

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.30	-21.28	3.30	-7.02
	Q25, Q75	2.70, 4.30	-37.74, 0.00	3.00, 5.00	-21.28, 6.00
	Min, Max	1.0, 6.7	-83.3, 430.0	1.7, 7.0	-43.4, 60.6
	Mean (SD)	3.44 (1.238)	-13.60 (59.186)	3.82 (1.319)	-5.51 (23.711)
	95% CI of Mean	3.15, 3.73	-27.22, 0.02	3.40, 4.24	-13.00, 1.98

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	75	75	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.30	-18.87	3.70	-6.98
	Q25, Q75	3.00, 4.00	-36.17, 0.00	3.00, 4.70	-23.33, 12.77
	Min, Max	1.0, 6.7	-80.0, 300.0	1.3, 7.0	-67.5, 50.0
	Mean (SD)	3.56 (1.163)	-11.84 (45.986)	3.81 (1.315)	-4.84 (26.349)
	95% CI of Mean	3.28, 3.83	-22.43, -1.25	3.39, 4.23	-13.17, 3.48

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	74		41	
	Median	4.30		4.00	
	Q25, Q75	3.70, 5.30		3.00, 5.00	
	Min, Max	1.0, 7.0		2.0, 7.0	
	Mean (SD)	4.39 (1.247)		4.11 (1.238)	
	95% CI of Mean	4.09, 4.68		3.71, 4.50	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 2**

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	74	41	41
	Median	3.85	-10.81	4.00	0.00
	Q25, Q75	3.30, 4.30	-29.79, 9.30	3.30, 4.70	-18.87, 22.22
	Min, Max	1.7, 7.0	-50.0, 300.0	2.0, 6.3	-51.1, 87.0
	Mean (SD)	3.88 (1.044)	-4.83 (43.578)	4.07 (1.022)	4.61 (30.134)
	95% CI of Mean	3.63, 4.13	-14.93, 5.27	3.75, 4.40	-4.91, 14.12

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41	
	Median	4.30		4.00	
	Q25, Q75	3.70, 5.30		3.00, 5.00	
	Min, Max	1.0, 7.0		2.0, 7.0	
	Mean (SD)	4.34 (1.261)		4.11 (1.238)	
	95% CI of Mean	4.04, 4.65		3.71, 4.50	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 3**

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	71	41	41
	Median	3.70	-10.00	4.00	-6.98
	Q25, Q75	3.00, 4.70	-30.23, 8.11	3.00, 4.70	-18.57, 9.30
	Min, Max	1.3, 7.0	-67.9, 600.0	1.7, 6.3	-52.9, 73.9
	Mean (SD)	3.83 (1.297)	-1.76 (78.264)	3.93 (1.139)	-1.06 (25.205)
	95% CI of Mean	3.52, 4.14	-20.29, 16.77	3.57, 4.30	-9.02, 6.90

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41	
	Median	4.30		4.00	
	Q25, Q75	3.70, 5.30		3.00, 5.00	
	Min, Max	1.0, 7.0		2.0, 7.0	
	Mean (SD)	4.38 (1.246)		4.11 (1.238)	
	95% CI of Mean	4.08, 4.68		3.71, 4.50	

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.1 Descriptive Statistics of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	69	41	41
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0
	Median	3.70	-11.32	3.70	-6.98
	Q25, Q75	3.00, 4.70	-28.33, 6.00	3.00, 4.30	-18.92, 0.00
	Min, Max	1.0, 7.0	-69.7, 600.0	1.7, 6.7	-38.6, 50.0
	Mean (SD)	3.95 (1.233)	-1.07 (77.580)	3.80 (1.013)	-3.94 (23.133)
	95% CI of Mean	3.65, 4.25	-19.71, 17.57	3.48, 4.13	-11.25, 3.36

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.

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	77		42	
	Missing, n(%)	1 (1.3)		0	
	Median	1.00		1.00	
	Q25, Q75	1.00, 2.00		1.00, 2.00	
	Min, Max	1.0, 5.5		1.0, 4.0	
	Mean (SD)	1.66 (1.031)		1.57 (0.831)	
	95% CI of Mean	1.42, 1.89		1.31, 1.84	

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.

Appendix: 15.3.6.14

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**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	77	77	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	1.50	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	0.00, 33.33	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 4.5	-66.7, 300.0	1.0, 4.0	-57.1, 300.0
	Mean (SD)	1.68 (0.855)	18.11 (69.559)	1.57 (0.834)	7.77 (57.409)
	95% CI of Mean	1.48, 1.88	2.32, 33.90	1.31, 1.84	-10.35, 25.90

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	-25.00, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 5.5	-75.0, 300.0	1.0, 7.0	-71.4, 600.0
	Mean (SD)	1.58 (0.895)	8.50 (63.162)	1.63 (1.163)	15.05 (101.248)
	95% CI of Mean	1.37, 1.79	-5.94, 22.94	1.26, 2.01	-16.92, 47.01

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	-25.00, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 3.5	-72.7, 200.0	1.0, 4.5	-71.4, 300.0
	Mean (SD)	1.51 (0.696)	2.75 (47.983)	1.55 (0.907)	6.59 (56.930)
	95% CI of Mean	1.34, 1.67	-8.22, 13.72	1.26, 1.84	-11.38, 24.57

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	-25.00, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 4.5	-66.7, 350.0	1.0, 7.0	-71.4, 600.0
	Mean (SD)	1.51 (0.841)	4.75 (66.529)	1.67 (1.192)	19.60 (103.160)
	95% CI of Mean	1.32, 1.71	-10.46, 19.96	1.29, 2.05	-12.97, 52.17

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	-33.33, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 4.5	-75.0, 350.0	1.0, 4.0	-71.4, 300.0
	Mean (SD)	1.57 (0.832)	10.75 (68.544)	1.48 (0.799)	3.56 (56.273)
	95% CI of Mean	1.38, 1.77	-4.92, 26.42	1.22, 1.73	-14.20, 21.33

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	77	76	41	41
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.50	0.00
	Q25, Q75	1.00, 2.00	-30.30, 10.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 5.0	-66.7, 350.0	1.0, 4.0	-71.4, 250.0
	Mean (SD)	1.59 (0.862)	11.18 (65.616)	1.60 (0.808)	12.69 (55.613)
	95% CI of Mean	1.39, 1.79	-3.82, 26.18	1.34, 1.86	-4.87, 30.25

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	77	76	41	41
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.00	0.00
	Q25, Q75	1.00, 2.00	-25.00, 0.00	1.00, 2.00	0.00, 0.00
	Min, Max	1.0, 3.5	-66.7, 200.0	1.0, 3.5	-50.0, 200.0
	Mean (SD)	1.52 (0.652)	3.91 (43.493)	1.46 (0.637)	2.94 (46.569)
	95% CI of Mean	1.37, 1.67	-6.04, 13.85	1.26, 1.67	-11.77, 17.64

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	76	75	41	41
	Missing, n(%)	2 (2.6)	3 (3.8)	1 (2.4)	1 (2.4)
	Median	1.00	0.00	1.50	0.00
	Q25, Q75	1.00, 2.00	-25.00, 0.00	1.00, 1.50	0.00, 50.00
	Min, Max	1.0, 5.0	-63.6, 233.3	1.0, 6.0	-66.7, 300.0
	Mean (SD)	1.56 (0.809)	5.68 (51.197)	1.67 (1.111)	13.63 (58.938)
	95% CI of Mean	1.37, 1.75	-6.10, 17.47	1.32, 2.03	-4.98, 32.24

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	77		42	
	Missing, n(%)	1 (1.3)		0	
	Median	4.0		5.0	
	Q25, Q75	3.0, 5.0		3.0, 5.0	
	Min, Max	1, 7		1, 7	
	Mean (SD)	4.3 (1.47)		4.5 (1.46)	
	95% CI of Mean	4.0, 4.7		3.9, 5.0	

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	77	77	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	-20.00	4.0	0.00
	Q25, Q75	3.0, 4.0	-40.00, 0.00	3.0, 5.0	-20.00, 0.00
	Min, Max	1, 7	-75.0, 200.0	1, 7	-60.0, 200.0
	Mean (SD)	3.7 (1.48)	-8.83 (42.784)	4.3 (1.55)	0.49 (41.679)
	95% CI of Mean	3.3, 4.0	-18.54, 0.89	3.7, 4.8	-12.67, 13.65

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.0	-20.00	4.0	0.00
	Q25, Q75	3.0, 4.0	-40.00, 0.00	3.0, 5.0	-20.00, 0.00
	Min, Max	1, 7	-75.0, 500.0	1, 7	-50.0, 200.0
	Mean (SD)	3.6 (1.40)	-3.93 (76.843)	4.2 (1.58)	-1.23 (42.308)
	95% CI of Mean	3.2, 4.0	-21.49, 13.64	3.7, 4.8	-14.59, 12.13

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.0	-20.00	4.0	-14.29
	Q25, Q75	3.0, 4.0	-40.00, 0.00	3.0, 5.0	-20.00, 0.00
	Min, Max	1, 7	-80.0, 500.0	2, 7	-57.1, 200.0
	Mean (SD)	3.6 (1.41)	-4.03 (76.653)	3.9 (1.23)	-5.83 (41.021)
	95% CI of Mean	3.2, 4.0	-21.55, 13.49	3.5, 4.3	-18.78, 7.12

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.0	-16.67	4.0	-14.29
	Q25, Q75	3.0, 4.0	-40.00, 0.00	3.0, 5.0	-25.00, 0.00
	Min, Max	1, 7	-85.7, 400.0	1, 7	-75.0, 200.0
	Mean (SD)	3.5 (1.34)	-8.74 (65.922)	4.1 (1.56)	-3.89 (44.121)
	95% CI of Mean	3.1, 3.8	-23.81, 6.33	3.5, 4.6	-17.82, 10.04

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.5	-16.67	4.0	-14.29
	Q25, Q75	3.0, 5.0	-40.00, 0.00	3.0, 5.0	-33.33, 0.00
	Min, Max	1, 7	-80.0, 500.0	1, 7	-83.3, 200.0
	Mean (SD)	3.7 (1.54)	-4.38 (72.807)	3.8 (1.42)	-9.80 (43.211)
	95% CI of Mean	3.3, 4.1	-21.02, 12.26	3.3, 4.3	-23.45, 3.84

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	77	76	41	41
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	4.0	0.00	4.0	0.00
	Q25, Q75	3.0, 5.0	-25.00, 20.00	4.0, 5.0	-20.00, 20.00
	Min, Max	1, 7	-66.7, 400.0	1, 6	-57.1, 300.0
	Mean (SD)	4.2 (1.39)	7.38 (59.563)	4.4 (1.28)	8.27 (58.799)
	95% CI of Mean	3.8, 4.6	-6.23, 21.00	3.9, 4.8	-10.29, 26.83

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	77	76	41	41
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	4.0	0.00	4.0	0.00
	Q25, Q75	3.0, 5.0	-25.00, 22.50	3.0, 5.0	-25.00, 20.00
	Min, Max	1, 7	-57.1, 600.0	1, 7	-50.0, 200.0
	Mean (SD)	4.2 (1.42)	13.86 (96.478)	4.1 (1.41)	-2.24 (41.278)
	95% CI of Mean	3.8, 4.6	-8.19, 35.91	3.7, 4.6	-15.28, 10.79

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	76	75	41	41
	Missing, n(%)	2 (2.6)	3 (3.8)	1 (2.4)	1 (2.4)
	Median	4.0	0.00	4.0	0.00
	Q25, Q75	3.0, 5.0	-25.00, 20.00	3.0, 5.0	-20.00, 0.00
	Min, Max	1, 7	-57.1, 500.0	1, 7	-50.0, 200.0
	Mean (SD)	4.1 (1.27)	10.90 (84.106)	4.3 (1.41)	2.10 (45.251)
	95% CI of Mean	3.8, 4.4	-8.46, 30.25	3.8, 4.8	-12.19, 16.39

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	77		42	
	Missing, n(%)	1 (1.3)		0	
	Median	4.0		3.0	
	Q25, Q75	2.0, 5.0		2.0, 4.0	
	Min, Max	1, 7		1, 7	
	Mean (SD)	3.7 (1.57)		3.5 (1.68)	
	95% CI of Mean	3.3, 4.1		3.0, 4.1	

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	77	77	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.0	0.00	4.0	0.00
	Q25, Q75	2.0, 4.0	-33.33, 0.00	3.0, 4.0	0.00, 0.00
	Min, Max	1, 6	-75.0, 300.0	1, 7	-33.3, 100.0
	Mean (SD)	3.1 (1.32)	-3.84 (55.904)	3.5 (1.33)	10.78 (37.652)
	95% CI of Mean	2.8, 3.5	-16.53, 8.86	3.0, 4.0	-1.11, 22.67

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.0	0.00	4.0	0.00
	Q25, Q75	2.0, 4.0	-25.00, 0.00	2.0, 5.0	0.00, 0.00
	Min, Max	1, 6	-75.0, 300.0	1, 7	-50.0, 200.0
	Mean (SD)	3.1 (1.20)	-1.47 (55.084)	3.6 (1.68)	13.62 (56.482)
	95% CI of Mean	2.8, 3.5	-14.06, 11.12	3.0, 4.2	-4.21, 31.45

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.0	0.00	4.0	0.00
	Q25, Q75	2.0, 4.0	-25.00, 0.00	2.0, 4.0	-25.00, 0.00
	Min, Max	1, 6	-75.0, 300.0	1, 7	-50.0, 150.0
	Mean (SD)	3.3 (1.34)	0.93 (56.241)	3.3 (1.58)	3.73 (50.839)
	95% CI of Mean	2.9, 3.6	-11.93, 13.79	2.8, 3.9	-12.32, 19.78

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.0	0.00	4.0	0.00
	Q25, Q75	2.5, 4.0	-25.00, 0.00	2.0, 4.0	-25.00, 0.00
	Min, Max	1, 6	-75.0, 300.0	1, 7	-66.7, 200.0
	Mean (SD)	3.3 (1.33)	1.75 (58.196)	3.5 (1.57)	11.74 (57.666)
	95% CI of Mean	2.9, 3.6	-11.55, 15.05	2.9, 4.0	-6.46, 29.95

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.0	0.00	3.0	0.00
	Q25, Q75	3.0, 4.0	-25.00, 0.00	2.0, 4.0	-33.33, 0.00
	Min, Max	1, 6	-75.0, 300.0	1, 7	-50.0, 200.0
	Mean (SD)	3.3 (1.25)	4.92 (62.377)	3.3 (1.51)	8.12 (62.685)
	95% CI of Mean	3.0, 3.7	-9.34, 19.18	2.8, 3.8	-11.67, 27.91

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	77	76	41	41
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	4.0	0.00	4.0	0.00
	Q25, Q75	3.0, 5.0	-20.00, 36.67	3.0, 5.0	0.00, 33.33
	Min, Max	1, 7	-75.0, 500.0	1, 6	-66.7, 300.0
	Mean (SD)	3.9 (1.39)	27.03 (83.873)	3.7 (1.28)	27.40 (80.543)
	95% CI of Mean	3.5, 4.3	7.86, 46.20	3.2, 4.1	1.97, 52.83

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	77	76	41	41
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	4.0	0.00	4.0	0.00
	Q25, Q75	3.0, 5.0	-20.00, 33.33	3.0, 5.0	-25.00, 50.00
	Min, Max	1, 7	-60.0, 500.0	1, 6	-57.1, 200.0
	Mean (SD)	3.9 (1.39)	26.63 (85.903)	3.6 (1.43)	21.60 (67.861)
	95% CI of Mean	3.5, 4.2	7.00, 46.27	3.1, 4.1	0.18, 43.03

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	76	75	41	41
	Missing, n(%)	2 (2.6)	3 (3.8)	1 (2.4)	1 (2.4)
	Median	4.0	0.00	3.0	0.00
	Q25, Q75	3.0, 5.0	-20.00, 33.33	3.0, 4.0	-25.00, 33.33
	Min, Max	1, 7	-75.0, 600.0	1, 6	-66.7, 200.0
	Mean (SD)	3.9 (1.41)	24.52 (90.007)	3.4 (1.15)	19.20 (66.944)
	95% CI of Mean	3.5, 4.2	3.81, 45.23	3.0, 3.8	-1.93, 40.34

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	77		42	
	Missing, n(%)	1 (1.3)		0	
	Median	3.40		2.90	
	Q25, Q75	2.60, 4.20		2.00, 4.00	
	Min, Max	1.0, 6.6		1.4, 6.4	
	Mean (SD)	3.45 (1.182)		3.21 (1.350)	
	95% CI of Mean	3.17, 3.72		2.78, 3.63	

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	77	77	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	2.80	-17.65	2.80	-6.25
	Q25, Q75	2.00, 3.20	-33.33, -4.76	2.00, 3.60	-16.67, 11.11
	Min, Max	1.0, 6.2	-78.3, 120.0	1.2, 6.6	-40.0, 71.4
	Mean (SD)	2.76 (1.042)	-14.98 (33.134)	2.98 (1.240)	-3.32 (22.560)
	95% CI of Mean	2.52, 3.00	-22.50, -7.45	2.58, 3.37	-10.44, 3.81

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	2.70	-17.42	2.60	0.00
	Q25, Q75	2.20, 3.60	-33.33, 0.00	2.00, 3.80	-23.53, 0.00
	Min, Max	1.0, 6.2	-78.3, 120.0	1.0, 7.0	-44.4, 40.0
	Mean (SD)	2.79 (0.991)	-14.00 (32.270)	2.96 (1.434)	-6.34 (21.030)
	95% CI of Mean	2.56, 3.03	-21.38, -6.62	2.50, 3.41	-12.98, 0.31

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	2.70	-18.35	2.80	-10.00
	Q25, Q75	2.20, 3.20	-30.79, 0.00	2.00, 4.00	-26.32, 11.11
	Min, Max	1.0, 5.6	-78.3, 260.0	1.0, 5.4	-58.3, 75.0
	Mean (SD)	2.78 (1.014)	-13.87 (41.066)	2.87 (1.293)	-6.91 (29.919)
	95% CI of Mean	2.54, 3.01	-23.26, -4.48	2.46, 3.29	-16.36, 2.54

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	2.80	-17.16	2.60	-7.69
	Q25, Q75	2.10, 3.60	-37.47, 0.00	1.80, 3.80	-28.57, 0.00
	Min, Max	1.0, 5.6	-78.3, 140.0	1.0, 6.2	-50.0, 50.0
	Mean (SD)	2.80 (1.084)	-14.35 (34.867)	2.85 (1.380)	-9.50 (24.419)
	95% CI of Mean	2.54, 3.05	-22.32, -6.37	2.41, 3.29	-17.21, -1.78

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	2.80	-19.26	2.60	-10.00
	Q25, Q75	2.20, 3.40	-33.33, -3.85	2.00, 3.60	-28.57, 3.70
	Min, Max	1.0, 6.0	-78.3, 100.0	1.0, 5.6	-50.0, 75.0
	Mean (SD)	2.78 (1.033)	-15.54 (28.866)	2.81 (1.237)	-8.75 (27.996)
	95% CI of Mean	2.54, 3.02	-22.14, -8.94	2.42, 3.21	-17.59, 0.10

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	77	76	41	41
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.20	-14.91	3.00	0.00
	Q25, Q75	2.40, 3.60	-26.49, 10.32	2.20, 3.80	-17.86, 11.11
	Min, Max	1.0, 6.0	-58.3, 112.5	1.2, 6.0	-50.0, 57.1
	Mean (SD)	3.08 (0.990)	-5.40 (31.245)	3.08 (1.173)	1.63 (25.461)
	95% CI of Mean	2.85, 3.30	-12.54, 1.75	2.70, 3.45	-6.41, 9.67

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	77	76	41	41
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.00	-9.52	2.80	0.00
	Q25, Q75	2.20, 3.80	-28.64, 8.01	2.00, 3.80	-17.65, 10.00
	Min, Max	1.0, 6.8	-73.7, 480.0	1.0, 5.6	-58.3, 55.6
	Mean (SD)	3.12 (1.121)	0.29 (64.917)	2.96 (1.239)	-4.22 (25.190)
	95% CI of Mean	2.86, 3.38	-14.55, 15.13	2.56, 3.36	-12.18, 3.74

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	76	75	41	41
	Missing, n(%)	2 (2.6)	3 (3.8)	1 (2.4)	1 (2.4)
	Median	3.10	-14.29	2.80	-10.00
	Q25, Q75	2.30, 3.80	-33.33, 6.25	2.00, 4.00	-28.57, 20.00
	Min, Max	1.0, 5.8	-58.3, 420.0	1.0, 5.8	-50.0, 66.7
	Mean (SD)	3.06 (1.065)	-2.84 (59.009)	2.92 (1.296)	-5.20 (30.904)
	95% CI of Mean	2.81, 3.31	-16.42, 10.74	2.50, 3.33	-14.96, 4.56

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	77		42	
	Missing, n(%)	1 (1.3)		0	
	Median	4.30		4.00	
	Q25, Q75	3.70, 5.30		3.00, 5.00	
	Min, Max	1.0, 7.0		2.0, 7.0	
	Mean (SD)	4.38 (1.230)		4.12 (1.226)	
	95% CI of Mean	4.10, 4.67		3.73, 4.51	

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	77	77	41	41
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Median	3.00	-24.53	4.00	-6.98
	Q25, Q75	2.30, 4.00	-42.86, -6.98	3.00, 4.70	-18.92, 10.00
	Min, Max	1.0, 6.7	-80.0, 70.0	1.7, 7.0	-38.6, 48.1
	Mean (SD)	3.19 (1.148)	-23.25 (28.366)	3.90 (1.203)	-3.08 (21.747)
	95% CI of Mean	2.93, 3.46	-29.69, -16.81	3.51, 4.28	-9.95, 3.79

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 2	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.30	-23.33	3.70	0.00
	Q25, Q75	2.70, 4.00	-37.74, -5.83	3.00, 4.70	-14.81, 11.67
	Min, Max	1.0, 6.3	-80.0, 130.0	2.3, 7.0	-30.2, 74.1
	Mean (SD)	3.32 (1.077)	-19.61 (30.524)	4.02 (1.214)	0.63 (23.296)
	95% CI of Mean	3.07, 3.57	-26.59, -12.63	3.64, 4.41	-6.73, 7.99

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 3	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.30	-23.29	3.30	0.00
	Q25, Q75	2.70, 4.00	-34.50, -2.83	2.70, 5.00	-23.26, 7.50
	Min, Max	1.0, 6.7	-80.0, 370.0	2.0, 7.0	-43.4, 60.6
	Mean (SD)	3.45 (1.199)	-15.05 (51.208)	3.83 (1.250)	-4.46 (22.624)
	95% CI of Mean	3.17, 3.73	-26.76, -3.34	3.43, 4.23	-11.61, 2.68

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.30	-20.10	3.30	-7.02
	Q25, Q75	2.70, 4.30	-35.87, 0.00	3.00, 5.00	-21.28, 6.00
	Min, Max	1.0, 6.7	-83.3, 430.0	1.7, 7.0	-43.4, 60.6
	Mean (SD)	3.45 (1.231)	-13.62 (58.790)	3.82 (1.319)	-5.51 (23.711)
	95% CI of Mean	3.16, 3.74	-27.06, -0.18	3.40, 4.24	-13.00, 1.98

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 5	n	76	76	41	41
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.50	-18.18	3.70	-6.98
	Q25, Q75	3.00, 4.00	-36.17, 0.00	3.00, 4.70	-23.33, 12.77
	Min, Max	1.0, 6.7	-80.0, 300.0	1.3, 7.0	-67.5, 50.0
	Mean (SD)	3.56 (1.157)	-11.88 (45.680)	3.81 (1.315)	-4.84 (26.349)
	95% CI of Mean	3.29, 3.83	-22.32, -1.44	3.39, 4.23	-13.17, 3.48

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	77	76	41	41
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	4.00	-10.81	4.00	0.00
	Q25, Q75	3.30, 4.30	-29.79, 9.65	3.30, 4.70	-18.87, 22.22
	Min, Max	1.7, 7.0	-50.0, 300.0	2.0, 6.3	-51.1, 87.0
	Mean (SD)	3.91 (1.051)	-4.62 (43.113)	4.07 (1.022)	4.61 (30.134)
	95% CI of Mean	3.67, 4.15	-14.48, 5.23	3.75, 4.40	-4.91, 14.12

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	77	76	41	41
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)
	Median	3.70	-11.07	4.00	-6.98
	Q25, Q75	3.00, 4.70	-30.99, 7.55	3.00, 4.70	-18.57, 9.30
	Min, Max	1.3, 7.0	-67.9, 600.0	1.7, 6.3	-52.9, 73.9
	Mean (SD)	3.83 (1.303)	-3.77 (76.125)	3.93 (1.139)	-1.06 (25.205)
	95% CI of Mean	3.53, 4.13	-21.17, 13.63	3.57, 4.30	-9.02, 6.90

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.

**Table 15.2.4.37.2 Descriptive Statistics of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)	
		Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	76	75	41	41
	Missing, n(%)	2 (2.6)	3 (3.8)	1 (2.4)	1 (2.4)
	Median	3.85	-11.32	3.70	-6.98
	Q25, Q75	3.00, 4.70	-28.33, 6.00	3.00, 4.30	-18.92, 0.00
	Min, Max	1.0, 7.0	-69.7, 600.0	1.7, 6.7	-38.6, 50.0
	Mean (SD)	3.96 (1.215)	-1.67 (74.725)	3.80 (1.013)	-3.94 (23.133)
	95% CI of Mean	3.68, 4.24	-18.87, 15.53	3.48, 4.13	-11.25, 3.36

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.

**Table 15.2.4.38.1 Analysis of MCEQ Subscales - PP Set****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	75	41	
	LS Mean	1.66	1.60	0.07
	95% CI	1.48, 1.85	1.35, 1.84	-0.24, 0.37
Day 2	n	75	41	
	LS Mean	1.57	1.67	-0.10
	95% CI	1.35, 1.79	1.37, 1.97	-0.47, 0.26
Day 3	n	75	41	
	LS Mean	1.50	1.58	-0.08
	95% CI	1.34, 1.66	1.37, 1.79	-0.34, 0.18
Day 4	n	75	41	
	LS Mean	1.49	1.68	-0.19
	95% CI	1.27, 1.70	1.39, 1.97	-0.55, 0.16

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.1 Analysis of MCEQ Subscales - PP Set****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 5	n	75	41	
	LS Mean	1.56	1.49	0.07
	95% CI	1.38, 1.74	1.25, 1.73	-0.23, 0.37
Day 30	n	74	41	
	LS Mean	1.59	1.62	-0.03
	95% CI	1.40, 1.77	1.37, 1.87	-0.34, 0.27
Day 60	n	71	41	
	LS Mean	1.46	1.47	-0.01
	95% CI	1.34, 1.59	1.31, 1.64	-0.21, 0.20
Day 90	n	69	41	
	LS Mean	1.57	1.72	-0.16
	95% CI	1.36, 1.77	1.46, 1.99	-0.49, 0.18

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.1 Analysis of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	75	41	
	LS Mean	3.65	4.19	-0.54
	95% CI	3.35, 3.96	3.78, 4.60	-1.05, -0.03
Day 2	n	75	41	
	LS Mean	3.58	4.14	-0.56
	95% CI	3.28, 3.88	3.74, 4.55	-1.06, -0.06
Day 3	n	75	41	
	LS Mean	3.57	3.84	-0.27
	95% CI	3.29, 3.85	3.46, 4.22	-0.74, 0.20
Day 4	n	75	41	
	LS Mean	3.48	3.98	-0.50
	95% CI	3.19, 3.77	3.59, 4.37	-0.98, -0.02

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.1 Analysis of MCEQ Subscales - PP Set****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 5	n	75	41	
	LS Mean	3.63	3.66	-0.02
	95% CI	3.32, 3.95	3.24, 4.08	-0.55, 0.50
Day 30	n	74	41	
	LS Mean	4.19	4.30	-0.11
	95% CI	3.90, 4.49	3.91, 4.70	-0.60, 0.38
Day 60	n	71	41	
	LS Mean	4.22	4.08	0.13
	95% CI	3.90, 4.53	3.67, 4.50	-0.39, 0.65
Day 90	n	69	41	
	LS Mean	4.08	4.22	-0.15
	95% CI	3.79, 4.36	3.85, 4.60	-0.62, 0.32

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.1 Analysis of MCEQ Subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	75	41	
	LS Mean	3.05	3.60	-0.56
	95% CI	2.81, 3.28	3.28, 3.93	-0.96, -0.16
Day 2	n	75	41	
	LS Mean	3.09	3.71	-0.62
	95% CI	2.84, 3.34	3.37, 4.05	-1.04, -0.20
Day 3	n	75	41	
	LS Mean	3.23	3.43	-0.20
	95% CI	2.96, 3.49	3.07, 3.78	-0.64, 0.24
Day 4	n	75	41	
	LS Mean	3.22	3.54	-0.32
	95% CI	2.96, 3.48	3.18, 3.90	-0.76, 0.12

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.1 Analysis of MCEQ Subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 5	n	75	41	
	LS Mean	3.26	3.39	-0.13
	95% CI	3.01, 3.51	3.05, 3.73	-0.55, 0.29
Day 30	n	74	41	
	LS Mean	3.84	3.70	0.14
	95% CI	3.55, 4.12	3.32, 4.08	-0.33, 0.61
Day 60	n	71	41	
	LS Mean	3.84	3.64	0.19
	95% CI	3.54, 4.13	3.25, 4.03	-0.29, 0.68
Day 90	n	69	41	
	LS Mean	3.77	3.47	0.30
	95% CI	3.48, 4.07	3.09, 3.86	-0.18, 0.78

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.1 Analysis of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	75	41	
	LS Mean	2.67	3.08	-0.41
	95% CI	2.49, 2.86	2.83, 3.33	-0.72, -0.10
Day 2	n	75	41	
	LS Mean	2.74	3.09	-0.35
	95% CI	2.55, 2.93	2.83, 3.34	-0.67, -0.04
Day 3	n	75	41	
	LS Mean	2.73	2.99	-0.27
	95% CI	2.53, 2.92	2.73, 3.26	-0.59, 0.06
Day 4	n	75	41	
	LS Mean	2.73	2.97	-0.24
	95% CI	2.53, 2.93	2.70, 3.24	-0.57, 0.09

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.1 Analysis of MCEQ Subscales - PP Set****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 5	n	75	41	
	LS Mean	2.72	2.93	-0.21
	95% CI	2.54, 2.91	2.68, 3.17	-0.51, 0.10
Day 30	n	74	41	
	LS Mean	3.04	3.18	-0.14
	95% CI	2.85, 3.23	2.93, 3.43	-0.45, 0.17
Day 60	n	71	41	
	LS Mean	3.09	3.05	0.04
	95% CI	2.86, 3.32	2.74, 3.35	-0.33, 0.42
Day 90	n	69	41	
	LS Mean	3.01	3.01	0.00
	95% CI	2.78, 3.23	2.72, 3.31	-0.37, 0.36

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.1 Analysis of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	75	41	
	LS Mean	3.09	3.95	-0.86
	95% CI	2.85, 3.32	3.64, 4.27	-1.26, -0.47
Day 2	n	75	41	
	LS Mean	3.26	4.12	-0.86
	95% CI	3.04, 3.48	3.82, 4.42	-1.23, -0.50
Day 3	n	75	41	
	LS Mean	3.40	3.93	-0.54
	95% CI	3.15, 3.64	3.60, 4.26	-0.94, -0.13
Day 4	n	75	41	
	LS Mean	3.39	3.92	-0.53
	95% CI	3.13, 3.65	3.57, 4.27	-0.96, -0.10

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.1 Analysis of MCEQ Subscales - PP Set****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 5	n	75	41	
	LS Mean	3.51	3.89	-0.39
	95% CI	3.25, 3.76	3.55, 4.23	-0.81, 0.03
Day 30	n	74	41	
	LS Mean	3.83	4.15	-0.31
	95% CI	3.62, 4.05	3.86, 4.44	-0.67, 0.05
Day 60	n	71	41	
	LS Mean	3.79	4.00	-0.21
	95% CI	3.52, 4.06	3.65, 4.35	-0.65, 0.23
Day 90	n	69	41	
	LS Mean	3.89	3.89	0.01
	95% CI	3.65, 4.14	3.57, 4.21	-0.39, 0.41

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.2 Analysis of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	77	41	
	LS Mean	1.68	1.59	0.09
	95% CI	1.50, 1.86	1.35, 1.84	-0.22, 0.39
Day 2	n	76	41	
	LS Mean	1.57	1.67	-0.10
	95% CI	1.35, 1.79	1.38, 1.97	-0.46, 0.26
Day 3	n	76	41	
	LS Mean	1.50	1.58	-0.08
	95% CI	1.34, 1.65	1.37, 1.79	-0.34, 0.18
Day 4	n	76	41	
	LS Mean	1.49	1.68	-0.20
	95% CI	1.27, 1.70	1.39, 1.97	-0.55, 0.16

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.2 Analysis of MCEQ Subscales - FAS****Parameter: Aversion Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 5	n	76	41	
	LS Mean	1.57	1.49	0.08
	95% CI	1.39, 1.75	1.25, 1.73	-0.22, 0.37
Day 30	n	76	41	
	LS Mean	1.59	1.62	-0.03
	95% CI	1.41, 1.78	1.37, 1.87	-0.33, 0.28
Day 60	n	76	41	
	LS Mean	1.52	1.50	0.02
	95% CI	1.40, 1.64	1.33, 1.66	-0.18, 0.23
Day 90	n	75	41	
	LS Mean	1.57	1.72	-0.15
	95% CI	1.37, 1.76	1.46, 1.98	-0.47, 0.17

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.2 Analysis of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	77	41	
	LS Mean	3.69	4.21	-0.53
	95% CI	3.39, 3.99	3.81, 4.62	-1.03, -0.03
Day 2	n	76	41	
	LS Mean	3.62	4.15	-0.53
	95% CI	3.32, 3.92	3.74, 4.56	-1.03, -0.03
Day 3	n	76	41	
	LS Mean	3.61	3.85	-0.24
	95% CI	3.33, 3.89	3.46, 4.23	-0.71, 0.24
Day 4	n	76	41	
	LS Mean	3.51	3.99	-0.49
	95% CI	3.22, 3.79	3.60, 4.38	-0.97, 0.00

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.2 Analysis of MCEQ Subscales - FAS****Parameter: Craving Reduction Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 5	n	76	41	
	LS Mean	3.67	3.66	0.01
	95% CI	3.36, 3.99	3.24, 4.09	-0.51, 0.53
Day 30	n	76	41	
	LS Mean	4.21	4.31	-0.10
	95% CI	3.92, 4.51	3.92, 4.71	-0.58, 0.39
Day 60	n	76	41	
	LS Mean	4.20	4.09	0.11
	95% CI	3.90, 4.50	3.68, 4.50	-0.40, 0.61
Day 90	n	75	41	
	LS Mean	4.11	4.22	-0.11
	95% CI	3.84, 4.39	3.85, 4.59	-0.57, 0.35

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.2 Analysis of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	77	41	
	LS Mean	3.06	3.62	-0.55
	95% CI	2.83, 3.30	3.30, 3.94	-0.95, -0.16
Day 2	n	76	41	
	LS Mean	3.11	3.71	-0.61
	95% CI	2.86, 3.36	3.37, 4.05	-1.02, -0.19
Day 3	n	76	41	
	LS Mean	3.23	3.44	-0.20
	95% CI	2.97, 3.50	3.08, 3.79	-0.64, 0.24
Day 4	n	76	41	
	LS Mean	3.22	3.55	-0.32
	95% CI	2.96, 3.49	3.19, 3.90	-0.76, 0.12

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.2 Analysis of MCEQ Subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 5	n	76	41	
	LS Mean	3.26	3.40	-0.13
	95% CI	3.01, 3.51	3.06, 3.74	-0.55, 0.29
Day 30	n	76	41	
	LS Mean	3.86	3.70	0.15
	95% CI	3.58, 4.14	3.33, 4.08	-0.31, 0.62
Day 60	n	76	41	
	LS Mean	3.80	3.65	0.14
	95% CI	3.51, 4.08	3.27, 4.04	-0.33, 0.62
Day 90	n	75	41	
	LS Mean	3.80	3.49	0.31
	95% CI	3.52, 4.08	3.11, 3.86	-0.15, 0.78

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.2 Analysis of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	77	41	
	LS Mean	2.70	3.07	-0.38
	95% CI	2.50, 2.89	2.81, 3.33	-0.70, -0.06
Day 2	n	76	41	
	LS Mean	2.73	3.08	-0.35
	95% CI	2.54, 2.92	2.83, 3.34	-0.67, -0.04
Day 3	n	76	41	
	LS Mean	2.73	2.99	-0.26
	95% CI	2.53, 2.92	2.73, 3.25	-0.59, 0.06
Day 4	n	76	41	
	LS Mean	2.72	2.97	-0.25
	95% CI	2.52, 2.92	2.70, 3.24	-0.58, 0.08

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.2 Analysis of MCEQ Subscales - FAS****Parameter: Psychological Reward Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 5	n	76	41	
	LS Mean	2.72	2.92	-0.21
	95% CI	2.53, 2.90	2.68, 3.17	-0.51, 0.10
Day 30	n	76	41	
	LS Mean	3.03	3.18	-0.15
	95% CI	2.84, 3.21	2.93, 3.43	-0.46, 0.16
Day 60	n	76	41	
	LS Mean	3.07	3.06	0.01
	95% CI	2.85, 3.30	2.76, 3.36	-0.36, 0.38
Day 90	n	75	41	
	LS Mean	3.02	3.03	-0.01
	95% CI	2.80, 3.23	2.74, 3.32	-0.37, 0.35

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.2 Analysis of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	77	41	
	LS Mean	3.12	3.95	-0.84
	95% CI	2.88, 3.35	3.64, 4.27	-1.23, -0.45
Day 2	n	76	41	
	LS Mean	3.27	4.12	-0.86
	95% CI	3.05, 3.49	3.83, 4.42	-1.22, -0.49
Day 3	n	76	41	
	LS Mean	3.40	3.93	-0.54
	95% CI	3.16, 3.64	3.60, 4.26	-0.94, -0.13
Day 4	n	76	41	
	LS Mean	3.39	3.92	-0.52
	95% CI	3.14, 3.65	3.57, 4.27	-0.95, -0.09

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.38.2 Analysis of MCEQ Subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Time point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 5	n	76	41	
	LS Mean	3.51	3.89	-0.38
	95% CI	3.26, 3.76	3.55, 4.23	-0.80, 0.03
Day 30	n	76	41	
	LS Mean	3.84	4.14	-0.31
	95% CI	3.63, 4.05	3.86, 4.43	-0.66, 0.05
Day 60	n	76	41	
	LS Mean	3.75	4.01	-0.26
	95% CI	3.49, 4.01	3.65, 4.36	-0.69, 0.18
Day 90	n	75	41	
	LS Mean	3.89	3.89	0.00
	95% CI	3.66, 4.12	3.57, 4.20	-0.39, 0.39

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 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: MCEQ subscales scores are reported on a 7-point scale. Higher scores indicate greater intensity on that scale.

**Table 15.2.4.39.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	75		42		39	
	Missing, n(%)	1 (1.3)		0		0	
	Median	0.89		0.78		0.67	
	Q25, Q75	0.44, 1.11		0.33, 0.89		0.44, 1.44	
	Min, Max	0.0, 2.7		0.0, 2.4		0.0, 3.0	
	Mean (SD)	0.89 (0.625)		0.77 (0.523)		0.93 (0.750)	
	95% CI of Mean	0.74, 1.03		0.60, 0.94		0.68, 1.18	
Day 1							
	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	0.67	-10.53	0.56	-16.67	1.44	75.00
	Q25, Q75	0.33, 1.22	-28.57, 18.18	0.33, 0.89	-37.50, 0.00	1.00, 2.22	0.00, 225.00
	Min, Max	0.0, 2.6	-100.0, 450.0	0.0, 2.4	-100.0, 100.0	0.0, 3.4	-100.0, 1400.0
	Mean (SD)	0.81 (0.562)	7.84 (89.068)	0.69 (0.552)	-9.60 (42.428)	1.56 (0.907)	138.91 (251.764)
	95% CI of Mean	0.67, 0.94	-12.65, 28.34	0.51, 0.86	-23.00, 3.79	1.26, 1.86	57.29, 220.52

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

Appendix: 15.3.6.13

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**Table 15.2.4.39.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2							
	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	0.67	-4.17	0.56	-18.18	1.22	53.33
	Q25, Q75	0.44, 1.22	-33.33, 12.50	0.22, 1.00	-37.50, 0.00	0.89, 1.89	0.00, 133.33
	Min, Max	0.0, 2.6	-100.0, 300.0	0.0, 1.9	-100.0, 142.9	0.0, 3.2	-100.0, 1800.0
	Mean (SD)	0.81 (0.565)	-1.40 (58.218)	0.64 (0.475)	-12.03 (43.751)	1.41 (0.878)	122.26 (300.769)
	95% CI of Mean	0.68, 0.95	-14.80, 12.00	0.48, 0.79	-25.85, 1.78	1.12, 1.70	24.76, 219.76
Day 3							
	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	0.67	-10.00	0.56	0.00	1.22	75.00
	Q25, Q75	0.44, 1.11	-33.33, 11.11	0.33, 1.00	-33.33, 27.27	0.78, 2.22	0.00, 183.33
	Min, Max	0.0, 2.1	-100.0, 200.0	0.1, 1.9	-66.7, 400.0	0.0, 3.3	-100.0, 2600.0
	Mean (SD)	0.80 (0.543)	-3.86 (50.039)	0.70 (0.457)	5.99 (73.813)	1.50 (0.955)	151.71 (421.916)
	95% CI of Mean	0.67, 0.93	-15.38, 7.65	0.55, 0.85	-17.31, 29.30	1.18, 1.81	14.94, 288.48

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

Note: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

Appendix: 15.3.6.13

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**Table 15.2.4.39.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	0.67	-10.00	0.56	0.00	1.22	33.33
	Q25, Q75	0.44, 1.11	-37.50, 16.67	0.33, 0.89	-42.86, 33.33	0.44, 2.11	0.00, 140.00
	Min, Max	0.0, 2.8	-100.0, 500.0	0.1, 1.7	-83.3, 400.0	0.0, 3.7	-100.0, 1900.0
	Mean (SD)	0.83 (0.609)	0.53 (80.788)	0.64 (0.410)	4.71 (79.537)	1.39 (0.959)	128.39 (345.196)
	95% CI of	0.69, 0.98	-18.06, 19.12	0.51, 0.78	-20.39, 29.82	1.07, 1.70	16.49, 240.30
	Mean						
Day 5	n	75	75	41	41	39	39
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	0	0
	Median	0.78	0.00	0.67	0.00	1.11	20.00
	Q25, Q75	0.44, 1.22	-25.00, 33.33	0.33, 1.00	-42.86, 25.00	0.56, 1.89	-15.38, 100.00
	Min, Max	0.0, 3.0	-100.0, 600.0	0.1, 2.0	-75.0, 350.0	0.0, 3.3	-100.0, 1900.0
	Mean (SD)	0.91 (0.644)	11.31 (86.736)	0.70 (0.485)	12.93 (86.669)	1.25 (0.941)	91.65 (315.575)
	95% CI of	0.76, 1.06	-8.65, 31.28	0.54, 0.86	-14.43, 40.29	0.94, 1.55	-10.65, 193.95
	Mean						

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

Appendix: 15.3.6.13

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Table 15.2.4.39.1 Descriptive Statistics of MNWS Total Scores - PP Set
Parameter: MNWS-R withdrawal score
Product Use Time Period: Period 2

Time point	Statistic	THSm2.2 (N=74)		mCC (N=41)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	74		41		39	
	Median	0.89		0.78		0.67	
	Q25, Q75	0.44, 1.11		0.33, 0.89		0.44, 1.44	
	Min, Max	0.0, 2.7		0.0, 2.4		0.0, 3.0	
	Mean (SD)	0.88 (0.628)		0.75 (0.519)		0.93 (0.750)	
	95% CI of Mean	0.73, 1.03		0.58, 0.92		0.68, 1.18	
Day 30							
	n	74	74	41	41	38	38
	Missing, n(%)	0	0	0	0	1 (2.6)	1 (2.6)
	Median	0.67	-23.64	0.56	-14.29	0.67	-3.57
	Q25, Q75	0.22, 1.00	-55.56, 11.11	0.33, 0.89	-47.06, 18.18	0.22, 1.33	-62.96, 37.50
	Min, Max	0.0, 2.8	-100.0, 300.0	0.0, 1.7	-100.0, 300.0	0.0, 3.1	-100.0, 1600.0
	Mean (SD)	0.71 (0.542)	-11.32 (66.246)	0.63 (0.442)	-2.05 (76.235)	0.90 (0.852)	46.23 (276.452)
	95% CI of Mean	0.58, 0.84	-26.67, 4.03	0.48, 0.77	-26.11, 22.02	0.62, 1.19	-44.64, 137.10

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

Note: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

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Table 15.2.4.39.1 Descriptive Statistics of MNWS Total Scores - PP Set
Parameter: MNWS-R withdrawal score
Product Use Time Period: Period 3

Time point	Statistic	THSm2.2 (N=71)		mCC (N=41)		SA (N=38)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	71		41		38	
	Median	0.78		0.78		0.67	
	Q25, Q75	0.44, 1.11		0.33, 0.89		0.44, 1.33	
	Min, Max	0.0, 2.7		0.0, 2.4		0.0, 3.0	
	Mean (SD)	0.86 (0.626)		0.75 (0.519)		0.92 (0.755)	
	95% CI of	0.71, 1.01		0.58, 0.92		0.67, 1.17	
	Mean						
Day 60	n	71	71	41	41	38	38
	Median	0.56	-28.57	0.44	-25.00	0.56	-3.13
	Q25, Q75	0.22, 1.11	-60.00, 10.00	0.22, 0.78	-63.64, 0.00	0.22, 1.00	-66.67, 40.00
	Min, Max	0.0, 2.3	-100.0, 700.0	0.0, 2.1	-100.0, 350.0	0.0, 3.3	-100.0, 500.0
	Mean (SD)	0.69 (0.560)	-7.42 (108.902)	0.54 (0.455)	-13.58 (84.266)	0.75 (0.764)	11.43 (132.078)
	95% CI of	0.55, 0.83	-33.21, 18.36	0.40, 0.69	-40.18, 13.03	0.49, 1.00	-31.99, 54.84
	Mean						

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

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Table 15.2.4.39.1 Descriptive Statistics of MNWS Total Scores - PP Set
Parameter: MNWS-R withdrawal score
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	70		41		37	
	Median	0.83		0.78		0.67	
	Q25, Q75	0.44, 1.11		0.33, 0.89		0.44, 1.33	
	Min, Max	0.0, 2.7		0.0, 2.4		0.0, 3.0	
	Mean (SD)	0.87 (0.642)		0.75 (0.519)		0.93 (0.763)	
	95% CI of Mean	0.71, 1.03		0.58, 0.92		0.67, 1.19	
Day 90							
	n	69	69	41	41	37	37
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0	0	0
	Median	0.67	-14.29	0.44	-14.29	0.33	-64.29
	Q25, Q75	0.22, 1.11	-50.00, 10.00	0.11, 1.00	-57.14, 10.00	0.11, 0.67	-83.33, 0.00
	Min, Max	0.0, 2.9	-100.0, 1700.0	0.0, 2.0	-100.0, 500.0	0.0, 2.4	-100.0, 57.1
	Mean (SD)	0.77 (0.618)	17.94 (229.866)	0.60 (0.500)	-2.09 (110.966)	0.47 (0.571)	-39.20 (50.868)
	95% CI of Mean	0.62, 0.92	-37.28, 73.17	0.44, 0.76	-37.12, 32.94	0.27, 0.66	-56.17, -22.24

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

Note: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

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**Table 15.2.4.39.2 Descriptive Statistics of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	77		42		40	
	Missing, n(%)	1 (1.3)		0		0	
	Median	0.89		0.78		0.67	
	Q25, Q75	0.44, 1.11		0.33, 0.89		0.44, 1.39	
	Min, Max	0.0, 2.7		0.0, 2.4		0.0, 3.0	
	Mean (SD)	0.89 (0.620)		0.77 (0.523)		0.93 (0.741)	
	95% CI of Mean	0.74, 1.03		0.60, 0.94		0.68, 1.17	
Day 1							
	n	76	76	41	41	40	40
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	0	0
	Median	0.67	-10.26	0.56	-16.67	1.44	70.83
	Q25, Q75	0.33, 1.22	-28.17, 16.23	0.33, 0.89	-37.50, 0.00	1.00, 2.11	1.85, 218.06
	Min, Max	0.0, 2.6	-100.0, 450.0	0.0, 2.4	-100.0, 100.0	0.0, 3.4	-100.0, 1400.0
	Mean (SD)	0.81 (0.559)	7.74 (88.477)	0.69 (0.552)	-9.60 (42.428)	1.55 (0.899)	136.68 (248.912)
	95% CI of Mean	0.67, 0.94	-12.48, 27.96	0.51, 0.86	-23.00, 3.79	1.25, 1.84	57.07, 216.29

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

Note: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

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Table 15.2.4.39.2 Descriptive Statistics of MNWS Total Scores - FAS
Parameter: MNWS-R withdrawal score

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 2							
	n	76	76	41	41	40	40
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	0	0
	Median	0.67	-2.08	0.56	-18.18	1.22	51.67
	Q25, Q75	0.44, 1.17	-32.29, 13.39	0.22, 1.00	-37.50, 0.00	0.83, 1.83	0.00, 129.17
	Min, Max	0.0, 2.6	-100.0, 300.0	0.0, 1.9	-100.0, 142.9	0.0, 3.2	-100.0, 1800.0
	Mean (SD)	0.81 (0.561)	-0.86 (58.024)	0.64 (0.475)	-12.03 (43.751)	1.39 (0.875)	119.20 (297.517)
	95% CI of Mean	0.68, 0.94	-14.12, 12.41	0.48, 0.79	-25.85, 1.78	1.11, 1.68	24.05, 214.36
Day 3							
	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	0.67	-5.00	0.56	0.00	1.22	75.00
	Q25, Q75	0.44, 1.11	-31.25, 11.11	0.33, 1.00	-33.33, 27.27	0.78, 2.22	0.00, 183.33
	Min, Max	0.0, 2.1	-100.0, 200.0	0.1, 1.9	-66.7, 400.0	0.0, 3.3	-100.0, 2600.0
	Mean (SD)	0.79 (0.540)	-3.81 (49.707)	0.70 (0.457)	5.99 (73.813)	1.50 (0.955)	151.71 (421.916)
	95% CI of Mean	0.67, 0.92	-15.18, 7.55	0.55, 0.85	-17.31, 29.30	1.18, 1.81	14.94, 288.48

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

Note: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

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Table 15.2.4.39.2 Descriptive Statistics of MNWS Total Scores - FAS
Parameter: MNWS-R withdrawal score

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4							
	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	0.67	-9.17	0.56	0.00	1.22	33.33
	Q25, Q75	0.44, 1.11	-36.93, 18.33	0.33, 0.89	-42.86, 33.33	0.44, 2.11	0.00, 140.00
	Min, Max	0.0, 2.8	-100.0, 500.0	0.1, 1.7	-83.3, 400.0	0.0, 3.7	-100.0, 1900.0
	Mean (SD)	0.83 (0.605)	0.78 (80.279)	0.64 (0.410)	4.71 (79.537)	1.39 (0.959)	128.39 (345.196)
	95% CI of Mean	0.69, 0.97	-17.57, 19.13	0.51, 0.78	-20.39, 29.82	1.07, 1.70	16.49, 240.30
Day 5							
	n	76	76	41	41	39	39
	Missing, n(%)	2 (2.6)	2 (2.6)	1 (2.4)	1 (2.4)	1 (2.5)	1 (2.5)
	Median	0.78	0.00	0.67	0.00	1.11	20.00
	Q25, Q75	0.44, 1.22	-22.92, 30.30	0.33, 1.00	-42.86, 25.00	0.56, 1.89	-15.38, 100.00
	Min, Max	0.0, 3.0	-100.0, 600.0	0.1, 2.0	-75.0, 350.0	0.0, 3.3	-100.0, 1900.0
	Mean (SD)	0.91 (0.641)	11.43 (86.161)	0.70 (0.485)	12.93 (86.669)	1.25 (0.941)	91.65 (315.575)
	95% CI of Mean	0.76, 1.06	-8.26, 31.12	0.54, 0.86	-14.43, 40.29	0.94, 1.55	-10.65, 193.95

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 10 AM on Day 1 in the SA arm

Note: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

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Table 15.2.4.39.2 Descriptive Statistics of MNWS Total Scores - FAS
Parameter: MNWS-R withdrawal score

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30							
	n	77	76	41	41	38	38
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	0.67	-18.33	0.56	-14.29	0.67	-3.57
	Q25, Q75	0.22, 1.00	-52.78, 11.81	0.33, 0.89	-47.06, 18.18	0.22, 1.33	-62.96, 37.50
	Min, Max	0.0, 2.8	-100.0, 300.0	0.0, 1.7	-100.0, 300.0	0.0, 3.1	-100.0, 1600.0
	Mean (SD)	0.71 (0.544)	-10.26 (65.705)	0.63 (0.442)	-2.05 (76.235)	0.90 (0.852)	46.23 (276.452)
	95% CI of	0.58, 0.84	-25.27, 4.76	0.48, 0.77	-26.11, 22.02	0.62, 1.19	-44.64, 137.10
	Mean						

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

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Table 15.2.4.39.2 Descriptive Statistics of MNWS Total Scores - FAS
Parameter: MNWS-R withdrawal score

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60							
	n	77	76	41	41	38	38
	Missing, n(%)	1 (1.3)	2 (2.6)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	0.56	-26.79	0.44	-25.00	0.56	-3.13
	Q25, Q75	0.22, 1.11	-61.25, 10.56	0.22, 0.78	-63.64, 0.00	0.22, 1.00	-66.67, 40.00
	Min, Max	0.0, 2.3	-100.0, 700.0	0.0, 2.1	-100.0, 350.0	0.0, 3.3	-100.0, 500.0
	Mean (SD)	0.70 (0.578)	-7.42 (106.445)	0.54 (0.455)	-13.58 (84.266)	0.75 (0.764)	11.43 (132.078)
	95% CI of Mean	0.57, 0.84	-31.75, 16.91	0.40, 0.69	-40.18, 13.03	0.49, 1.00	-31.99, 54.84

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

Note: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

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Table 15.2.4.39.2 Descriptive Statistics of MNWS Total Scores - FAS
Parameter: MNWS-R withdrawal score

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90							
	n	76	75	41	41	38	38
	Missing, n(%)	2 (2.6)	3 (3.8)	1 (2.4)	1 (2.4)	2 (5.0)	2 (5.0)
	Median	0.67	-14.29	0.44	-14.29	0.33	-62.14
	Q25, Q75	0.22, 1.11	-50.00, 12.50	0.11, 1.00	-57.14, 10.00	0.11, 0.67	-83.33, 0.00
	Min, Max	0.0, 2.9	-100.0, 1700.0	0.0, 2.0	-100.0, 500.0	0.0, 2.4	-100.0, 57.1
	Mean (SD)	0.77 (0.612)	15.68 (220.966)	0.60 (0.500)	-2.09 (110.966)	0.47 (0.564)	-38.70 (50.272)
	95% CI of Mean	0.63, 0.92	-35.17, 66.52	0.44, 0.76	-37.12, 32.94	0.28, 0.66	-55.22, -22.17

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

Note: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

Appendix: 15.3.6.13

Study ID: ZRHM-REXA-07-JP

Program: t1502043902-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.40.1 Analysis of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 1	n	75	41	39		
	LS Mean	0.80	0.78	1.52	0.02	-0.72
	95% CI	0.69, 0.91	0.62, 0.93	1.36, 1.67	-0.17, 0.21	-0.91, -0.53
Day 2	n	75	41	39		
	LS Mean	0.80	0.73	1.37	0.08	-0.57
	95% CI	0.69, 0.92	0.58, 0.87	1.22, 1.52	-0.10, 0.26	-0.75, -0.38
Day 3	n	75	41	39		
	LS Mean	0.80	0.78	1.47	0.01	-0.67
	95% CI	0.67, 0.92	0.62, 0.95	1.30, 1.64	-0.19, 0.22	-0.88, -0.46

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

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: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

**Table 15.2.4.40.1 Analysis of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 4						
	n	75	41	39		
	LS Mean	0.83	0.74	1.36	0.10	-0.52
	95% CI	0.71, 0.96	0.57, 0.91	1.18, 1.53	-0.11, 0.30	-0.73, -0.31
Day 5						
	n	75	41	39		
	LS Mean	0.90	0.79	1.20	0.11	-0.30
	95% CI	0.78, 1.02	0.63, 0.96	1.03, 1.37	-0.10, 0.31	-0.51, -0.09
Day 30						
	n	74	41	38		
	LS Mean	0.70	0.68	0.87	0.02	-0.18
	95% CI	0.57, 0.82	0.51, 0.85	0.70, 1.05	-0.19, 0.22	-0.39, 0.04

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

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: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

**Table 15.2.4.40.1 Analysis of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 60						
	n	71	41	38		
	LS Mean	0.69	0.60	0.72	0.09	-0.03
	95% CI	0.56, 0.82	0.43, 0.76	0.55, 0.89	-0.11, 0.30	-0.24, 0.18
Day 90						
	n	69	41	37		
	LS Mean	0.76	0.65	0.44	0.11	0.33
	95% CI	0.64, 0.88	0.50, 0.81	0.27, 0.60	-0.09, 0.30	0.12, 0.53

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

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: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

**Table 15.2.4.40.2 Analysis of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 1	n	76	41	40		
	LS Mean	0.80	0.77	1.51	0.02	-0.71
	95% CI	0.68, 0.91	0.62, 0.93	1.35, 1.66	-0.17, 0.21	-0.90, -0.52
Day 2	n	76	41	40		
	LS Mean	0.81	0.72	1.35	0.08	-0.55
	95% CI	0.69, 0.92	0.57, 0.87	1.20, 1.50	-0.10, 0.26	-0.73, -0.36
Day 3	n	76	41	39		
	LS Mean	0.80	0.78	1.47	0.01	-0.67
	95% CI	0.67, 0.92	0.62, 0.95	1.30, 1.64	-0.19, 0.22	-0.88, -0.46

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

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: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

**Table 15.2.4.40.2 Analysis of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 4	n	76	41	39		
	LS Mean	0.83	0.74	1.35	0.10	-0.52
	95% CI	0.71, 0.96	0.57, 0.90	1.18, 1.53	-0.11, 0.30	-0.73, -0.31
Day 5	n	76	41	39		
	LS Mean	0.90	0.79	1.20	0.11	-0.30
	95% CI	0.78, 1.02	0.63, 0.96	1.03, 1.37	-0.10, 0.31	-0.51, -0.09
Day 30	n	76	41	38		
	LS Mean	0.71	0.68	0.87	0.03	-0.17
	95% CI	0.58, 0.83	0.51, 0.85	0.70, 1.05	-0.18, 0.23	-0.38, 0.04

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

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: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

**Table 15.2.4.40.2 Analysis of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Time point	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 60						
	n	76	41	38		
	LS Mean	0.71	0.61	0.72	0.10	-0.02
	95% CI	0.58, 0.83	0.44, 0.77	0.55, 0.90	-0.10, 0.31	-0.23, 0.20
Day 90						
	n	75	41	38		
	LS Mean	0.77	0.66	0.44	0.11	0.32
	95% CI	0.65, 0.88	0.50, 0.81	0.28, 0.60	-0.08, 0.30	0.13, 0.52

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

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: MNWS-R score is reported on a scale of 0 to 4. Higher scores indicate greater intensity on that scale.

Note: The assessments performed at Day 1 to Day 6 are used to evaluate withdrawal symptoms at Day 0 to Day 5, respectively.

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 1

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	57		33		33	
	Missing, n(%)	19 (25.0)		9 (21.4)		6 (15.4)	
	Mean (SD)	3.68 (1.089)		3.42 (1.032)		3.52 (0.834)	
	95% CI	3.39, 3.98		3.05, 3.80		3.21, 3.82	
	Median	4.00		4.00		3.00	
	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	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 1

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	0	32	0		
	Missing, n(%)	0		10 (23.8)			
	Mean (SD)	3.92 (0.845)		3.19 (0.998)			
	95% CI	3.72, 4.12		2.82, 3.55			
	Median	4.00		3.00			
	Q25, Q75	3.50, 4.00		3.00, 4.00			
	Min, Max	1.0, 5.0		1.0, 5.0			

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 2

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	56		32		33	
	Missing, n(%)	18 (24.3)		9 (22.0)		6 (15.4)	
	Mean (SD)	3.68 (1.098)		3.38 (1.009)		3.52 (0.834)	
	95% CI	3.38, 3.98		3.01, 3.74		3.21, 3.82	
	Median	4.00		4.00		3.00	
	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	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 2

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	0	32	0		
	Missing, n(%)	0		9 (22.0)			
	Mean (SD)	3.61 (1.005)		3.16 (0.884)			
	95% CI	3.37, 3.85		2.83, 3.48			
	Median	4.00		3.00			
	Q25, Q75	3.00, 4.00		2.50, 4.00			
	Min, Max	1.0, 5.0		2.0, 5.0			

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 3

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		32		32	
	Missing, n(%)	16 (22.5)		9 (22.0)		6 (15.8)	
	Mean (SD)	3.65 (1.093)		3.38 (1.009)		3.53 (0.842)	
	95% CI	3.35, 3.95		3.01, 3.74		3.22, 3.84	
	Median	4.00		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	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 3

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	0	32	0		
	Missing, n(%)	0		9 (22.0)			
	Mean (SD)	3.38 (1.074)		3.03 (0.647)			
	95% CI	3.12, 3.64		2.79, 3.27			
	Median	3.00		3.00			
	Q25, Q75	3.00, 4.00		3.00, 3.00			
	Min, Max	1.0, 5.0		2.0, 5.0			

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 4

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		32		31	
	Missing, n(%)	18 (25.7)		9 (22.0)		6 (16.2)	
	Mean (SD)	3.63 (1.104)		3.38 (1.009)		3.52 (0.852)	
	95% CI	3.32, 3.95		3.01, 3.74		3.20, 3.83	
	Median	4.00		4.00		3.00	
	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	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 4

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	0	32	0		
	Missing, n(%)	1 (1.4)		9 (22.0)			
	Mean (SD)	3.35 (0.998)		3.03 (0.740)			
	95% CI	3.10, 3.59		2.76, 3.30			
	Median	3.00		3.00			
	Q25, Q75	3.00, 4.00		3.00, 3.00			
	Min, Max	1.0, 5.0		2.0, 5.0			

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Enjoy smoking****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	57		33		33	
	Missing, n(%)	19 (25.0)		9 (21.4)		6 (15.4)	
	Mean (SD)	2.75 (1.074)		2.73 (1.040)		2.70 (1.046)	
	95% CI	2.46, 3.04		2.35, 3.10		2.32, 3.07	
	Median	3.00		2.00		3.00	
	Q25, Q75	2.00, 4.00		2.00, 4.00		2.00, 3.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

Appendix: 15.3.7.2

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Enjoy smoking****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	0	32	0		
	Missing, n(%)	0		10 (23.8)			
	Mean (SD)	2.49 (1.077)		2.91 (0.893)			
	95% CI	2.24, 2.74		2.58, 3.23			
	Median	2.00		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; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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 HST Questionnaire Data - PP Set****Parameter: Enjoy smoking****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	56		32		33	
	Missing, n(%)	18 (24.3)		9 (22.0)		6 (15.4)	
	Mean (SD)	2.75 (1.083)		2.72 (1.055)		2.70 (1.046)	
	95% CI	2.45, 3.05		2.33, 3.10		2.32, 3.07	
	Median	2.50		2.00		3.00	
	Q25, Q75	2.00, 4.00		2.00, 4.00		2.00, 3.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

Appendix: 15.3.7.2

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Enjoy smoking****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	0	32	0		
	Missing, n(%)	0		9 (22.0)			
	Mean (SD)	2.88 (0.965)		3.03 (0.740)			
	95% CI	2.65, 3.11		2.76, 3.30			
	Median	3.00		3.00			
	Q25, Q75	2.00, 4.00		2.50, 4.00			
	Min, Max	1.0, 5.0		2.0, 4.0			

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Enjoy smoking****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		32		32	
	Missing, n(%)	16 (22.5)		9 (22.0)		6 (15.8)	
	Mean (SD)	2.78 (1.084)		2.72 (1.055)		2.72 (1.055)	
	95% CI	2.48, 3.08		2.33, 3.10		2.33, 3.10	
	Median	3.00		2.00		3.00	
	Q25, Q75	2.00, 4.00		2.00, 4.00		2.00, 3.50	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Enjoy smoking****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	0	32	0		
	Missing, n(%)	0		9 (22.0)			
	Mean (SD)	2.92 (1.025)		2.97 (0.823)			
	95% CI	2.67, 3.16		2.67, 3.27			
	Median	3.00		3.00			
	Q25, Q75	2.00, 4.00		3.00, 3.50			
	Min, Max	1.0, 5.0		1.0, 4.0			

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Enjoy smoking****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		32		31	
	Missing, n(%)	18 (25.7)		9 (22.0)		6 (16.2)	
	Mean (SD)	2.81 (1.086)		2.72 (1.055)		2.71 (1.071)	
	95% CI	2.50, 3.11		2.33, 3.10		2.31, 3.11	
	Median	3.00		2.00		3.00	
	Q25, Q75	2.00, 4.00		2.00, 4.00		2.00, 4.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Enjoy smoking****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	0	32	0		
	Missing, n(%)	1 (1.4)		9 (22.0)			
	Mean (SD)	2.96 (1.050)		3.13 (0.794)			
	95% CI	2.70, 3.21		2.83, 3.42			
	Median	3.00		3.00			
	Q25, Q75	2.00, 4.00		3.00, 4.00			
	Min, Max	1.0, 5.0		1.0, 4.0			

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

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	57		33		33	
	Missing, n(%)	19 (25.0)		9 (21.4)		6 (15.4)	
	Mean (SD)	3.00 (1.225)		2.76 (1.091)		3.12 (1.167)	
	95% CI	2.67, 3.33		2.37, 3.15		2.70, 3.54	
	Median	3.00		3.00		3.00	
	Q25, Q75	2.00, 4.00		2.00, 4.00		2.00, 4.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	0	32	0		
	Missing, n(%)	0		10 (23.8)			
	Mean (SD)	3.41 (1.074)		2.88 (1.185)			
	95% CI	3.16, 3.66		2.44, 3.31			
	Median	3.00		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; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	56		32		33	
	Missing, n(%)	18 (24.3)		9 (22.0)		6 (15.4)	
	Mean (SD)	3.00 (1.236)		2.75 (1.108)		3.12 (1.167)	
	95% CI	2.66, 3.34		2.35, 3.15		2.70, 3.54	
	Median	3.00		3.00		3.00	
	Q25, Q75	2.00, 4.00		2.00, 4.00		2.00, 4.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	0	32	0		
	Missing, n(%)	0		9 (22.0)			
	Mean (SD)	3.09 (0.996)		3.00 (0.951)			
	95% CI	2.86, 3.33		2.65, 3.35			
	Median	3.00		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; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		32		32	
	Missing, n(%)	16 (22.5)		9 (22.0)		6 (15.8)	
	Mean (SD)	2.96 (1.217)		2.75 (1.108)		3.06 (1.135)	
	95% CI	2.63, 3.30		2.35, 3.15		2.65, 3.48	
	Median	3.00		3.00		3.00	
	Q25, Q75	2.00, 4.00		2.00, 4.00		2.00, 4.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	0	32	0		
	Missing, n(%)	0		9 (22.0)			
	Mean (SD)	2.96 (1.007)		2.75 (0.763)			
	95% CI	2.71, 3.20		2.47, 3.03			
	Median	3.00		3.00			
	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; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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 HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		32		31	
	Missing, n(%)	18 (25.7)		9 (22.0)		6 (16.2)	
	Mean (SD)	2.98 (1.245)		2.75 (1.108)		3.06 (1.153)	
	95% CI	2.63, 3.33		2.35, 3.15		2.64, 3.49	
	Median	3.00		3.00		3.00	
	Q25, Q75	2.00, 4.00		2.00, 4.00		2.00, 4.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	0	32	0		
	Missing, n(%)	1 (1.4)		9 (22.0)			
	Mean (SD)	2.94 (1.056)		2.88 (0.833)			
	95% CI	2.68, 3.20		2.57, 3.18			
	Median	3.00		3.00			
	Q25, Q75	2.00, 4.00		2.50, 3.00			
	Min, Max	1.0, 5.0		1.0, 5.0			

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

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	57		33		33	
	Missing, n(%)	19 (25.0)		9 (21.4)		6 (15.4)	
	Mean (SD)	3.75 (1.074)		3.73 (1.009)		3.67 (0.958)	
	95% CI	3.46, 4.04		3.36, 4.09		3.32, 4.01	
	Median	4.00		4.00		4.00	
	Q25, Q75	3.00, 5.00		3.00, 4.00		3.00, 4.00	
	Min, Max	2.0, 5.0		1.0, 5.0		2.0, 5.0	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	0	32	0		
	Missing, n(%)	0		10 (23.8)			
	Mean (SD)	3.46 (1.077)		3.78 (0.871)			
	95% CI	3.21, 3.71		3.46, 4.10			
	Median	4.00		4.00			
	Q25, Q75	3.00, 4.00		3.00, 4.00			
	Min, Max	1.0, 5.0		2.0, 5.0			

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

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	56		32		33	
	Missing, n(%)	18 (24.3)		9 (22.0)		6 (15.4)	
	Mean (SD)	3.75 (1.083)		3.69 (0.998)		3.67 (0.958)	
	95% CI	3.45, 4.05		3.32, 4.05		3.32, 4.01	
	Median	4.00		4.00		4.00	
	Q25, Q75	3.00, 5.00		3.00, 4.00		3.00, 4.00	
	Min, Max	2.0, 5.0		1.0, 5.0		2.0, 5.0	

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

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	0	32	0		
	Missing, n(%)	0		9 (22.0)			
	Mean (SD)	3.41 (0.950)		3.56 (0.841)			
	95% CI	3.18, 3.63		3.25, 3.87			
	Median	3.50		4.00			
	Q25, Q75	3.00, 4.00		3.00, 4.00			
	Min, Max	1.0, 5.0		2.0, 5.0			

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

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		32		32	
	Missing, n(%)	16 (22.5)		9 (22.0)		6 (15.8)	
	Mean (SD)	3.75 (1.076)		3.69 (0.998)		3.63 (0.942)	
	95% CI	3.45, 4.04		3.32, 4.05		3.28, 3.97	
	Median	4.00		4.00		4.00	
	Q25, Q75	3.00, 5.00		3.00, 4.00		3.00, 4.00	
	Min, Max	2.0, 5.0		1.0, 5.0		2.0, 5.0	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	0	32	0		
	Missing, n(%)	0		9 (22.0)			
	Mean (SD)	3.68 (0.859)		3.72 (0.635)			
	95% CI	3.47, 3.88		3.49, 3.95			
	Median	4.00		4.00			
	Q25, Q75	3.00, 4.00		3.00, 4.00			
	Min, Max	1.0, 5.0		3.0, 5.0			

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

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		32		31	
	Missing, n(%)	18 (25.7)		9 (22.0)		6 (16.2)	
	Mean (SD)	3.73 (1.105)		3.69 (0.998)		3.65 (0.951)	
	95% CI	3.42, 4.04		3.32, 4.05		3.29, 4.00	
	Median	4.00		4.00		4.00	
	Q25, Q75	3.00, 5.00		3.00, 4.00		3.00, 4.00	
	Min, Max	2.0, 5.0		1.0, 5.0		2.0, 5.0	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	0	32	0		
	Missing, n(%)	1 (1.4)		9 (22.0)			
	Mean (SD)	3.65 (0.953)		3.72 (0.635)			
	95% CI	3.42, 3.89		3.49, 3.95			
	Median	4.00		4.00			
	Q25, Q75	3.00, 4.00		3.00, 4.00			
	Min, Max	1.0, 5.0		3.0, 5.0			

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

Appendix: 15.3.7.2

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking disturbed****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	57		33		33	
	Missing, n(%)	19 (25.0)		9 (21.4)		6 (15.4)	
	Mean (SD)	3.21 (1.014)		3.18 (1.103)		3.48 (0.940)	
	95% CI	2.94, 3.48		2.79, 3.58		3.15, 3.82	
	Median	3.00		3.00		3.00	
	Q25, Q75	3.00, 4.00		2.00, 4.00		3.00, 4.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking disturbed****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	76	0	32	0		
	Missing, n(%)	0		10 (23.8)			
	Mean (SD)	3.61 (0.981)		3.19 (1.030)			
	95% CI	3.38, 3.83		2.81, 3.56			
	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; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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 HST Questionnaire Data - PP Set****Parameter: Smoking disturbed****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	56		32		33	
	Missing, n(%)	18 (24.3)		9 (22.0)		6 (15.4)	
	Mean (SD)	3.21 (1.022)		3.19 (1.120)		3.48 (0.940)	
	95% CI	2.94, 3.49		2.78, 3.60		3.15, 3.82	
	Median	3.00		3.00		3.00	
	Q25, Q75	2.50, 4.00		2.00, 4.00		3.00, 4.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

Appendix: 15.3.7.2

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking disturbed****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	74	0	32	0		
	Missing, n(%)	0		9 (22.0)			
	Mean (SD)	3.26 (1.074)		2.94 (0.801)			
	95% CI	3.00, 3.51		2.64, 3.23			
	Median	3.00		3.00			
	Q25, Q75	2.00, 4.00		2.00, 3.00			
	Min, Max	1.0, 5.0		2.0, 5.0			

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking disturbed****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		32		32	
	Missing, n(%)	16 (22.5)		9 (22.0)		6 (15.8)	
	Mean (SD)	3.16 (0.996)		3.19 (1.120)		3.44 (0.914)	
	95% CI	2.89, 3.44		2.78, 3.60		3.10, 3.77	
	Median	3.00		3.00		3.00	
	Q25, Q75	2.00, 4.00		2.00, 4.00		3.00, 4.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking disturbed****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	71	0	32	0		
	Missing, n(%)	0		9 (22.0)			
	Mean (SD)	3.15 (1.051)		3.00 (0.673)			
	95% CI	2.90, 3.41		2.75, 3.25			
	Median	3.00		3.00			
	Q25, Q75	3.00, 4.00		3.00, 3.00			
	Min, Max	1.0, 5.0		2.0, 5.0			

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

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking disturbed****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		32		31	
	Missing, n(%)	18 (25.7)		9 (22.0)		6 (16.2)	
	Mean (SD)	3.17 (1.005)		3.19 (1.120)		3.45 (0.926)	
	95% CI	2.89, 3.46		2.78, 3.60		3.11, 3.80	
	Median	3.00		3.00		3.00	
	Q25, Q75	2.50, 4.00		2.00, 4.00		3.00, 4.00	
	Min, Max	1.0, 5.0		1.0, 5.0		1.0, 5.0	

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

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**Table 15.2.4.41 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking disturbed****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	69	0	32	0		
	Missing, n(%)	1 (1.4)		9 (22.0)			
	Mean (SD)	3.19 (0.975)		2.88 (0.833)			
	95% CI	2.95, 3.43		2.57, 3.18			
	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; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in 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 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	18.30 (6.222)		16.67 (5.120)		17.51 (6.649)	
	95% CI	16.56, 20.04		14.72, 18.63		15.07, 19.96	
	Median	17.77		15.08		15.88	
	Q25, Q75	13.60, 21.92		13.56, 20.10		12.83, 23.00	
	Min, Max	8.4, 33.8		9.5, 27.5		8.1, 32.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	18.69 (6.452)	9.83 (33.288)	16.86 (6.103)	0.10 (14.323)		
	95% CI	17.17, 20.21	0.36, 19.29	14.54, 19.19	-5.46, 5.66		
	Median	17.33	3.12	15.50	-3.20		
	Q25, Q75	15.11, 19.94	-12.46, 32.33	12.88, 19.63	-8.12, 7.56		
	Min, Max	11.5, 50.0	-45.0, 94.8	8.9, 33.5	-18.8, 42.6		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	18.09 (5.204)	6.03 (34.740)	16.33 (5.671)	0.71 (13.446)		
	95% CI	16.87, 19.31	-3.96, 16.01	14.03, 18.62	-4.84, 6.27		
	Median	16.88	0.33	15.43	2.75		
	Q25, Q75	14.85, 20.55	-13.44, 25.54	11.57, 18.29	-6.76, 10.66		
	Min, Max	3.0, 35.2	-84.3, 101.8	10.0, 30.0	-30.7, 27.7		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	18.30 (6.222)		16.55 (5.171)		17.51 (6.649)	
	95% CI	16.56, 20.04		14.54, 18.56		15.07, 19.96	
	Median	17.77		14.83		15.88	
	Q25, Q75	13.60, 21.92		13.11, 19.85		12.83, 23.00	
	Min, Max	8.4, 33.8		9.5, 27.5		8.1, 32.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	16.75 (4.983)	-2.93 (33.601)	14.65 (4.415)	-9.75 (13.705)		
	95% CI	15.56, 17.93	-12.39, 6.52	12.93, 16.36	-15.29, -4.21		
	Median	16.00	-8.54	13.50	-8.77		
	Q25, Q75	14.00, 18.67	-25.61, 8.42	11.67, 16.17	-14.19, -6.07		
	Min, Max	6.0, 35.0	-59.4, 118.2	9.3, 25.0	-44.1, 33.3		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	18.08 (6.074)		16.55 (5.171)		17.72 (6.655)	
	95% CI	16.36, 19.79		14.54, 18.56		15.23, 20.21	
	Median	17.62		14.83		16.10	
	Q25, Q75	13.20, 21.90		13.11, 19.85		13.00, 23.00	
	Min, Max	8.4, 33.8		9.5, 27.5		8.1, 32.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	18.58 (6.682)	10.19 (36.575)	13.93 (4.998)	-12.94 (16.626)		
	95% CI	16.89, 20.26	-0.56, 20.93	11.90, 15.95	-19.97, -5.92		
	Median	17.50	9.85	12.25	-14.26		
	Q25, Q75	15.00, 21.40	-15.81, 31.12	10.33, 15.50	-27.07, -2.99		
	Min, Max	4.0, 47.0	-72.3, 97.3	7.3, 25.0	-41.2, 23.8		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	17.73 (6.060)		16.55 (5.171)		18.00 (6.590)	
	95% CI	15.97, 19.50		14.54, 18.56		15.49, 20.52	
	Median	16.80		14.83		16.33	
	Q25, Q75	13.10, 21.00		13.11, 19.85		13.00, 23.00	
	Min, Max	8.4, 33.8		9.5, 27.5		8.1, 32.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	18.80 (7.505)	9.96 (33.275)	14.89 (4.347)	-9.23 (15.269)		
	95% CI	16.91, 20.70	-0.29, 20.21	13.20, 16.58	-15.54, -2.93		
	Median	18.00	7.17	14.29	-10.53		
	Q25, Q75	14.50, 20.40	-16.22, 32.60	11.17, 17.42	-19.90, 2.73		
	Min, Max	7.0, 50.0	-42.4, 100.6	9.7, 28.8	-35.3, 27.3		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	907.59 (438.578)		829.78 (291.062)		991.64 (587.788)	
	95% CI	785.49, 1029.70		719.06, 940.49		776.03, 1207.24	
	Median	733.02		775.25		830.62	
	Q25, Q75	601.83, 1122.39		616.84, 1085.60		559.33, 1306.85	
	Min, Max	355.8, 2362.9		399.2, 1371.2		363.8, 3051.8	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	695.10 (272.688)	-7.70 (41.695)	816.49 (326.643)	-1.74 (17.584)		
	95% CI	631.02, 759.19	-19.56, 4.15	692.24, 940.74	-8.57, 5.08		
	Median	701.10	-14.94	749.11	-6.39		
	Q25, Q75	509.42, 914.12	-42.78, 22.68	578.60, 1072.61	-13.86, 5.36		
	Min, Max	100.3, 1336.1	-81.0, 105.2	350.0, 1507.0	-18.1, 64.6		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	758.35 (377.237)	-0.13 (44.683)	779.68 (342.638)	-2.80 (14.808)		
	95% CI	670.33, 846.37	-12.97, 12.71	641.28, 918.08	-8.92, 3.32		
	Median	722.12	-3.22	631.79	-4.70		
	Q25, Q75	586.30, 865.31	-25.84, 28.22	512.70, 1042.14	-12.61, 7.04		
	Min, Max	16.9, 3005.3	-98.5, 104.3	386.5, 1725.0	-34.7, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	907.59 (438.578)		817.77 (288.996)		991.64 (587.788)	
	95% CI	785.49, 1029.70		705.70, 929.83		776.03, 1207.24	
	Median	733.02		761.35		830.62	
	Q25, Q75	601.83, 1122.39		603.96, 1082.80		559.33, 1306.85	
	Min, Max	355.8, 2362.9		399.2, 1371.2		363.8, 3051.8	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	685.16 (360.732)	-14.18 (39.811)	726.50 (333.799)	-10.22 (17.619)		
	95% CI	599.77, 770.55	-25.39, -2.98	597.06, 855.94	-17.34, -3.09		
	Median	616.95	-20.70	641.59	-9.23		
	Q25, Q75	527.13, 768.17	-48.09, 15.43	488.31, 865.31	-18.93, -2.59		
	Min, Max	209.5, 2968.1	-72.7, 103.4	323.6, 1951.7	-48.4, 42.3		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	886.36 (415.070)		817.77 (288.996)		1005.93 (592.331)	
	95% CI	769.62, 1003.11		705.70, 929.83		784.74, 1227.11	
	Median	720.77		761.35		834.09	
	Q25, Q75	601.72, 1122.02		603.96, 1082.80		559.33, 1306.85	
	Min, Max	355.8, 2362.9		399.2, 1371.2		363.8, 3051.8	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	791.58 (427.867)	-1.35 (50.374)	642.38 (261.774)	-17.49 (17.521)		
	95% CI	683.82, 899.34	-16.15, 13.44	536.64, 748.12	-24.89, -10.09		
	Median	713.98	-17.76	580.42	-14.57		
	Q25, Q75	517.43, 925.74	-38.26, 29.49	431.73, 817.93	-25.83, -8.09		
	Min, Max	122.7, 2731.1	-78.1, 104.3	331.4, 1280.5	-59.1, 18.6		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	869.14 (408.413)		817.77 (288.996)		1023.99 (594.349)	
	95% CI	750.54, 987.73		705.70, 929.83		797.91, 1250.07	
	Median	714.39		761.35		837.55	
	Q25, Q75	601.57, 1089.59		603.96, 1082.80		567.70, 1306.85	
	Min, Max	355.8, 2362.9		399.2, 1371.2		363.8, 3051.8	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	735.32 (358.168)	-6.02 (39.393)	794.54 (482.984)	-7.55 (17.466)		
	95% CI	645.11, 825.53	-18.14, 6.11	607.25, 981.82	-14.76, -0.34		
	Median	675.16	-16.97	691.11	-4.12		
	Q25, Q75	500.49, 920.71	-38.09, 18.18	495.87, 876.43	-20.22, 2.97		
	Min, Max	122.8, 2431.5	-58.9, 93.1	389.6, 2748.6	-49.6, 25.9		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	52.03 (23.250)		51.27 (16.300)		55.83 (19.611)	
	95% CI	45.56, 58.51		45.06, 57.47		48.63, 63.03	
	Median	44.82		45.86		51.74	
	Q25, Q75	37.13, 63.81		42.85, 58.19		42.72, 66.18	
	Min, Max	18.2, 124.4		29.4, 102.1		27.4, 117.9	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	39.79 (18.563)	-16.00 (28.067)	49.91 (15.927)	-2.24 (8.101)		
	95% CI	35.42, 44.16	-23.98, -8.02	43.84, 55.97	-5.39, 0.90		
	Median	35.65	-16.19	48.20	-3.29		
	Q25, Q75	27.37, 51.62	-30.66, -8.85	38.20, 57.65	-7.64, 1.91		
	Min, Max	7.8, 93.4	-74.9, 57.1	26.1, 97.9	-14.8, 15.3		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	44.17 (22.864)	-6.35 (32.396)	49.02 (17.527)	-3.54 (9.267)		
	95% CI	38.83, 49.51	-15.66, 2.96	41.93, 56.10	-7.37, 0.29		
	Median	40.66	-8.59	44.29	-2.87		
	Q25, Q75	32.21, 51.04	-21.78, 14.63	35.72, 59.93	-9.18, 2.16		
	Min, Max	5.6, 152.1	-90.4, 88.3	26.0, 92.6	-28.4, 17.6		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	52.03 (23.250)		51.02 (16.546)		55.83 (19.611)	
	95% CI	45.56, 58.51		44.60, 57.45		48.63, 63.03	
	Median	44.82		45.77		51.74	
	Q25, Q75	37.13, 63.81		41.07, 58.35		42.72, 66.18	
	Min, Max	18.2, 124.4		29.4, 102.1		27.4, 117.9	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	43.31 (21.615)	-10.91 (30.801)	50.29 (18.346)	-0.58 (16.283)		
	95% CI	38.19, 48.43	-19.58, -2.24	43.17, 57.41	-7.16, 6.00		
	Median	38.82	-13.11	44.46	-3.05		
	Q25, Q75	31.88, 50.57	-31.50, 9.69	37.58, 57.70	-9.50, 4.78		
	Min, Max	9.8, 154.1	-61.5, 91.2	27.6, 92.8	-27.9, 51.5		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	51.76 (23.396)		51.02 (16.546)		56.01 (19.922)	
	95% CI	45.17, 58.34		44.60, 57.45		48.56, 63.45	
	Median	44.66		45.77		53.95	
	Q25, Q75	37.06, 61.54		41.07, 58.35		42.72, 66.18	
	Min, Max	18.2, 124.4		29.4, 102.1		27.4, 117.9	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	44.46 (23.085)	-11.91 (29.676)	47.50 (17.344)	-6.22 (12.403)		
	95% CI	38.64, 50.28	-20.62, -3.19	40.49, 54.51	-11.46, -0.97		
	Median	38.13	-20.60	42.31	-4.33		
	Q25, Q75	30.68, 48.95	-30.86, 7.56	36.78, 51.22	-14.33, 1.67		
	Min, Max	15.8, 156.5	-62.9, 63.5	27.3, 93.2	-34.0, 13.8		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	51.90 (23.625)		51.02 (16.546)		56.19 (20.247)	
	95% CI	45.04, 58.77		44.60, 57.45		48.49, 63.90	
	Median	44.26		45.77		56.15	
	Q25, Q75	37.13, 60.54		41.07, 58.35		42.72, 66.18	
	Min, Max	18.2, 124.4		29.4, 102.1		27.4, 117.9	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	42.18 (21.998)	-13.31 (29.342)	52.90 (23.330)	1.88 (17.626)		
	95% CI	36.64, 47.73	-22.34, -4.27	43.85, 61.95	-5.40, 9.16		
	Median	38.68	-17.73	45.00	-0.81		
	Q25, Q75	28.28, 49.34	-32.48, 2.71	37.52, 57.85	-5.22, 6.81		
	Min, Max	9.6, 128.0	-66.9, 72.9	29.4, 137.4	-25.9, 56.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	1.68 (0.686)		1.67 (0.456)		1.70 (0.521)	
	95% CI	1.48, 1.87		1.49, 1.85		1.50, 1.90	
	Median	1.46		1.63		1.73	
	Q25, Q75	1.19, 2.07		1.43, 1.86		1.30, 1.95	
	Min, Max	0.8, 3.6		0.8, 2.7		0.8, 3.4	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	1.81 (0.794)	13.85 (29.807)	1.70 (0.441)	2.41 (8.857)		
	95% CI	1.61, 2.00	5.37, 22.32	1.53, 1.87	-1.03, 5.85		
	Median	1.58	11.13	1.61	2.12		
	Q25, Q75	1.32, 2.24	-5.12, 25.91	1.45, 1.81	-4.85, 5.85		
	Min, Max	0.6, 4.7	-33.4, 120.9	0.8, 2.7	-9.4, 26.8		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	1.82 (0.785)	17.40 (24.376)	1.68 (0.499)	0.44 (12.130)		
	95% CI	1.64, 2.01	10.39, 24.41	1.47, 1.88	-4.57, 5.45		
	Median	1.71	14.83	1.52	0.76		
	Q25, Q75	1.31, 2.18	1.36, 35.05	1.44, 2.05	-7.27, 9.25		
	Min, Max	0.5, 4.1	-34.7, 68.2	0.9, 2.8	-32.1, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	1.68 (0.686)		1.66 (0.462)		1.70 (0.521)	
	95% CI	1.48, 1.87		1.48, 1.85		1.50, 1.90	
	Median	1.46		1.61		1.73	
	Q25, Q75	1.19, 2.07		1.37, 1.79		1.30, 1.95	
	Min, Max	0.8, 3.6		0.8, 2.7		0.8, 3.4	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	1.76 (0.826)	11.78 (30.469)	1.67 (0.532)	0.15 (14.379)		
	95% CI	1.56, 1.96	3.20, 20.35	1.46, 1.88	-5.67, 5.96		
	Median	1.55	5.50	1.52	0.82		
	Q25, Q75	1.17, 2.31	-6.55, 25.01	1.33, 2.00	-7.74, 10.05		
	Min, Max	0.6, 5.2	-37.8, 112.1	0.9, 3.2	-30.4, 35.8		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	1.67 (0.692)		1.66 (0.462)		1.70 (0.529)	
	95% CI	1.47, 1.87		1.48, 1.85		1.49, 1.90	
	Median	1.44		1.61		1.72	
	Q25, Q75	1.17, 2.18		1.37, 1.79		1.30, 1.95	
	Min, Max	0.8, 3.6		0.8, 2.7		0.8, 3.4	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	1.91 (0.839)	16.65 (30.627)	1.59 (0.444)	-4.23 (10.443)		
	95% CI	1.69, 2.13	7.65, 25.64	1.40, 1.77	-8.64, 0.19		
	Median	1.79	21.51	1.50	-3.11		
	Q25, Q75	1.25, 2.48	-8.95, 34.14	1.30, 1.80	-9.92, 2.41		
	Min, Max	0.6, 4.4	-44.6, 100.6	0.9, 2.6	-24.7, 19.2		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	1.70 (0.696)		1.66 (0.462)		1.70 (0.538)	
	95% CI	1.49, 1.91		1.48, 1.85		1.49, 1.91	
	Median	1.46		1.61		1.73	
	Q25, Q75	1.24, 2.18		1.37, 1.79		1.30, 1.95	
	Min, Max	0.8, 3.6		0.8, 2.7		0.8, 3.4	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	1.80 (0.904)	18.62 (37.019)	1.69 (0.574)	1.44 (12.796)		
	95% CI	1.57, 2.04	7.22, 30.01	1.46, 1.92	-3.84, 6.73		
	Median	1.58	12.31	1.58	2.25		
	Q25, Q75	1.12, 2.22	-4.76, 39.37	1.35, 1.89	-5.24, 6.71		
	Min, Max	0.5, 4.6	-40.7, 162.1	0.8, 3.3	-27.3, 39.7		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	28.90 (12.269)		26.97 (8.949)		29.32 (12.979)	
	95% CI	25.48, 32.32		23.56, 30.38		24.55, 34.09	
	Median	26.88		24.77		28.70	
	Q25, Q75	19.05, 33.84		21.79, 30.86		19.21, 40.63	
	Min, Max	13.5, 74.9		10.6, 52.4		11.3, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	31.87 (12.873)	24.88 (47.878)	28.08 (11.465)	3.46 (21.585)		
	95% CI	28.84, 34.90	11.27, 38.49	23.71, 32.44	-4.92, 11.83		
	Median	29.95	14.18	26.04	-4.55		
	Q25, Q75	22.08, 40.08	-8.45, 54.29	21.19, 30.49	-10.47, 10.87		
	Min, Max	10.5, 66.5	-58.6, 137.8	11.9, 57.7	-24.5, 81.2		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	31.79 (13.316)	23.15 (45.197)	26.70 (11.529)	1.51 (19.105)		
	95% CI	28.68, 34.90	10.16, 36.14	22.04, 31.36	-6.38, 9.40		
	Median	30.77	20.12	24.35	-0.87		
	Q25, Q75	21.40, 39.40	-9.43, 46.11	19.24, 28.30	-10.96, 9.32		
	Min, Max	4.2, 65.2	-81.1, 139.8	13.9, 60.5	-36.8, 40.6		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	28.90 (12.269)		26.56 (8.830)		29.32 (12.979)	
	95% CI	25.48, 32.32		23.13, 29.99		24.55, 34.09	
	Median	26.88		24.30		28.70	
	Q25, Q75	19.05, 33.84		21.70, 30.54		19.21, 40.63	
	Min, Max	13.5, 74.9		10.6, 52.4		11.3, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	27.73 (11.831)	5.62 (38.403)	24.39 (11.502)	-9.23 (17.407)		
	95% CI	24.92, 30.53	-5.19, 16.42	19.93, 28.85	-16.27, -2.19		
	Median	24.11	-3.53	21.58	-8.88		
	Q25, Q75	18.94, 35.73	-23.32, 24.66	18.32, 27.00	-14.41, 1.46		
	Min, Max	10.6, 68.6	-47.4, 107.3	10.9, 68.8	-56.7, 31.3		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	28.34 (11.708)		26.56 (8.830)		29.62 (13.089)	
	95% CI	25.04, 31.64		23.13, 29.99		24.73, 34.51	
	Median	26.83		24.30		29.08	
	Q25, Q75	19.05, 33.32		21.70, 30.54		19.21, 40.63	
	Min, Max	13.5, 74.9		10.6, 52.4		11.3, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	34.41 (18.154)	28.30 (55.014)	21.49 (7.719)	-15.44 (18.819)		
	95% CI	29.83, 38.98	12.14, 44.46	18.37, 24.62	-23.39, -7.49		
	Median	31.60	21.65	21.25	-20.22		
	Q25, Q75	21.41, 41.38	-2.57, 56.73	17.63, 23.54	-25.77, -5.36		
	Min, Max	5.4, 101.0	-65.4, 215.4	10.0, 48.5	-45.7, 28.8		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	28.38 (11.929)		26.56 (8.830)		30.12 (13.031)	
	95% CI	24.91, 31.85		23.13, 29.99		25.16, 35.08	
	Median	26.60		24.30		29.46	
	Q25, Q75	19.05, 33.29		21.70, 30.54		21.70, 40.63	
	Min, Max	13.5, 74.9		10.6, 52.4		11.3, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	32.91 (18.475)	33.04 (76.756)	24.86 (10.264)	-7.54 (18.191)		
	95% CI	28.26, 37.57	9.41, 56.66	20.87, 28.84	-15.05, -0.03		
	Median	28.99	23.76	24.33	-10.36		
	Q25, Q75	19.79, 40.43	-8.98, 50.71	19.11, 27.32	-20.13, -0.04		
	Min, Max	4.6, 87.4	-41.5, 411.3	8.5, 60.5	-45.4, 34.2		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	33.48 (9.649)		32.97 (8.462)		36.21 (12.299)	
	95% CI	30.79, 36.17		29.75, 36.20		31.69, 40.73	
	Median	32.21		31.25		34.73	
	Q25, Q75	27.98, 37.91		28.30, 36.70		30.03, 40.75	
	Min, Max	16.7, 63.4		18.4, 54.9		15.0, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	23.99 (7.661)	-25.26 (17.982)	31.47 (7.765)	-4.31 (6.771)		
	95% CI	22.19, 25.80	-30.38, -20.15	28.52, 34.43	-6.94, -1.68		
	Median	24.10	-26.05	29.18	-4.12		
	Q25, Q75	18.99, 28.18	-32.95, -16.31	26.30, 37.08	-9.91, -0.42		
	Min, Max	6.6, 44.5	-76.3, 29.6	16.0, 49.1	-18.2, 9.2		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	26.18 (9.756)	-20.50 (21.375)	31.35 (7.995)	-3.61 (7.343)		
	95% CI	23.90, 28.46	-26.65, -14.36	28.12, 34.59	-6.64, -0.57		
	Median	24.27	-22.53	29.86	-3.36		
	Q25, Q75	21.31, 31.06	-31.52, -8.27	25.16, 37.88	-10.12, 2.56		
	Min, Max	4.1, 74.1	-92.1, 30.9	18.2, 46.2	-15.8, 8.8		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	33.48 (9.649)		33.04 (8.611)		36.21 (12.299)	
	95% CI	30.79, 36.17		29.69, 36.38		31.69, 40.73	
	Median	32.21		31.08		34.73	
	Q25, Q75	27.98, 37.91		27.91, 36.74		30.03, 40.75	
	Min, Max	16.7, 63.4		18.4, 54.9		15.0, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	27.55 (12.092)	-18.61 (24.813)	32.18 (7.565)	-0.07 (10.678)		
	95% CI	24.68, 30.41	-25.59, -11.62	29.24, 35.12	-4.39, 4.25		
	Median	26.52	-19.58	33.34	0.06		
	Q25, Q75	19.65, 32.35	-40.49, 0.95	26.70, 36.82	-10.39, 6.91		
	Min, Max	7.6, 100.5	-66.5, 32.5	18.7, 48.9	-17.5, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	33.44 (9.741)		33.04 (8.611)		36.43 (12.444)	
	95% CI	30.69, 36.18		29.69, 36.38		31.78, 41.09	
	Median	32.15		31.08		34.85	
	Q25, Q75	27.97, 38.15		27.91, 36.74		30.05, 40.75	
	Min, Max	16.7, 63.4		18.4, 54.9		15.0, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	26.04 (11.345)	-22.54 (25.385)	32.16 (8.907)	-1.02 (12.433)		
	95% CI	23.18, 28.90	-30.00, -15.08	28.55, 35.76	-6.27, 4.24		
	Median	26.01	-22.03	31.35	-1.07		
	Q25, Q75	18.60, 31.10	-40.50, -11.89	27.08, 35.12	-6.54, 6.37		
	Min, Max	8.6, 89.2	-64.4, 67.8	17.4, 50.8	-32.5, 23.4		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	32.90 (9.688)		33.04 (8.611)		36.56 (12.645)	
	95% CI	30.08, 35.72		29.69, 36.38		31.75, 41.37	
	Median	31.91		31.08		34.96	
	Q25, Q75	27.54, 37.57		27.91, 36.74		30.05, 40.75	
	Min, Max	16.7, 63.4		18.4, 54.9		15.0, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	27.14 (14.159)	-23.85 (26.623)	33.69 (11.152)	1.20 (12.637)		
	95% CI	23.57, 30.72	-32.05, -15.65	29.36, 38.02	-4.02, 6.42		
	Median	25.76	-24.67	30.10	1.33		
	Q25, Q75	17.92, 33.80	-39.67, -4.74	27.21, 37.03	-4.58, 7.93		
	Min, Max	7.3, 89.5	-70.7, 53.9	21.2, 76.4	-21.5, 32.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	51.90 (15.301)		50.54 (13.273)		55.12 (19.221)	
	95% CI	47.63, 56.16		45.48, 55.59		48.06, 62.17	
	Median	48.75		48.45		52.22	
	Q25, Q75	40.23, 62.89		41.58, 60.04		41.92, 62.81	
	Min, Max	25.4, 95.3		23.8, 74.9		20.8, 102.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	36.49 (11.621)	-25.70 (18.707)	48.20 (12.945)	-5.03 (7.357)		
	95% CI	33.75, 39.23	-31.02, -20.37	43.27, 53.13	-7.88, -2.17		
	Median	36.42	-26.53	48.60	-5.96		
	Q25, Q75	27.49, 44.91	-34.49, -20.22	38.65, 59.04	-11.24, -0.58		
	Min, Max	11.2, 62.5	-72.5, 30.9	22.3, 69.7	-19.7, 10.9		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	39.22 (13.867)	-21.11 (22.028)	47.34 (13.071)	-6.07 (6.873)		
	95% CI	35.98, 42.46	-27.44, -14.78	42.06, 52.63	-8.91, -3.22		
	Median	36.76	-25.03	44.75	-7.97		
	Q25, Q75	31.90, 44.54	-33.94, -8.09	37.53, 57.13	-10.25, -2.24		
	Min, Max	12.5, 100.5	-80.2, 42.3	24.6, 72.2	-17.0, 9.0		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	51.90 (15.301)		50.59 (13.513)		55.12 (19.221)	
	95% CI	47.63, 56.16		45.34, 55.83		48.06, 62.17	
	Median	48.75		48.39		52.22	
	Q25, Q75	40.23, 62.89		41.34, 60.08		41.92, 62.81	
	Min, Max	25.4, 95.3		23.8, 74.9		20.8, 102.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	40.24 (15.366)	-21.51 (24.619)	49.32 (12.668)	-0.89 (9.970)		
	95% CI	36.60, 43.88	-28.44, -14.59	44.40, 54.23	-4.92, 3.14		
	Median	39.74	-23.49	49.32	1.83		
	Q25, Q75	28.48, 47.83	-42.82, -2.39	40.80, 59.88	-10.19, 6.24		
	Min, Max	9.7, 115.3	-66.6, 36.6	25.3, 69.4	-18.2, 21.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	51.96 (15.445)		50.59 (13.513)		55.59 (19.365)	
	95% CI	47.61, 56.31		45.34, 55.83		48.35, 62.83	
	Median	49.01		48.39		52.86	
	Q25, Q75	39.61, 63.09		41.34, 60.08		44.67, 62.81	
	Min, Max	25.4, 95.3		23.8, 74.9		20.8, 102.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	38.58 (15.478)	-24.90 (27.260)	49.29 (15.701)	-2.22 (11.606)		
	95% CI	34.67, 42.48	-32.91, -16.89	42.94, 55.63	-7.13, 2.68		
	Median	39.44	-25.63	48.29	-3.04		
	Q25, Q75	27.54, 47.21	-44.02, -15.14	40.45, 57.45	-9.63, 4.04		
	Min, Max	15.6, 112.3	-67.2, 71.4	24.5, 86.3	-27.5, 19.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	51.54 (15.636)		50.59 (13.513)		55.97 (19.597)	
	95% CI	46.99, 56.08		45.34, 55.83		48.51, 63.42	
	Median	48.75		48.39		53.49	
	Q25, Q75	39.38, 62.89		41.34, 60.08		44.67, 62.81	
	Min, Max	25.4, 95.3		23.8, 74.9		20.8, 102.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	39.68 (18.789)	-25.05 (28.391)	50.96 (16.786)	-0.12 (12.188)		
	95% CI	34.94, 44.41	-33.79, -16.31	44.45, 57.48	-5.15, 4.92		
	Median	36.90	-24.92	49.75	1.75		
	Q25, Q75	25.00, 51.19	-44.50, -8.50	38.59, 59.96	-9.68, 6.13		
	Min, Max	12.0, 112.0	-75.2, 59.5	25.8, 109.9	-19.4, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	206.37 (66.009)		206.91 (60.794)		207.49 (51.732)	
	95% CI	187.98, 224.75		183.78, 230.04		188.51, 226.47	
	Median	195.61		191.16		200.77	
	Q25, Q75	158.27, 236.33		160.15, 229.29		160.69, 251.18	
	Min, Max	96.8, 363.4		117.1, 342.7		94.8, 300.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	197.51 (59.329)	3.93 (35.237)	206.91 (54.806)	2.44 (13.251)		
	95% CI	183.57, 211.46	-6.09, 13.95	186.06, 227.76	-2.71, 7.58		
	Median	201.11	-1.93	204.43	1.09		
	Q25, Q75	145.58, 246.50	-20.41, 27.30	166.20, 229.91	-3.98, 11.74		
	Min, Max	90.2, 318.8	-51.3, 93.8	118.0, 334.4	-34.7, 28.0		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	183.89 (59.679)	-4.57 (35.718)	206.72 (71.112)	2.10 (21.351)		
	95% CI	169.96, 197.82	-14.83, 5.69	178.00, 235.45	-6.72, 10.91		
	Median	178.00	-2.90	201.06	1.01		
	Q25, Q75	145.37, 220.79	-28.33, 16.00	161.06, 226.86	-6.68, 13.54		
	Min, Max	27.1, 306.3	-92.4, 98.3	75.1, 381.1	-38.5, 72.2		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	206.37 (66.009)		207.55 (61.811)		207.49 (51.732)	
	95% CI	187.98, 224.75		183.58, 231.52		188.51, 226.47	
	Median	195.61		195.18		200.77	
	Q25, Q75	158.27, 236.33		159.91, 229.34		160.69, 251.18	
	Min, Max	96.8, 363.4		117.1, 342.7		94.8, 300.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	164.40 (70.103)	-22.70 (30.286)	181.24 (66.864)	-7.69 (22.332)		
	95% CI	147.80, 181.00	-31.22, -14.18	155.31, 207.17	-16.72, 1.33		
	Median	142.63	-23.38	172.77	-8.04		
	Q25, Q75	113.37, 214.33	-49.18, -3.79	132.21, 227.69	-16.94, 1.37		
	Min, Max	34.9, 320.5	-63.9, 55.6	69.3, 386.0	-56.6, 47.0		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	203.29 (62.781)		207.55 (61.811)		208.48 (52.319)	
	95% CI	185.62, 220.95		183.58, 231.52		188.94, 228.02	
	Median	195.60		195.18		204.48	
	Q25, Q75	157.99, 235.87		159.91, 229.34		160.69, 251.18	
	Min, Max	96.8, 357.8		117.1, 342.7		94.8, 300.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	169.72 (72.149)	-11.09 (36.996)	186.16 (68.114)	-5.76 (22.931)		
	95% CI	151.54, 187.89	-21.96, -0.22	158.64, 213.68	-15.44, 3.93		
	Median	149.73	-14.04	173.38	-7.75		
	Q25, Q75	111.30, 217.95	-34.78, 13.17	134.10, 224.72	-24.92, 7.04		
	Min, Max	14.5, 319.2	-93.7, 99.3	95.2, 357.8	-42.0, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	201.90 (62.453)		207.55 (61.811)		207.73 (53.082)	
	95% CI	183.76, 220.04		183.58, 231.52		187.54, 227.93	
	Median	194.01		195.18		200.77	
	Q25, Q75	155.89, 235.65		159.91, 229.34		160.69, 251.18	
	Min, Max	96.8, 357.8		117.1, 342.7		94.8, 300.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	172.51 (79.943)	-13.68 (37.479)	178.99 (62.871)	-8.95 (22.078)		
	95% CI	152.37, 192.65	-25.22, -2.14	154.60, 203.37	-18.07, 0.17		
	Median	145.69	-19.67	183.20	-8.60		
	Q25, Q75	112.21, 255.47	-40.62, 4.18	140.20, 213.73	-17.00, 6.26		
	Min, Max	34.7, 371.5	-63.0, 93.9	69.7, 367.4	-66.7, 39.0		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	12.45 (5.088)		13.22 (3.656)		14.13 (7.077)	
	95% CI	11.02, 13.87		11.82, 14.61		11.53, 16.73	
	Median	10.98		12.67		12.41	
	Q25, Q75	9.10, 14.80		10.76, 15.50		8.26, 18.94	
	Min, Max	5.8, 30.5		5.3, 22.2		4.6, 29.2	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	11.64 (5.121)	-4.81 (22.441)	13.60 (4.564)	4.58 (19.211)		
	95% CI	10.43, 12.84	-11.19, 1.57	11.86, 15.34	-2.87, 12.03		
	Median	10.18	-7.57	12.29	6.23		
	Q25, Q75	7.53, 15.65	-19.00, 7.84	10.10, 16.48	-3.76, 16.89		
	Min, Max	4.7, 25.8	-53.6, 45.5	4.5, 23.7	-43.0, 37.8		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	10.86 (4.616)	-10.67 (23.460)	13.63 (4.401)	3.20 (23.993)		
	95% CI	9.78, 11.94	-17.41, -3.93	11.85, 15.42	-6.71, 13.11		
	Median	9.44	-9.16	12.62	4.38		
	Q25, Q75	7.65, 12.60	-28.24, 0.38	11.79, 15.91	-12.10, 17.71		
	Min, Max	4.1, 24.2	-54.3, 41.2	2.8, 23.7	-46.1, 53.2		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	12.45 (5.088)		13.32 (3.679)		14.13 (7.077)	
	95% CI	11.02, 13.87		11.89, 14.75		11.53, 16.73	
	Median	10.98		13.11		12.41	
	Q25, Q75	9.10, 14.80		10.99, 15.60		8.26, 18.94	
	Min, Max	5.8, 30.5		5.3, 22.2		4.6, 29.2	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	10.08 (4.131)	-19.99 (24.182)	12.92 (3.917)	3.27 (26.147)		
	95% CI	9.10, 11.06	-26.80, -13.18	11.40, 14.45	-7.29, 13.84		
	Median	8.92	-22.62	12.79	5.43		
	Q25, Q75	7.25, 12.46	-39.54, -3.11	10.94, 15.91	-10.77, 14.90		
	Min, Max	3.7, 21.8	-67.3, 40.2	4.9, 19.9	-43.5, 55.2		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	12.44 (5.138)		13.32 (3.679)		14.06 (7.188)	
	95% CI	10.99, 13.89		11.89, 14.75		11.37, 16.75	
	Median	10.84		13.11		11.97	
	Q25, Q75	9.05, 15.22		10.99, 15.60		8.26, 18.94	
	Min, Max	5.8, 30.5		5.3, 22.2		4.6, 29.2	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	9.76 (4.731)	-19.47 (27.802)	14.84 (6.400)	14.67 (41.037)		
	95% CI	8.57, 10.96	-27.64, -11.30	12.25, 17.43	-2.67, 32.00		
	Median	8.29	-22.86	14.31	-2.18		
	Q25, Q75	6.54, 12.14	-37.90, -6.16	11.36, 17.31	-10.27, 34.59		
	Min, Max	3.6, 27.1	-77.1, 58.0	6.0, 38.4	-35.9, 151.0		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	12.62 (5.227)		13.32 (3.679)		13.70 (7.032)	
	95% CI	11.10, 14.14		11.89, 14.75		11.02, 16.38	
	Median	10.98		13.11		11.53	
	Q25, Q75	9.10, 15.22		10.99, 15.60		8.26, 18.05	
	Min, Max	5.8, 30.5		5.3, 22.2		4.6, 29.2	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	9.82 (5.022)	-19.94 (30.459)	12.65 (4.384)	0.67 (25.229)		
	95% CI	8.55, 11.09	-29.31, -10.56	10.94, 14.35	-9.75, 11.09		
	Median	8.66	-24.81	12.34	-2.07		
	Q25, Q75	6.58, 12.18	-42.07, 1.52	8.90, 15.88	-21.22, 18.96		
	Min, Max	3.7, 25.9	-69.2, 55.4	3.9, 20.5	-61.4, 44.3		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	235.26 (68.740)		233.88 (62.830)		236.81 (48.248)	
	95% CI	216.12, 254.40		209.98, 257.79		219.11, 254.51	
	Median	230.04		222.11		233.47	
	Q25, Q75	182.85, 271.44		188.49, 251.67		198.15, 275.55	
	Min, Max	121.9, 420.7		142.2, 378.6		124.8, 321.4	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	229.39 (59.355)	6.22 (34.330)	234.98 (58.535)	2.32 (11.426)		
	95% CI	215.43, 243.34	-3.54, 15.98	212.71, 257.25	-2.12, 6.75		
	Median	234.34	1.74	229.23	2.34		
	Q25, Q75	175.38, 273.58	-18.63, 26.04	191.98, 260.78	-4.29, 11.53		
	Min, Max	121.1, 353.0	-48.3, 96.6	142.6, 390.4	-27.6, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	215.68 (58.964)	-1.16 (35.204)	233.42 (72.845)	2.13 (18.280)		
	95% CI	201.92, 229.44	-11.28, 8.95	204.00, 262.85	-5.42, 9.68		
	Median	216.43	-0.99	223.39	-0.39		
	Q25, Q75	175.97, 257.85	-21.11, 14.33	184.81, 250.69	-5.57, 12.21		
	Min, Max	31.3, 328.4	-91.8, 105.5	135.6, 418.0	-26.8, 64.7		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	235.26 (68.740)		234.11 (63.971)		236.81 (48.248)	
	95% CI	216.12, 254.40		209.30, 258.92		219.11, 254.51	
	Median	230.04		221.90		233.47	
	Q25, Q75	182.85, 271.44		185.12, 252.12		198.15, 275.55	
	Min, Max	121.9, 420.7		142.2, 378.6		124.8, 321.4	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	192.13 (69.673)	-19.22 (28.919)	205.63 (70.080)	-7.98 (20.246)		
	95% CI	175.63, 208.63	-27.35, -11.08	178.45, 232.81	-16.16, 0.21		
	Median	172.27	-19.81	198.06	-9.09		
	Q25, Q75	138.78, 242.53	-44.56, -2.89	155.79, 246.61	-15.95, -0.62		
	Min, Max	66.2, 339.3	-56.8, 55.7	90.3, 419.1	-52.1, 39.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	231.63 (64.172)		234.11 (63.971)		238.10 (48.527)	
	95% CI	213.57, 249.68		209.30, 258.92		219.97, 256.22	
	Median	227.69		221.90		237.54	
	Q25, Q75	181.62, 267.39		185.12, 252.12		200.88, 275.55	
	Min, Max	121.9, 380.0		142.2, 378.6		124.8, 321.4	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	204.13 (73.239)	-5.91 (36.267)	207.65 (72.163)	-7.03 (20.482)		
	95% CI	185.68, 222.58	-16.56, 4.75	178.50, 236.81	-15.68, 1.62		
	Median	196.79	-8.04	196.32	-6.60		
	Q25, Q75	146.02, 253.73	-30.13, 22.30	151.18, 245.66	-23.74, 7.76		
	Min, Max	19.9, 340.6	-91.9, 93.9	115.5, 387.0	-41.5, 38.6		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	230.28 (63.849)		234.11 (63.971)		237.85 (49.366)	
	95% CI	211.74, 248.83		209.30, 258.92		219.07, 256.63	
	Median	226.38		221.90		233.47	
	Q25, Q75	180.79, 266.52		185.12, 252.12		200.88, 275.55	
	Min, Max	121.9, 380.0		142.2, 378.6		124.8, 321.4	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	205.42 (83.741)	-8.18 (35.671)	203.84 (63.740)	-8.44 (19.444)		
	95% CI	184.33, 226.52	-19.17, 2.80	179.12, 228.57	-16.48, -0.41		
	Median	180.79	-15.24	198.55	-9.84		
	Q25, Q75	146.29, 281.09	-35.38, 14.83	160.88, 236.14	-16.05, 2.50		
	Min, Max	39.3, 441.8	-55.3, 86.8	95.8, 396.2	-64.8, 33.2		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	2501.57 (1621.077)		2289.28 (1099.059)		2756.63 (1847.228)	
	95% CI	2050.26, 2952.89		1871.22, 2707.35		2079.06, 3434.20	
	Median	1988.32		2322.90		2065.46	
	Q25, Q75	1257.61, 3605.36		1352.21, 3040.38		1414.52, 3968.35	
	Min, Max	582.0, 7633.1		502.9, 5116.6		636.9, 8825.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	1918.89 (1083.252)	-3.33 (47.636)	2154.16 (1039.798)	-6.03 (14.201)		
	95% CI	1664.34, 2173.45	-16.87, 10.21	1758.64, 2549.68	-11.54, -0.52		
	Median	1892.98	-9.58	2311.58	-8.15		
	Q25, Q75	1034.61, 2529.50	-43.95, 29.88	1193.64, 2966.37	-14.75, 0.98		
	Min, Max	103.4, 5304.3	-83.9, 110.3	514.2, 4323.6	-28.2, 45.0		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	2047.39 (1080.919)	6.39 (52.529)	2022.27 (1106.124)	-8.32 (14.947)		
	95% CI	1795.19, 2299.59	-8.70, 21.48	1575.50, 2469.05	-14.49, -2.14		
	Median	1962.41	6.54	1888.62	-9.19		
	Q25, Q75	1311.04, 2575.85	-32.51, 35.34	1149.45, 2741.01	-16.74, -0.23		
	Min, Max	118.0, 7084.0	-97.7, 131.8	551.1, 4271.6	-37.9, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	2501.57 (1621.077)		2262.24 (1109.359)		2756.63 (1847.228)	
	95% CI	2050.26, 2952.89		1832.07, 2692.41		2079.06, 3434.20	
	Median	1988.32		2316.87		2065.46	
	Q25, Q75	1257.61, 3605.36		1282.46, 3002.03		1414.52, 3968.35	
	Min, Max	582.0, 7633.1		502.9, 5116.6		636.9, 8825.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	2313.01 (1361.868)	12.50 (57.819)	1969.82 (1011.236)	-9.66 (23.289)		
	95% CI	1990.65, 2635.36	-3.77, 28.76	1577.70, 2361.94	-19.07, -0.25		
	Median	2084.87	3.75	1932.69	-12.35		
	Q25, Q75	1538.13, 2739.82	-33.17, 50.70	1139.60, 2497.36	-24.92, 2.50		
	Min, Max	352.4, 9522.0	-81.5, 161.6	446.2, 4817.2	-47.6, 62.5		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	2444.94 (1584.406)		2262.24 (1109.359)		2799.99 (1862.694)	
	95% CI	1999.31, 2890.57		1832.07, 2692.41		2104.44, 3495.53	
	Median	1964.69		2316.87		2251.87	
	Q25, Q75	1205.25, 3544.54		1282.46, 3002.03		1414.52, 3968.35	
	Min, Max	582.0, 7633.1		502.9, 5116.6		636.9, 8825.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	2775.41 (1716.702)	32.44 (84.311)	1791.33 (1048.193)	-17.74 (19.535)		
	95% CI	2343.06, 3207.76	7.68, 57.20	1367.95, 2214.71	-26.00, -9.49		
	Median	2476.72	17.37	1618.27	-12.36		
	Q25, Q75	1731.30, 3358.06	-25.58, 67.95	934.31, 2541.69	-28.63, -3.71		
	Min, Max	407.4, 10737.4	-76.8, 281.0	439.9, 4646.5	-62.3, 9.4		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	2370.95 (1544.820)		2262.24 (1109.359)		2843.86 (1879.826)	
	95% CI	1922.37, 2819.52		1832.07, 2692.41		2128.80, 3558.91	
	Median	1933.77		2316.87		2438.27	
	Q25, Q75	1257.61, 3329.01		1282.46, 3002.03		1414.52, 3968.35	
	Min, Max	582.0, 7633.1		502.9, 5116.6		636.9, 8825.1	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	2705.55 (1392.114)	33.68 (68.522)	2010.53 (1127.483)	-8.81 (19.540)		
	95% CI	2354.95, 3056.16	12.59, 54.77	1573.33, 2447.72	-16.88, -0.74		
	Median	2585.27	11.24	1763.80	-7.18		
	Q25, Q75	1937.53, 3377.04	-23.36, 74.71	1135.71, 2565.24	-23.20, 4.56		
	Min, Max	446.3, 6864.6	-47.3, 222.2	578.6, 5547.3	-51.5, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	143.31 (85.661)		142.18 (72.331)		157.12 (75.773)	
	95% CI	119.45, 167.16		114.66, 169.70		129.32, 184.92	
	Median	117.85		130.14		146.00	
	Q25, Q75	80.05, 202.56		94.23, 169.37		108.88, 183.10	
	Min, Max	31.6, 366.4		37.2, 382.1		42.6, 330.9	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	114.17 (74.026)	-10.81 (38.310)	133.38 (64.975)	-5.77 (10.592)		
	95% CI	96.77, 131.57	-21.70, 0.08	108.66, 158.10	-9.88, -1.66		
	Median	107.63	-13.46	121.93	-7.96		
	Q25, Q75	55.48, 142.23	-36.43, 2.40	86.68, 168.56	-13.92, 1.48		
	Min, Max	8.2, 350.7	-78.2, 108.4	30.7, 323.9	-21.8, 20.7		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	122.28 (70.074)	1.93 (45.447)	128.65 (73.010)	-8.81 (12.751)		
	95% CI	105.93, 138.64	-11.13, 14.98	99.15, 158.14	-14.08, -3.54		
	Median	109.09	3.93	103.70	-10.92		
	Q25, Q75	78.17, 157.96	-23.84, 24.74	82.56, 155.91	-19.18, 2.71		
	Min, Max	9.4, 343.0	-85.4, 152.7	34.0, 355.4	-30.3, 19.8		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	143.31 (85.661)		141.80 (73.628)		157.12 (75.773)	
	95% CI	119.45, 167.16		113.24, 170.35		129.32, 184.92	
	Median	117.85		126.73		146.00	
	Q25, Q75	80.05, 202.56		94.21, 177.29		108.88, 183.10	
	Min, Max	31.6, 366.4		37.2, 382.1		42.6, 330.9	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	149.79 (91.026)	19.82 (60.294)	138.20 (69.898)	0.41 (23.384)		
	95% CI	128.24, 171.34	2.85, 36.78	111.09, 165.31	-9.04, 9.86		
	Median	126.84	8.75	127.10	0.87		
	Q25, Q75	89.11, 183.86	-27.03, 46.39	89.55, 174.08	-11.88, 11.06		
	Min, Max	15.5, 493.4	-62.4, 234.6	38.0, 336.7	-37.9, 75.9		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	142.62 (86.369)		141.80 (73.628)		157.97 (76.918)	
	95% CI	118.32, 166.92		113.24, 170.35		129.24, 186.69	
	Median	114.40		126.73		150.04	
	Q25, Q75	77.43, 211.44		94.21, 177.29		108.88, 183.10	
	Min, Max	31.6, 366.4		37.2, 382.1		42.6, 330.9	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	158.72 (96.895)	16.58 (58.528)	133.48 (80.778)	-6.26 (17.445)		
	95% CI	134.31, 183.13	-0.61, 33.77	100.85, 166.11	-13.63, 1.11		
	Median	141.75	0.79	115.54	-9.53		
	Q25, Q75	94.65, 200.03	-23.16, 37.44	72.55, 156.87	-16.87, 9.26		
	Min, Max	20.9, 615.2	-58.1, 206.9	37.3, 344.4	-37.8, 22.9		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	142.04 (87.207)		141.80 (73.628)		157.88 (78.279)	
	95% CI	116.71, 167.37		113.24, 170.35		128.10, 187.66	
	Median	113.93		126.73		146.00	
	Q25, Q75	80.05, 202.56		94.21, 177.29		108.88, 183.10	
	Min, Max	31.6, 366.4		37.2, 382.1		42.6, 330.9	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	159.06 (84.474)	22.80 (50.983)	136.07 (65.024)	1.40 (24.183)		
	95% CI	137.79, 180.34	7.11, 38.50	110.85, 161.29	-8.59, 11.39		
	Median	149.80	18.59	132.68	-1.12		
	Q25, Q75	86.88, 211.07	-17.50, 48.57	79.72, 168.53	-16.33, 17.64		
	Min, Max	12.4, 361.3	-51.1, 173.0	54.7, 277.4	-35.0, 63.4		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	223.15 (73.412)		227.51 (69.725)		239.88 (81.800)	
	95% CI	202.70, 243.59		200.98, 254.04		209.88, 269.89	
	Median	219.44		217.94		238.03	
	Q25, Q75	176.82, 259.48		178.62, 276.75		191.61, 288.93	
	Min, Max	91.8, 434.9		114.9, 404.7		98.1, 430.0	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	242.92 (93.068)	9.93 (26.130)	220.91 (68.333)	-3.19 (8.094)		
	95% CI	221.05, 264.79	2.50, 17.36	194.91, 246.91	-6.33, -0.04		
	Median	241.81	11.65	211.86	-3.84		
	Q25, Q75	174.95, 295.97	-2.37, 22.41	162.08, 266.69	-8.52, 1.31		
	Min, Max	84.0, 499.1	-48.2, 110.8	100.8, 354.8	-16.3, 16.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	248.00 (100.066)	9.89 (22.475)	216.46 (70.521)	-4.16 (8.415)		
	95% CI	224.65, 271.35	3.43, 16.35	187.97, 244.95	-7.63, -0.68		
	Median	234.16	11.43	197.49	-1.81		
	Q25, Q75	176.08, 279.80	-6.16, 21.99	165.13, 260.59	-9.95, 2.69		
	Min, Max	83.3, 536.2	-32.9, 84.2	116.1, 348.6	-23.3, 8.5		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	223.15 (73.412)		227.69 (70.998)		239.88 (81.800)	
	95% CI	202.70, 243.59		200.15, 255.22		209.88, 269.89	
	Median	219.44		217.16		238.03	
	Q25, Q75	176.82, 259.48		172.87, 282.24		191.61, 288.93	
	Min, Max	91.8, 434.9		114.9, 404.7		98.1, 430.0	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	303.63 (107.704)	38.47 (44.013)	226.80 (66.102)	1.08 (12.929)		
	95% CI	278.14, 329.13	26.09, 50.86	201.16, 252.44	-4.15, 6.30		
	Median	286.53	25.30	234.74	1.04		
	Q25, Q75	226.60, 381.77	5.29, 66.88	167.32, 274.58	-9.83, 9.66		
	Min, Max	112.1, 553.8	-37.2, 176.1	122.2, 352.4	-22.4, 30.9		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	222.73 (74.081)		227.69 (70.998)		240.01 (83.195)	
	95% CI	201.89, 243.57		200.15, 255.22		208.94, 271.08	
	Median	218.22		217.16		241.94	
	Q25, Q75	176.47, 261.40		172.87, 282.24		191.61, 288.93	
	Min, Max	91.8, 434.9		114.9, 404.7		98.1, 430.0	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	316.15 (118.215)	36.33 (40.827)	226.57 (71.037)	0.13 (12.330)		
	95% CI	286.38, 345.93	24.34, 48.32	197.87, 255.26	-5.08, 5.34		
	Median	307.40	22.15	233.66	0.32		
	Q25, Q75	227.71, 373.03	7.54, 65.50	166.60, 259.52	-8.65, 10.55		
	Min, Max	104.0, 640.3	-32.2, 125.4	115.2, 409.9	-25.1, 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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	220.48 (73.838)		227.69 (70.998)		238.18 (84.047)	
	95% CI	199.04, 241.93		200.15, 255.22		206.20, 270.15	
	Median	217.36		217.16		238.03	
	Q25, Q75	174.42, 259.48		172.87, 282.24		191.61, 287.42	
	Min, Max	91.8, 434.9		114.9, 404.7		98.1, 430.0	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	336.07 (124.999)	50.74 (49.795)	218.36 (68.330)	-0.70 (12.595)		
	95% CI	304.58, 367.55	35.41, 66.07	191.86, 244.86	-5.91, 4.50		
	Median	316.46	31.56	210.72	-1.99		
	Q25, Q75	255.02, 405.98	15.03, 86.04	166.49, 260.92	-6.23, 8.20		
	Min, Max	105.1, 704.2	-29.3, 195.9	125.3, 367.1	-21.4, 25.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	374.59 (128.237)		376.21 (118.590)		394.84 (150.671)	
	95% CI	338.89, 410.30		331.10, 421.33		339.57, 450.11	
	Median	364.83		365.82		385.26	
	Q25, Q75	270.19, 462.56		282.70, 462.23		312.02, 445.64	
	Min, Max	126.1, 690.7		164.4, 640.9		138.9, 822.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	390.26 (148.803)	7.26 (24.535)	364.01 (120.590)	-4.27 (8.784)		
	95% CI	355.29, 425.23	0.28, 14.23	318.13, 409.88	-7.68, -0.86		
	Median	398.91	5.26	353.68	-6.33		
	Q25, Q75	279.46, 491.69	-7.41, 23.39	258.44, 443.13	-11.06, 2.71		
	Min, Max	129.2, 756.8	-57.7, 96.5	147.5, 615.6	-15.6, 17.0		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	392.89 (158.082)	7.40 (23.058)	349.85 (121.924)	-7.18 (8.301)		
	95% CI	356.00, 429.77	0.77, 14.03	300.60, 399.10	-10.62, -3.75		
	Median	366.77	9.38	335.20	-6.65		
	Q25, Q75	278.29, 486.34	-8.45, 22.08	260.15, 428.74	-14.35, -0.59		
	Min, Max	126.4, 955.1	-43.3, 77.8	169.5, 626.7	-21.6, 5.4		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	374.59 (128.237)		376.04 (120.763)		394.84 (150.671)	
	95% CI	338.89, 410.30		329.21, 422.87		339.57, 450.11	
	Median	364.83		362.87		385.26	
	Q25, Q75	270.19, 462.56		278.46, 464.59		312.02, 445.64	
	Min, Max	126.1, 690.7		164.4, 640.9		138.9, 822.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	476.25 (180.021)	30.66 (41.001)	373.18 (118.268)	-0.26 (13.002)		
	95% CI	433.63, 518.86	19.12, 42.19	327.31, 419.04	-5.51, 5.00		
	Median	474.29	24.07	389.41	0.51		
	Q25, Q75	358.50, 556.67	4.95, 54.81	291.09, 468.31	-8.25, 11.33		
	Min, Max	133.0, 928.2	-65.8, 124.5	177.7, 617.5	-31.7, 23.0		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	374.87 (129.498)		376.04 (120.763)		396.51 (152.954)	
	95% CI	338.44, 411.30		329.21, 422.87		339.39, 453.63	
	Median	368.45		362.87		389.17	
	Q25, Q75	264.04, 462.59		278.46, 464.59		312.02, 445.64	
	Min, Max	126.1, 690.7		164.4, 640.9		138.9, 822.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	503.55 (180.167)	30.50 (40.391)	375.69 (139.755)	-0.88 (13.365)		
	95% CI	458.17, 548.93	18.63, 42.36	319.24, 432.15	-6.53, 4.77		
	Median	504.68	20.47	372.84	-3.18		
	Q25, Q75	388.61, 614.84	5.92, 54.43	276.63, 458.95	-9.40, 7.69		
	Min, Max	153.6, 899.4	-49.4, 116.1	164.1, 758.3	-23.1, 25.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	374.00 (131.407)		376.04 (120.763)		395.65 (155.588)	
	95% CI	335.84, 412.16		329.21, 422.87		336.47, 454.84	
	Median	364.83		362.87		385.26	
	Q25, Q75	270.19, 462.56		278.46, 464.59		312.02, 445.64	
	Min, Max	126.1, 690.7		164.4, 640.9		138.9, 822.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	527.82 (180.033)	44.25 (42.381)	357.74 (117.159)	-1.85 (12.045)		
	95% CI	482.48, 573.17	31.20, 57.30	312.31, 403.18	-6.82, 3.13		
	Median	504.82	34.13	352.11	-0.76		
	Q25, Q75	424.11, 620.10	17.42, 76.67	264.32, 452.05	-7.64, 7.02		
	Min, Max	157.8, 889.8	-48.0, 174.3	170.3, 607.3	-24.3, 15.9		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	4.14 (1.940)		3.79 (1.434)		4.61 (3.098)	
	95% CI	3.60, 4.69		3.24, 4.34		3.47, 5.76	
	Median	3.64		3.81		3.21	
	Q25, Q75	2.85, 4.97		2.78, 4.46		2.30, 7.06	
	Min, Max	1.1, 10.3		1.7, 8.1		1.2, 15.8	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	3.45 (1.724)	-8.35 (38.547)	3.71 (1.527)	-1.42 (23.227)		
	95% CI	3.04, 3.86	-19.31, 2.61	3.13, 4.30	-10.43, 7.59		
	Median	3.26	-11.50	3.49	-6.66		
	Q25, Q75	2.14, 4.70	-31.23, 13.21	2.65, 4.26	-15.78, 5.52		
	Min, Max	0.7, 7.8	-73.4, 124.5	1.6, 9.2	-27.8, 79.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	3.90 (2.099)	3.62 (41.857)	3.79 (2.354)	0.19 (24.792)		
	95% CI	3.40, 4.39	-8.41, 15.65	2.84, 4.75	-10.04, 10.43		
	Median	4.00	2.70	3.26	1.92		
	Q25, Q75	2.39, 4.79	-28.48, 26.07	2.56, 4.42	-16.89, 14.52		
	Min, Max	0.5, 14.6	-82.3, 123.1	1.3, 13.4	-53.8, 65.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	4.14 (1.940)		3.72 (1.397)		4.61 (3.098)	
	95% CI	3.60, 4.69		3.17, 4.26		3.47, 5.76	
	Median	3.64		3.59		3.21	
	Q25, Q75	2.85, 4.97		2.73, 4.43		2.30, 7.06	
	Min, Max	1.1, 10.3		1.7, 8.1		1.2, 15.8	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	4.10 (2.119)	14.34 (58.099)	3.93 (1.911)	4.34 (33.668)		
	95% CI	3.60, 4.61	-2.00, 30.69	3.18, 4.68	-9.27, 17.94		
	Median	3.76	-1.82	3.54	2.95		
	Q25, Q75	2.66, 5.37	-28.64, 34.08	2.61, 4.57	-20.20, 13.99		
	Min, Max	0.7, 13.3	-66.7, 153.6	1.3, 9.6	-43.1, 123.0		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	4.13 (1.956)		3.72 (1.397)		4.67 (3.135)	
	95% CI	3.57, 4.68		3.17, 4.26		3.49, 5.85	
	Median	3.63		3.59		3.35	
	Q25, Q75	2.81, 4.99		2.73, 4.43		2.30, 7.06	
	Min, Max	1.1, 10.3		1.7, 8.1		1.2, 15.8	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	4.34 (2.328)	12.58 (58.314)	3.35 (1.364)	-8.20 (23.783)		
	95% CI	3.75, 4.93	-4.54, 29.71	2.80, 3.91	-18.24, 1.85		
	Median	3.82	4.05	3.03	-9.05		
	Q25, Q75	2.50, 5.65	-28.90, 33.88	2.25, 4.31	-27.61, 8.96		
	Min, Max	1.2, 13.7	-64.8, 203.9	1.6, 7.0	-45.7, 41.5		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	4.08 (1.963)		3.72 (1.397)		4.76 (3.154)	
	95% CI	3.51, 4.66		3.17, 4.26		3.55, 5.96	
	Median	3.57		3.59		3.48	
	Q25, Q75	2.79, 4.90		2.73, 4.43		2.38, 7.06	
	Min, Max	1.1, 10.3		1.7, 8.1		1.2, 15.8	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	4.30 (2.580)	17.51 (78.099)	4.25 (2.548)	7.30 (38.128)		
	95% CI	3.65, 4.95	-6.53, 41.55	3.25, 5.24	-8.45, 23.04		
	Median	3.73	-1.95	3.64	2.51		
	Q25, Q75	2.16, 5.56	-29.87, 34.01	2.59, 4.81	-20.67, 17.67		
	Min, Max	1.2, 12.5	-64.5, 308.1	1.7, 13.3	-30.6, 149.7		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	13.25 (5.252)		12.54 (5.064)		13.61 (6.797)	
	95% CI	11.79, 14.72		10.61, 14.48		11.12, 16.11	
	Median	13.66		11.97		12.95	
	Q25, Q75	8.99, 17.16		9.58, 14.10		7.77, 20.38	
	Min, Max	4.5, 25.2		4.0, 31.7		4.4, 27.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	15.50 (6.685)	23.30 (40.975)	12.83 (5.416)	3.61 (26.200)		
	95% CI	13.92, 17.07	11.65, 34.95	10.76, 14.89	-6.56, 13.77		
	Median	15.12	21.26	11.90	-3.38		
	Q25, Q75	9.64, 19.93	-6.35, 46.34	9.80, 14.52	-10.41, 9.47		
	Min, Max	4.8, 31.9	-35.4, 183.6	5.0, 34.6	-26.1, 82.7		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	16.11 (6.905)	30.79 (39.332)	12.94 (7.729)	4.68 (28.226)		
	95% CI	14.49, 17.72	19.49, 42.09	9.81, 16.07	-6.98, 16.33		
	Median	15.41	24.60	11.18	-0.02		
	Q25, Q75	10.39, 21.88	2.87, 53.52	9.72, 14.68	-10.05, 20.45		
	Min, Max	3.2, 29.9	-43.7, 172.9	3.5, 47.0	-56.3, 70.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	13.25 (5.252)		12.29 (4.957)		13.61 (6.797)	
	95% CI	11.79, 14.72		10.36, 14.21		11.12, 16.11	
	Median	13.66		11.40		12.95	
	Q25, Q75	8.99, 17.16		9.45, 14.07		7.77, 20.38	
	Min, Max	4.5, 25.2		4.0, 31.7		4.4, 27.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	16.67 (8.136)	41.39 (66.319)	12.94 (5.792)	6.15 (41.235)		
	95% CI	14.74, 18.60	22.73, 60.05	10.69, 15.19	-10.51, 22.81		
	Median	15.92	23.34	12.42	0.91		
	Q25, Q75	9.94, 23.62	4.84, 62.04	9.37, 15.50	-15.44, 20.52		
	Min, Max	4.3, 47.2	-47.0, 354.1	6.0, 33.4	-52.2, 165.4		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	13.24 (5.304)		12.29 (4.957)		13.71 (6.890)	
	95% CI	11.74, 14.74		10.36, 14.21		11.14, 16.29	
	Median	13.43		11.40		13.37	
	Q25, Q75	8.93, 17.85		9.45, 14.07		7.77, 20.38	
	Min, Max	4.5, 25.2		4.0, 31.7		4.4, 27.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	18.70 (8.973)	44.79 (56.599)	11.25 (3.824)	-5.50 (25.868)		
	95% CI	16.44, 20.96	28.16, 61.41	9.71, 12.80	-16.43, 5.42		
	Median	18.49	41.75	10.90	0.64		
	Q25, Q75	10.95, 25.01	12.54, 67.39	8.50, 13.90	-31.10, 9.22		
	Min, Max	4.8, 42.8	-36.6, 304.1	4.9, 19.4	-44.0, 55.4		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	13.33 (5.392)		12.29 (4.957)		13.95 (6.886)	
	95% CI	11.76, 14.90		10.36, 14.21		11.33, 16.58	
	Median	13.71		11.40		13.79	
	Q25, Q75	8.99, 17.92		9.45, 14.07		7.92, 20.38	
	Min, Max	4.5, 25.2		4.0, 31.7		4.4, 27.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	17.75 (8.852)	55.13 (79.031)	13.52 (7.582)	8.45 (44.033)		
	95% CI	15.51, 19.98	30.80, 79.46	10.57, 16.46	-9.73, 26.63		
	Median	17.35	34.15	11.17	4.40		
	Q25, Q75	10.76, 23.85	18.11, 75.15	9.81, 15.90	-18.23, 19.34		
	Min, Max	2.8, 43.0	-49.6, 316.4	5.1, 46.5	-37.0, 186.1		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Mean (SD)	4.93 (1.507)		4.49 (1.168)		4.79 (2.063)	
	95% CI	4.51, 5.36		4.04, 4.94		4.03, 5.55	
	Median	5.03		4.39		4.58	
	Q25, Q75	3.92, 5.83		3.39, 5.02		2.95, 6.13	
	Min, Max	1.9, 8.7		2.7, 8.0		2.0, 9.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Mean (SD)	5.40 (1.972)	8.02 (22.486)	4.53 (1.423)	-0.07 (18.314)		
	95% CI	4.93, 5.87	1.63, 14.42	3.99, 5.08	-7.18, 7.03		
	Median	5.20	8.36	4.45	-3.50		
	Q25, Q75	3.75, 6.85	-5.17, 15.52	3.61, 5.34	-10.48, 3.15		
	Min, Max	2.3, 10.0	-31.1, 92.4	2.5, 9.6	-23.8, 56.9		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Mean (SD)	5.50 (1.861)	12.32 (27.318)	4.56 (1.728)	2.70 (20.926)		
	95% CI	5.06, 5.94	4.47, 20.17	3.86, 5.26	-5.94, 11.34		
	Median	5.60	4.70	4.46	2.08		
	Q25, Q75	4.01, 6.58	-4.92, 24.72	3.70, 5.02	-11.56, 12.96		
	Min, Max	2.2, 10.3	-32.8, 89.0	2.4, 11.4	-35.2, 47.5		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Mean (SD)	4.93 (1.507)		4.43 (1.144)		4.79 (2.063)	
	95% CI	4.51, 5.36		3.98, 4.88		4.03, 5.55	
	Median	5.03		4.29		4.58	
	Q25, Q75	3.92, 5.83		3.39, 4.98		2.95, 6.13	
	Min, Max	1.9, 8.7		2.7, 8.0		2.0, 9.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Mean (SD)	5.84 (2.094)	24.58 (34.349)	4.69 (1.529)	4.63 (33.032)		
	95% CI	5.34, 6.34	14.92, 34.25	4.09, 5.28	-8.72, 17.98		
	Median	5.64	19.04	4.40	-4.06		
	Q25, Q75	4.15, 6.87	-1.05, 42.26	3.63, 5.21	-13.61, 9.83		
	Min, Max	2.5, 14.3	-29.5, 126.5	2.8, 9.2	-30.4, 135.8		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Mean (SD)	4.95 (1.520)		4.43 (1.144)		4.83 (2.083)	
	95% CI	4.51, 5.38		3.98, 4.88		4.05, 5.62	
	Median	5.05		4.29		4.76	
	Q25, Q75	3.92, 5.88		3.39, 4.98		2.95, 6.13	
	Min, Max	1.9, 8.7		2.7, 8.0		2.0, 9.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Mean (SD)	6.04 (2.228)	26.28 (43.985)	4.35 (1.434)	-1.85 (23.791)		
	95% CI	5.47, 6.60	13.36, 39.19	3.77, 4.94	-11.90, 8.20		
	Median	5.94	18.48	4.01	0.85		
	Q25, Q75	4.49, 7.01	2.28, 43.83	3.55, 4.90	-20.05, 13.50		
	Min, Max	2.2, 13.4	-38.5, 229.5	2.0, 8.3	-43.1, 45.8		

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Mean (SD)	4.87 (1.519)		4.43 (1.144)		4.91 (2.075)	
	95% CI	4.43, 5.32		3.98, 4.88		4.12, 5.71	
	Median	4.91		4.29		4.95	
	Q25, Q75	3.86, 5.79		3.39, 4.98		3.03, 6.13	
	Min, Max	1.9, 8.7		2.7, 8.0		2.0, 9.6	

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]).

**Table 15.2.4.42 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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Mean (SD)	6.19 (2.482)	29.77 (47.860)	4.82 (1.705)	6.02 (39.488)		
	95% CI	5.56, 6.82	15.04, 44.51	4.15, 5.49	-10.29, 22.32		
	Median	5.90	19.65	4.33	-0.21		
	Q25, Q75	4.35, 7.42	0.14, 56.82	3.43, 5.88	-13.82, 11.85		
	Min, Max	2.2, 15.5	-35.5, 204.1	2.7, 8.8	-28.9, 176.5		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	17.27 (35.97)		15.98 (29.97)		16.37 (38.66)	
	95% CI of Geometric Mean	15.66, 19.03		14.29, 17.87		14.27, 18.77	
	Median	17.77		15.08		15.88	
	Q25, Q75	13.60, 21.92		13.56, 20.10		12.83, 23.00	
	Min, Max	8.4, 33.8		9.5, 27.5		8.1, 32.1	

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]).

Appendix: 15.3.7.1

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	17.88 (28.70)		15.91 (35.43)			
	95% CI of Geometric Mean	16.74, 19.11		13.95, 18.13			
	Mean (SD)		9.83 (33.288)		0.10 (14.323)		
	95% CI		0.36, 19.29		-5.46, 5.66		
	Median	17.33	3.12	15.50	-3.20		
	Q25, Q75	15.11, 19.94	-12.46, 32.33	12.88, 19.63	-8.12, 7.56		
	Min, Max	11.5, 50.0	-45.0, 94.8	8.9, 33.5	-18.8, 42.6		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	17.31 (32.90)		15.49 (33.27)			
	95% CI of Geometric Mean	16.06, 18.66		13.59, 17.66			
	Mean (SD)		6.03 (34.740)		0.71 (13.446)		
	95% CI		-3.96, 16.01		-4.84, 6.27		
	Median	16.88	0.33	15.43	2.75		
	Q25, Q75	14.85, 20.55	-13.44, 25.54	11.57, 18.29	-6.76, 10.66		
	Min, Max	3.0, 35.2	-84.3, 101.8	10.0, 30.0	-30.7, 27.7		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	17.27 (35.97)		15.85 (30.18)		16.37 (38.66)	
	95% CI of Geometric Mean	15.66, 19.03		14.13, 17.77		14.27, 18.77	
	Median	17.77		14.83		15.88	
	Q25, Q75	13.60, 21.92		13.11, 19.85		12.83, 23.00	
	Min, Max	8.4, 33.8		9.5, 27.5		8.1, 32.1	

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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	16.05 (30.31)		14.08 (28.48)			
	95% CI of Geometric Mean	14.96, 17.23		12.63, 15.69			
	Mean (SD)		-2.93 (33.601)		-9.75 (13.705)		
	95% CI		-12.39, 6.52		-15.29, -4.21		
	Median	16.00	-8.54	13.50	-8.77		
	Q25, Q75	14.00, 18.67	-25.61, 8.42	11.67, 16.17	-14.19, -6.07		
	Min, Max	6.0, 35.0	-59.4, 118.2	9.3, 25.0	-44.1, 33.3		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	17.08 (35.42)		15.85 (30.18)		16.58 (38.59)	
	95% CI of Geometric Mean	15.50, 18.82		14.13, 17.77		14.42, 19.06	
	Median	17.62		14.83		16.10	
	Q25, Q75	13.20, 21.90		13.11, 19.85		13.00, 23.00	
	Min, Max	8.4, 33.8		9.5, 27.5		8.1, 32.1	

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 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	17.33 (41.95)		13.16 (34.90)			
	95% CI of Geometric Mean	15.66, 19.19		11.47, 15.09			
	Mean (SD)		10.19 (36.575)		-12.94 (16.626)		
	95% CI		-0.56, 20.93		-19.97, -5.92		
	Median	17.50	9.85	12.25	-14.26		
	Q25, Q75	15.00, 21.40	-15.81, 31.12	10.33, 15.50	-27.07, -2.99		
	Min, Max	4.0, 47.0	-72.3, 97.3	7.3, 25.0	-41.2, 23.8		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	16.75 (35.41)		15.85 (30.18)		16.89 (37.68)	
	95% CI of Geometric Mean	15.15, 18.51		14.13, 17.77		14.70, 19.41	
	Median	16.80		14.83		16.33	
	Q25, Q75	13.10, 21.00		13.11, 19.85		13.00, 23.00	
	Min, Max	8.4, 33.8		9.5, 27.5		8.1, 32.1	

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 4

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	17.65 (35.77)		14.35 (27.79)			
	95% CI of Geometric Mean	16.17, 19.27		12.90, 15.95			
	Mean (SD)		9.96 (33.275)		-9.23 (15.269)		
	95% CI		-0.29, 20.21		-15.54, -2.93		
	Median	18.00	7.17	14.29	-10.53		
	Q25, Q75	14.50, 20.40	-16.22, 32.60	11.17, 17.42	-19.90, 2.73		
	Min, Max	7.0, 50.0	-42.4, 100.6	9.7, 28.8	-35.3, 27.3		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	820.93 (46.61)		779.13 (38.05)		859.07 (57.17)	
	95% CI of Geometric Mean	725.60, 928.77		677.44, 896.10		706.84, 1044.07	
	Median	733.02		775.25		830.62	
	Q25, Q75	601.83, 1122.39		616.84, 1085.60		559.33, 1306.85	
	Min, Max	355.8, 2362.9		399.2, 1371.2		363.8, 3051.8	

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 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	625.67 (55.47)		756.62 (41.49)			
	95% CI of Geometric Mean	553.96, 706.65		650.19, 880.48			
	Mean (SD)		-7.70 (41.695)		-1.74 (17.584)		
	95% CI		-19.56, 4.15		-8.57, 5.08		
	Median	701.10	-14.94	749.11	-6.39		
	Q25, Q75	509.42, 914.12	-42.78, 22.68	578.60, 1072.61	-13.86, 5.36		
	Min, Max	100.3, 1336.1	-81.0, 105.2	350.0, 1507.0	-18.1, 64.6		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	667.14 (67.19)		716.49 (43.06)			
	95% CI of Geometric Mean	578.59, 769.25		606.54, 846.36			
	Mean (SD)		-0.13 (44.683)		-2.80 (14.808)		
	95% CI		-12.97, 12.71		-8.92, 3.32		
	Median	722.12	-3.22	631.79	-4.70		
	Q25, Q75	586.30, 865.31	-25.84, 28.22	512.70, 1042.14	-12.61, 7.04		
	Min, Max	16.9, 3005.3	-98.5, 104.3	386.5, 1725.0	-34.7, 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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	820.93 (46.61)		768.00 (37.87)		859.07 (57.17)	
	95% CI of Geometric Mean	725.60, 928.77		666.38, 885.11		706.84, 1044.07	
	Median	733.02		761.35		830.62	
	Q25, Q75	601.83, 1122.39		603.96, 1082.80		559.33, 1306.85	
	Min, Max	355.8, 2362.9		399.2, 1371.2		363.8, 3051.8	

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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	624.00 (44.13)		667.24 (42.93)			
	95% CI of Geometric Mean	564.71, 689.52		568.88, 782.60			
	Mean (SD)		-14.18 (39.811)		-10.22 (17.619)		
	95% CI		-25.39, -2.98		-17.34, -3.09		
	Median	616.95	-20.70	641.59	-9.23		
	Q25, Q75	527.13, 768.17	-48.09, 15.43	488.31, 865.31	-18.93, -2.59		
	Min, Max	209.5, 2968.1	-72.7, 103.4	323.6, 1951.7	-48.4, 42.3		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	806.79 (45.01)		768.00 (37.87)		871.26 (57.56)	
	95% CI of Geometric Mean	714.99, 910.39		666.38, 885.11		713.52, 1063.88	
	Median	720.77		761.35		834.09	
	Q25, Q75	601.72, 1122.02		603.96, 1082.80		559.33, 1306.85	
	Min, Max	355.8, 2362.9		399.2, 1371.2		363.8, 3051.8	

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 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	695.97 (56.58)		595.06 (41.31)			
	95% CI of Geometric Mean	609.48, 794.75		506.91, 698.52			
	Mean (SD)		-1.35 (50.374)		-17.49 (17.521)		
	95% CI		-16.15, 13.44		-24.89, -10.09		
	Median	713.98	-17.76	580.42	-14.57		
	Q25, Q75	517.43, 925.74	-38.26, 29.49	431.73, 817.93	-25.83, -8.09		
	Min, Max	122.7, 2731.1	-78.1, 104.3	331.4, 1280.5	-59.1, 18.6		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	792.58 (44.34)		768.00 (37.87)		889.22 (57.24)	
	95% CI of Geometric Mean	700.84, 896.33		666.38, 885.11		726.22, 1088.81	
	Median	714.39		761.35		837.55	
	Q25, Q75	601.57, 1089.59		603.96, 1082.80		567.70, 1306.85	
	Min, Max	355.8, 2362.9		399.2, 1371.2		363.8, 3051.8	

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 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	663.21 (49.25)		707.20 (47.91)			
	95% CI of Geometric Mean	589.77, 745.79		592.92, 843.52			
	Mean (SD)		-6.02 (39.393)		-7.55 (17.466)		
	95% CI		-18.14, 6.11		-14.76, -0.34		
	Median	675.16	-16.97	691.11	-4.12		
	Q25, Q75	500.49, 920.71	-38.09, 18.18	495.87, 876.43	-20.22, 2.97		
	Min, Max	122.8, 2431.5	-58.9, 93.1	389.6, 2748.6	-49.6, 25.9		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	47.68 (43.50)		49.11 (29.80)		52.73 (35.55)	
	95% CI of Geometric Mean	42.46, 53.54		43.95, 54.88		46.46, 59.84	
	Median	44.82		45.86		51.74	
	Q25, Q75	37.13, 63.81		42.85, 58.19		42.72, 66.18	
	Min, Max	18.2, 124.4		29.4, 102.1		27.4, 117.9	

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 1

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	35.21 (57.15)		47.74 (30.49)			
	95% CI of Geometric Mean	31.07, 39.90		42.62, 53.48			
	Mean (SD)		-16.00 (28.067)		-2.24 (8.101)		
	95% CI		-23.98, -8.02		-5.39, 0.90		
	Median	35.65	-16.19	48.20	-3.29		
	Q25, Q75	27.37, 51.62	-30.66, -8.85	38.20, 57.65	-7.64, 1.91		
	Min, Max	7.8, 93.4	-74.9, 57.1	26.1, 97.9	-14.8, 15.3		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	38.85 (58.17)		46.38 (34.11)			
	95% CI of Geometric Mean	34.25, 44.07		40.56, 53.04			
	Mean (SD)		-6.35 (32.396)		-3.54 (9.267)		
	95% CI		-15.66, 2.96		-7.37, 0.29		
	Median	40.66	-8.59	44.29	-2.87		
	Q25, Q75	32.21, 51.04	-21.78, 14.63	35.72, 59.93	-9.18, 2.16		
	Min, Max	5.6, 152.1	-90.4, 88.3	26.0, 92.6	-28.4, 17.6		

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 (IDay 1 – Day 6 confinement), Period 2 (IDay 6 ambulatory – Day 30 Visit), Period 3 (IDay 30 Visit – Day 60 Visit) and Period 4 (IDay 60 Visit – Day 90 Visit).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	47.68 (43.50)		48.82 (30.17)		52.73 (35.55)	
	95% CI of Geometric Mean	42.46, 53.54		43.54, 54.74		46.46, 59.84	
	Median	44.82		45.77		51.74	
	Q25, Q75	37.13, 63.81		41.07, 58.35		42.72, 66.18	
	Min, Max	18.2, 124.4		29.4, 102.1		27.4, 117.9	

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 2

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	38.96 (49.39)		47.53 (34.27)			
	95% CI of Geometric Mean	34.88, 43.53		41.77, 54.09			
	Mean (SD)		-10.91 (30.801)		-0.58 (16.283)		
	95% CI		-19.58, -2.24		-7.16, 6.00		
	Median	38.82	-13.11	44.46	-3.05		
	Q25, Q75	31.88, 50.57	-31.50, 9.69	37.58, 57.70	-9.50, 4.78		
	Min, Max	9.8, 154.1	-61.5, 91.2	27.6, 92.8	-27.9, 51.5		

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 (IDay 1 – Day 6 confinement), Period 2 (IDay 6 ambulatory – Day 30 Visit), Period 3 (IDay 30 Visit – Day 60 Visit) and Period 4 (IDay 60 Visit – Day 90 Visit).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	47.38 (43.68)		48.82 (30.17)		52.80 (36.18)	
	95% CI of Geometric Mean	42.12, 53.29		43.54, 54.74		46.31, 60.19	
	Median	44.66		45.77		53.95	
	Q25, Q75	37.06, 61.54		41.07, 58.35		42.72, 66.18	
	Min, Max	18.2, 124.4		29.4, 102.1		27.4, 117.9	

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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	40.12 (46.47)		45.03 (32.86)			
	95% CI of Geometric Mean	35.89, 44.85		39.56, 51.25			
	Mean (SD)		-11.91 (29.676)		-6.22 (12.403)		
	95% CI		-20.62, -3.19		-11.46, -0.97		
	Median	38.13	-20.60	42.31	-4.33		
	Q25, Q75	30.68, 48.95	-30.86, 7.56	36.78, 51.22	-14.33, 1.67		
	Min, Max	15.8, 156.5	-62.9, 63.5	27.3, 93.2	-34.0, 13.8		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	47.49 (43.76)		48.82 (30.17)		52.88 (36.85)	
	95% CI of Geometric Mean	42.05, 53.63		43.54, 54.74		46.16, 60.57	
	Median	44.26		45.77		56.15	
	Q25, Q75	37.13, 60.54		41.07, 58.35		42.72, 66.18	
	Min, Max	18.2, 124.4		29.4, 102.1		27.4, 117.9	

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 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	37.50 (52.01)		49.33 (36.95)			
	95% CI of Geometric Mean	33.15, 42.42		42.94, 56.68			
	Mean (SD)		-13.31 (29.342)		1.88 (17.626)		
	95% CI		-22.34, -4.27		-5.40, 9.16		
	Median	38.68	-17.73	45.00	-0.81		
	Q25, Q75	28.28, 49.34	-32.48, 2.71	37.52, 57.85	-5.22, 6.81		
	Min, Max	9.6, 128.0	-66.9, 72.9	29.4, 137.4	-25.9, 56.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	1.55 (40.57)		1.61 (28.03)		1.63 (31.49)	
	95% CI of Geometric Mean	1.39, 1.74		1.45, 1.79		1.45, 1.83	
	Median	1.46		1.63		1.73	
	Q25, Q75	1.19, 2.07		1.43, 1.86		1.30, 1.95	
	Min, Max	0.8, 3.6		0.8, 2.7		0.8, 3.4	

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 duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	1.65 (44.91)		1.65 (26.71)			
	95% CI of Geometric Mean	1.49, 1.83		1.48, 1.82			
	Mean (SD)		13.85 (29.807)		2.41 (8.857)		
	95% CI		5.37, 22.32		-1.03, 5.85		
	Median	1.58	11.13	1.61	2.12		
	Q25, Q75	1.32, 2.24	-5.12, 25.91	1.45, 1.81	-4.85, 5.85		
	Min, Max	0.6, 4.7	-33.4, 120.9	0.8, 2.7	-9.4, 26.8		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	1.67 (45.07)		1.60 (31.48)			
	95% CI of Geometric Mean	1.50, 1.85		1.41, 1.82			
	Mean (SD)		17.40 (24.376)		0.44 (12.130)		
	95% CI		10.39, 24.41		-4.57, 5.45		
	Median	1.71	14.83	1.52	0.76		
	Q25, Q75	1.31, 2.18	1.36, 35.05	1.44, 2.05	-7.27, 9.25		
	Min, Max	0.5, 4.1	-34.7, 68.2	0.9, 2.8	-32.1, 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 (IDay 1 – Day 6 confinement), Period 2 (IDay 6 ambulatory – Day 30 Visit), Period 3 (IDay 30 Visit – Day 60 Visit) and Period 4 (IDay 60 Visit – Day 90 Visit).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	1.55 (40.57)		1.60 (28.36)		1.63 (31.49)	
	95% CI of Geometric Mean	1.39, 1.74		1.43, 1.79		1.45, 1.83	
	Median	1.46		1.61		1.73	
	Q25, Q75	1.19, 2.07		1.37, 1.79		1.30, 1.95	
	Min, Max	0.8, 3.6		0.8, 2.7		0.8, 3.4	

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 duration (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	1.59 (47.85)		1.60 (30.99)			
	95% CI of Geometric Mean	1.42, 1.78		1.42, 1.80			
	Mean (SD)		11.78 (30.469)		0.15 (14.379)		
	95% CI		3.20, 20.35		-5.67, 5.96		
	Median	1.55	5.50	1.52	0.82		
	Q25, Q75	1.17, 2.31	-6.55, 25.01	1.33, 2.00	-7.74, 10.05		
	Min, Max	0.6, 5.2	-37.8, 112.1	0.9, 3.2	-30.4, 35.8		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	1.55 (40.85)		1.60 (28.36)		1.62 (31.98)	
	95% CI of Geometric Mean	1.38, 1.73		1.43, 1.79		1.44, 1.83	
	Median	1.44		1.61		1.72	
	Q25, Q75	1.17, 2.18		1.37, 1.79		1.30, 1.95	
	Min, Max	0.8, 3.6		0.8, 2.7		0.8, 3.4	

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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Study ID: ZRHM-REXA-07-JP

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	1.74 (47.24)		1.53 (27.58)			
	95% CI of Geometric Mean	1.55, 1.95		1.37, 1.71			
	Mean (SD)		16.65 (30.627)		-4.23 (10.443)		
	95% CI		7.65, 25.64		-8.64, 0.19		
	Median	1.79	21.51	1.50	-3.11		
	Q25, Q75	1.25, 2.48	-8.95, 34.14	1.30, 1.80	-9.92, 2.41		
	Min, Max	0.6, 4.4	-44.6, 100.6	0.9, 2.6	-24.7, 19.2		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	1.58 (40.47)		1.60 (28.36)		1.62 (32.57)	
	95% CI of Geometric Mean	1.40, 1.77		1.43, 1.79		1.43, 1.83	
	Median	1.46		1.61		1.73	
	Q25, Q75	1.24, 2.18		1.37, 1.79		1.30, 1.95	
	Min, Max	0.8, 3.6		0.8, 2.7		0.8, 3.4	

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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Study ID: ZRHM-REXA-07-JP

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	1.61 (51.91)		1.61 (32.90)			
	95% CI of Geometric Mean	1.42, 1.82		1.41, 1.82			
	Mean (SD)		18.62 (37.019)		1.44 (12.796)		
	95% CI		7.22, 30.01		-3.84, 6.73		
	Median	1.58	12.31	1.58	2.25		
	Q25, Q75	1.12, 2.22	-4.76, 39.37	1.35, 1.89	-5.24, 6.71		
	Min, Max	0.5, 4.6	-40.7, 162.1	0.8, 3.3	-27.3, 39.7		

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 (IDay 1 – Day 6 confinement), Period 2 (IDay 6 ambulatory – Day 30 Visit), Period 3 (IDay 30 Visit – Day 60 Visit) and Period 4 (IDay 60 Visit – Day 90 Visit).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	26.76 (40.34)		25.64 (33.36)		26.52 (49.31)	
	95% CI of Geometric Mean	24.01, 29.82		22.66, 29.02		22.34, 31.47	
	Median	26.88		24.77		28.70	
	Q25, Q75	19.05, 33.84		21.79, 30.86		19.21, 40.63	
	Min, Max	13.5, 74.9		10.6, 52.4		11.3, 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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Program: t1502044201_ZRHM-REXA-07_JP_v1_PMI.sas

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	29.32 (43.88)		26.16 (38.90)			
	95% CI of Geometric Mean	26.57, 32.37		22.67, 30.18			
	Mean (SD)		24.88 (47.878)		3.46 (21.585)		
	95% CI		11.27, 38.49		-4.92, 11.83		
	Median	29.95	14.18	26.04	-4.55		
	Q25, Q75	22.08, 40.08	-8.45, 54.29	21.19, 30.49	-10.47, 10.87		
	Min, Max	10.5, 66.5	-58.6, 137.8	11.9, 57.7	-24.5, 81.2		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	28.84 (50.23)		24.80 (39.03)			
	95% CI of Geometric Mean	25.81, 32.22		21.30, 28.88			
	Mean (SD)		23.15 (45.197)		1.51 (19.105)		
	95% CI		10.16, 36.14		-6.38, 9.40		
	Median	30.77	20.12	24.35	-0.87		
	Q25, Q75	21.40, 39.40	-9.43, 46.11	19.24, 28.30	-10.96, 9.32		
	Min, Max	4.2, 65.2	-81.1, 139.8	13.9, 60.5	-36.8, 40.6		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	26.76 (40.34)		25.27 (32.96)		26.52 (49.31)	
	95% CI of Geometric Mean	24.01, 29.82		22.31, 28.63		22.34, 31.47	
	Median	26.88		24.30		28.70	
	Q25, Q75	19.05, 33.84		21.70, 30.54		19.21, 40.63	
	Min, Max	13.5, 74.9		10.6, 52.4		11.3, 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: Total puff duration (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	25.55 (42.02)		22.48 (41.02)			
	95% CI of Geometric Mean	23.22, 28.11		19.29, 26.20			
	Mean (SD)		5.62 (38.403)		-9.23 (17.407)		
	95% CI		-5.19, 16.42		-16.27, -2.19		
	Median	24.11	-3.53	21.58	-8.88		
	Q25, Q75	18.94, 35.73	-23.32, 24.66	18.32, 27.00	-14.41, 1.46		
	Min, Max	10.6, 68.6	-47.4, 107.3	10.9, 68.8	-56.7, 31.3		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	26.36 (39.05)		25.27 (32.96)		26.76 (49.93)	
	95% CI of Geometric Mean	23.71, 29.32		22.31, 28.63		22.43, 31.92	
	Median	26.83		24.30		29.08	
	Q25, Q75	19.05, 33.32		21.70, 30.54		19.21, 40.63	
	Min, Max	13.5, 74.9		10.6, 52.4		11.3, 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: Total puff duration (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	30.21 (56.62)		20.33 (35.02)			
	95% CI of Geometric Mean	26.44, 34.50		17.71, 23.32			
	Mean (SD)		28.30 (55.014)		-15.44 (18.819)		
	95% CI		12.14, 44.46		-23.39, -7.49		
	Median	31.60	21.65	21.25	-20.22		
	Q25, Q75	21.41, 41.38	-2.57, 56.73	17.63, 23.54	-25.77, -5.36		
	Min, Max	5.4, 101.0	-65.4, 215.4	10.0, 48.5	-45.7, 28.8		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	26.35 (39.66)		25.27 (32.96)		27.28 (49.46)	
	95% CI of Geometric Mean	23.58, 29.44		22.31, 28.63		22.83, 32.60	
	Median	26.60		24.30		29.46	
	Q25, Q75	19.05, 33.29		21.70, 30.54		21.70, 40.63	
	Min, Max	13.5, 74.9		10.6, 52.4		11.3, 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: Total puff duration (s) (average over visit)
Product Use Time Period: Period 4

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	28.34 (61.73)		23.06 (41.34)			
	95% CI of Geometric Mean	24.56, 32.71		19.77, 26.91			
	Mean (SD)		33.04 (76.756)		-7.54 (18.191)		
	95% CI		9.41, 56.66		-15.05, -0.03		
	Median	28.99	23.76	24.33	-10.36		
	Q25, Q75	19.79, 40.43	-8.98, 50.71	19.11, 27.32	-20.13, -0.04		
	Min, Max	4.6, 87.4	-41.5, 411.3	8.5, 60.5	-45.4, 34.2		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	32.18 (29.13)		31.98 (25.62)		34.33 (34.43)	
	95% CI of Geometric Mean	29.72, 34.84		29.05, 35.20		30.36, 38.82	
	Median	32.21		31.25		34.73	
	Q25, Q75	27.98, 37.91		28.30, 36.70		30.03, 40.75	
	Min, Max	16.7, 63.4		18.4, 54.9		15.0, 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: Average flow (mL/s) (average over visit)
Product Use Time Period: Period 1

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	22.60 (38.50)		30.55 (25.57)			
	95% CI of Geometric Mean	20.70, 24.67		27.75, 33.62			
	Mean (SD)		-25.26 (17.982)		-4.31 (6.771)		
	95% CI		-30.38, -20.15		-6.94, -1.68		
	Median	24.10	-26.05	29.18	-4.12		
	Q25, Q75	18.99, 28.18	-32.95, -16.31	26.30, 37.08	-9.91, -0.42		
	Min, Max	6.6, 44.5	-76.3, 29.6	16.0, 49.1	-18.2, 9.2		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	24.43 (41.26)		30.41 (25.64)			
	95% CI of Geometric Mean	22.27, 26.80		27.45, 33.67			
	Mean (SD)		-20.50 (21.375)		-3.61 (7.343)		
	95% CI		-26.65, -14.36		-6.64, -0.57		
	Median	24.27	-22.53	29.86	-3.36		
	Q25, Q75	21.31, 31.06	-31.52, -8.27	25.16, 37.88	-10.12, 2.56		
	Min, Max	4.1, 74.1	-92.1, 30.9	18.2, 46.2	-15.8, 8.8		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	32.18 (29.13)		32.00 (26.10)		34.33 (34.43)	
	95% CI of Geometric Mean	29.72, 34.84		28.97, 35.36		30.36, 38.82	
	Median	32.21		31.08		34.73	
	Q25, Q75	27.98, 37.91		27.91, 36.74		30.03, 40.75	
	Min, Max	16.7, 63.4		18.4, 54.9		15.0, 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: Average flow (mL/s) (average over visit)
Product Use Time Period: Period 2

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	25.53 (40.64)		31.32 (24.35)			
	95% CI of Geometric Mean	23.27, 28.02		28.53, 34.37			
	Mean (SD)		-18.61 (24.813)		-0.07 (10.678)		
	95% CI		-25.59, -11.62		-4.39, 4.25		
	Median	26.52	-19.58	33.34	0.06		
	Q25, Q75	19.65, 32.35	-40.49, 0.95	26.70, 36.82	-10.39, 6.91		
	Min, Max	7.6, 100.5	-66.5, 32.5	18.7, 48.9	-17.5, 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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	32.11 (29.39)		32.00 (26.10)		34.51 (34.92)	
	95% CI of Geometric Mean	29.61, 34.83		28.97, 35.36		30.40, 39.17	
	Median	32.15		31.08		34.85	
	Q25, Q75	27.97, 38.15		27.91, 36.74		30.05, 40.75	
	Min, Max	16.7, 63.4		18.4, 54.9		15.0, 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: Average flow (mL/s) (average over visit)
Product Use Time Period: Period 3

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	24.12 (40.78)		31.04 (27.59)			
	95% CI of Geometric Mean	21.85, 26.63		27.82, 34.63			
	Mean (SD)		-22.54 (25.385)		-1.02 (12.433)		
	95% CI		-30.00, -15.08		-6.27, 4.24		
	Median	26.01	-22.03	31.35	-1.07		
	Q25, Q75	18.60, 31.10	-40.50, -11.89	27.08, 35.12	-6.54, 6.37		
	Min, Max	8.6, 89.2	-64.4, 67.8	17.4, 50.8	-32.5, 23.4		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	31.59 (29.28)		32.00 (26.10)		34.57 (35.56)	
	95% CI of Geometric Mean	29.06, 34.34		28.97, 35.36		30.31, 39.42	
	Median	31.91		31.08		34.96	
	Q25, Q75	27.54, 37.57		27.91, 36.74		30.05, 40.75	
	Min, Max	16.7, 63.4		18.4, 54.9		15.0, 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: Average flow (mL/s) (average over visit)
Product Use Time Period: Period 4

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	24.22 (51.06)		32.32 (28.58)			
	95% CI of Geometric Mean	21.45, 27.35		28.99, 36.03			
	Mean (SD)		-23.85 (26.623)		1.20 (12.637)		
	95% CI		-32.05, -15.65		-4.02, 6.42		
	Median	25.76	-24.67	30.10	1.33		
	Q25, Q75	17.92, 33.80	-39.67, -4.74	27.21, 37.03	-4.58, 7.93		
	Min, Max	7.3, 89.5	-70.7, 53.9	21.2, 76.4	-21.5, 32.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	49.75 (30.14)		48.74 (28.74)		51.96 (36.74)	
	95% CI of Geometric Mean	45.83, 54.01		43.79, 54.26		45.60, 59.21	
	Median	48.75		48.45		52.22	
	Q25, Q75	40.23, 62.89		41.58, 60.04		41.92, 62.81	
	Min, Max	25.4, 95.3		23.8, 74.9		20.8, 102.1	

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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	34.39 (38.02)		46.38 (29.76)			
	95% CI of Geometric Mean	31.54, 37.50		41.51, 51.82			
	Mean (SD)		-25.70 (18.707)		-5.03 (7.357)		
	95% CI		-31.02, -20.37		-7.88, -2.17		
	Median	36.42	-26.53	48.60	-5.96		
	Q25, Q75	27.49, 44.91	-34.49, -20.22	38.65, 59.04	-11.24, -0.58		
	Min, Max	11.2, 62.5	-72.5, 30.9	22.3, 69.7	-19.7, 10.9		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	36.99 (36.05)		45.56 (29.37)			
	95% CI of Geometric Mean	34.08, 40.13		40.56, 51.17			
	Mean (SD)		-21.11 (22.028)		-6.07 (6.873)		
	95% CI		-27.44, -14.78		-8.91, -3.22		
	Median	36.76	-25.03	44.75	-7.97		
	Q25, Q75	31.90, 44.54	-33.94, -8.09	37.53, 57.13	-10.25, -2.24		
	Min, Max	12.5, 100.5	-80.2, 42.3	24.6, 72.2	-17.0, 9.0		

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 (IDay 1 – Day 6 confinement), Period 2 (IDay 6 ambulatory – Day 30 Visit), Period 3 (IDay 30 Visit – Day 60 Visit) and Period 4 (IDay 60 Visit – Day 90 Visit).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	49.75 (30.14)		48.73 (29.29)		51.96 (36.74)	
	95% CI of Geometric Mean	45.83, 54.01		43.60, 54.47		45.60, 59.21	
	Median	48.75		48.39		52.22	
	Q25, Q75	40.23, 62.89		41.34, 60.08		41.92, 62.81	
	Min, Max	25.4, 95.3		23.8, 74.9		20.8, 102.1	

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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	37.53 (40.23)		47.62 (28.30)			
	95% CI of Geometric Mean	34.24, 41.14		42.76, 53.03			
	Mean (SD)		-21.51 (24.619)		-0.89 (9.970)		
	95% CI		-28.44, -14.59		-4.92, 3.14		
	Median	39.74	-23.49	49.32	1.83		
	Q25, Q75	28.48, 47.83	-42.82, -2.39	40.80, 59.88	-10.19, 6.24		
	Min, Max	9.7, 115.3	-66.6, 36.6	25.3, 69.4	-18.2, 21.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	49.78 (30.45)		48.73 (29.29)		52.38 (37.10)	
	95% CI of Geometric Mean	45.77, 54.13		43.60, 54.47		45.80, 59.89	
	Median	49.01		48.39		52.86	
	Q25, Q75	39.61, 63.09		41.34, 60.08		44.67, 62.81	
	Min, Max	25.4, 95.3		23.8, 74.9		20.8, 102.1	

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 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	35.80 (40.96)		46.95 (32.93)			
	95% CI of Geometric Mean	32.42, 39.54		41.24, 53.45			
	Mean (SD)		-24.90 (27.260)		-2.22 (11.606)		
	95% CI		-32.91, -16.89		-7.13, 2.68		
	Median	39.44	-25.63	48.29	-3.04		
	Q25, Q75	27.54, 47.21	-44.02, -15.14	40.45, 57.45	-9.63, 4.04		
	Min, Max	15.6, 112.3	-67.2, 71.4	24.5, 86.3	-27.5, 19.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	49.31 (30.84)		48.73 (29.29)		52.66 (37.66)	
	95% CI of Geometric Mean	45.17, 53.82		43.60, 54.47		45.85, 60.49	
	Median	48.75		48.39		53.49	
	Q25, Q75	39.38, 62.89		41.34, 60.08		44.67, 62.81	
	Min, Max	25.4, 95.3		23.8, 74.9		20.8, 102.1	

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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Program: t1502044201_ZRHM-REXA-07_JP_v1_PMI.sas

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	35.58 (51.01)		48.65 (31.27)			
	95% CI of Geometric Mean	31.52, 40.17		43.22, 54.77			
	Mean (SD)		-25.05 (28.391)		-0.12 (12.188)		
	95% CI		-33.79, -16.31		-5.15, 4.92		
	Median	36.90	-24.92	49.75	1.75		
	Q25, Q75	25.00, 51.19	-44.50, -8.50	38.59, 59.96	-9.68, 6.13		
	Min, Max	12.0, 112.0	-75.2, 59.5	25.8, 109.9	-19.4, 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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	196.49 (32.49)		198.83 (29.15)		200.79 (27.28)	
	95% CI of Geometric Mean	179.90, 214.61		178.36, 221.65		182.00, 221.52	
	Median	195.61		191.16		200.77	
	Q25, Q75	158.27, 236.33		160.15, 229.29		160.69, 251.18	
	Min, Max	96.8, 363.4		117.1, 342.7		94.8, 300.6	

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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Study ID: ZRHM-REXA-07-JP

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	188.24 (32.79)		200.10 (26.89)			
	95% CI of Geometric Mean	174.62, 202.92		180.96, 221.25			
	Mean (SD)		3.93 (35.237)		2.44 (13.251)		
	95% CI		-6.09, 13.95		-2.71, 7.58		
	Median	201.11	-1.93	204.43	1.09		
	Q25, Q75	145.58, 246.50	-20.41, 27.30	166.20, 229.91	-3.98, 11.74		
	Min, Max	90.2, 318.8	-51.3, 93.8	118.0, 334.4	-34.7, 28.0		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	172.78 (39.95)		195.41 (35.82)			
	95% CI of Geometric Mean	157.94, 189.01		169.82, 224.86			
	Mean (SD)		-4.57 (35.718)		2.10 (21.351)		
	95% CI		-14.83, 5.69		-6.72, 10.91		
	Median	178.00	-2.90	201.06	1.01		
	Q25, Q75	145.37, 220.79	-28.33, 16.00	161.06, 226.86	-6.68, 13.54		
	Min, Max	27.1, 306.3	-92.4, 98.3	75.1, 381.1	-38.5, 72.2		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	196.49 (32.49)		199.19 (29.69)		200.79 (27.28)	
	95% CI of Geometric Mean	179.90, 214.61		177.95, 222.95		182.00, 221.52	
	Median	195.61		195.18		200.77	
	Q25, Q75	158.27, 236.33		159.91, 229.34		160.69, 251.18	
	Min, Max	96.8, 363.4		117.1, 342.7		94.8, 300.6	

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 inter puff interval (s) (average over visit)
Product Use Time Period: Period 2

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	149.89 (46.57)		170.47 (36.80)			
	95% CI of Geometric Mean	134.97, 166.47		148.47, 195.74			
	Mean (SD)		-22.70 (30.286)		-7.69 (22.332)		
	95% CI		-31.22, -14.18		-16.72, 1.33		
	Median	142.63	-23.38	172.77	-8.04		
	Q25, Q75	113.37, 214.33	-49.18, -3.79	132.21, 227.69	-16.94, 1.37		
	Min, Max	34.9, 320.5	-63.9, 55.6	69.3, 386.0	-56.6, 47.0		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	194.13 (31.51)		199.19 (29.69)		201.60 (27.66)	
	95% CI of Geometric Mean	178.04, 211.68		177.95, 222.95		182.16, 223.12	
	Median	195.60		195.18		204.48	
	Q25, Q75	157.99, 235.87		159.91, 229.34		160.69, 251.18	
	Min, Max	96.8, 357.8		117.1, 342.7		94.8, 300.6	

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 inter puff interval (s) (average over visit)
Product Use Time Period: Period 3

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	152.10 (56.53)		174.83 (37.46)			
	95% CI of Geometric Mean	133.21, 173.68		151.02, 202.39			
	Mean (SD)		-11.09 (36.996)		-5.76 (22.931)		
	95% CI		-21.96, -0.22		-15.44, 3.93		
	Median	149.73	-14.04	173.38	-7.75		
	Q25, Q75	111.30, 217.95	-34.78, 13.17	134.10, 224.72	-24.92, 7.04		
	Min, Max	14.5, 319.2	-93.7, 99.3	95.2, 357.8	-42.0, 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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	192.78 (31.61)		199.19 (29.69)		200.69 (28.04)	
	95% CI of Geometric Mean	176.25, 210.85		177.95, 222.95		180.74, 222.83	
	Median	194.01		195.18		200.77	
	Q25, Q75	155.89, 235.65		159.91, 229.34		160.69, 251.18	
	Min, Max	96.8, 357.8		117.1, 342.7		94.8, 300.6	

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 inter puff interval (s) (average over visit)
Product Use Time Period: Period 4

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	154.40 (51.92)		168.21 (38.21)			
	95% CI of Geometric Mean	136.52, 174.62		145.77, 194.09			
	Mean (SD)		-13.68 (37.479)		-8.95 (22.078)		
	95% CI		-25.22, -2.14		-18.07, 0.17		
	Median	145.69	-19.67	183.20	-8.60		
	Q25, Q75	112.21, 255.47	-40.62, 4.18	140.20, 213.73	-17.00, 6.26		
	Min, Max	34.7, 371.5	-63.0, 93.9	69.7, 367.4	-66.7, 39.0		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	11.64 (36.83)		12.70 (30.35)		12.44 (56.05)	
	95% CI of Geometric Mean	10.53, 12.86		11.34, 14.22		10.27, 15.08	
	Median	10.98		12.67		12.41	
	Q25, Q75	9.10, 14.80		10.76, 15.50		8.26, 18.94	
	Min, Max	5.8, 30.5		5.3, 22.2		4.6, 29.2	

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 inter puff interval (s) (average over visit)
Product Use Time Period: Period 1

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	10.62 (44.95)		12.86 (36.18)			
	95% CI of Geometric Mean	9.60, 11.75		11.25, 14.70			
	Mean (SD)		-4.81 (22.441)		4.58 (19.211)		
	95% CI		-11.19, 1.57		-2.87, 12.03		
	Median	10.18	-7.57	12.29	6.23		
	Q25, Q75	7.53, 15.65	-19.00, 7.84	10.10, 16.48	-3.76, 16.89		
	Min, Max	4.7, 25.8	-53.6, 45.5	4.5, 23.7	-43.0, 37.8		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	10.01 (42.06)		12.80 (41.66)			
	95% CI of Geometric Mean	9.10, 11.00		10.89, 15.05			
	Mean (SD)		-10.67 (23.460)		3.20 (23.993)		
	95% CI		-17.41, -3.93		-6.71, 13.11		
	Median	9.44	-9.16	12.62	4.38		
	Q25, Q75	7.65, 12.60	-28.24, 0.38	11.79, 15.91	-12.10, 17.71		
	Min, Max	4.1, 24.2	-54.3, 41.2	2.8, 23.7	-46.1, 53.2		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	11.64 (36.83)		12.79 (30.64)		12.44 (56.05)	
	95% CI of Geometric Mean	10.53, 12.86		11.39, 14.37		10.27, 15.08	
	Median	10.98		13.11		12.41	
	Q25, Q75	9.10, 14.80		10.99, 15.60		8.26, 18.94	
	Min, Max	5.8, 30.5		5.3, 22.2		4.6, 29.2	

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 inter puff interval (s) (average over visit)
Product Use Time Period: Period 2

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	9.31 (41.77)		12.27 (35.50)			
	95% CI of Geometric Mean	8.47, 10.25		10.73, 14.03			
	Mean (SD)		-19.99 (24.182)		3.27 (26.147)		
	95% CI		-26.80, -13.18		-7.29, 13.84		
	Median	8.92	-22.62	12.79	5.43		
	Q25, Q75	7.25, 12.46	-39.54, -3.11	10.94, 15.91	-10.77, 14.90		
	Min, Max	3.7, 21.8	-67.3, 40.2	4.9, 19.9	-43.5, 55.2		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	11.61 (37.18)		12.79 (30.64)		12.33 (56.86)	
	95% CI of Geometric Mean	10.49, 12.86		11.39, 14.37		10.12, 15.03	
	Median	10.84		13.11		11.97	
	Q25, Q75	9.05, 15.22		10.99, 15.60		8.26, 18.94	
	Min, Max	5.8, 30.5		5.3, 22.2		4.6, 29.2	

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 inter puff interval (s) (average over visit)
Product Use Time Period: Period 3

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	8.82 (46.98)		13.75 (40.94)			
	95% CI of Geometric Mean	7.88, 9.88		11.72, 16.12			
	Mean (SD)		-19.47 (27.802)		14.67 (41.037)		
	95% CI		-27.64, -11.30		-2.67, 32.00		
	Median	8.29	-22.86	14.31	-2.18		
	Q25, Q75	6.54, 12.14	-37.90, -6.16	11.36, 17.31	-10.27, 34.59		
	Min, Max	3.6, 27.1	-77.1, 58.0	6.0, 38.4	-35.9, 151.0		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	11.77 (37.66)		12.79 (30.64)		12.04 (55.98)	
	95% CI of Geometric Mean	10.58, 13.09		11.39, 14.37		9.87, 14.69	
	Median	10.98		13.11		11.53	
	Q25, Q75	9.10, 15.22		10.99, 15.60		8.26, 18.05	
	Min, Max	5.8, 30.5		5.3, 22.2		4.6, 29.2	

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 inter puff interval (s) (average over visit)
Product Use Time Period: Period 4

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	8.81 (48.13)		11.81 (41.18)			
	95% CI of Geometric Mean	7.85, 9.89		10.13, 13.78			
	Mean (SD)		-19.94 (30.459)		0.67 (25.229)		
	95% CI		-29.31, -10.56		-9.75, 11.09		
	Median	8.66	-24.81	12.34	-2.07		
	Q25, Q75	6.58, 12.18	-42.07, 1.52	8.90, 15.88	-21.22, 18.96		
	Min, Max	3.7, 25.9	-69.2, 55.4	3.9, 20.5	-61.4, 44.3		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	225.91 (29.31)		226.51 (25.74)		231.80 (21.73)	
	95% CI of Geometric Mean	208.55, 244.71		205.70, 249.42		214.24, 250.79	
	Median	230.04		222.11		233.47	
	Q25, Q75	182.85, 271.44		188.49, 251.67		198.15, 275.55	
	Min, Max	121.9, 420.7		142.2, 378.6		124.8, 321.4	

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 smoking duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	221.34 (28.05)		228.48 (24.21)			
	95% CI of Geometric Mean	207.48, 236.14		208.64, 250.19			
	Mean (SD)		6.22 (34.330)		2.32 (11.426)		
	95% CI		-3.54, 15.98		-2.12, 6.75		
	Median	234.34	1.74	229.23	2.34		
	Q25, Q75	175.38, 273.58	-18.63, 26.04	191.98, 260.78	-4.29, 11.53		
	Min, Max	121.1, 353.0	-48.3, 96.6	142.6, 390.4	-27.6, 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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	205.59 (35.66)		223.77 (29.68)			
	95% CI of Geometric Mean	189.65, 222.88		198.99, 251.64			
	Mean (SD)		-1.16 (35.204)		2.13 (18.280)		
	95% CI		-11.28, 8.95		-5.42, 9.68		
	Median	216.43	-0.99	223.39	-0.39		
	Q25, Q75	175.97, 257.85	-21.11, 14.33	184.81, 250.69	-5.57, 12.21		
	Min, Max	31.3, 328.4	-91.8, 105.5	135.6, 418.0	-26.8, 64.7		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	225.91 (29.31)		226.47 (26.23)		231.80 (21.73)	
	95% CI of Geometric Mean	208.55, 244.71		204.91, 250.30		214.24, 250.79	
	Median	230.04		221.90		233.47	
	Q25, Q75	182.85, 271.44		185.12, 252.12		198.15, 275.55	
	Min, Max	121.9, 420.7		142.2, 378.6		124.8, 321.4	

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 smoking duration (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	179.73 (38.72)		195.25 (33.48)			
	95% CI of Geometric Mean	164.51, 196.35		172.07, 221.56			
	Mean (SD)		-19.22 (28.919)		-7.98 (20.246)		
	95% CI		-27.35, -11.08		-16.16, 0.21		
	Median	172.27	-19.81	198.06	-9.09		
	Q25, Q75	138.78, 242.53	-44.56, -2.89	155.79, 246.61	-15.95, -0.62		
	Min, Max	66.2, 339.3	-56.8, 55.7	90.3, 419.1	-52.1, 39.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	223.17 (28.14)		226.47 (26.23)		233.01 (21.90)	
	95% CI of Geometric Mean	206.50, 241.18		204.91, 250.30		214.92, 252.62	
	Median	227.69		221.90		237.54	
	Q25, Q75	181.62, 267.39		185.12, 252.12		200.88, 275.55	
	Min, Max	121.9, 380.0		142.2, 378.6		124.8, 321.4	

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 smoking duration (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	187.49 (50.01)		196.66 (34.33)			
	95% CI of Geometric Mean	166.45, 211.18		171.86, 225.04			
	Mean (SD)		-5.91 (36.267)		-7.03 (20.482)		
	95% CI		-16.56, 4.75		-15.68, 1.62		
	Median	196.79	-8.04	196.32	-6.60		
	Q25, Q75	146.02, 253.73	-30.13, 22.30	151.18, 245.66	-23.74, 7.76		
	Min, Max	19.9, 340.6	-91.9, 93.9	115.5, 387.0	-41.5, 38.6		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	221.87 (28.18)		226.47 (26.23)		232.60 (22.27)	
	95% CI of Geometric Mean	204.75, 240.41		204.91, 250.30		213.92, 252.90	
	Median	226.38		221.90		233.47	
	Q25, Q75	180.79, 266.52		185.12, 252.12		200.88, 275.55	
	Min, Max	121.9, 380.0		142.2, 378.6		124.8, 321.4	

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 smoking duration (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	188.07 (46.37)		194.62 (32.04)			
	95% CI of Geometric Mean	168.29, 210.19		172.40, 219.70			
	Mean (SD)		-8.18 (35.671)		-8.44 (19.444)		
	95% CI		-19.17, 2.80		-16.48, -0.41		
	Median	180.79	-15.24	198.55	-9.84		
	Q25, Q75	146.29, 281.09	-35.38, 14.83	160.88, 236.14	-16.05, 2.50		
	Min, Max	39.3, 441.8	-55.3, 86.8	95.8, 396.2	-64.8, 33.2		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	2054.04 (70.94)		1996.54 (62.43)		2262.42 (71.09)	
	95% CI of Geometric Mean	1719.58, 2453.56		1605.12, 2483.41		1789.35, 2860.56	
	Median	1988.32		2322.90		2065.46	
	Q25, Q75	1257.61, 3605.36		1352.21, 3040.38		1414.52, 3968.35	
	Min, Max	582.0, 7633.1		502.9, 5116.6		636.9, 8825.1	

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 1

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	1563.90 (84.62)		1869.73 (63.45)			
	95% CI of Geometric Mean	1315.87, 1858.67		1498.66, 2332.68			
	Mean (SD)		-3.33 (47.636)		-6.03 (14.201)		
	95% CI		-16.87, 10.21		-11.54, -0.52		
	Median	1892.98	-9.58	2311.58	-8.15		
	Q25, Q75	1034.61, 2529.50	-43.95, 29.88	1193.64, 2966.37	-14.75, 0.98		
	Min, Max	103.4, 5304.3	-83.9, 110.3	514.2, 4323.6	-28.2, 45.0		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	1732.05 (74.81)		1725.91 (65.36)			
	95% CI of Geometric Mean	1482.54, 2023.55		1356.46, 2195.99			
	Mean (SD)		6.39 (52.529)		-8.32 (14.947)		
	95% CI		-8.70, 21.48		-14.49, -2.14		
	Median	1962.41	6.54	1888.62	-9.19		
	Q25, Q75	1311.04, 2575.85	-32.51, 35.34	1149.45, 2741.01	-16.74, -0.23		
	Min, Max	118.0, 7084.0	-97.7, 131.8	551.1, 4271.6	-37.9, 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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	2054.04 (70.94)		1966.63 (63.03)		2262.42 (71.09)	
	95% CI of Geometric Mean	1719.58, 2453.56		1571.57, 2461.01		1789.35, 2860.56	
	Median	1988.32		2316.87		2065.46	
	Q25, Q75	1257.61, 3605.36		1282.46, 3002.03		1414.52, 3968.35	
	Min, Max	582.0, 7633.1		502.9, 5116.6		636.9, 8825.1	

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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Study ID: ZRHM-REXA-07-JP

Program: t1502044201_ZRHM-REXA-07_JP_v1_PMI.sas

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	1996.98 (60.85)		1705.53 (63.24)			
	95% CI of Geometric Mean	1748.55, 2280.70		1362.04, 2135.65			
	Mean (SD)		12.50 (57.819)		-9.66 (23.289)		
	95% CI		-3.77, 28.76		-19.07, -0.25		
	Median	2084.87	3.75	1932.69	-12.35		
	Q25, Q75	1538.13, 2739.82	-33.17, 50.70	1139.60, 2497.36	-24.92, 2.50		
	Min, Max	352.4, 9522.0	-81.5, 161.6	446.2, 4817.2	-47.6, 62.5		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	2015.56 (69.79)		1966.63 (63.03)		2295.91 (71.85)	
	95% CI of Geometric Mean	1688.34, 2406.19		1571.57, 2461.01		1804.42, 2921.28	
	Median	1964.69		2316.87		2251.87	
	Q25, Q75	1205.25, 3544.54		1282.46, 3002.03		1414.52, 3968.35	
	Min, Max	582.0, 7633.1		502.9, 5116.6		636.9, 8825.1	

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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Study ID: ZRHM-REXA-07-JP

Program: t1502044201_ZRHM-REXA-07_JP_v1_PMI.sas

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	2323.62 (69.95)		1508.10 (68.17)			
	95% CI of Geometric Mean	1982.16, 2723.90		1175.07, 1935.50			
	Mean (SD)		32.44 (84.311)		-17.74 (19.535)		
	95% CI		7.68, 57.20		-26.00, -9.49		
	Median	2476.72	17.37	1618.27	-12.36		
	Q25, Q75	1731.30, 3358.06	-25.58, 67.95	934.31, 2541.69	-28.63, -3.71		
	Min, Max	407.4, 10737.4	-76.8, 281.0	439.9, 4646.5	-62.3, 9.4		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	1964.49 (68.30)		1966.63 (63.03)		2328.38 (72.77)	
	95% CI of Geometric Mean	1641.43, 2351.12		1571.57, 2461.01		1817.06, 2983.59	
	Median	1933.77		2316.87		2438.27	
	Q25, Q75	1257.61, 3329.01		1282.46, 3002.03		1414.52, 3968.35	
	Min, Max	582.0, 7633.1		502.9, 5116.6		636.9, 8825.1	

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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Study ID: ZRHM-REXA-07-JP

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	2328.53 (65.59)		1738.23 (60.37)			
	95% CI of Geometric Mean	2002.91, 2707.08		1400.37, 2157.60			
	Mean (SD)		33.68 (68.522)		-8.81 (19.540)		
	95% CI		12.59, 54.77		-16.88, -0.74		
	Median	2585.27	11.24	1763.80	-7.18		
	Q25, Q75	1937.53, 3377.04	-23.36, 74.71	1135.71, 2565.24	-23.20, 4.56		
	Min, Max	446.3, 6864.6	-47.3, 222.2	578.6, 5547.3	-51.5, 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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	119.43 (69.53)		125.99 (54.89)		139.66 (54.94)	
	95% CI of Geometric Mean	100.27, 142.25		103.64, 153.15		115.67, 168.61	
	Median	117.85		130.14		146.00	
	Q25, Q75	80.05, 202.56		94.23, 169.37		108.88, 183.10	
	Min, Max	31.6, 366.4		37.2, 382.1		42.6, 330.9	

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 Work (mJ) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	89.06 (92.27)		118.36 (55.50)			
	95% CI of Geometric Mean	74.06, 107.10		97.18, 144.14			
	Mean (SD)		-10.81 (38.310)		-5.77 (10.592)		
	95% CI		-21.70, 0.08		-9.88, -1.66		
	Median	107.63	-13.46	121.93	-7.96		
	Q25, Q75	55.48, 142.23	-36.43, 2.40	86.68, 168.56	-13.92, 1.48		
	Min, Max	8.2, 350.7	-78.2, 108.4	30.7, 323.9	-21.8, 20.7		

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 (IDay 1 – Day 6 confinement), Period 2 (IDay 6 ambulatory – Day 30 Visit), Period 3 (IDay 30 Visit – Day 60 Visit) and Period 4 (IDay 60 Visit – Day 90 Visit).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	101.30 (77.09)		111.78 (58.47)			
	95% CI of Geometric Mean	86.38, 118.81		89.79, 139.16			
	Mean (SD)		1.93 (45.447)		-8.81 (12.751)		
	95% CI		-11.13, 14.98		-14.08, -3.54		
	Median	109.09	3.93	103.70	-10.92		
	Q25, Q75	78.17, 157.96	-23.84, 24.74	82.56, 155.91	-19.18, 2.71		
	Min, Max	9.4, 343.0	-85.4, 152.7	34.0, 355.4	-30.3, 19.8		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	119.43 (69.53)		125.12 (55.87)		139.66 (54.94)	
	95% CI of Geometric Mean	100.27, 142.25		102.22, 153.15		115.67, 168.61	
	Median	117.85		126.73		146.00	
	Q25, Q75	80.05, 202.56		94.21, 177.29		108.88, 183.10	
	Min, Max	31.6, 366.4		37.2, 382.1		42.6, 330.9	

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 Work (mJ) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	124.96 (71.82)		121.78 (56.63)			
	95% CI of Geometric Mean	107.26, 145.57		99.26, 149.42			
	Mean (SD)		19.82 (60.294)		0.41 (23.384)		
	95% CI		2.85, 36.78		-9.04, 9.86		
	Median	126.84	8.75	127.10	0.87		
	Q25, Q75	89.11, 183.86	-27.03, 46.39	89.55, 174.08	-11.88, 11.06		
	Min, Max	15.5, 493.4	-62.4, 234.6	38.0, 336.7	-37.9, 75.9		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	118.50 (70.02)		125.12 (55.87)		139.93 (56.00)	
	95% CI of Geometric Mean	99.20, 141.54		102.22, 153.15		115.14, 170.07	
	Median	114.40		126.73		150.04	
	Q25, Q75	77.43, 211.44		94.21, 177.29		108.88, 183.10	
	Min, Max	31.6, 366.4		37.2, 382.1		42.6, 330.9	

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 Work (mJ) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	134.37 (66.30)		114.53 (60.20)			
	95% CI of Geometric Mean	115.41, 156.43		91.48, 143.38			
	Mean (SD)		16.58 (58.528)		-6.26 (17.445)		
	95% CI		-0.61, 33.77		-13.63, 1.11		
	Median	141.75	0.79	115.54	-9.53		
	Q25, Q75	94.65, 200.03	-23.16, 37.44	72.55, 156.87	-16.87, 9.26		
	Min, Max	20.9, 615.2	-58.1, 206.9	37.3, 344.4	-37.8, 22.9		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	117.82 (70.16)		125.12 (55.87)		139.27 (57.05)	
	95% CI of Geometric Mean	98.04, 141.58		102.22, 153.15		113.80, 170.44	
	Median	113.93		126.73		146.00	
	Q25, Q75	80.05, 202.56		94.21, 177.29		108.88, 183.10	
	Min, Max	31.6, 366.4		37.2, 382.1		42.6, 330.9	

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 Work (mJ) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	132.76 (77.00)		121.52 (52.23)			
	95% CI of Geometric Mean	111.80, 157.66		100.45, 147.02			
	Mean (SD)		22.80 (50.983)		1.40 (24.183)		
	95% CI		7.11, 38.50		-8.59, 11.39		
	Median	149.80	18.59	132.68	-1.12		
	Q25, Q75	86.88, 211.07	-17.50, 48.57	79.72, 168.53	-16.33, 17.64		
	Min, Max	12.4, 361.3	-51.1, 173.0	54.7, 277.4	-35.0, 63.4		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	211.15 (35.42)		217.68 (30.95)		225.47 (38.43)	
	95% CI of Geometric Mean	191.87, 232.36		194.03, 244.23		196.76, 258.35	
	Median	219.44		217.94		238.03	
	Q25, Q75	176.82, 259.48		178.62, 276.75		191.61, 288.93	
	Min, Max	91.8, 434.9		114.9, 404.7		98.1, 430.0	

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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Program: t1502044201_ZRHM-REXA-07_JP_v1_PMI.sas

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	224.68 (42.95)		210.74 (32.41)			
	95% CI of Geometric Mean	203.97, 247.50		186.86, 237.66			
	Mean (SD)		9.93 (26.130)		-3.19 (8.094)		
	95% CI		2.50, 17.36		-6.33, -0.04		
	Median	241.81	11.65	211.86	-3.84		
	Q25, Q75	174.95, 295.97	-2.37, 22.41	162.08, 266.69	-8.52, 1.31		
	Min, Max	84.0, 499.1	-48.2, 110.8	100.8, 354.8	-16.3, 16.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	229.35 (41.93)		206.12 (32.49)			
	95% CI of Geometric Mean	208.79, 251.93		181.36, 234.26			
	Mean (SD)		9.89 (22.475)		-4.16 (8.415)		
	95% CI		3.43, 16.35		-7.63, -0.68		
	Median	234.16	11.43	197.49	-1.81		
	Q25, Q75	176.08, 279.80	-6.16, 21.99	165.13, 260.59	-9.95, 2.69		
	Min, Max	83.3, 536.2	-32.9, 84.2	116.1, 348.6	-23.3, 8.5		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	211.15 (35.42)		217.51 (31.54)		225.47 (38.43)	
	95% CI of Geometric Mean	191.87, 232.36		193.03, 245.10		196.76, 258.35	
	Median	219.44		217.16		238.03	
	Q25, Q75	176.82, 259.48		172.87, 282.24		191.61, 288.93	
	Min, Max	91.8, 434.9		114.9, 404.7		98.1, 430.0	

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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Study ID: ZRHM-REXA-07-JP

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	283.22 (40.63)		217.21 (31.13)			
	95% CI of Geometric Mean	258.19, 310.67		193.04, 244.40			
	Mean (SD)		38.47 (44.013)		1.08 (12.929)		
	95% CI		26.09, 50.86		-4.15, 6.30		
	Median	286.53	25.30	234.74	1.04		
	Q25, Q75	226.60, 381.77	5.29, 66.88	167.32, 274.58	-9.83, 9.66		
	Min, Max	112.1, 553.8	-37.2, 176.1	122.2, 352.4	-22.4, 30.9		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	210.55 (35.73)		217.51 (31.54)		225.12 (39.13)	
	95% CI of Geometric Mean	190.99, 232.11		193.03, 245.10		195.53, 259.19	
	Median	218.22		217.16		241.94	
	Q25, Q75	176.47, 261.40		172.87, 282.24		191.61, 288.93	
	Min, Max	91.8, 434.9		114.9, 404.7		98.1, 430.0	

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 3

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	294.70 (40.20)		215.99 (32.69)			
	95% CI of Geometric Mean	267.32, 324.87		189.90, 245.66			
	Mean (SD)		36.33 (40.827)		0.13 (12.330)		
	95% CI		24.34, 48.32		-5.08, 5.34		
	Median	307.40	22.15	233.66	0.32		
	Q25, Q75	227.71, 373.03	7.54, 65.50	166.60, 259.52	-8.65, 10.55		
	Min, Max	104.0, 640.3	-32.2, 125.4	115.2, 409.9	-25.1, 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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	208.31 (35.92)		217.51 (31.54)		223.08 (39.50)	
	95% CI of Geometric Mean	188.27, 230.48		193.03, 245.10		193.00, 257.84	
	Median	217.36		217.16		238.03	
	Q25, Q75	174.42, 259.48		172.87, 282.24		191.61, 287.42	
	Min, Max	91.8, 434.9		114.9, 404.7		98.1, 430.0	

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 4

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	312.11 (42.29)		208.67 (31.25)			
	95% CI of Geometric Mean	281.80, 345.68		185.38, 234.89			
	Mean (SD)		50.74 (49.795)		-0.70 (12.595)		
	95% CI		35.41, 66.07		-5.91, 4.50		
	Median	316.46	31.56	210.72	-1.99		
	Q25, Q75	255.02, 405.98	15.03, 86.04	166.49, 260.92	-6.23, 8.20		
	Min, Max	105.1, 704.2	-29.3, 195.9	125.3, 367.1	-21.4, 25.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	352.01 (38.08)		357.11 (34.84)		367.26 (41.36)	
	95% CI of Geometric Mean	317.73, 389.99		313.98, 406.18		317.44, 424.89	
	Median	364.83		365.82		385.26	
	Q25, Q75	270.19, 462.56		282.70, 462.23		312.02, 445.64	
	Min, Max	126.1, 690.7		164.4, 640.9		138.9, 822.6	

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 Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	359.78 (44.44)		343.42 (37.05)			
	95% CI of Geometric Mean	325.62, 397.52		299.62, 393.62			
	Mean (SD)		7.26 (24.535)		-4.27 (8.784)		
	95% CI		0.28, 14.23		-7.68, -0.86		
	Median	398.91	5.26	353.68	-6.33		
	Q25, Q75	279.46, 491.69	-7.41, 23.39	258.44, 443.13	-11.06, 2.71		
	Min, Max	129.2, 756.8	-57.7, 96.5	147.5, 615.6	-15.6, 17.0		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	363.17 (42.21)		329.94 (36.31)			
	95% CI of Geometric Mean	330.43, 399.16		286.23, 380.33			
	Mean (SD)		7.40 (23.058)		-7.18 (8.301)		
	95% CI		0.77, 14.03		-10.62, -3.75		
	Median	366.77	9.38	335.20	-6.65		
	Q25, Q75	278.29, 486.34	-8.45, 22.08	260.15, 428.74	-14.35, -0.59		
	Min, Max	126.4, 955.1	-43.3, 77.8	169.5, 626.7	-21.6, 5.4		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	352.01 (38.08)		356.29 (35.49)		367.26 (41.36)	
	95% CI of Geometric Mean	317.73, 389.99		311.75, 407.19		317.44, 424.89	
	Median	364.83		362.87		385.26	
	Q25, Q75	270.19, 462.56		278.46, 464.59		312.02, 445.64	
	Min, Max	126.1, 690.7		164.4, 640.9		138.9, 822.6	

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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Study ID: ZRHM-REXA-07-JP

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	438.98 (44.94)		353.51 (35.76)			
	95% CI of Geometric Mean	396.60, 485.89		309.02, 404.41			
	Mean (SD)		30.66 (41.001)		-0.26 (13.002)		
	95% CI		19.12, 42.19		-5.51, 5.00		
	Median	474.29	24.07	389.41	0.51		
	Q25, Q75	358.50, 556.67	4.95, 54.81	291.09, 468.31	-8.25, 11.33		
	Min, Max	133.0, 928.2	-65.8, 124.5	177.7, 617.5	-31.7, 23.0		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	351.85 (38.49)		356.29 (35.49)		368.03 (42.11)	
	95% CI of Geometric Mean	316.93, 390.62		311.75, 407.19		316.50, 427.96	
	Median	368.45		362.87		389.17	
	Q25, Q75	264.04, 462.59		278.46, 464.59		312.02, 445.64	
	Min, Max	126.1, 690.7		164.4, 640.9		138.9, 822.6	

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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Study ID: ZRHM-REXA-07-JP

Program: t1502044201_ZRHM-REXA-07_JP_v1_PMI.sas

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	468.26 (42.15)		351.32 (39.35)			
	95% CI of Geometric Mean	422.92, 518.47		301.39, 409.51			
	Mean (SD)		30.50 (40.391)		-0.88 (13.365)		
	95% CI		18.63, 42.36		-6.53, 4.77		
	Median	504.68	20.47	372.84	-3.18		
	Q25, Q75	388.61, 614.84	5.92, 54.43	276.63, 458.95	-9.40, 7.69		
	Min, Max	153.6, 899.4	-49.4, 116.1	164.1, 758.3	-23.1, 25.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	350.39 (39.07)		356.29 (35.49)		366.32 (42.82)	
	95% CI of Geometric Mean	314.06, 390.92		311.75, 407.19		313.38, 428.20	
	Median	364.83		362.87		385.26	
	Q25, Q75	270.19, 462.56		278.46, 464.59		312.02, 445.64	
	Min, Max	126.1, 690.7		164.4, 640.9		138.9, 822.6	

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 Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	492.62 (41.73)		338.91 (35.07)			
	95% CI of Geometric Mean	445.34, 544.92		296.99, 386.75			
	Mean (SD)		44.25 (42.381)		-1.85 (12.045)		
	95% CI		31.20, 57.30		-6.82, 3.13		
	Median	504.82	34.13	352.11	-0.76		
	Q25, Q75	424.11, 620.10	17.42, 76.67	264.32, 452.05	-7.64, 7.02		
	Min, Max	157.8, 889.8	-48.0, 174.3	170.3, 607.3	-24.3, 15.9		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	3.74 (48.71)		3.55 (38.91)		3.84 (66.62)	
	95% CI of Geometric Mean	3.28, 4.26		3.07, 4.10		3.07, 4.79	
	Median	3.64		3.81		3.21	
	Q25, Q75	2.85, 4.97		2.78, 4.46		2.30, 7.06	
	Min, Max	1.1, 10.3		1.7, 8.1		1.2, 15.8	

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: Smoking Intensity (mL/s) (average over visit)
Product Use Time Period: Period 1

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	2.98 (63.44)		3.45 (39.93)			
	95% CI of Geometric Mean	2.59, 3.42		2.98, 4.00			
	Mean (SD)		-8.35 (38.547)		-1.42 (23.227)		
	95% CI		-19.31, 2.61		-10.43, 7.59		
	Median	3.26	-11.50	3.49	-6.66		
	Q25, Q75	2.14, 4.70	-31.23, 13.21	2.65, 4.26	-15.78, 5.52		
	Min, Max	0.7, 7.8	-73.4, 124.5	1.6, 9.2	-27.8, 79.1		

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 (IDay 1 – Day 6 confinement), Period 2 (IDay 6 ambulatory – Day 30 Visit), Period 3 (IDay 30 Visit – Day 60 Visit) and Period 4 (IDay 60 Visit – Day 90 Visit).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	3.35 (64.99)		3.35 (50.83)			
	95% CI of Geometric Mean	2.92, 3.86		2.75, 4.07			
	Mean (SD)		3.62 (41.857)		0.19 (24.792)		
	95% CI		-8.41, 15.65		-10.04, 10.43		
	Median	4.00	2.70	3.26	1.92		
	Q25, Q75	2.39, 4.79	-28.48, 26.07	2.56, 4.42	-16.89, 14.52		
	Min, Max	0.5, 14.6	-82.3, 123.1	1.3, 13.4	-53.8, 65.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	3.74 (48.71)		3.48 (38.15)		3.84 (66.62)	
	95% CI of Geometric Mean	3.28, 4.26		3.01, 4.02		3.07, 4.79	
	Median	3.64		3.59		3.21	
	Q25, Q75	2.85, 4.97		2.73, 4.43		2.30, 7.06	
	Min, Max	1.1, 10.3		1.7, 8.1		1.2, 15.8	

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: Smoking Intensity (mL/s) (average over visit)
Product Use Time Period: Period 2

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	3.59 (58.17)		3.56 (47.74)			
	95% CI of Geometric Mean	3.16, 4.09		2.98, 4.25			
	Mean (SD)		14.34 (58.099)		4.34 (33.668)		
	95% CI		-2.00, 30.69		-9.27, 17.94		
	Median	3.76	-1.82	3.54	2.95		
	Q25, Q75	2.66, 5.37	-28.64, 34.08	2.61, 4.57	-20.20, 13.99		
	Min, Max	0.7, 13.3	-66.7, 153.6	1.3, 9.6	-43.1, 123.0		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	3.72 (49.05)		3.48 (38.15)		3.87 (67.73)	
	95% CI of Geometric Mean	3.26, 4.24		3.01, 4.02		3.07, 4.87	
	Median	3.63		3.59		3.35	
	Q25, Q75	2.81, 4.99		2.73, 4.43		2.30, 7.06	
	Min, Max	1.1, 10.3		1.7, 8.1		1.2, 15.8	

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: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	3.79 (57.89)		3.10 (41.78)			
	95% CI of Geometric Mean	3.30, 4.34		2.64, 3.66			
	Mean (SD)		12.58 (58.314)		-8.20 (23.783)		
	95% CI		-4.54, 29.71		-18.24, 1.85		
	Median	3.82	4.05	3.03	-9.05		
	Q25, Q75	2.50, 5.65	-28.90, 33.88	2.25, 4.31	-27.61, 8.96		
	Min, Max	1.2, 13.7	-64.8, 203.9	1.6, 7.0	-45.7, 41.5		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	3.67 (49.55)		3.48 (38.15)		3.95 (67.81)	
	95% CI of Geometric Mean	3.20, 4.21		3.01, 4.02		3.12, 4.99	
	Median	3.57		3.59		3.48	
	Q25, Q75	2.79, 4.90		2.73, 4.43		2.38, 7.06	
	Min, Max	1.1, 10.3		1.7, 8.1		1.2, 15.8	

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: Smoking Intensity (mL/s) (average over visit)
Product Use Time Period: Period 4

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	3.58 (69.31)		3.74 (51.34)			
	95% CI of Geometric Mean	3.05, 4.20		3.10, 4.52			
	Mean (SD)		17.51 (78.099)		7.30 (38.128)		
	95% CI		-6.53, 41.55		-8.45, 23.04		
	Median	3.73	-1.95	3.64	2.51		
	Q25, Q75	2.16, 5.56	-29.87, 34.01	2.59, 4.81	-20.67, 17.67		
	Min, Max	1.2, 12.5	-64.5, 308.1	1.7, 13.3	-30.6, 149.7		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	12.19 (44.54)		11.72 (38.86)		11.91 (58.59)	
	95% CI of Geometric Mean	10.83, 13.73		10.15, 13.52		9.76, 14.54	
	Median	13.66		11.97		12.95	
	Q25, Q75	8.99, 17.16		9.58, 14.10		7.77, 20.38	
	Min, Max	4.5, 25.2		4.0, 31.7		4.4, 27.6	

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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Study ID: ZRHM-REXA-07-JP

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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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	14.01 (49.42)		11.98 (38.19)			
	95% CI of Geometric Mean	12.55, 15.64		10.40, 13.78			
	Mean (SD)		23.30 (40.975)		3.61 (26.200)		
	95% CI		11.65, 34.95		-6.56, 13.77		
	Median	15.12	21.26	11.90	-3.38		
	Q25, Q75	9.64, 19.93	-6.35, 46.34	9.80, 14.52	-10.41, 9.47		
	Min, Max	4.8, 31.9	-35.4, 183.6	5.0, 34.6	-26.1, 82.7		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	14.44 (53.29)		11.62 (47.16)			
	95% CI of Geometric Mean	12.85, 16.23		9.69, 13.93			
	Mean (SD)		30.79 (39.332)		4.68 (28.226)		
	95% CI		19.49, 42.09		-6.98, 16.33		
	Median	15.41	24.60	11.18	-0.02		
	Q25, Q75	10.39, 21.88	2.87, 53.52	9.72, 14.68	-10.05, 20.45		
	Min, Max	3.2, 29.9	-43.7, 172.9	3.5, 47.0	-56.3, 70.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	12.19 (44.54)		11.50 (38.06)		11.91 (58.59)	
	95% CI of Geometric Mean	10.83, 13.73		9.97, 13.27		9.76, 14.54	
	Median	13.66		11.40		12.95	
	Q25, Q75	8.99, 17.16		9.45, 14.07		7.77, 20.38	
	Min, Max	4.5, 25.2		4.0, 31.7		4.4, 27.6	

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: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	14.68 (57.02)		11.95 (40.97)			
	95% CI of Geometric Mean	12.94, 16.65		10.26, 13.93			
	Mean (SD)		41.39 (66.319)		6.15 (41.235)		
	95% CI		22.73, 60.05		-10.51, 22.81		
	Median	15.92	23.34	12.42	0.91		
	Q25, Q75	9.94, 23.62	4.84, 62.04	9.37, 15.50	-15.44, 20.52		
	Min, Max	4.3, 47.2	-47.0, 354.1	6.0, 33.4	-52.2, 165.4		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	12.16 (44.98)		11.50 (38.06)		11.96 (59.69)	
	95% CI of Geometric Mean	10.77, 13.73		9.97, 13.27		9.73, 14.70	
	Median	13.43		11.40		13.37	
	Q25, Q75	8.93, 17.85		9.45, 14.07		7.77, 20.38	
	Min, Max	4.5, 25.2		4.0, 31.7		4.4, 27.6	

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: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	16.43 (58.11)		10.63 (36.28)			
	95% CI of Geometric Mean	14.34, 18.83		9.21, 12.25			
	Mean (SD)		44.79 (56.599)		-5.50 (25.868)		
	95% CI		28.16, 61.41		-16.43, 5.42		
	Median	18.49	41.75	10.90	0.64		
	Q25, Q75	10.95, 25.01	12.54, 67.39	8.50, 13.90	-31.10, 9.22		
	Min, Max	4.8, 42.8	-36.6, 304.1	4.9, 19.4	-44.0, 55.4		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	12.21 (45.88)		11.50 (38.06)		12.19 (59.62)	
	95% CI of Geometric Mean	10.75, 13.87		9.97, 13.27		9.88, 15.04	
	Median	13.71		11.40		13.79	
	Q25, Q75	8.99, 17.92		9.45, 14.07		7.92, 20.38	
	Min, Max	4.5, 25.2		4.0, 31.7		4.4, 27.6	

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: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	15.33 (64.31)		12.25 (44.02)			
	95% CI of Geometric Mean	13.21, 17.78		10.40, 14.43			
	Mean (SD)		55.13 (79.031)		8.45 (44.033)		
	95% CI		30.80, 79.46		-9.73, 26.63		
	Median	17.35	34.15	11.17	4.40		
	Q25, Q75	10.76, 23.85	18.11, 75.15	9.81, 15.90	-18.23, 19.34		
	Min, Max	2.8, 43.0	-49.6, 316.4	5.1, 46.5	-37.0, 186.1		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		29		31	
	Missing, n(%)	24 (31.6)		13 (31.0)		8 (20.5)	
	Geometric Mean (CV%)	4.70 (33.41)		4.36 (25.21)		4.37 (45.91)	
	95% CI of Geometric Mean	4.29, 5.15		3.96, 4.79		3.72, 5.14	
	Median	5.03		4.39		4.58	
	Q25, Q75	3.92, 5.83		3.39, 5.02		2.95, 6.13	
	Min, Max	1.9, 8.7		2.7, 8.0		2.0, 9.6	

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: Puff Frequency (puffs/min) (average over visit)
Product Use Time Period: Period 1

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	72	50	29	28		
	Missing, n(%)	4 (5.3)	26 (34.2)	13 (31.0)	14 (33.3)		
	Geometric Mean (CV%)	5.05 (38.98)		4.34 (30.12)			
	95% CI of Geometric Mean	4.62, 5.52		3.88, 4.86			
	Mean (SD)		8.02 (22.486)		-0.07 (18.314)		
	95% CI		1.63, 14.42		-7.18, 7.03		
	Median	5.20	8.36	4.45	-3.50		
	Q25, Q75	3.75, 6.85	-5.17, 15.52	3.61, 5.34	-10.48, 3.15		
	Min, Max	2.3, 10.0	-31.1, 92.4	2.5, 9.6	-23.8, 56.9		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	73	49	26	25		
	Missing, n(%)	3 (3.9)	27 (35.5)	16 (38.1)	17 (40.5)		
	Geometric Mean (CV%)	5.19 (36.27)		4.32 (32.55)			
	95% CI of Geometric Mean	4.77, 5.64		3.80, 4.92			
	Mean (SD)		12.32 (27.318)		2.70 (20.926)		
	95% CI		4.47, 20.17		-5.94, 11.34		
	Median	5.60	4.70	4.46	2.08		
	Q25, Q75	4.01, 6.58	-4.92, 24.72	3.70, 5.02	-11.56, 12.96		
	Min, Max	2.2, 10.3	-32.8, 89.0	2.4, 11.4	-35.2, 47.5		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	52		28		31	
	Missing, n(%)	22 (29.7)		13 (31.7)		8 (20.5)	
	Geometric Mean (CV%)	4.70 (33.41)		4.30 (24.74)		4.37 (45.91)	
	95% CI of Geometric Mean	4.29, 5.15		3.91, 4.73		3.72, 5.14	
	Median	5.03		4.29		4.58	
	Q25, Q75	3.92, 5.83		3.39, 4.98		2.95, 6.13	
	Min, Max	1.9, 8.7		2.7, 8.0		2.0, 9.6	

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: Puff Frequency (puffs/min) (average over visit)
Product Use Time Period: Period 2

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	71	51	28	26		
	Missing, n(%)	3 (4.1)	23 (31.1)	13 (31.7)	15 (36.6)		
	Geometric Mean (CV%)	5.51 (35.41)		4.48 (30.18)			
	95% CI of Geometric Mean	5.07, 5.98		3.99, 5.03			
	Mean (SD)		24.58 (34.349)		4.63 (33.032)		
	95% CI		14.92, 34.25		-8.72, 17.98		
	Median	5.64	19.04	4.40	-4.06		
	Q25, Q75	4.15, 6.87	-1.05, 42.26	3.63, 5.21	-13.61, 9.83		
	Min, Max	2.5, 14.3	-29.5, 126.5	2.8, 9.2	-30.4, 135.8		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	51		28		30	
	Missing, n(%)	20 (28.2)		13 (31.7)		8 (21.1)	
	Geometric Mean (CV%)	4.71 (33.74)		4.30 (24.74)		4.41 (46.53)	
	95% CI of Geometric Mean	4.29, 5.17		3.91, 4.73		3.73, 5.20	
	Median	5.05		4.29		4.76	
	Q25, Q75	3.92, 5.88		3.39, 4.98		2.95, 6.13	
	Min, Max	1.9, 8.7		2.7, 8.0		2.0, 9.6	

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: Puff Frequency (puffs/min) (average over visit)
Product Use Time Period: Period 3

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	63	47	26	24		
	Missing, n(%)	8 (11.3)	24 (33.8)	15 (36.6)	17 (41.5)		
	Geometric Mean (CV%)	5.65 (38.25)		4.15 (31.84)			
	95% CI of Geometric Mean	5.15, 6.21		3.66, 4.71			
	Mean (SD)		26.28 (43.985)		-1.85 (23.791)		
	95% CI		13.36, 39.19		-11.90, 8.20		
	Median	5.94	18.48	4.01	0.85		
	Q25, Q75	4.49, 7.01	2.28, 43.83	3.55, 4.90	-20.05, 13.50		
	Min, Max	2.2, 13.4	-38.5, 229.5	2.0, 8.3	-43.1, 45.8		

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]).

**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=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	48		28		29	
	Missing, n(%)	22 (31.4)		13 (31.7)		8 (21.6)	
	Geometric Mean (CV%)	4.63 (33.95)		4.30 (24.74)		4.49 (46.06)	
	95% CI of Geometric Mean	4.21, 5.11		3.91, 4.73		3.79, 5.31	
	Median	4.91		4.29		4.95	
	Q25, Q75	3.86, 5.79		3.39, 4.98		3.03, 6.13	
	Min, Max	1.9, 8.7		2.7, 8.0		2.0, 9.6	

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: Puff Frequency (puffs/min) (average over visit)
Product Use Time Period: Period 4

Time Point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	63	43	28	25		
	Missing, n(%)	7 (10.0)	27 (38.6)	13 (31.7)	16 (39.0)		
	Geometric Mean (CV%)	5.73 (42.11)		4.57 (33.64)			
	95% CI of Geometric Mean	5.17, 6.34		4.02, 5.19			
	Mean (SD)		29.77 (47.860)		6.02 (39.488)		
	95% CI		15.04, 44.51		-10.29, 22.32		
	Median	5.90	19.65	4.33	-0.21		
	Q25, Q75	4.35, 7.42	0.14, 56.82	3.43, 5.88	-13.82, 11.85		
	Min, Max	2.2, 15.5	-35.5, 204.1	2.7, 8.8	-28.9, 176.5		

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]).

**Table 15.2.4.43 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 Difference
Day 1	n	50	28	
	LS Mean	19.05	18.17	0.87
	95% CI	17.55, 20.55	16.21, 20.14	-1.52, 3.26
Day 4	n	49	25	
	LS Mean	17.61	17.17	0.43
	95% CI	16.31, 18.90	15.39, 18.95	-1.70, 2.57
Day 30	n	51	26	
	LS Mean	16.55	15.55	1.00
	95% CI	15.58, 17.51	14.23, 16.87	-0.61, 2.60
Day 60	n	47	24	
	LS Mean	18.46	14.97	3.49
	95% CI	16.92, 20.00	12.86, 17.09	0.92, 6.05
Day 90	n	43	25	
	LS Mean	18.57	15.37	3.19
	95% CI	16.88, 20.25	13.17, 17.57	0.49, 5.89

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-07-JP

Program: t15020443-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.43 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 Difference
Day 1	n	50	28	
	LS Mean	723.39	839.26	-115.87
	95% CI	649.85, 796.93	741.55, 936.97	-233.83, 2.09
Day 4	n	49	25	
	LS Mean	758.25	794.07	-35.82
	95% CI	677.05, 839.45	680.86, 907.27	-170.54, 98.90
Day 30	n	51	26	
	LS Mean	648.78	747.60	-98.82
	95% CI	578.43, 719.14	649.47, 845.73	-216.72, 19.09
Day 60	n	47	24	
	LS Mean	757.33	670.68	86.65
	95% CI	674.08, 840.59	552.99, 788.37	-53.83, 227.13
Day 90	n	43	25	
	LS Mean	729.85	753.32	-23.47
	95% CI	657.19, 802.51	656.30, 850.34	-141.54, 94.61

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-07-JP

Program: t15020443-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.43 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 Difference
Day 1	n	50	28	
	LS Mean	41.27	49.58	-8.32
	95% CI	37.79, 44.75	44.99, 54.18	-13.84, -2.79
Day 4	n	49	25	
	LS Mean	45.42	48.47	-3.05
	95% CI	41.52, 49.32	43.09, 53.86	-9.45, 3.35
Day 30	n	51	26	
	LS Mean	42.84	50.12	-7.28
	95% CI	39.33, 46.34	45.28, 54.96	-13.09, -1.47
Day 60	n	47	24	
	LS Mean	43.37	48.20	-4.83
	95% CI	39.76, 46.98	43.14, 53.26	-10.83, 1.17
Day 90	n	43	25	
	LS Mean	41.49	51.17	-9.67
	95% CI	37.66, 45.33	46.04, 56.30	-15.87, -3.48

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-07-JP

Program: t15020443-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.43 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 Difference
Day 1	n	50	28	
	LS Mean	1.89	1.69	0.19
	95% CI	1.77, 2.01	1.54, 1.85	0.01, 0.38
Day 4	n	49	25	
	LS Mean	1.94	1.64	0.30
	95% CI	1.83, 2.05	1.50, 1.78	0.13, 0.47
Day 30	n	51	26	
	LS Mean	1.82	1.61	0.21
	95% CI	1.68, 1.96	1.42, 1.81	-0.02, 0.44
Day 60	n	47	24	
	LS Mean	1.88	1.54	0.34
	95% CI	1.75, 2.01	1.36, 1.73	0.12, 0.56
Day 90	n	43	25	
	LS Mean	1.90	1.64	0.26
	95% CI	1.72, 2.08	1.40, 1.87	-0.02, 0.54

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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Study ID:ZRHM-REXA-07-JP

Program: t15020443-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.43 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 Difference
Day 1	n	50	28	
	LS Mean	33.40	29.34	4.06
	95% CI	30.42, 36.37	25.40, 33.28	-0.71, 8.82
Day 4	n	49	25	
	LS Mean	32.45	27.53	4.92
	95% CI	29.64, 35.25	23.64, 31.42	0.29, 9.55
Day 30	n	51	26	
	LS Mean	27.35	24.99	2.37
	95% CI	24.88, 29.82	21.55, 28.42	-1.76, 6.49
Day 60	n	47	24	
	LS Mean	32.86	21.87	10.99
	95% CI	29.62, 36.09	17.32, 26.41	5.56, 16.42
Day 90	n	43	25	
	LS Mean	34.06	23.94	10.12
	95% CI	29.85, 38.27	18.34, 29.54	3.31, 16.92

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 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 Difference
Day 1	n	50	28	
	LS Mean	24.20	31.24	-7.04
	95% CI	22.73, 25.67	29.30, 33.18	-9.39, -4.70
Day 4	n	49	25	
	LS Mean	25.39	31.08	-5.69
	95% CI	23.46, 27.32	28.41, 33.75	-8.88, -2.51
Day 30	n	51	26	
	LS Mean	26.31	32.73	-6.41
	95% CI	24.47, 28.16	30.17, 35.29	-9.49, -3.34
Day 60	n	47	24	
	LS Mean	25.34	33.34	-8.00
	95% CI	23.33, 27.36	30.52, 36.16	-11.36, -4.64
Day 90	n	43	25	
	LS Mean	25.35	33.82	-8.46
	95% CI	23.20, 27.51	30.95, 36.68	-11.94, -4.98

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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Study ID: ZRHM-REXA-07-JP

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**Table 15.2.4.43 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 Difference
Day 1	n	50	28	
	LS Mean	37.09	47.81	-10.71
	95% CI	34.75, 39.43	44.71, 50.90	-14.45, -6.98
Day 4	n	49	25	
	LS Mean	39.04	46.84	-7.80
	95% CI	36.10, 41.98	42.76, 50.92	-12.66, -2.95
Day 30	n	51	26	
	LS Mean	39.34	50.22	-10.87
	95% CI	36.43, 42.26	46.17, 54.27	-15.74, -6.01
Day 60	n	47	24	
	LS Mean	37.96	51.07	-13.11
	95% CI	34.54, 41.38	46.26, 55.88	-18.83, -7.39
Day 90	n	43	25	
	LS Mean	38.36	51.45	-13.09
	95% CI	34.80, 41.92	46.70, 56.20	-18.85, -7.32

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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Study ID: ZRHM-REXA-07-JP

Program: t15020443-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.43 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 Difference
Day 1	n	50	28	
	LS Mean	201.17	207.04	-5.87
	95% CI	186.48, 215.86	187.44, 226.64	-29.29, 17.55
Day 4	n	49	25	
	LS Mean	181.64	206.20	-24.56
	95% CI	163.11, 200.17	180.46, 231.94	-54.93, 5.82
Day 30	n	51	26	
	LS Mean	155.95	189.30	-33.35
	95% CI	139.69, 172.21	166.82, 211.77	-60.16, -6.53
Day 60	n	47	24	
	LS Mean	173.43	194.73	-21.30
	95% CI	153.99, 192.87	167.50, 221.96	-53.38, 10.77
Day 90	n	43	25	
	LS Mean	168.55	181.05	-12.50
	95% CI	147.79, 189.31	153.70, 208.40	-45.24, 20.24

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 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 Difference
Day 1	n	50	28	
	LS Mean	11.58	12.64	-1.07
	95% CI	10.69, 12.46	11.46, 13.82	-2.49, 0.36
Day 4	n	49	25	
	LS Mean	10.82	12.73	-1.91
	95% CI	9.85, 11.78	11.37, 14.08	-3.51, -0.31
Day 30	n	51	26	
	LS Mean	9.70	12.96	-3.26
	95% CI	8.79, 10.61	11.69, 14.23	-4.79, -1.74
Day 60	n	47	24	
	LS Mean	9.84	14.74	-4.90
	95% CI	8.44, 11.24	12.74, 16.73	-7.27, -2.53
Day 90	n	43	25	
	LS Mean	9.75	12.74	-3.00
	95% CI	8.36, 11.14	10.88, 14.61	-5.25, -0.74

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.

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**Table 15.2.4.43 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 Difference
Day 1	n	50	28	
	LS Mean	235.24	237.70	-2.47
	95% CI	219.56, 250.92	216.87, 258.54	-27.44, 22.51
Day 4	n	49	25	
	LS Mean	214.85	234.48	-19.63
	95% CI	195.55, 234.16	207.71, 261.25	-51.28, 12.03
Day 30	n	51	26	
	LS Mean	183.84	214.58	-30.74
	95% CI	166.93, 200.74	191.25, 237.91	-58.63, -2.86
Day 60	n	47	24	
	LS Mean	207.34	217.01	-9.67
	95% CI	186.84, 227.84	188.45, 245.56	-43.43, 24.10
Day 90	n	43	25	
	LS Mean	202.93	204.77	-1.84
	95% CI	181.32, 224.54	176.40, 233.14	-35.93, 32.24

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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Program: t15020443-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.43 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	50	28	
	LS Mean	1968.73	2132.13	-163.40
	95% CI	1720.82, 2216.63	1803.33, 2460.92	-560.17, 233.37
Day 4	n	49	25	
	LS Mean	2031.40	1995.61	35.79
	95% CI	1770.76, 2292.05	1633.15, 2358.08	-395.68, 467.26
Day 30	n	51	26	
	LS Mean	2154.82	1933.83	220.99
	95% CI	1897.79, 2411.84	1575.90, 2291.76	-209.00, 650.98
Day 60	n	47	24	
	LS Mean	2552.83	1793.49	759.34
	95% CI	2209.56, 2896.09	1308.90, 2278.08	182.29, 1336.38
Day 90	n	43	25	
	LS Mean	2715.79	1917.80	798.00
	95% CI	2425.58, 3006.01	1530.30, 2305.29	326.36, 1269.64

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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Study ID:ZRHM-REXA-07-JP

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**Table 15.2.4.43 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	50	28	
	LS Mean	118.64	128.95	-10.30
	95% CI	106.79, 130.50	113.32, 144.57	-29.14, 8.53
Day 4	n	49	25	
	LS Mean	126.47	124.83	1.64
	95% CI	111.93, 141.00	104.72, 144.93	-22.28, 25.55
Day 30	n	51	26	
	LS Mean	145.68	131.34	14.34
	95% CI	129.84, 161.52	109.42, 153.27	-11.99, 40.67
Day 60	n	47	24	
	LS Mean	147.71	131.39	16.32
	95% CI	130.72, 164.69	107.61, 155.16	-11.91, 44.55
Day 90	n	43	25	
	LS Mean	157.20	134.51	22.69
	95% CI	142.60, 171.80	114.95, 154.07	-0.97, 46.34

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 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 Difference
Day 1	n	50	28	
	LS Mean	237.80	207.43	30.37
	95% CI	224.88, 250.72	190.41, 224.46	9.76, 50.98
Day 4	n	49	25	
	LS Mean	243.27	215.13	28.15
	95% CI	229.86, 256.68	196.56, 233.69	6.02, 50.27
Day 30	n	51	26	
	LS Mean	292.39	216.01	76.38
	95% CI	272.27, 312.50	188.09, 243.92	42.83, 109.93
Day 60	n	47	24	
	LS Mean	296.79	221.25	75.53
	95% CI	273.33, 320.24	188.45, 254.05	36.45, 114.61
Day 90	n	43	25	
	LS Mean	331.29	218.29	113.00
	95% CI	303.70, 358.87	181.62, 254.96	68.47, 157.53

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

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**Table 15.2.4.43 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 Difference
Day 1	n	50	28	
	LS Mean	388.24	343.41	44.83
	95% CI	368.36, 408.12	317.22, 369.60	13.17, 76.49
Day 4	n	49	25	
	LS Mean	397.23	347.60	49.63
	95% CI	375.36, 419.10	317.32, 377.89	13.56, 85.70
Day 30	n	51	26	
	LS Mean	465.12	356.26	108.86
	95% CI	432.19, 498.04	310.58, 401.94	53.98, 163.73
Day 60	n	47	24	
	LS Mean	472.59	367.47	105.12
	95% CI	436.94, 508.23	317.54, 417.39	45.76, 164.48
Day 90	n	43	25	
	LS Mean	527.93	362.43	165.50
	95% CI	492.82, 563.05	315.59, 409.27	108.69, 222.31

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 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 Difference
Day 1	n	50	28	
	LS Mean	3.58	3.91	-0.33
	95% CI	3.21, 3.94	3.42, 4.40	-0.91, 0.25
Day 4	n	49	25	
	LS Mean	3.93	4.10	-0.17
	95% CI	3.48, 4.39	3.46, 4.74	-0.92, 0.59
Day 30	n	51	26	
	LS Mean	4.13	3.99	0.15
	95% CI	3.67, 4.60	3.33, 4.65	-0.64, 0.93
Day 60	n	47	24	
	LS Mean	4.19	3.54	0.66
	95% CI	3.74, 4.65	2.88, 4.19	-0.11, 1.43
Day 90	n	43	25	
	LS Mean	4.32	4.36	-0.04
	95% CI	3.74, 4.90	3.57, 5.14	-0.98, 0.91

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 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Day 1	n	50	28	
	LS Mean	16.07	13.58	2.48
	95% CI	14.95, 17.18	12.10, 15.07	0.70, 4.27
Day 4	n	49	25	
	LS Mean	16.93	14.15	2.78
	95% CI	15.78, 18.08	12.55, 15.75	0.89, 4.67
Day 30	n	51	26	
	LS Mean	17.49	12.98	4.51
	95% CI	15.90, 19.08	10.76, 15.20	1.86, 7.15
Day 60	n	47	24	
	LS Mean	18.09	11.77	6.32
	95% CI	16.56, 19.62	9.58, 13.95	3.74, 8.90
Day 90	n	43	25	
	LS Mean	18.92	13.55	5.37
	95% CI	16.96, 20.89	10.93, 16.18	2.20, 8.54

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 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 Difference
Day 1	n	50	28	
	LS Mean	5.32	5.00	0.32
	95% CI	5.07, 5.56	4.67, 5.33	-0.08, 0.72
Day 4	n	49	25	
	LS Mean	5.37	5.14	0.22
	95% CI	5.06, 5.67	4.72, 5.57	-0.28, 0.73
Day 30	n	51	26	
	LS Mean	5.93	4.98	0.95
	95% CI	5.50, 6.37	4.37, 5.59	0.22, 1.68
Day 60	n	47	24	
	LS Mean	5.93	4.64	1.30
	95% CI	5.42, 6.45	3.91, 5.36	0.42, 2.17
Day 90	n	43	25	
	LS Mean	6.20	5.18	1.03
	95% CI	5.64, 6.77	4.42, 5.93	0.11, 1.94

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 number of puffs (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	50	28	
	Geometric LS Mean (CV%)	18.14	16.75	108.27 (22.83)
	95% CI	16.95, 19.40	15.33, 18.30	97.24, 120.55
Day 4	n	49	25	
	Geometric LS Mean (CV%)	16.75	15.96	104.96 (30.21)
	95% CI	15.31, 18.32	14.11, 18.05	90.58, 121.63
Day 30	n	51	26	
	Geometric LS Mean (CV%)	15.99	14.78	108.22 (21.87)
	95% CI	15.01, 17.04	13.54, 16.13	97.36, 120.27
Day 60	n	47	24	
	Geometric LS Mean (CV%)	17.49	13.80	126.69 (30.97)
	95% CI	15.93, 19.20	12.13, 15.70	108.46, 147.97
Day 90	n	43	25	
	Geometric LS Mean (CV%)	17.75	14.46	122.76 (23.99)
	95% CI	16.45, 19.15	13.09, 15.97	108.71, 138.63

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	50	28	
	Geometric LS Mean (CV%)	657.44	757.93	86.74 (39.79)
	95% CI	586.69, 736.71	651.85, 881.28	72.30, 104.07
Day 4	n	49	25	
	Geometric LS Mean (CV%)	660.84	694.82	95.11 (61.04)
	95% CI	558.27, 782.26	549.45, 878.65	71.93, 125.76
Day 30	n	51	26	
	Geometric LS Mean (CV%)	610.04	677.38	90.06 (36.56)
	95% CI	550.54, 675.96	587.18, 781.44	75.85, 106.93
Day 60	n	47	24	
	Geometric LS Mean (CV%)	690.51	615.07	112.27 (43.35)
	95% CI	609.00, 782.94	515.22, 734.27	90.89, 138.67
Day 90	n	43	25	
	Geometric LS Mean (CV%)	685.83	690.27	99.36 (31.27)
	95% CI	622.82, 755.22	607.05, 784.89	84.98, 116.16

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	50	28	
	Geometric LS Mean (CV%)	37.14	45.75	81.18 (30.17)
	95% CI	33.99, 40.59	40.74, 51.38	70.56, 93.39
Day 4	n	49	25	
	Geometric LS Mean (CV%)	40.46	44.25	91.44 (37.92)
	95% CI	36.22, 45.20	37.99, 51.54	76.27, 109.63
Day 30	n	51	26	
	Geometric LS Mean (CV%)	39.16	46.06	85.03 (29.65)
	95% CI	35.97, 42.64	40.98, 51.77	73.87, 97.86
Day 60	n	47	24	
	Geometric LS Mean (CV%)	39.98	44.85	89.13 (28.39)
	95% CI	36.72, 43.53	39.85, 50.48	77.45, 102.58
Day 90	n	43	25	
	Geometric LS Mean (CV%)	38.85	48.19	80.62 (28.62)
	95% CI	35.54, 42.47	42.83, 54.21	69.91, 92.98

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	50	28	
	Geometric LS Mean (CV%)	1.75	1.61	108.76 (20.40)
	95% CI	1.64, 1.86	1.48, 1.75	98.81, 119.71
Day 4	n	49	25	
	Geometric LS Mean (CV%)	1.82	1.56	116.65 (18.40)
	95% CI	1.72, 1.93	1.44, 1.69	106.55, 127.71
Day 30	n	51	26	
	Geometric LS Mean (CV%)	1.66	1.51	109.74 (22.73)
	95% CI	1.55, 1.78	1.38, 1.66	98.40, 122.39
Day 60	n	47	24	
	Geometric LS Mean (CV%)	1.73	1.46	118.97 (23.02)
	95% CI	1.61, 1.86	1.32, 1.61	106.06, 133.46
Day 90	n	43	25	
	Geometric LS Mean (CV%)	1.73	1.52	114.00 (25.13)
	95% CI	1.60, 1.88	1.37, 1.69	100.50, 129.32

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	50	28	
	Geometric LS Mean (CV%)	31.10	26.86	115.80 (32.76)
	95% CI	28.28, 34.19	23.69, 30.45	99.50, 134.76
Day 4	n	49	25	
	Geometric LS Mean (CV%)	29.67	25.13	118.06 (36.28)
	95% CI	26.70, 32.97	21.71, 29.09	99.19, 140.51
Day 30	n	51	26	
	Geometric LS Mean (CV%)	25.68	22.71	113.08 (30.47)
	95% CI	23.55, 28.00	20.14, 25.61	97.90, 130.62
Day 60	n	47	24	
	Geometric LS Mean (CV%)	29.75	20.50	145.17 (39.36)
	95% CI	26.52, 33.38	17.44, 24.08	119.76, 175.98
Day 90	n	43	25	
	Geometric LS Mean (CV%)	30.06	22.10	136.04 (36.19)
	95% CI	26.91, 33.58	19.07, 25.60	113.79, 162.64

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: Average flow (mL/s) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	50	28	
	Geometric LS Mean (CV%)	22.72	30.02	75.69 (22.69)
	95% CI	21.25, 24.29	27.49, 32.78	68.05, 84.19
Day 4	n	49	25	
	Geometric LS Mean (CV%)	23.71	29.72	79.77 (32.50)
	95% CI	21.56, 26.08	26.05, 33.92	68.17, 93.34
Day 30	n	51	26	
	Geometric LS Mean (CV%)	24.96	31.97	78.06 (27.21)
	95% CI	23.09, 26.97	28.70, 35.61	68.59, 88.84
Day 60	n	47	24	
	Geometric LS Mean (CV%)	24.29	32.47	74.80 (24.56)
	95% CI	22.57, 26.14	29.29, 35.99	66.18, 84.54
Day 90	n	43	25	
	Geometric LS Mean (CV%)	23.70	33.65	70.44 (29.82)
	95% CI	21.61, 25.99	29.76, 38.04	60.69, 81.75

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	50	28	
	Geometric LS Mean (CV%)	34.80	45.79	76.00 (22.81)
	95% CI	32.54, 37.22	41.91, 50.04	68.29, 84.58
Day 4	n	49	25	
	Geometric LS Mean (CV%)	36.89	45.05	81.89 (25.34)
	95% CI	34.23, 39.76	40.60, 49.98	72.36, 92.66
Day 30	n	51	26	
	Geometric LS Mean (CV%)	37.00	48.82	75.79 (27.89)
	95% CI	34.18, 40.06	43.72, 54.52	66.38, 86.52
Day 60	n	47	24	
	Geometric LS Mean (CV%)	35.97	49.37	72.86 (27.72)
	95% CI	33.12, 39.06	43.97, 55.44	63.48, 83.63
Day 90	n	43	25	
	Geometric LS Mean (CV%)	35.58	50.96	69.82 (32.18)
	95% CI	32.22, 39.29	44.65, 58.16	59.47, 81.97

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	50	28	
	Geometric LS Mean (CV%)	190.07	199.52	95.26 (27.19)
	95% CI	175.50, 205.84	179.38, 221.92	83.88, 108.18
Day 4	n	49	25	
	Geometric LS Mean (CV%)	167.41	190.63	87.82 (40.37)
	95% CI	148.87, 188.26	161.91, 224.43	72.44, 106.47
Day 30	n	51	26	
	Geometric LS Mean (CV%)	141.87	176.98	80.16 (36.36)
	95% CI	127.96, 157.28	153.40, 204.17	67.60, 95.05
Day 60	n	47	24	
	Geometric LS Mean (CV%)	157.14	185.21	84.84 (47.07)
	95% CI	137.08, 180.13	152.86, 224.41	67.67, 106.38
Day 90	n	43	25	
	Geometric LS Mean (CV%)	152.66	167.64	91.07 (38.50)
	95% CI	135.52, 171.97	143.16, 196.30	75.38, 110.01

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	50	28	
	Geometric LS Mean (CV%)	10.67	11.63	91.72 (21.05)
	95% CI	10.02, 11.35	10.70, 12.64	82.98, 101.37
Day 4	n	49	25	
	Geometric LS Mean (CV%)	10.07	11.48	87.69 (24.53)
	95% CI	9.36, 10.83	10.36, 12.72	77.68, 98.99
Day 30	n	51	26	
	Geometric LS Mean (CV%)	9.03	12.01	75.18 (29.29)
	95% CI	8.30, 9.82	10.68, 13.51	65.33, 86.51
Day 60	n	47	24	
	Geometric LS Mean (CV%)	9.05	13.27	68.18 (34.97)
	95% CI	8.16, 10.03	11.45, 15.38	57.18, 81.29
Day 90	n	43	25	
	Geometric LS Mean (CV%)	8.73	11.51	75.85 (37.15)
	95% CI	7.79, 9.79	9.88, 13.42	63.02, 91.28

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	50	28	
	Geometric LS Mean (CV%)	225.58	230.38	97.91 (24.56)
	95% CI	209.86, 242.47	209.27, 253.62	87.26, 109.86
Day 4	n	49	25	
	Geometric LS Mean (CV%)	201.38	221.08	91.09 (36.99)
	95% CI	180.75, 224.38	190.26, 256.89	76.28, 108.77
Day 30	n	51	26	
	Geometric LS Mean (CV%)	172.08	202.77	84.87 (31.90)
	95% CI	157.10, 188.49	178.76, 230.01	73.01, 98.65
Day 60	n	47	24	
	Geometric LS Mean (CV%)	192.53	207.60	92.74 (43.01)
	95% CI	169.75, 218.36	174.10, 247.54	75.32, 114.18
Day 90	n	43	25	
	Geometric LS Mean (CV%)	188.79	193.63	97.50 (33.66)
	95% CI	169.97, 209.69	168.56, 222.43	82.55, 115.16

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	50	28	
	Geometric LS Mean (CV%)	1605.15	1776.41	90.36 (49.00)
	95% CI	1398.27, 1842.63	1480.53, 2131.43	72.50, 112.61
Day 4	n	49	25	
	Geometric LS Mean (CV%)	1703.32	1658.40	102.71 (62.08)
	95% CI	1435.33, 2021.35	1307.60, 2103.32	77.40, 136.28
Day 30	n	51	26	
	Geometric LS Mean (CV%)	1887.18	1654.46	114.07 (45.16)
	95% CI	1665.75, 2138.04	1390.88, 1967.98	92.61, 140.50
Day 60	n	47	24	
	Geometric LS Mean (CV%)	2171.00	1535.06	141.43 (55.66)
	95% CI	1855.25, 2540.50	1230.20, 1915.47	108.67, 184.06
Day 90	n	43	25	
	Geometric LS Mean (CV%)	2355.51	1706.90	138.00 (38.89)
	95% CI	2092.61, 2651.43	1457.69, 1998.71	113.92, 167.17

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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Program: t1502044301_ZRHM-REXA-07_JP_v1_PMI.sas

Status: Final v1.0/17DEC2015

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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	50	28	
	Geometric LS Mean (CV%)	91.91	106.82	86.04 (40.15)
	95% CI	81.85, 103.20	91.78, 124.33	71.60, 103.38
Day 4	n	49	25	
	Geometric LS Mean (CV%)	105.90	105.12	100.74 (45.08)
	95% CI	93.03, 120.55	87.91, 125.68	81.43, 124.64
Day 30	n	51	26	
	Geometric LS Mean (CV%)	121.36	111.95	108.41 (40.62)
	95% CI	108.30, 136.00	95.66, 131.01	89.73, 130.97
Day 60	n	47	24	
	Geometric LS Mean (CV%)	126.79	111.85	113.35 (38.88)
	95% CI	113.11, 142.12	95.38, 131.16	93.80, 136.98
Day 90	n	43	25	
	Geometric LS Mean (CV%)	135.78	119.27	113.84 (34.72)
	95% CI	122.06, 151.04	103.51, 137.42	95.90, 135.15

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.

Appendix: 15.3.7.1

Study ID: ZRHM-REXA-07-JP

Program: t1502044301_ZRHM-REXA-07_JP_v1_PMI.sas

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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	50	28	
	Geometric LS Mean (CV%)	217.27	196.08	110.81 (18.00)
	95% CI	206.02, 229.14	182.82, 210.30	101.80, 120.62
Day 4	n	49	25	
	Geometric LS Mean (CV%)	226.67	203.18	111.56 (17.34)
	95% CI	215.26, 238.68	189.16, 218.23	102.45, 121.48
Day 30	n	51	26	
	Geometric LS Mean (CV%)	273.17	206.78	132.10 (25.80)
	95% CI	253.78, 294.03	186.72, 229.01	116.84, 149.35
Day 60	n	47	24	
	Geometric LS Mean (CV%)	277.46	211.84	130.98 (25.38)
	95% CI	257.23, 299.28	190.56, 235.49	115.46, 148.58
Day 90	n	43	25	
	Geometric LS Mean (CV%)	304.41	208.52	145.98 (26.13)
	95% CI	280.72, 330.09	187.23, 232.23	128.09, 166.37

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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Study ID: ZRHM-REXA-07-JP

Program: t1502044301_ZRHM-REXA-07_JP_v1_PMI.sas

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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	50	28	
	Geometric LS Mean (CV%)	352.08	321.39	109.55 (18.93)
	95% CI	332.94, 372.32	298.59, 345.94	100.21, 119.75
Day 4	n	49	25	
	Geometric LS Mean (CV%)	367.11	325.21	112.88 (18.79)
	95% CI	347.15, 388.21	301.00, 351.36	102.94, 123.79
Day 30	n	51	26	
	Geometric LS Mean (CV%)	424.30	336.83	125.97 (30.16)
	95% CI	389.50, 462.21	299.14, 379.28	109.22, 145.28
Day 60	n	47	24	
	Geometric LS Mean (CV%)	439.57	345.85	127.10 (27.52)
	95% CI	405.01, 477.07	308.38, 387.87	110.89, 145.67
Day 90	n	43	25	
	Geometric LS Mean (CV%)	486.57	341.36	142.54 (25.43)
	95% CI	449.66, 526.51	307.30, 379.19	125.48, 161.91

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	50	28	
	Geometric LS Mean (CV%)	3.11	3.53	88.13 (38.27)
	95% CI	2.78, 3.48	3.04, 4.10	73.89, 105.10
Day 4	n	49	25	
	Geometric LS Mean (CV%)	3.45	3.49	98.66 (44.14)
	95% CI	3.03, 3.92	2.92, 4.18	79.97, 121.72
Day 30	n	51	26	
	Geometric LS Mean (CV%)	3.66	3.54	103.37 (44.37)
	95% CI	3.23, 4.14	2.97, 4.21	84.15, 126.98
Day 60	n	47	24	
	Geometric LS Mean (CV%)	3.71	3.18	116.73 (42.65)
	95% CI	3.28, 4.21	2.66, 3.80	94.72, 143.85
Day 90	n	43	25	
	Geometric LS Mean (CV%)	3.73	3.78	98.69 (48.63)
	95% CI	3.22, 4.31	3.10, 4.60	77.95, 124.95

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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Study ID: ZRHM-REXA-07-JP

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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	50	28	
	Geometric LS Mean (CV%)	14.69	12.50	117.47 (28.18)
	95% CI	13.52, 15.95	11.20, 13.96	102.99, 133.99
Day 4	n	49	25	
	Geometric LS Mean (CV%)	15.48	12.45	124.28 (29.65)
	95% CI	14.18, 16.90	11.02, 14.07	107.62, 143.52
Day 30	n	51	26	
	Geometric LS Mean (CV%)	15.48	11.79	131.30 (37.68)
	95% CI	13.92, 17.22	10.17, 13.67	110.07, 156.62
Day 60	n	47	24	
	Geometric LS Mean (CV%)	16.17	10.63	152.09 (34.30)
	95% CI	14.62, 17.90	9.21, 12.28	128.38, 180.16
Day 90	n	43	25	
	Geometric LS Mean (CV%)	16.43	11.97	137.31 (45.16)
	95% CI	14.33, 18.83	9.97, 14.36	110.27, 170.98

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	50	28	
	Geometric LS Mean (CV%)	5.00	4.71	106.14 (17.65)
	95% CI	4.74, 5.27	4.39, 5.06	97.58, 115.46
Day 4	n	49	25	
	Geometric LS Mean (CV%)	5.10	4.77	106.93 (20.33)
	95% CI	4.79, 5.42	4.37, 5.19	96.65, 118.31
Day 30	n	51	26	
	Geometric LS Mean (CV%)	5.61	4.62	121.48 (24.76)
	95% CI	5.22, 6.03	4.18, 5.10	107.78, 136.93
Day 60	n	47	24	
	Geometric LS Mean (CV%)	5.58	4.30	129.70 (28.66)
	95% CI	5.12, 6.08	3.81, 4.86	112.18, 149.96
Day 90	n	43	25	
	Geometric LS Mean (CV%)	5.75	4.71	121.95 (32.12)
	95% CI	5.20, 6.35	4.12, 5.39	103.78, 143.30

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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Study ID: ZRHM-REXA-07-JP

Program: t1502044301_ZRHM-REXA-07_JP_v1_PMI.sas

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**Table 15.2.4.44.1 Descriptive Statistics of CYP2A6 Activity (%) - PP Set****Parameter: CYP2A6 Activity (%)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	21.70 (72.75)		24.37 (68.62)		21.92 (68.90)	
	95% CI	18.69, 25.19		20.08, 29.58		17.91, 26.84	
	Median	23.17		29.70		26.61	
	Q25, Q75	15.67, 33.60		15.66, 36.80		13.72, 35.75	
	Min, Max	4.1, 96.2		5.1, 70.9		6.4, 58.5	
	Mean (SD)	26.23 (16.294)		28.53 (14.414)		26.05 (14.581)	
	95% CI of Mean	22.50, 29.96		24.03, 33.02		21.31, 30.78	
Day 6/Discharge Confinement	n	76	76	42	42	39	39
	Geometric Mean (CV%)	23.85 (70.78)		27.03 (66.43)		67.54 (99.78)	
	95% CI	20.61, 27.59		22.39, 32.64		51.59, 88.44	
	Median	25.53	10.62	34.77	11.77	65.14	206.11
	Q25, Q75	16.84, 36.96	3.23, 19.95	16.48, 41.97	-0.87, 24.97	38.77, 129.67	135.08, 295.22
	Min, Max	4.0, 97.8	-68.4, 45.6	5.8, 60.5	-21.1, 39.6	15.0, 315.3	55.6, 1111.9
	Mean (SD)	28.51 (16.852)	11.44 (16.236)	31.42 (15.222)	11.95 (15.104)	92.97 (76.110)	237.55 (180.132)
	95% CI of Mean	24.65, 32.36	7.72, 15.15	26.67, 36.17	7.24, 16.66	68.29, 117.65	179.16, 295.95

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.16



Table 15.2.4.44.1 Descriptive Statistics of CYP2A6 Activity (%) - PP Set
Parameter: CYP2A6 Activity (%)
Product Use Time Period: Period 4

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	70		41		37	
	Geometric Mean (CV%)	21.41 (75.35)		24.28 (69.59)		21.44 (69.87)	
	95% CI	18.24, 25.13		19.90, 29.61		17.37, 26.46	
	Median	23.17		30.85		23.60	
	Q25, Q75	15.61, 33.45		15.66, 36.80		13.72, 32.85	
	Min, Max	4.1, 96.2		5.1, 70.9		6.4, 58.5	
	Mean (SD)	26.18 (16.797)		28.53 (14.593)		25.62 (14.767)	
	95% CI of Mean	22.17, 30.19		23.92, 33.14		20.69, 30.55	
Day 90							
	n	70	70	41	41	37	37
	Geometric Mean (CV%)	21.86 (82.04)		24.66 (75.59)		39.17 (144.74)	
	95% CI	18.42, 25.94		19.94, 30.50		27.48, 55.83	
	Median	23.83	2.56	32.08	1.66	43.23	40.12
	Q25, Q75	13.54, 34.16	-8.41, 16.31	16.07, 39.50	-7.95, 13.56	21.30, 91.67	12.61, 222.95
	Min, Max	4.1, 103.5	-71.5, 111.1	4.1, 58.6	-29.0, 54.5	0.6, 196.2	-97.9, 1330.1
	Mean (SD)	27.66 (19.639)	5.32 (25.640)	29.54 (15.493)	3.14 (18.610)	57.57 (45.964)	181.30 (293.939)
	95% CI of Mean	22.97, 32.35	-0.80, 11.44	24.65, 34.44	-2.74, 9.02	42.23, 72.90	83.29, 279.30

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized 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: 15.3.6.16

**Table 15.2.4.44.1.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set****Parameter: CYP2A6 Activity (%)****Product Use Time Period: Period 1**

Time point	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	76		42		39	
	Geometric Mean (CV%)	21.70 (72.75)		24.37 (68.62)		21.92 (68.90)	
	95% CI	18.69, 25.19		20.08, 29.58		17.91, 26.84	
	Median	23.17		29.70		26.61	
	Q25, Q75	15.67, 33.60		15.66, 36.80		13.72, 35.75	
	Min, Max	4.1, 96.2		5.1, 70.9		6.4, 58.5	
	Mean (SD)	26.23 (16.294)		28.53 (14.414)		26.05 (14.581)	
	95% CI of Mean	22.50, 29.96		24.03, 33.02		21.31, 30.78	
Day 6/Discharge Confinement	n	76	76	42	42	39	39
	Geometric Mean (CV%)	23.85 (70.78)		27.03 (66.43)		67.54 (99.78)	
	95% CI	20.61, 27.59		22.39, 32.64		51.59, 88.44	
	Median	25.53	10.62	34.77	11.77	65.14	206.11
	Q25, Q75	16.84, 36.96	3.23, 19.95	16.48, 41.97	-0.87, 24.97	38.77, 129.67	135.08, 295.22
	Min, Max	4.0, 97.8	-68.4, 45.6	5.8, 60.5	-21.1, 39.6	15.0, 315.3	55.6, 1111.9
	Mean (SD)	28.51 (16.852)	11.44 (16.236)	31.42 (15.222)	11.95 (15.104)	92.97 (76.110)	237.55 (180.132)
	95% CI of Mean	24.65, 32.36	7.72, 15.15	26.67, 36.17	7.24, 16.66	68.29, 117.65	179.16, 295.95

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

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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: 15.3.6.16

**Table 15.2.4.44.1.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set****Parameter: CYP2A6 Activity (%)****Product Use Time Period: Period 4**

Time point	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	70		41		37	
	Geometric Mean (CV%)	21.41 (75.35)		24.28 (69.59)		21.44 (69.87)	
	95% CI	18.24, 25.13		19.90, 29.61		17.37, 26.46	
	Median	23.17		30.85		23.60	
	Q25, Q75	15.61, 33.45		15.66, 36.80		13.72, 32.85	
	Min, Max	4.1, 96.2		5.1, 70.9		6.4, 58.5	
	Mean (SD)	26.18 (16.797)		28.53 (14.593)		25.62 (14.767)	
	95% CI of Mean	22.17, 30.19		23.92, 33.14		20.69, 30.55	
Day 90	n	69	69	41	41	37	37
	Missing, n(%)	1 (1.4)	1 (1.4)	0	0	0	0
	Geometric Mean (CV%)	21.67 (82.29)		24.66 (75.59)		39.17 (144.74)	
	95% CI	18.23, 25.77		19.94, 30.50		27.48, 55.83	
	Median	23.75	2.65	32.08	1.66	43.23	40.12
	Q25, Q75	13.54, 33.62	-8.41, 16.31	16.07, 39.50	-7.95, 13.56	21.30, 91.67	12.61, 222.95
	Min, Max	4.1, 103.5	-71.5, 111.1	4.1, 58.6	-29.0, 54.5	0.6, 196.2	-97.9, 1330.1
	Mean (SD)	27.49 (19.733)	5.49 (25.788)	29.54 (15.493)	3.14 (18.610)	57.57 (45.964)	181.30 (293.939)
	95% CI of Mean	22.75, 32.24	-0.71, 11.69	24.65, 34.44	-2.74, 9.02	42.23, 72.90	83.29, 279.30

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

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 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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Study ID: ZRHM-REXA-07-JP

Program: t150204440101-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.44.2 Descriptive Statistics of CYP2A6 Activity (%) - FAS****Parameter: CYP2A6 Activity (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	78		42		40	
	Geometric Mean (CV%)	21.86 (72.23)		24.37 (68.62)		22.72 (73.27)	
	95% CI	18.88, 25.30		20.08, 29.58		18.42, 28.03	
	Median	23.17		29.70		26.78	
	Q25, Q75	15.71, 33.75		15.66, 36.80		13.74, 36.42	
	Min, Max	4.1, 96.2		5.1, 70.9		6.4, 91.7	
	Mean (SD)	26.35 (16.208)		28.53 (14.414)		27.69 (17.743)	
	95% CI of Mean	22.69, 30.01		24.03, 33.02		22.01, 33.37	

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.44.2 Descriptive Statistics of CYP2A6 Activity (%) - FAS****Parameter: CYP2A6 Activity (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge Confinement	n	78	78	42	42	40	40
	Geometric Mean (CV%)	23.98 (70.28)		27.03 (66.43)		64.70 (105.41)	
	95% CI	20.78, 27.66		22.39, 32.64		49.07, 85.31	
	Median	25.53	9.98	34.77	11.77	62.56	204.67
	Q25, Q75	16.85, 37.08	2.59, 19.90	16.48, 41.97	-0.87, 24.97	36.75, 127.01	134.31, 278.69
	Min, Max	4.0, 97.8	-68.4, 45.6	5.8, 60.5	-21.1, 39.6	12.1, 315.3	-86.8, 1111.9
	Mean (SD)	28.60 (16.771)	11.22 (16.088)	31.42 (15.222)	11.95 (15.104)	90.95 (76.208)	229.44 (185.056)
	95% CI of Mean	24.82, 32.39	7.59, 14.85	26.67, 36.17	7.24, 16.66	66.57, 115.33	170.26, 288.63

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.44.2 Descriptive Statistics of CYP2A6 Activity (%) - FAS****Parameter: CYP2A6 Activity (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90							
	n	78	78	42	42	40	40
	Geometric Mean (CV%)	22.38 (78.84)		24.84 (74.67)		38.03 (139.28)	
	95% CI	19.13, 26.18		20.18, 30.57		27.28, 53.01	
	Median	23.83	1.99	32.69	2.33	41.49	34.50
	Q25, Q75	14.31, 35.58	-7.95, 16.31	16.07, 39.50	-7.95, 13.80	18.71, 91.67	10.28, 212.25
	Min, Max	4.1, 103.5	-71.5, 111.1	4.1, 58.6	-29.0, 54.5	0.6, 196.2	-97.9, 1330.1
	Mean (SD)	27.90 (19.092)	5.44 (25.028)	29.63 (15.314)	3.47 (18.500)	55.52 (44.916)	166.42 (287.653)
	95% CI of Mean	23.59, 32.21	-0.21, 11.08	24.86, 34.41	-2.30, 9.24	41.15, 69.89	74.42, 258.42

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 10 AM on Day 1 in the SA arm.

**Table 15.2.4.44.2.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS****Parameter: CYP2A6 Activity (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline							
	n	78		42		40	
	Geometric Mean (CV%)	21.86 (72.23)		24.37 (68.62)		22.72 (73.27)	
	95% CI	18.88, 25.30		20.08, 29.58		18.42, 28.03	
	Median	23.17		29.70		26.78	
	Q25, Q75	15.71, 33.75		15.66, 36.80		13.74, 36.42	
	Min, Max	4.1, 96.2		5.1, 70.9		6.4, 91.7	
	Mean (SD)	26.35 (16.208)		28.53 (14.414)		27.69 (17.743)	
	95% CI of Mean	22.69, 30.01		24.03, 33.02		22.01, 33.37	

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.44.2.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS****Parameter: CYP2A6 Activity (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 6/Discharge Confinement	n	78	78	42	42	40	40
	Geometric Mean (CV%)	23.98 (70.28)		27.03 (66.43)		64.70 (105.41)	
	95% CI	20.78, 27.66		22.39, 32.64		49.07, 85.31	
	Median	25.53	9.98	34.77	11.77	62.56	204.67
	Q25, Q75	16.85, 37.08	2.59, 19.90	16.48, 41.97	-0.87, 24.97	36.75, 127.01	134.31, 278.69
	Min, Max	4.0, 97.8	-68.4, 45.6	5.8, 60.5	-21.1, 39.6	12.1, 315.3	-86.8, 1111.9
	Mean (SD)	28.60 (16.771)	11.22 (16.088)	31.42 (15.222)	11.95 (15.104)	90.95 (76.208)	229.44 (185.056)
	95% CI of Mean	24.82, 32.39	7.59, 14.85	26.67, 36.17	7.24, 16.66	66.57, 115.33	170.26, 288.63

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.44.2.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS****Parameter: CYP2A6 Activity (%)**

Time point	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	77	77	42	42	40	40
	Missing, n(%)	1 (1.3)	1 (1.3)	0	0	0	0
	Geometric Mean (CV%)	22.21 (79.06)		24.84 (74.67)		38.03 (139.28)	
	95% CI	18.96, 26.03		20.18, 30.57		27.28, 53.01	
	Median	23.75	2.47	32.69	2.33	41.49	34.50
	Q25, Q75	14.31, 34.16	-7.95, 16.31	16.07, 39.50	-7.95, 13.80	18.71, 91.67	10.28, 212.25
	Min, Max	4.1, 103.5	-71.5, 111.1	4.1, 58.6	-29.0, 54.5	0.6, 196.2	-97.9, 1330.1
	Mean (SD)	27.75 (19.173)	5.59 (25.156)	29.63 (15.314)	3.47 (18.500)	55.52 (44.916)	166.42 (287.653)
	95% CI of Mean	23.39, 32.11	-0.13, 11.30	24.86, 34.41	-2.30, 9.24	41.15, 69.89	74.42, 258.42

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

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

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.45.1 Analysis of CYP2A6 Activity (%) - PP Set****Parameter: CYP2A6 Activity (%)**

Time point		Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Day 5	n		76	42	39		
	Geometric LS Mean (CV%)		24.85	25.26	69.67	98.39 (24.69)	35.67 (24.69)
	95% CI of Geometric Mean		23.51, 26.27	23.43, 27.23	64.49, 75.26	89.67, 107.96	32.44, 39.22
	p-value (one-sided)					0.365	
Day 90	n		70	41	37		
	Geometric LS Mean (CV%)		22.70	22.99	40.68	98.73 (61.36)	55.79 (61.36)
	95% CI of Geometric Mean		19.84, 25.96	19.27, 27.42	33.83, 48.92	79.17, 123.12	44.44, 70.02

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

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: p-value for one-sided test for comparison between products.

Appendix: 15.3.6.16

Study ID:ZRHM-REXA-07-JP

Program: t1502044501-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.45.1.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set****Parameter: CYP2A6 Activity (%)**

Time point		Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Day 5	n		76	42	39		
	Geometric LS Mean (CV%)		24.85	25.26	69.67	98.39 (24.69)	35.67 (24.69)
	95% CI of Geometric Mean		23.51, 26.27	23.43, 27.23	64.49, 75.26	89.67, 107.96	32.44, 39.22
	p-value (one-sided)					0.365	
Day 90	n		69	41	37		
	Geometric LS Mean (CV%)		22.60	22.90	40.53	98.69 (61.61)	55.76 (61.61)
	95% CI of Geometric Mean		19.73, 25.88	19.18, 27.33	33.68, 48.77	79.02, 123.25	44.37, 70.09

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

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: p-value for one-sided test for comparison between products.

Appendix: 15.3.6.16

Study ID: ZRHM-REXA-07-JP

Program: t150204450101-ZRHM-REXA-07-JP-v3.0.sas

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**Table 15.2.4.45.2 Analysis of CYP2A6 Activity (%) - FAS****Parameter: CYP2A6 Activity (%)**

Time point		Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Day 5	n		78	42	40		
	Geometric LS Mean (CV%)		25.00	25.63	65.08	97.57 (35.46)	38.42 (35.46)
	95% CI of Geometric Mean		23.13, 27.02	23.05, 28.49	58.43, 72.48	85.63, 111.18	33.66, 43.86
	p-value (one-sided)					0.355	
Day 90	n		78	42	40		
	Geometric LS Mean (CV%)		23.22	23.60	38.17	98.40 (63.26)	60.85 (63.26)
	95% CI of Geometric Mean		20.37, 26.47	19.74, 28.21	31.83, 45.77	78.96, 122.62	48.68, 76.05

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

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: p-value for one-sided test for comparison between products.

Appendix: 15.3.6.16

Study ID:ZRHM-REXA-07-JP

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**Table 15.2.4.45.2.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS****Parameter: CYP2A6 Activity (%)**

Time point		Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Day 5	n		78	42	40		
	Geometric LS Mean (CV%)		25.00	25.63	65.08	97.57 (35.46)	38.42 (35.46)
	95% CI of Geometric Mean		23.13, 27.02	23.05, 28.49	58.43, 72.48	85.63, 111.18	33.66, 43.86
	p-value (one-sided)					0.355	
Day 90	n		77	42	40		
	Geometric LS Mean (CV%)		23.14	23.53	38.05	98.37 (63.51)	60.83 (63.51)
	95% CI of Geometric Mean		20.28, 26.41	19.67, 28.14	31.71, 45.65	78.83, 122.74	48.61, 76.13

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

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: p-value for one-sided test for comparison between products.

Appendix: 15.3.6.16

Study ID: ZRHM-REXA-07-JP

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**Table 15.2.4.46.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - PP Set****Parameter (units): Ames Mutagenicity (REV/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		38		35	
	Missing, n (%)	11 (14.5)		4 (9.5)		4 (10.3)	
	Geometric Mean (CV%)	NC		7.76 (70.60)		NC	
	95% CI of Geometric Mean	NC		6.29, 9.56		NC	
	Median	7.66		8.10		6.85	
	Q25, Q75	5.12, 11.70		5.36, 12.00		4.92, 10.40	
	Min, Max	0.0, 32.2		2.1, 28.5		0.0, 21.7	
	Mean (SD)	9.07 (5.798)		9.41 (6.176)		7.93 (5.243)	
	95% CI of Mean	7.63, 10.52		7.38, 11.45		6.12, 9.74	

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - PP Set****Parameter (units): Ames Mutagenicity (REV/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)		mCC (N=42)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	65	40	38	37	35
	Missing, n (%)	3 (3.9)	11 (14.5)	2 (4.8)	4 (9.5)	2 (5.1)	4 (10.3)
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	2.71	-52.31	8.01	-4.00	3.39	-28.63
	Q25, Q75	1.74, 4.74	-82.23, 0.00	4.11, 10.70	-39.59, 0.00	2.09, 5.40	-74.60, 0.00
	Min, Max	0.0, 18.1	-100.0, 64.7	0.0, 25.1	-100.0, 162.1	0.0, 21.2	-100.0, 22.5
	Mean (SD)	3.76 (3.731)	-47.40 (41.960)	8.08 (5.017)	-5.37 (50.510)	4.66 (4.754)	-33.78 (38.716)
	95% CI of Mean	2.89, 4.64	-57.81, -37.00	6.47, 9.69	-21.98, 11.24	3.07, 6.25	-47.08, -20.47

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - PP Set****Parameter (units): Ames Mutagenicity (REV/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	60		37		33	
	Missing, n (%)	10 (14.3)		4 (9.8)		4 (10.8)	
	Geometric Mean (CV%)	NC		7.68 (71.36)		NC	
	95% CI of Geometric Mean	NC		6.19, 9.51		NC	
	Median	7.73		8.02		6.73	
	Q25, Q75	5.07, 11.95		5.36, 12.00		4.92, 8.94	
	Min, Max	0.0, 32.2		2.1, 28.5		0.0, 21.7	
	Mean (SD)	9.27 (5.986)		9.36 (6.253)		7.80 (5.329)	
	95% CI of Mean	7.71, 10.82		7.27, 11.45		5.91, 9.70	

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - PP Set****Parameter (units): Ames Mutagenicity (REV/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=70)		mCC (N=41)		SA (N=37)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	60	40	37	37	33
	Missing, n (%)	0	10 (14.3)	1 (2.4)	4 (9.8)	0	4 (10.8)
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	3.22	-56.20	8.73	22.60	3.18	-34.54
	Q25, Q75	2.21, 4.97	-74.69, -12.43	4.91, 14.20	-11.03, 51.59	2.47, 6.19	-76.71, 0.00
	Min, Max	0.0, 17.0	-100.0, 60.9	0.0, 26.4	-100.0, 129.6	0.0, 15.5	-100.0, 308.0
	Mean (SD)	3.67 (2.798)	-45.61 (42.248)	9.80 (6.294)	19.19 (53.837)	4.25 (3.587)	-24.97 (81.789)
	95% CI of Mean	3.00, 4.34	-56.53, -34.69	7.78, 11.82	1.24, 37.15	3.05, 5.45	-53.98, 4.04

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - PP Set****Parameter (units): Ames Mutagenicity (REV/24h)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Baseline	n	65	38	35
	Missing, n (%)	11 (14.5)	4 (9.5)	4 (10.3)
	Geometric Mean (CV%)	NC	11858.12 (86.04)	NC
	95% CI of Geometric Mean	NC	9284.59, 15145.00	NC
	Median	13943.72	13235.99	14000.04
	Q25, Q75	8398.26, 21406.00	8050.44, 20372.80	6876.90, 20698.62
	Min, Max	0.0, 51505.1	2331.6, 51400.0	0.0, 44541.2
	Mean (SD)	17293.80 (12542.53)	15132.36 (10702.14)	14508.13 (10211.61)
	95% CI of Mean	14185.90, 20401.69	11614.65, 18650.07	11000.31, 18015.94

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - PP Set****Parameter (units): Ames Mutagenicity (REV/24h)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=76)	mCC (N=42)	SA (N=39)
Day 5	n	73	40	37
	Missing, n (%)	3 (3.9)	2 (4.8)	2 (5.1)
	Geometric Mean (CV%)	NC	NC	NC
	95% CI of Geometric Mean	NC	NC	NC
	Median	4856.25	13578.55	6385.80
	Q25, Q75	2920.94, 9683.10	8265.04, 17876.00	3388.44, 10009.78
	Min, Max	0.0, 47872.0	0.0, 39632.9	0.0, 44541.2
	Mean (SD)	7500.05 (8886.202)	13476.64 (7826.055)	9237.10 (10000.88)
	95% CI of Mean	5426.74, 9573.36	10973.74, 15979.54	5902.64, 12571.57

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - PP Set****Parameter (units): Ames Mutagenicity (REV/24h)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)
Baseline	n	60	37	33
	Missing, n (%)	10 (14.3)	4 (9.8)	4 (10.8)
	Geometric Mean (CV%)	NC	11801.17 (87.51)	NC
	95% CI of Geometric Mean	NC	9177.93, 15174.19	NC
	Median	13949.74	12743.78	13085.26
	Q25, Q75	7599.80, 23110.55	8050.44, 20372.80	6876.90, 17037.00
	Min, Max	0.0, 51505.1	2331.6, 51400.0	0.0, 44541.2
	Mean (SD)	17642.22 (12947.59)	15158.37 (10848.55)	13810.64 (10036.88)
	95% CI of Mean	14297.50, 20986.94	11541.28, 18775.46	10251.71, 17369.57

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - PP Set****Parameter (units): Ames Mutagenicity (REV/24h)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=70)	mCC (N=41)	SA (N=37)
Day 90	n	70	40	37
	Missing, n (%)	0	1 (2.4)	0
	Geometric Mean (CV%)	NC	NC	NC
	95% CI of Geometric Mean	NC	NC	NC
	Median	5399.62	13192.79	4977.36
	Q25, Q75	2920.94, 9437.22	8337.02, 23117.80	2744.36, 11718.27
	Min, Max	0.0, 47872.0	0.0, 47824.0	0.0, 35588.0
	Mean (SD)	6761.03 (6689.370)	17204.22 (12257.97)	8136.60 (8523.113)
	95% CI of Mean	5166.00, 8356.06	13283.93, 21124.52	5294.85, 10978.36

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - FAS****Parameter (units): Ames Mutagenicity (REV/mL)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		38		36	
	Missing, n (%)	11 (14.1)		4 (9.5)		4 (10.0)	
	Geometric Mean (CV%)	NC		7.76 (70.60)		NC	
	95% CI of Geometric Mean	NC		6.29, 9.56		NC	
	Median	7.66		8.10		6.91	
	Q25, Q75	5.02, 11.90		5.36, 12.00		4.96, 10.90	
	Min, Max	0.0, 32.2		2.1, 28.5		0.0, 21.7	
	Mean (SD)	9.13 (5.840)		9.41 (6.176)		8.11 (5.276)	
	95% CI of Mean	7.70, 10.56		7.38, 11.45		6.32, 9.90	

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - FAS****Parameter (units): Ames Mutagenicity (REV/mL)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	75	67	40	38	38	36
	Missing, n (%)	3 (3.8)	11 (14.1)	2 (4.8)	4 (9.5)	2 (5.0)	4 (10.0)
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	2.80	-51.73	8.01	-4.00	3.43	-25.41
	Q25, Q75	1.74, 5.08	-82.23, 0.00	4.11, 10.70	-39.59, 0.00	2.09, 6.01	-72.97, 0.00
	Min, Max	0.0, 18.1	-100.0, 64.7	0.0, 25.1	-100.0, 162.1	0.0, 21.2	-100.0, 22.5
	Mean (SD)	3.95 (4.016)	-45.99 (42.111)	8.08 (5.017)	-5.37 (50.510)	4.92 (4.943)	-32.84 (38.572)
	95% CI of Mean	3.02, 4.88	-56.27, -35.71	6.47, 9.69	-21.98, 11.24	3.29, 6.55	-45.90, -19.78

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - FAS****Parameter (units): Ames Mutagenicity (REV/mL)**

Timepoint	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	67	41	38	40	36
	Missing, n (%)	0	11 (14.1)	1 (2.4)	4 (9.5)	0	4 (10.0)
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	3.23	-54.05	9.28	22.26	3.26	-34.13
	Q25, Q75	2.21, 4.98	-75.44, -8.00	4.93, 13.50	-11.03, 51.59	2.48, 6.34	-77.17, 0.00
	Min, Max	0.0, 17.7	-100.0, 64.7	0.0, 26.4	-100.0, 129.6	0.0, 15.5	-100.0, 308.0
	Mean (SD)	3.84 (3.162)	-43.88 (43.776)	9.84 (6.220)	18.69 (53.196)	4.51 (3.821)	-25.44 (78.919)
	95% CI of Mean	3.12, 4.55	-54.56, -33.19	7.87, 11.80	1.20, 36.18	3.29, 5.74	-52.15, 1.27

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - FAS****Parameter (units): Ames Mutagenicity (REV/24h)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Baseline	n	67	38	36
	Missing, n (%)	11 (14.1)	4 (9.5)	4 (10.0)
	Geometric Mean (CV%)	NC	11858.12 (86.04)	NC
	95% CI of Geometric Mean	NC	9284.59, 15145.00	NC
	Median	13943.72	13235.99	14042.52
	Q25, Q75	7618.40, 22665.10	8050.44, 20372.80	7165.53, 20843.01
	Min, Max	0.0, 51505.1	2331.6, 51400.0	0.0, 44541.2
	Mean (SD)	17216.05 (12533.94)	15132.36 (10702.14)	14909.90 (10349.33)
	95% CI of Mean	14158.78, 20273.33	11614.65, 18650.07	11408.18, 18411.61

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - FAS****Parameter (units): Ames Mutagenicity (REV/24h)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 5	n	75	40	38
	Missing, n (%)	3 (3.8)	2 (4.8)	2 (5.0)
	Geometric Mean (CV%)	NC	NC	NC
	95% CI of Geometric Mean	NC	NC	NC
	Median	4856.25	13578.55	6494.00
	Q25, Q75	2905.76, 9706.04	8265.04, 17876.00	3388.44, 11382.94
	Min, Max	0.0, 47872.0	0.0, 39632.9	0.0, 44541.2
	Mean (SD)	7691.77 (9059.355)	13476.64 (7826.055)	9756.44 (10371.27)
	95% CI of Mean	5607.39, 9776.14	10973.74, 15979.54	6347.48, 13165.39

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 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]).

Note: NC = Not calculated

**Table 15.2.4.46.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) - FAS****Parameter (units): Ames Mutagenicity (REV/24h)**

Timepoint	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)
Day 90	n	78	41	40
	Missing, n (%)	0	1 (2.4)	0
	Geometric Mean (CV%)	NC	NC	NC
	95% CI of Geometric Mean	NC	NC	NC
	Median	5399.62	13428.90	5022.00
	Q25, Q75	2704.06, 9502.92	8498.88, 22743.00	2762.80, 12439.29
	Min, Max	0.0, 47872.0	0.0, 47824.0	0.0, 35588.0
	Mean (SD)	6901.56 (6859.626)	17130.22 (12113.05)	8603.01 (8856.734)
	95% CI of Mean	5354.94, 8448.17	13306.87, 20953.58	5770.49, 11435.54

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 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]).

Note: NC = Not calculated

**Table 15.2.4.47 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=78)	
		n	(%)
Day 1	n of THS 2.2 products used	887	
	0	828	(93.3%)
	1	5	(0.6%)
	2	1	(0.1%)
	Missing	53	(6.0%)
Day 2	n of THS 2.2 products used	923	
	0	899	(97.4%)
	1	10	(1.1%)
	Missing	14	(1.5%)
Day 3	n of THS 2.2 products used	936	
	0	918	(98.1%)
	1	13	(1.4%)
	Missing	5	(0.5%)
Day 4	n of THS 2.2 products used	947	
	0	926	(97.8%)
	1	7	(0.7%)
	Missing	14	(1.5%)

Note: THS = Tobacco Heating System.

Note: Percentages are based on the number n of THS 2.2 products used.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper. 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 15.2.4.47 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=78)	
		n	(%)
Day 5	n of THS 2.2 products used	1069	
	0	1045	(97.8%)
	1	13	(1.2%)
	Missing	11	(1.0%)
Day 30	n of THS 2.2 products used	686	
	0	678	(98.8%)
	1	4	(0.6%)
	Missing	4	(0.6%)
Day 60	n of THS 2.2 products used	711	
	0	698	(98.2%)
	1	8	(1.1%)
	Missing	5	(0.7%)
Day 90	n of THS 2.2 products used	804	
	0	795	(98.9%)
	1	5	(0.6%)
	Missing	4	(0.5%)

Note: THS = Tobacco Heating System.

Note: Percentages are based on the number n of THS 2.2 products used.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper. 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 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece			
Absolute UV TAR			
Absorbance			
	Day 1		
		n (THS 2.2 product smoked)	883
		n (filters analysed)	883
		n (subjects)	78
		Geometric Mean (CV%)	0.78827 (48.76)
		95% CI of Geometric Mean	0.71031, 0.87477
		Median	0.80775
		Q25, Q75	0.59350, 1.12720
		Min, Max	0.2168, 1.9791
		Mean (SD)	0.86835 (0.368313)
		95% CI of Mean	0.78530, 0.95140

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece			
Absolute UV TAR			
Absorbance			
	Day 2	n (THS 2.2 product smoked)	922
		n (filters analysed)	922
		n (subjects)	77
		Geometric Mean (CV%)	0.84020 (47.71)
		95% CI of Geometric Mean	0.75813, 0.93115
		Median	0.82240
		Q25, Q75	0.62910, 1.13760
		Min, Max	0.3085, 3.2021
		Mean (SD)	0.92997 (0.450320)
		95% CI of Mean	0.82775, 1.03218

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece			
Absolute UV TAR			
Absorbance			
	Day 3	n (THS 2.2 product smoked)	931
		n (filters analysed)	931
		n (subjects)	77
		Geometric Mean (CV%)	0.88433 (46.06)
		95% CI of Geometric Mean	0.80053, 0.97690
		Median	0.92180
		Q25, Q75	0.68340, 1.22520
		Min, Max	0.2579, 2.1724
		Mean (SD)	0.96693 (0.402129)
		95% CI of Mean	0.87565, 1.05821

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece			
Absolute UV TAR			
Absorbance			
	Day 4	n (THS 2.2 product smoked)	954
		n (filters analysed)	954
		n (subjects)	77
		Geometric Mean (CV%)	0.98154 (39.34)
		95% CI of Geometric Mean	0.90056, 1.06979
		Median	0.99720
		Q25, Q75	0.76320, 1.32150
		Min, Max	0.3210, 1.9813
		Mean (SD)	1.04869 (0.365769)
		95% CI of Mean	0.96566, 1.13171

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece			
Absolute UV TAR			
Absorbance			
	Day 5	n (THS 2.2 product smoked)	1071
		n (filters analysed)	1071
		n (subjects)	77
		Geometric Mean (CV%)	1.06019 (37.91)
		95% CI of Geometric Mean	0.97558, 1.15213
		Median	1.15000
		Q25, Q75	0.84720, 1.38520
		Min, Max	0.3992, 2.1317
		Mean (SD)	1.12813 (0.382338)
		95% CI of Mean	1.04135, 1.21492

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Nicotine Amount per mL (mg/mL)	Day 1	n (THS 2.2 product smoked)	883
		n (filters analysed)	883
		n (subjects)	78
		Geometric Mean (CV%)	0.26684 (47.33)
		95% CI of Geometric Mean	0.24112, 0.29531
		Median	0.26835
		Q25, Q75	0.19440, 0.37940
		Min, Max	0.0764, 0.6341
		Mean (SD)	0.29365 (0.128475)
		95% CI of Mean	0.26468, 0.32262

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Nicotine Amount per mL (mg/mL)	Day 2	n (THS 2.2 product smoked)	922
		n (filters analysed)	922
		n (subjects)	77
		Geometric Mean (CV%)	0.30146 (46.30)
		95% CI of Geometric Mean	0.27277, 0.33318
		Median	0.28430
		Q25, Q75	0.22690, 0.39440
		Min, Max	0.1185, 0.8942
		Mean (SD)	0.33213 (0.153873)
		95% CI of Mean	0.29720, 0.36706

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Nicotine Amount per mL (mg/mL)	Day 3	n (THS 2.2 product smoked)	931
		n (filters analysed)	931
		n (subjects)	77
		Geometric Mean (CV%)	0.31665 (41.25)
		95% CI of Geometric Mean	0.28940, 0.34646
		Median	0.31510
		Q25, Q75	0.23780, 0.40840
		Min, Max	0.1240, 0.7632
		Mean (SD)	0.34209 (0.138634)
		95% CI of Mean	0.31062, 0.37356

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Nicotine Amount per mL (mg/mL)	Day 4	n (THS 2.2 product smoked)	954
		n (filters analysed)	954
		n (subjects)	77
		Geometric Mean (CV%)	0.32681 (40.58)
		95% CI of Geometric Mean	0.29909, 0.35709
		Median	0.33860
		Q25, Q75	0.25960, 0.42890
		Min, Max	0.1150, 0.6646
		Mean (SD)	0.35054 (0.126452)
		95% CI of Mean	0.32184, 0.37925

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Nicotine Amount per mL (mg/mL)	Day 5	n (THS 2.2 product smoked)	1071
		n (filters analysed)	1071
		n (subjects)	77
		Geometric Mean (CV%)	0.36330 (41.42)
		95% CI of Geometric Mean	0.33192, 0.39764
		Median	0.37170
		Q25, Q75	0.27620, 0.49170
		Min, Max	0.1143, 0.6803
		Mean (SD)	0.39069 (0.142863)
		95% CI of Mean	0.35826, 0.42312

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Nicotine Amount per filter (mg/filter)	Day 1	n (THS 2.2 product smoked)	883
		n (filters analysed)	883
		n (subjects)	78
		Geometric Mean (CV%)	2.66828 (47.33)
		95% CI of Geometric Mean	2.41105, 2.95294
		Median	2.68360
		Q25, Q75	1.94430, 3.79450
		Min, Max	0.7652, 6.3395
		Mean (SD)	2.93638 (1.284673)
		95% CI of Mean	2.64673, 3.22604

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Nicotine Amount per filter (mg/filter)	Day 2	n (THS 2.2 product smoked)	922
		n (filters analysed)	922
		n (subjects)	77
		Geometric Mean (CV%)	3.01489 (46.29)
		95% CI of Geometric Mean	2.72798, 3.33196
		Median	2.84430
		Q25, Q75	2.26880, 3.94200
		Min, Max	1.1847, 8.9410
		Mean (SD)	3.32144 (1.538693)
		95% CI of Mean	2.97220, 3.67069

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Nicotine Amount per filter (mg/filter)	Day 3	n (THS 2.2 product smoked)	931
		n (filters analysed)	931
		n (subjects)	77
		Geometric Mean (CV%)	3.16628 (41.24)
		95% CI of Geometric Mean	2.89394, 3.46425
		Median	3.14770
		Q25, Q75	2.37730, 4.08520
		Min, Max	1.2415, 7.6313
		Mean (SD)	3.42056 (1.386081)
		95% CI of Mean	3.10595, 3.73517

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Nicotine Amount per filter (mg/filter)	Day 4	n (THS 2.2 product smoked)	954
		n (filters analysed)	954
		n (subjects)	77
		Geometric Mean (CV%)	3.26814 (40.57)
		95% CI of Geometric Mean	2.99108, 3.57087
		Median	3.38350
		Q25, Q75	2.59830, 4.28840
		Min, Max	1.1515, 6.6476
		Mean (SD)	3.50540 (1.264382)
		95% CI of Mean	3.21842, 3.79238

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Nicotine Amount per filter (mg/filter)	Day 5	n (THS 2.2 product smoked)	1071
		n (filters analysed)	1071
		n (subjects)	77
		Geometric Mean (CV%)	3.63298 (41.42)
		95% CI of Geometric Mean	3.31929, 3.97631
		Median	3.71990
		Q25, Q75	2.76170, 4.91810
		Min, Max	1.1422, 6.8047
		Mean (SD)	3.90683 (1.428512)
		95% CI of Mean	3.58259, 4.23106

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Normalized UV Absorbance (per filter)	Day 1	n (THS 2.2 product smoked)	883
		n (filters analysed)	883
		n (subjects)	78
		Geometric Mean (CV%)	4.60450 (52.11)
		95% CI of Geometric Mean	4.12282, 5.14245
		Median	4.80540
		Q25, Q75	3.47880, 6.76320
		Min, Max	1.3008, 11.8746
		Mean (SD)	5.13123 (2.282366)
		95% CI of Mean	4.61663, 5.64583

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Normalized UV Absorbance (per filter)	Day 2	n (THS 2.2 product smoked)	922
		n (filters analysed)	922
		n (subjects)	77
		Geometric Mean (CV%)	5.00842 (45.78)
		95% CI of Geometric Mean	4.53638, 5.52958
		Median	4.90260
		Q25, Q75	3.79380, 7.14540
		Min, Max	1.8510, 11.5632
		Mean (SD)	5.47992 (2.299311)
		95% CI of Mean	4.95804, 6.00181

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Normalized UV Absorbance (per filter)	Day 3	n (THS 2.2 product smoked)	931
		n (filters analysed)	931
		n (subjects)	77
		Geometric Mean (CV%)	5.75370 (40.08)
		95% CI of Geometric Mean	5.27118, 6.28039
		Median	5.81880
		Q25, Q75	4.37880, 7.77960
		Min, Max	2.2620, 13.0344
		Mean (SD)	6.18287 (2.363042)
		95% CI of Mean	5.64652, 6.71922

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Normalized UV Absorbance (per filter)	Day 4	n (THS 2.2 product smoked)	954
		n (filters analysed)	954
		n (subjects)	77
		Geometric Mean (CV%)	5.94040 (39.55)
		95% CI of Geometric Mean	5.44801, 6.47729
		Median	6.28740
		Q25, Q75	4.56480, 8.23740
		Min, Max	1.9260, 11.8878
		Mean (SD)	6.34914 (2.209611)
		95% CI of Mean	5.84761, 6.85066

Note: THS = Tobacco Heating System.

**Table 15.2.4.48 Descriptive Statistics of Filter Analysis per Visit from the THS 2.2 Menthol Products - FAS**

Variable(units)	Timepoint	Statistic	THSm2.2 (N=78)
Analysis Mouthpiece Normalized UV Absorbance (per filter)	Day 5	n (THS 2.2 product smoked)	1071
		n (filters analysed)	1071
		n (subjects)	77
		Geometric Mean (CV%)	6.26283 (37.70)
		95% CI of Geometric Mean	5.76555, 6.80300
		Median	6.78540
		Q25, Q75	5.03760, 7.84800
		Min, Max	2.3952, 12.7902
		Mean (SD)	6.66491 (2.289640)
		95% CI of Mean	6.14522, 7.18460

Note: THS = Tobacco Heating System.

**Table 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
THSm2.2	Period 2	n	18	39	8	11	76
		Mean (SD)	13.42 (4.980)	11.27 (6.107)	10.42 (9.278)	10.93 (5.258)	11.64 (6.108)
		95% CI	10.94, 15.91	9.29, 13.26	2.66, 18.18	7.39, 14.47	10.24, 13.04
		Median	12.27	11.54	8.67	9.70	11.00
		Min, Max	7.2, 23.3	0.0, 19.2	0.0, 26.2	5.0, 21.6	0.0, 26.2
	Period 3	n	18	39	8	11	76
		Mean (SD)	13.92 (5.619)	12.14 (6.415)	11.51 (8.811)	10.40 (5.934)	12.24 (6.418)
		95% CI	11.12, 16.72	10.06, 14.23	4.14, 18.88	6.41, 14.39	10.77, 13.72
		Median	12.37	12.00	8.76	9.26	11.85
		Min, Max	4.2, 26.2	0.0, 23.8	0.0, 26.9	3.5, 22.0	0.0, 26.9
	Period 4	n	18	39	8	11	76
		Mean (SD)	13.16 (5.156)	12.23 (6.848)	12.64 (9.762)	11.05 (6.118)	12.32 (6.641)
		95% CI	10.60, 15.73	10.01, 14.46	4.48, 20.81	6.93, 15.16	10.80, 13.85
		Median	11.83	12.13	8.45	8.69	11.84
		Min, Max	4.4, 24.6	0.0, 25.6	0.0, 28.7	3.2, 23.4	0.0, 28.7
	Overall	n	18	39	8	11	76
		Mean (SD)	13.53 (4.918)	11.92 (6.203)	11.60 (9.136)	10.77 (5.675)	12.10 (6.153)
		95% CI	11.08, 15.98	9.91, 13.94	3.96, 19.24	6.95, 14.59	10.69, 13.51
		Median	12.12	12.07	8.49	9.60	11.82
		Min, Max	5.4, 24.9	0.0, 22.2	0.0, 27.3	4.2, 22.4	0.0, 27.3

Note: mCC = 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]).

Appendix: 15.3.2.1.3

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**Table 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
CC/mCC	Period 2	n	34	82	17	23	156
		Mean (SD)	4.29 (7.198)	3.14 (5.978)	2.82 (5.635)	5.06 (7.600)	3.64 (6.464)
		95% CI	1.77, 6.81	1.82, 4.46	-0.08, 5.73	1.76, 8.35	2.61, 4.66
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 24.1	0.0, 22.7	0.0, 18.8	0.0, 22.8	0.0, 24.1
	Period 3	n	34	82	17	23	156
		Mean (SD)	5.36 (9.499)	3.23 (6.225)	2.73 (5.393)	5.05 (7.481)	3.91 (7.174)
		95% CI	2.04, 8.68	1.86, 4.60	-0.05, 5.50	1.81, 8.29	2.77, 5.05
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 39.0	0.0, 22.3	0.0, 18.0	0.0, 20.2	0.0, 39.0
	Period 4	n	34	81	17	23	155
		Mean (SD)	5.13 (8.934)	3.43 (6.488)	3.16 (6.381)	5.06 (7.400)	4.02 (7.192)
		95% CI	2.01, 8.26	1.99, 4.87	-0.13, 6.44	1.85, 8.26	2.87, 5.16
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 34.9	0.0, 20.5	0.0, 22.0	0.0, 19.5	0.0, 34.9
	Overall	n	34	82	17	23	156
		Mean (SD)	4.96 (8.538)	3.26 (6.217)	2.91 (5.799)	5.06 (7.483)	3.86 (6.921)
		95% CI	1.98, 7.94	1.89, 4.63	-0.08, 5.90	1.82, 8.30	2.76, 4.96
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 31.9	0.0, 21.8	0.0, 19.6	0.0, 20.7	0.0, 31.9

Note: mCC = 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 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
Inhaler	Period 2	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Overall	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0

Note: mCC = 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 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
Nasal Spray	Period 2	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Overall	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0

Note: mCC = 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 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
Gums	Period 2	n	34	82	17	23	156
		Mean (SD)	0.01 (0.064)	0.13 (0.582)	0.00 (0.000)	0.00 (0.000)	0.07 (0.426)
		95% CI	-0.01, 0.04	0.00, 0.26	0.00, 0.00	0.00, 0.00	0.00, 0.14
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.3	0.0, 4.2	0.0, 0.0	0.0, 0.0	0.0, 4.2
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.07 (0.402)	0.17 (0.681)	0.00 (0.000)	0.06 (0.304)	0.12 (0.542)
		95% CI	-0.08, 0.21	0.02, 0.33	0.00, 0.00	-0.07, 0.20	0.03, 0.21
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 2.3	0.0, 4.4	0.0, 0.0	0.0, 1.5	0.0, 4.4
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.04 (0.248)	0.20 (0.823)	0.00 (0.000)	0.05 (0.223)	0.12 (0.616)
		95% CI	-0.05, 0.13	0.02, 0.39	0.00, 0.00	-0.05, 0.15	0.02, 0.22
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 1.4	0.0, 5.0	0.0, 0.0	0.0, 1.1	0.0, 5.0
	Overall	n	34	82	17	23	156
		Mean (SD)	0.04 (0.245)	0.17 (0.651)	0.00 (0.000)	0.04 (0.194)	0.10 (0.494)
		95% CI	-0.05, 0.14	0.02, 0.32	0.00, 0.00	-0.05, 0.13	0.02, 0.19
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 1.4	0.0, 3.9	0.0, 0.0	0.0, 0.9	0.0, 3.9

Note: mCC = 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 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
Lozenges	Period 2	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.00 (0.000)	0.00 (0.006)	0.00 (0.000)	0.00 (0.000)	0.00 (0.004)
		95% CI	0.00, 0.00	-0.01, 0.01	0.00, 0.00	0.00, 0.00	-0.01, 0.01
		Median	0.00	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	0.0, 0.0
	Overall	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.002)	0.00 (0.000)	0.00 (0.000)	0.00 (0.002)
		95% CI	0.00, 0.00	-0.01, 0.01	0.00, 0.00	0.00, 0.00	-0.01, 0.01
		Median	0.00	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	0.0, 0.0

Note: mCC = 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 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
Patches	Period 2	n	34	82	17	23	156
		Mean (SD)	0.01 (0.055)	0.03 (0.145)	0.11 (0.456)	0.00 (0.000)	0.03 (0.185)
		95% CI	-0.01, 0.03	0.00, 0.07	-0.13, 0.35	0.00, 0.00	0.00, 0.06
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.3	0.0, 1.0	0.0, 1.9	0.0, 0.0	0.0, 1.9
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.01 (0.081)	0.06 (0.219)	0.05 (0.222)	0.00 (0.000)	0.04 (0.179)
		95% CI	-0.02, 0.05	0.01, 0.11	-0.07, 0.17	0.00, 0.00	0.01, 0.07
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.5	0.0, 1.0	0.0, 0.9	0.0, 0.0	0.0, 1.0
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.00 (0.007)	0.06 (0.218)	0.06 (0.252)	0.00 (0.000)	0.04 (0.179)
		95% CI	-0.01, 0.01	0.01, 0.11	-0.07, 0.20	0.00, 0.00	0.00, 0.07
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 1.0	0.0, 1.0	0.0, 0.0	0.0, 1.0
	Overall	n	34	82	17	23	156
		Mean (SD)	0.01 (0.051)	0.05 (0.186)	0.07 (0.300)	0.00 (0.000)	0.04 (0.169)
		95% CI	-0.01, 0.03	0.00, 0.10	-0.09, 0.23	0.00, 0.00	0.00, 0.07
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.3	0.0, 1.0	0.0, 1.2	0.0, 0.0	0.0, 1.2

Note: mCC = 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 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
Other NRT	Period 2	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Overall	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0

Note: mCC = 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]).

Appendix: 15.3.2.1.3

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**Table 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
Chew/Smokeless Tob.	Period 2	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Overall	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0

Note: mCC = 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]).

Appendix: 15.3.2.1.3

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**Table 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
Cigar/Cigarillo	Period 2	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Overall	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0

Note: mCC = 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 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
Pipes	Period 2	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Overall	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0

Note: mCC = 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 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
Tob. Not Listed	Period 2	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0
	Overall	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
		Median	0.00	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	0.0, 0.0

Note: mCC = 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 15.2.4.49 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product preference				Overall
			THS 2.2 menthol	mCC	SA	No preference	
E-Cigarette	Period 2	n	34	82	17	23	156
		Mean (SD)	0.23 (1.358)	0.92 (3.434)	1.25 (3.692)	0.08 (0.381)	0.68 (2.854)
		95% CI	-0.25, 0.71	0.16, 1.68	-0.66, 3.15	-0.09, 0.25	0.23, 1.14
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 7.9	0.0, 17.2	0.0, 13.7	0.0, 1.8	0.0, 17.2
	Period 3	n	34	82	17	23	156
		Mean (SD)	0.00 (0.000)	0.62 (2.792)	0.93 (3.851)	0.08 (0.392)	0.44 (2.394)
		95% CI	0.00, 0.00	0.00, 1.23	-1.05, 2.92	-0.09, 0.26	0.05, 0.82
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 14.9	0.0, 15.9	0.0, 1.9	0.0, 15.9
	Period 4	n	34	81	17	23	155
		Mean (SD)	0.00 (0.000)	0.61 (2.880)	0.81 (3.339)	0.07 (0.324)	0.42 (2.361)
		95% CI	0.00, 0.00	-0.03, 1.25	-0.91, 2.53	-0.08, 0.21	0.04, 0.80
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 17.9	0.0, 13.8	0.0, 1.6	0.0, 17.9
	Overall	n	34	82	17	23	156
		Mean (SD)	0.06 (0.368)	0.70 (2.912)	1.00 (3.543)	0.08 (0.366)	0.50 (2.427)
		95% CI	-0.07, 0.20	0.06, 1.35	-0.83, 2.83	-0.09, 0.24	0.11, 0.89
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 2.1	0.0, 16.4	0.0, 14.6	0.0, 1.8	0.0, 16.4

Note: mCC = 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 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Period 2**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
THSm2.2 Arm	18	40	9	11
THS 2.2 ([70-100]%)	18 (100)	35 (87.5)	7 (77.8)	11 (100)
Exclusively THS 2.2 (100%)	17 (94.4)	32 (80.0)	6 (66.7)	9 (81.8)
Primarily THS 2.2 ([95-100]%)	18 (100)	35 (87.5)	7 (77.8)	11 (100)
Predominantly THS 2.2 ([70-95]%)	0	0	0	0
Dual ([30-70]%)	0	0	0	0
Dual mostly THS 2.2 ([60-70]%)	0	0	0	0
Dual balanced ([40-60]%)	0	0	0	0
Dual mostly CC ([30-40]%)	0	0	0	0
CC ([0-30]%)	0	0	2 (22.2)	0
Predominantly CC ([5-30]%)	0	0	0	0
Primarily CC ([0-5]%)	0	0	2 (22.2)	0
Exclusively CC (0%)	0	0	1 (11.1)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Period 2**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
Abstinent	0	0	0	0
Predominantly Abstinent	0	0	0	0
Not Abstinent	0	4 (10.0)	0	0
Missing	0	0	0	0
Discontinued in previous period	0	1 (2.5)	0	0
mCC Arm	10	20	4	8
CC	10 (100)	19 (95.0)	4 (100)	8 (100)
CC Only (Exclusively CC)	10 (100)	19 (95.0)	4 (100)	8 (100)
CC Dual (Use of other products)	0	0	0	0
Missing	0	0	0	0
Discontinued in previous period	0	1 (5.0)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Period 2**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
SA Arm	6	25	5	4
Abstinent	6 (100)	23 (92.0)	5 (100)	4 (100)
Predominantly Abstinent	0	1 (4.0)	0	0
Not Abstinent	0	0	0	0
Missing	0	0	0	0
Discontinued in previous period	0	1 (4.0)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Period 3**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
THSm2.2 Arm	18	40	9	11
THS 2.2 ([70-100]%)	17 (94.4)	35 (87.5)	6 (66.7)	11 (100)
Exclusively THS 2.2 (100%)	17 (94.4)	34 (85.0)	6 (66.7)	9 (81.8)
Primarily THS 2.2 ([95-100]%)	17 (94.4)	35 (87.5)	6 (66.7)	11 (100)
Predominantly THS 2.2 ([70-95]%)	0	0	0	0
Dual ([30-70]%)	1 (5.6)	0	1 (11.1)	0
Dual mostly THS 2.2 ([60-70]%)	0	0	0	0
Dual balanced ([40-60]%)	1 (5.6)	0	1 (11.1)	0
Dual mostly CC ([30-40]%)	0	0	0	0
CC ([0-30]%)	0	1 (2.5)	1 (11.1)	0
Predominantly CC ([5-30]%)	0	0	0	0
Primarily CC ([0-5]%)	0	1 (2.5)	1 (11.1)	0
Exclusively CC (0%)	0	0	1 (11.1)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Period 3**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
Abstinent	0	0	0	0
Predominantly Abstinent	0	0	0	0
Not Abstinent	0	3 (7.5)	1 (11.1)	0
Missing	0	0	0	0
Discontinued in previous period	0	1 (2.5)	0	0
mCC Arm	10	20	4	8
CC	10 (100)	19 (95.0)	4 (100)	8 (100)
CC Only (Exclusively CC)	10 (100)	19 (95.0)	4 (100)	8 (100)
CC Dual (Use of other products)	0	0	0	0
Missing	0	0	0	0
Discontinued in previous period	0	1 (5.0)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Period 3**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
SA Arm	6	25	5	4
Abstinent	6 (100)	23 (92.0)	5 (100)	4 (100)
Predominantly Abstinent	0	0	0	0
Not Abstinent	0	1 (4.0)	0	0
Missing	0	0	0	0
Discontinued in previous period	0	1 (4.0)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Period 4**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
THSm2.2 Arm	18	40	9	11
THS 2.2 ([70-100]%)	17 (94.4)	33 (82.5)	7 (77.8)	11 (100)
Exclusively THS 2.2 (100%)	17 (94.4)	32 (80.0)	7 (77.8)	10 (90.9)
Primarily THS 2.2 ([95-100]%)	17 (94.4)	32 (80.0)	7 (77.8)	11 (100)
Predominantly THS 2.2 ([70-95]%)	0	1 (2.5)	0	0
Dual ([30-70]%)	1 (5.6)	1 (2.5)	0	0
Dual mostly THS 2.2 ([60-70]%)	0	0	0	0
Dual balanced ([40-60]%)	1 (5.6)	1 (2.5)	0	0
Dual mostly CC ([30-40]%)	0	0	0	0
CC ([0-30]%)	0	1 (2.5)	2 (22.2)	0
Predominantly CC ([5-30]%)	0	1 (2.5)	0	0
Primarily CC ([0-5]%)	0	0	2 (22.2)	0
Exclusively CC (0%)	0	0	1 (11.1)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Period 4**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
Abstinent	0	0	0	0
Predominantly Abstinent	0	0	0	0
Not Abstinent	0	4 (10.0)	0	0
Missing	0	0	0	0
Discontinued in previous period	0	1 (2.5)	0	0
mCC Arm	10	20	4	8
CC	10 (100)	19 (95.0)	4 (100)	8 (100)
CC Only (Exclusively CC)	10 (100)	19 (95.0)	4 (100)	8 (100)
CC Dual (Use of other products)	0	0	0	0
Missing	0	0	0	0
Discontinued in previous period	0	1 (5.0)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Period 4**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
SA Arm	6	25	5	4
Abstinent	5 (83.3)	23 (92.0)	5 (100)	4 (100)
Predominantly Abstinent	0	0	0	0
Not Abstinent	1 (16.7)	0	0	0
Missing	0	0	0	0
Discontinued in previous period	0	2 (8.0)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Ambulatory**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
THSm2.2 Arm	18	40	9	11
THS 2.2 ([70-100]%)	17 (94.4)	34 (85.0)	7 (77.8)	11 (100)
Exclusively THS 2.2 (100%)	16 (88.9)	29 (72.5)	6 (66.7)	8 (72.7)
Primarily THS 2.2 ([95-100]%)	17 (94.4)	33 (82.5)	6 (66.7)	11 (100)
Predominantly THS 2.2 ([70-95]%)	0	1 (2.5)	1 (11.1)	0
Dual ([30-70]%)	1 (5.6)	1 (2.5)	0	0
Dual mostly THS 2.2 ([60-70]%)	1 (5.6)	0	0	0
Dual balanced ([40-60]%)	0	1 (2.5)	0	0
Dual mostly CC ([30-40]%)	0	0	0	0
CC ([0-30]%)	0	0	1 (11.1)	0
Predominantly CC ([5-30]%)	0	0	0	0
Primarily CC ([0-5]%)	0	0	1 (11.1)	0
Exclusively CC (0%)	0	0	1 (11.1)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Ambulatory**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
Abstinent	0	0	0	0
Predominantly Abstinent	0	0	0	0
Not Abstinent	0	4 (10.0)	1 (11.1)	0
Missing	0	0	0	0
Discontinued in previous period	1 (5.6)	1 (2.5)	0	0
mCC Arm	10	20	4	8
CC	10 (100)	19 (95.0)	4 (100)	8 (100)
CC Only (Exclusively CC)	10 (100)	19 (95.0)	4 (100)	8 (100)
CC Dual (Use of other products)	0	0	0	0
Missing	0	0	0	0
Discontinued in previous period	0	1 (5.0)	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 the column header (N).

**Table 15.2.4.50 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS****Product Use Time Period: Ambulatory**

Product Use Categorization	Product preference			
	THS 2.2 menthol	mCC	SA	No preference
SA Arm	6	25	5	4
Abstinent	5 (83.3)	23 (92.0)	5 (100)	4 (100)
Predominantly Abstinent	0	0	0	0
Not Abstinent	1 (16.7)	0	0	0
Missing	0	0	0	0
Discontinued in previous period	0	2 (8.0)	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 the column header (N).



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=40)			
		8:00 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	40	40	40	40
	n (%) ≤10 ppm	40 (100)	40 (100)	40 (100)	40 (100)
	n (%) >10 ppm	0	0	0	0
Day 3	n	40	40	40	40
	n (%) ≤10 ppm	40 (100)	40 (100)	40 (100)	40 (100)
	n (%) >10 ppm	0	0	0	0
Day 4	n	40	40	40	40
	n (%) ≤10 ppm	40 (100)	40 (100)	40 (100)	40 (100)
	n (%) >10 ppm	0	0	0	0
Day 5	n	40	40	40	40
	n (%) ≤10 ppm	40 (100)	40 (100)	40 (100)	40 (100)
	n (%) >10 ppm	0	0	0	0

Note: SA = 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).

**Table 15.2.5.2 Summary of Compliance by Period and Overall - FAS**

Compliance	Confinement		Ambulatory		Overall FAS
	Period 1	Period 2	Period 3	Period 4	
THSm2.2 – N	78	78	78	78	78
Exclusive product use ⁽¹⁾ - n(%)					
Yes	76 (97.4)	63 (80.8)	65 (83.3)	65 (83.3)	57 (73.1)
No	2 (2.6)	14 (17.9)	12 (15.4)	12 (15.4)	21 (26.9)
PP criterion ⁽²⁾ - n(%)					
Yes	77 (98.7)	75 (96.2)	72 (92.3)	71 (91.0)	68 (87.2)
No	1 (1.3)	2 (2.6)	5 (6.4)	6 (7.7)	10 (12.8)
Discontinued ⁽³⁾ - n(%)	0	1 (1.3)	1 (1.3)	1 (1.3)	0
mCC – N	42	42	42	42	42
Exclusive product use ⁽¹⁾ - n(%)					
Yes	42 (100.0)	41 (97.6)	41 (97.6)	41 (97.6)	41 (97.6)
No	0	0	0	0	1 (2.4)
Discontinued ⁽³⁾ - n(%)	0	1 (2.4)	1 (2.4)	1 (2.4)	0
SA – N	40	40	40	40	40
Abstinent ⁽¹⁾ - n(%)					
Yes	39 (97.5)	38 (95.0)	38 (95.0)	37 (92.5)	37 (92.5)
No	1 (2.5)	1 (2.5)	1 (2.5)	1 (2.5)	3 (7.5)
PP criterion ⁽²⁾ - n(%)					
Yes	39 (97.5)	39 (97.5)	38 (95.0)	37 (92.5)	37 (92.5)
No	1 (2.5)	0	1 (2.5)	1 (2.5)	3 (7.5)
Discontinued ⁽³⁾ - n(%)	0	1 (2.5)	1 (2.5)	2 (5.0)	0

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 Study

[3]: Discontinued in previous period, for each 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 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Pre-Randomization**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	6 (7.7)	6	3 (7.1)	4	3 (7.5)	3	4 (26.7)	9	16 (9.1)	22
AE Serious										
Yes ("SAE")	0	0	0	0	0	0	0	0	0	0
No ("AE")	6 (7.7)	6	3 (7.1)	4	3 (7.5)	3	4 (26.7)	9	16 (9.1)	22
AE related to IP										
Not Related	6 (7.7)	6	3 (7.1)	4	3 (7.5)	3	4 (26.7)	9	16 (9.1)	22
Related	0	0	0	0	0	0	0	0	0	0
Expected										
Not expected										
AE related to study procedure										
Not Related	5 (6.4)	5	3 (7.1)	4	2 (5.0)	2	4 (26.7)	9	14 (8.0)	20
Related	1 (1.3)	1	0	0	1 (2.5)	1	0	0	2 (1.1)	2

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Pre-Randomization**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
AE severity										
Mild	6 (7.7)	6	3 (7.1)	4	2 (5.0)	2	3 (20.0)	7	14 (8.0)	19
Moderate	0	0	0	0	1 (2.5)	1	1 (6.7)	2	2 (1.1)	3
Severe	0	0	0	0	0	0	0	0	0	0
Action taken due to AE										
Action taken with study product										
Product use interrupted	0	0	0	0	0	0	0	0	0	0
Product use stopped	0	0	0	0	0	0	0	0	0	0
Product use reduced	0	0	0	0	0	0	0	0	0	0
Not applicable	0	0	0	0	3 (7.5)	3	3 (20.0)	7	6 (3.4)	10
None	6 (7.7)	6	3 (7.1)	4	0	0	1 (6.7)	2	10 (5.7)	12

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Pre-Randomization**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Treatment given										
Yes	0	0	0	0	1 (2.5)	1	1 (6.7)	1	2 (1.1)	2
No	6 (7.7)	6	3 (7.1)	4	2 (5.0)	2	3 (20.0)	8	14 (8.0)	20
Other actions taken										
Discontinued study	0	0	0	0	0	0	2 (13.3)	2	2 (1.1)	2
No action taken due to AE	6 (7.7)	6	3 (7.1)	4	2 (5.0)	2	1 (6.7)	6	12 (6.9)	18

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Post-Randomization**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	32 (41.0)	49	14 (33.3)	22	14 (35.0)	22	60 (37.5)	93
AE Serious								
Yes ("SAE")	0	0	0	0	0	0	0	0
No ("AE")	32 (41.0)	49	14 (33.3)	22	14 (35.0)	22	60 (37.5)	93
AE related to IP								
Not related	31 (39.7)	48	14 (33.3)	22	14 (35.0)	22	59 (36.9)	92
Related	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Expected	0	0					0	0
Not expected	1 (1.3)	1					1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Post-Randomization**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
AE related to study procedure								
Not Related	31 (39.7)	48	12 (28.6)	20	11 (27.5)	19	54 (33.8)	87
Related	1 (1.3)	1	2 (4.8)	2	3 (7.5)	3	6 (3.8)	6
AE severity								
Mild	32 (41.0)	49	13 (31.0)	21	13 (32.5)	21	58 (36.3)	91
Moderate	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Severe	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Post-Randomization**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		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	0	0	0	0
Product use stopped	0	0	0	0	0	0	0	0
Product use reduced	0	0	0	0	0	0	0	0
Not applicable	0	0	0	0	14 (35.0)	22	14 (8.8)	22
None	32 (41.0)	49	14 (33.3)	22	0	0	46 (28.8)	71
Treatment given								
Yes	9 (11.5)	10	5 (11.9)	5	4 (10.0)	4	18 (11.3)	19
No	23 (29.5)	39	9 (21.4)	17	10 (25.0)	18	42 (26.3)	74

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Post-Randomization**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Other actions taken								
Exdontia	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Tooth extraction	1 (1.3)	1	0	0	0	0	1 (0.6)	1
No action taken due to AE	23 (29.5)	39	9 (21.4)	17	10 (25.0)	18	42 (26.3)	74

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Confinement**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	6 (7.7)	9	1 (2.4)	2	8 (20.0)	10	15 (9.4)	21
AE Serious								
Yes ("SAE")	0	0	0	0	0	0	0	0
No ("AE")	6 (7.7)	9	1 (2.4)	2	8 (20.0)	10	15 (9.4)	21
AE related to IP								
Not related	5 (6.4)	8	1 (2.4)	2	8 (20.0)	10	14 (8.8)	20
Related	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Expected	0	0					0	0
Not expected	1 (1.3)	1					1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Confinement**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
AE related to study procedure								
Not Related	6 (7.7)	9	0	1	5 (12.5)	7	11 (6.9)	17
Related	0	0	1 (2.4)	1	3 (7.5)	3	4 (2.5)	4
AE severity								
Mild	6 (7.7)	9	1 (2.4)	2	7 (17.5)	9	14 (8.8)	20
Moderate	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Severe	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Confinement**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		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	0	0	0	0
Product use stopped	0	0	0	0	0	0	0	0
Product use reduced	0	0	0	0	0	0	0	0
Not applicable	0	0	0	0	8 (20.0)	10	8 (5.0)	10
None	6 (7.7)	9	1 (2.4)	2	0	0	7 (4.4)	11
Treatment given								
Yes	1 (1.3)	1	0	0	2 (5.0)	2	3 (1.9)	3
No	5 (6.4)	8	1 (2.4)	2	6 (15.0)	8	12 (7.5)	18
Other actions taken	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Confinement**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
No action taken due to AE	5 (6.4)	8	1 (2.4)	2	6 (15.0)	8	12 (7.5)	18

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Ambulatory**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	29 (37.2)	40	14 (33.3)	20	9 (22.5)	12	52 (32.5)	72
AE Serious								
Yes ("SAE")	0	0	0	0	0	0	0	0
No ("AE")	29 (37.2)	40	14 (33.3)	20	9 (22.5)	12	52 (32.5)	72
AE related to IP								
Not Related	29 (37.2)	40	14 (33.3)	20	9 (22.5)	12	52 (32.5)	72
Related	0	0	0	0	0	0	0	0
Expected								
Not expected								
AE related to study procedure								
Not Related	28 (35.9)	39	13 (31.0)	19	9 (22.5)	12	50 (31.3)	70
Related	1 (1.3)	1	1 (2.4)	1	0	0	2 (1.3)	2

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Ambulatory**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
AE severity								
Mild	29 (37.2)	40	13 (31.0)	19	9 (22.5)	12	51 (31.9)	71
Moderate	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Severe	0	0	0	0	0	0	0	0
Action taken due to AE								
Action taken with study product								
Product use interrupted	0	0	0	0	0	0	0	0
Product use stopped	0	0	0	0	0	0	0	0
Product use reduced	0	0	0	0	0	0	0	0
Not applicable	0	0	0	0	9 (22.5)	12	9 (5.6)	12
None	29 (37.2)	40	14 (33.3)	20	0	0	43 (26.9)	60

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Ambulatory**

Adverse events	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Treatment given								
Yes	8 (10.3)	9	5 (11.9)	5	2 (5.0)	2	15 (9.4)	16
No	21 (26.9)	31	9 (21.4)	15	7 (17.5)	10	37 (23.1)	56
Other actions taken								
Exdontia	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Tooth extraction	1 (1.3)	1	0	0	0	0	1 (0.6)	1
No action taken due to AE	21 (26.9)	31	9 (21.4)	15	7 (17.5)	10	37 (23.1)	56

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1.1 Summary of Adverse Events - Safety Population****Safety Time Period: Safety Follow-up**

	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

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

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

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.2.1 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

Adverse events	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)			
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	26 (36.6)	32	3 (60.0)	8	14 (34.1)	20	9 (23.7)	12	0	0
AE Serious										
Yes ("SAE")	0	0	0	0	0	0	0	0		
No ("AE")	26 (36.6)	32	3 (60.0)	8	14 (34.1)	20	9 (23.7)	12		
AE related to IP										
Not Related	26 (36.6)	32	3 (60.0)	8	14 (34.1)	20	9 (23.7)	12		
Related	0	0	0	0	0	0	0	0		
Expected										
Not expected										
AE related to study procedure										
Not Related	25 (35.2)	31	3 (60.0)	8	13 (31.7)	19	9 (23.7)	12		
Related	1 (1.4)	1	0	0	1 (2.4)	1	0	0		

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: IP=Investigational product (THSm2.2 or mCC).

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.2.1 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

Adverse events	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)			
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
AE severity										
Mild	26 (36.6)	32	3 (60.0)	8	13 (31.7)	19	9 (23.7)	12		
Moderate	0	0	0	0	1 (2.4)	1	0	0		
Severe	0	0	0	0	0	0	0	0		
Action taken due to AE										
Action taken with study product										
Product use interrupted	0	0	0	0	0	0	0	0		
Product use stopped	0	0	0	0	0	0	0	0		
Product use reduced	0	0	0	0	0	0	0	0		
Not applicable	0	0	0	0	0	0	9 (23.7)	12		
None	26 (36.6)	32	3 (60.0)	8	14 (34.1)	20	0	0		

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: IP=Investigational product (THSm2.2 or mCC).

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.2.1 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

Adverse events	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)			
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Treatment given										
Yes	6 (8.5)	6	2 (40.0)	3	5 (12.2)	5	2 (5.3)	2		
No	20 (28.2)	26	1 (20.0)	5	9 (22.0)	15	7 (18.4)	10		
Other actions taken										
Exdontia	0	0	0	0	1 (2.4)	1	0	0		
Tooth extraction	0	0	1 (20.0)	1	0	0	0	0		
No action taken due to AE	20 (28.2)	26	1 (20.0)	5	9 (22.0)	15	7 (18.4)	10		

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: IP=Investigational product (THSm2.2 or mCC).

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.3.1 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	6 (7.7)	6	3 (7.1)	4	3 (7.5)	3	4 (26.7)	9	16 (9.1)	22
Investigations	5 (6.4)	5	2 (4.8)	3	1 (2.5)	1	1 (6.7)	3	9 (5.1)	12
Neutrophil count decreased	3 (3.8)	3	1 (2.4)	1	1 (2.5)	1	0	0	5 (2.9)	5
Blood triglycerides increased	2 (2.6)	2	0	0	0	0	0	0	2 (1.1)	2
Blood cholesterol increased	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
C-reactive protein increased	0	0	0	0	0	0	1 (6.7)	1	1 (0.6)	1
Neutrophil count increased	0	0	0	0	0	0	1 (6.7)	1	1 (0.6)	1
White blood cell count decreased	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
White blood cell count increased	0	0	0	0	0	0	1 (6.7)	1	1 (0.6)	1
Infections and infestations	0	0	0	0	1 (2.5)	1	2 (13.3)	2	3 (1.7)	3
Nasopharyngitis					0	0	1 (6.7)	1	1 (0.6)	1
Parotitis					1 (2.5)	1	0	0	1 (0.6)	1
Pharyngitis					0	0	1 (6.7)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Nervous system disorders	0	0	0	0	0	0	2 (13.3)	2	2 (1.1)	2
Headache							2 (13.3)	2	2 (1.1)	2
Blood and lymphatic system disorders	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Anaemia			1 (2.4)	1					1 (0.6)	1
Gastrointestinal disorders	0	0	0	0	0	0	1 (6.7)	1	1 (0.6)	1
Nausea							1 (6.7)	1	1 (0.6)	1
General disorders and administration site conditions	0	0	0	0	1 (2.5)	1	0	0	1 (0.6)	1
Hunger					1 (2.5)	1			1 (0.6)	1
Psychiatric disorders	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Dysphoria	1 (1.3)	1							1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Vascular disorders	0	0	0	0	0	0	1 (6.7)	1	1 (0.6)	1
Hypotension							1 (6.7)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	32 (41.0)	49	14 (33.3)	22	14 (35.0)	22	60 (37.5)	93
Investigations	24 (30.8)	33	8 (19.0)	12	10 (25.0)	13	42 (26.3)	58
Haemoglobin decreased	11 (14.1)	13	3 (7.1)	5	3 (7.5)	4	17 (10.6)	22
Neutrophil count decreased	5 (6.4)	5	1 (2.4)	1	2 (5.0)	2	8 (5.0)	8
Blood triglycerides increased	3 (3.8)	4	1 (2.4)	1	2 (5.0)	2	6 (3.8)	7
White blood cell count decreased	2 (2.6)	2	0	0	1 (2.5)	1	3 (1.9)	3
Alanine aminotransferase increased	1 (1.3)	1	0	0	1 (2.5)	1	2 (1.3)	2
Gamma-glutamyltransferase increased	2 (2.6)	2	0	0	0	0	2 (1.3)	2
Protein urine present	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Aspartate aminotransferase increased	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Blood bilirubin increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Blood cholesterol increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Blood creatinine increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Blood glucose increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Eosinophil count increased	0	0	0	0	1 (2.5)	1	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Glucose urine present	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Lymphocyte count decreased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Lymphocyte count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Neutrophil count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Protein total decreased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
White blood cell count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Infections and infestations	6 (7.7)	7	3 (7.1)	3	3 (7.5)	3	12 (7.5)	13
Nasopharyngitis	3 (3.8)	3	1 (2.4)	1	2 (5.0)	2	6 (3.8)	6
Hordeolum	1 (1.3)	1	1 (2.4)	1	0	0	2 (1.3)	2
Pharyngitis	1 (1.3)	2	1 (2.4)	1	0	0	2 (1.3)	3
Periodontitis	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Rhinitis	1 (1.3)	1	0	0	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Gastrointestinal disorders	4 (5.1)	5	2 (4.8)	2	1 (2.5)	1	7 (4.4)	8
Constipation	2 (2.6)	2	1 (2.4)	1	1 (2.5)	1	4 (2.5)	4
Dental caries	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Diarrhoea	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Rectal prolapse	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Toothache	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Injury, poisoning and procedural complications	2 (2.6)	2	0	0	1 (2.5)	1	3 (1.9)	3
Hand fracture	0	0			1 (2.5)	1	1 (0.6)	1
Scar	1 (1.3)	1			0	0	1 (0.6)	1
Tooth fracture	1 (1.3)	1			0	0	1 (0.6)	1
Ear and labyrinth disorders	0	0	0	0	2 (5.0)	2	2 (1.3)	2
Vertigo					2 (5.0)	2	2 (1.3)	2

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Psychiatric disorders	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Insomnia			1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Blood and lymphatic system disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Anaemia			1 (2.4)	1			1 (0.6)	1
General disorders and administration site conditions	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Pyrexia					1 (2.5)	1	1 (0.6)	1
Musculoskeletal and connective tissue disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Intervertebral disc protrusion			1 (2.4)	1			1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Uterine leiomyoma			1 (2.4)	1			1 (0.6)	1
Nervous system disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Headache			1 (2.4)	1			1 (0.6)	1
Respiratory, thoracic and mediastinal disorders	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Oropharyngeal pain	1 (1.3)	1					1 (0.6)	1
Skin and subcutaneous tissue disorders	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Eczema	1 (1.3)	1					1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	6 (7.7)	9	1 (2.4)	2	8 (20.0)	10	15 (9.4)	21
Investigations	3 (3.8)	4	1 (2.4)	1	2 (5.0)	3	6 (3.8)	8
White blood cell count decreased	1 (1.3)	1	0	0	1 (2.5)	1	2 (1.3)	2
Alanine aminotransferase increased	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Aspartate aminotransferase increased	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Blood bilirubin increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Blood triglycerides increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Haemoglobin decreased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Neutrophil count decreased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Gastrointestinal disorders	2 (2.6)	3	1 (2.4)	1	1 (2.5)	1	4 (2.5)	5
Constipation	1 (1.3)	1	1 (2.4)	1	1 (2.5)	1	3 (1.9)	3
Diarrhoea	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Rectal prolapse	1 (1.3)	1	0	0	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Infections and infestations	1 (1.3)	1	0	0	2 (5.0)	2	3 (1.9)	3
Hordeolum	1 (1.3)	1			0	0	1 (0.6)	1
Nasopharyngitis	0	0			1 (2.5)	1	1 (0.6)	1
Periodontitis	0	0			1 (2.5)	1	1 (0.6)	1
Ear and labyrinth disorders	0	0	0	0	2 (5.0)	2	2 (1.3)	2
Vertigo					2 (5.0)	2	2 (1.3)	2
General disorders and administration site conditions	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Pyrexia					1 (2.5)	1	1 (0.6)	1
Injury, poisoning and procedural complications	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Scar	1 (1.3)	1					1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Psychiatric disorders	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Insomnia					1 (2.5)	1	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	29 (37.2)	40	14 (33.3)	20	9 (22.5)	12	52 (32.5)	72
Investigations	23 (29.5)	29	8 (19.0)	11	8 (20.0)	10	39 (24.4)	50
Haemoglobin decreased	11 (14.1)	13	3 (7.1)	4	3 (7.5)	4	17 (10.6)	21
Neutrophil count decreased	4 (5.1)	4	1 (2.4)	1	2 (5.0)	2	7 (4.4)	7
Blood triglycerides increased	3 (3.8)	3	1 (2.4)	1	2 (5.0)	2	6 (3.8)	6
Gamma-glutamyltransferase increased	2 (2.6)	2	0	0	0	0	2 (1.3)	2
Protein urine present	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Alanine aminotransferase increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Blood cholesterol increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Blood creatinine increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Blood glucose increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Eosinophil count increased	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Glucose urine present	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Lymphocyte count decreased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Lymphocyte count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Neutrophil count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Protein total decreased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
White blood cell count decreased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
White blood cell count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Infections and infestations	5 (6.4)	6	3 (7.1)	3	1 (2.5)	1	9 (5.6)	10
Nasopharyngitis	3 (3.8)	3	1 (2.4)	1	1 (2.5)	1	5 (3.1)	5
Pharyngitis	1 (1.3)	2	1 (2.4)	1	0	0	2 (1.3)	3
Hordeolum	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Rhinitis	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Gastrointestinal disorders	2 (2.6)	2	1 (2.4)	1	0	0	3 (1.9)	3
Constipation	1 (1.3)	1	0	0			1 (0.6)	1
Dental caries	1 (1.3)	1	0	0			1 (0.6)	1
Toothache	0	0	1 (2.4)	1			1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Injury, poisoning and procedural complications	1 (1.3)	1	0	0	1 (2.5)	1	2 (1.3)	2
Hand fracture	0	0			1 (2.5)	1	1 (0.6)	1
Tooth fracture	1 (1.3)	1			0	0	1 (0.6)	1
Blood and lymphatic system disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Anaemia			1 (2.4)	1			1 (0.6)	1
Musculoskeletal and connective tissue disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Intervertebral disc protrusion			1 (2.4)	1			1 (0.6)	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Uterine leiomyoma			1 (2.4)	1			1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Nervous system disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Headache			1 (2.4)	1			1 (0.6)	1
Psychiatric disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Insomnia			1 (2.4)	1			1 (0.6)	1
Respiratory, thoracic and mediastinal disorders	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Oropharyngeal pain	1 (1.3)	1					1 (0.6)	1
Skin and subcutaneous tissue disorders	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Eczema	1 (1.3)	1					1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Safety Follow-up**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.3.1.1 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=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	4 (26.7)	9	4 (2.3)	9
Infections and infestations							2 (13.3)	2	2 (1.1)	2
Nasopharyngitis							1 (6.7)	1	1 (0.6)	1
Pharyngitis							1 (6.7)	1	1 (0.6)	1
Nervous system disorders							2 (13.3)	2	2 (1.1)	2
Headache							2 (13.3)	2	2 (1.1)	2
Gastrointestinal disorders							1 (6.7)	1	1 (0.6)	1
Nausea							1 (6.7)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.3.1.1 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=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Investigations							1 (6.7)	3	1 (0.6)	3
C-reactive protein increased							1 (6.7)	1	1 (0.6)	1
Neutrophil count increased							1 (6.7)	1	1 (0.6)	1
White blood cell count increased							1 (6.7)	1	1 (0.6)	1
Vascular disorders							1 (6.7)	1	1 (0.6)	1
Hypotension							1 (6.7)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.3.1.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	16 (20.5)	18	4 (9.5)	6	4 (10.0)	6	24 (15.0)	30
Investigations	16 (20.5)	18	4 (9.5)	6	4 (10.0)	6	24 (15.0)	30
Haemoglobin decreased	11 (14.1)	13	3 (7.1)	5	3 (7.5)	4	17 (10.6)	22
Neutrophil count decreased	5 (6.4)	5	1 (2.4)	1	2 (5.0)	2	8 (5.0)	8

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.3.1.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.3.1.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	15 (19.2)	17	4 (9.5)	5	4 (10.0)	6	23 (14.4)	28
Investigations	15 (19.2)	17	4 (9.5)	5	4 (10.0)	6	23 (14.4)	28
Haemoglobin decreased	11 (14.1)	13	3 (7.1)	4	3 (7.5)	4	17 (10.6)	21
Neutrophil count decreased	4 (5.1)	4	1 (2.4)	1	2 (5.0)	2	7 (4.4)	7

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.3.1.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.4.1 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)			
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	26 (36.6)	32	3 (60.0)	8	14 (34.1)	20	9 (23.7)	12	0	0
Investigations	20 (28.2)	25	3 (60.0)	4	8 (19.5)	11	8 (21.1)	10		
Haemoglobin decreased	9 (12.7)	11	2 (40.0)	2	3 (7.3)	4	3 (7.9)	4		
Neutrophil count decreased	4 (5.6)	4	0	0	1 (2.4)	1	2 (5.3)	2		
Blood triglycerides increased	3 (4.2)	3	0	0	1 (2.4)	1	2 (5.3)	2		
Gamma-glutamyltransferase increased	1 (1.4)	1	1 (20.0)	1	0	0	0	0		
Protein urine present	0	0	0	0	1 (2.4)	1	1 (2.6)	1		
Alanine aminotransferase increased	0	0	1 (20.0)	1	0	0	0	0		

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.4.1 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)			
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood cholesterol increased	1 (1.4)	1	0	0	0	0	0	0		
Blood creatinine increased	1 (1.4)	1	0	0	0	0	0	0		
Blood glucose increased	1 (1.4)	1	0	0	0	0	0	0		
Eosinophil count increased	0	0	0	0	0	0	1 (2.6)	1		
Glucose urine present	1 (1.4)	1	0	0	0	0	0	0		
Lymphocyte count decreased	1 (1.4)	1	0	0	0	0	0	0		
Lymphocyte count increased	0	0	0	0	1 (2.4)	1	0	0		

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.4.1 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Neutrophil count increased	0	0	0	0	1 (2.4)	1	0	0		
Protein total decreased	0	0	0	0	1 (2.4)	1	0	0		
White blood cell count decreased	1 (1.4)	1	0	0	0	0	0	0		
White blood cell count increased	0	0	0	0	1 (2.4)	1	0	0		

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.4.1 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)			
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Infections and infestations	3 (4.2)	3	2 (40.0)	3	3 (7.3)	3	1 (2.6)	1		
Nasopharyngitis	2 (2.8)	2	1 (20.0)	1	1 (2.4)	1	1 (2.6)	1		
Pharyngitis	0	0	1 (20.0)	2	1 (2.4)	1	0	0		
Hordeolum	0	0	0	0	1 (2.4)	1	0	0		
Rhinitis	1 (1.4)	1	0	0	0	0	0	0		

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.4.1 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)			
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Gastrointestinal disorders	1 (1.4)	1	1 (20.0)	1	1 (2.4)	1	0	0		
Constipation	1 (1.4)	1	0	0	0	0				
Dental caries	0	0	1 (20.0)	1	0	0				
Toothache	0	0	0	0	1 (2.4)	1				
Injury, poisoning and procedural complications	1 (1.4)	1	0	0	0	0	1 (2.6)	1		
Hand fracture	0	0					1 (2.6)	1		
Tooth fracture	1 (1.4)	1					0	0		

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.4.1 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood and lymphatic system disorders	0	0	0	0	1 (2.4)	1	0	0		
Anaemia					1 (2.4)	1				
Musculoskeletal and connective tissue disorders	0	0	0	0	1 (2.4)	1	0	0		
Intervertebral disc protrusion					1 (2.4)	1				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	0	1 (2.4)	1	0	0		
Uterine leiomyoma					1 (2.4)	1				

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.4.1 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)			
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Nervous system disorders	0	0	0	0	1 (2.4)	1	0	0		
Headache					1 (2.4)	1				
Psychiatric disorders	0	0	0	0	1 (2.4)	1	0	0		
Insomnia					1 (2.4)	1				
Respiratory, thoracic and mediastinal disorders	1 (1.4)	1	0	0	0	0	0	0		
Oropharyngeal pain	1 (1.4)	1								

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.4.1 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)			
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Skin and subcutaneous tissue disorders	1 (1.4)	1	0	0	0	0	0	0		
Eczema	1 (1.4)	1								

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.5.1 Summary of Adverse Events by System Organ Class, 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=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	6 (7.7)	6	3 (7.1)	4	3 (7.5)	3	4 (26.7)	9	16 (9.1)	22
Not Related to IP	6 (7.7)	6	3 (7.1)	4	3 (7.5)	3	4 (26.7)	9	16 (9.1)	22
Related to IP	0	0	0	0	0	0	0	0	0	0
Expected										
Not expected										

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.5.1 Summary of Adverse Events by System Organ Class, 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	32 (41.0)	49	14 (33.3)	22	14 (35.0)	22	60 (37.5)	93
Not Related to IP	31 (39.7)	48	14 (33.3)	22	14 (35.0)	22	59 (36.9)	92
Related to IP	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Expected	0	0					0	0
Not expected	1 (1.3)	1					1 (0.6)	1
Gastrointestinal disorders	4 (5.1)	5	2 (4.8)	2	1 (2.5)	1	7 (4.4)	8
Diarrhoea	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Not Related to IP	0	0					0	0
Related to IP	1 (1.3)	1					1 (0.6)	1
Expected	0	0					0	0
Not expected	1 (1.3)	1					1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.5.1 Summary of Adverse Events by System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	6 (7.7)	9	1 (2.4)	2	8 (20.0)	10	15 (9.4)	21
Not Related to IP	5 (6.4)	8	1 (2.4)	2	8 (20.0)	10	14 (8.8)	20
Related to IP	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Expected	0	0					0	0
Not expected	1 (1.3)	1					1 (0.6)	1
Gastrointestinal disorders	2 (2.6)	3	1 (2.4)	1	1 (2.5)	1	4 (2.5)	5
Diarrhoea	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Not Related to IP	0	0					0	0
Related to IP	1 (1.3)	1					1 (0.6)	1
Expected	0	0					0	0
Not expected	1 (1.3)	1					1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.5.1 Summary of Adverse Events by System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	29 (37.2)	40	14 (33.3)	20	9 (22.5)	12	52 (32.5)	72
Not Related to IP	29 (37.2)	40	14 (33.3)	20	9 (22.5)	12	52 (32.5)	72
Related to IP	0	0	0	0	0	0	0	0
Expected								
Not expected								

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.5.1 Summary of Adverse Events by System Organ Class, 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse event	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.6.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)			
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	26 (36.6)	32	3 (60.0)	8	14 (34.1)	20	9 (23.7)	12	0	0
Not Related to IP	26 (36.6)	32	3 (60.0)	8	14 (34.1)	20	9 (23.7)	12		
Related to IP	0	0	0	0	0	0	0	0		
Expected										
Not expected										

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.7.1 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=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	2 (13.3)	2	2 (1.1)	2
Infections and infestations							1 (6.7)	1	1 (0.6)	1
Nasopharyngitis							1 (6.7)	1	1 (0.6)	1
Vascular disorders							1 (6.7)	1	1 (0.6)	1
Hypotension							1 (6.7)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.7.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.7.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.7.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.7.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.8.1 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	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)			
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
	0	0	0	0	0	0	0	0	0	0
Adverse Events Leading to Study Product Discontinuation, Interruption, or Reduction										

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.9.1 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=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	1 (1.3)	1	0	0	1 (2.5)	1	0	0	2 (1.1)	2
General disorders and administration site conditions	0	0			1 (2.5)	1			1 (0.6)	1
Hunger					1 (2.5)	1			1 (0.6)	1
Psychiatric disorders	1 (1.3)	1			0	0			1 (0.6)	1
Dysphoria	1 (1.3)	1							1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.9.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	1 (1.3)	1	2 (4.8)	2	3 (7.5)	3	6 (3.8)	6
Gastrointestinal disorders	1 (1.3)	1	1 (2.4)	1	1 (2.5)	1	3 (1.9)	3
Constipation	1 (1.3)	1	1 (2.4)	1	1 (2.5)	1	3 (1.9)	3
Psychiatric disorders	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Insomnia			1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Ear and labyrinth disorders	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Vertigo					1 (2.5)	1	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.9.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	1 (2.4)	1	3 (7.5)	3	4 (2.5)	4
Gastrointestinal disorders			1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Constipation			1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Ear and labyrinth disorders			0	0	1 (2.5)	1	1 (0.6)	1
Vertigo					1 (2.5)	1	1 (0.6)	1
Psychiatric disorders			0	0	1 (2.5)	1	1 (0.6)	1
Insomnia					1 (2.5)	1	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.9.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	1 (1.3)	1	1 (2.4)	1	0	0	2 (1.3)	2
Gastrointestinal disorders	1 (1.3)	1	0	0			1 (0.6)	1
Constipation	1 (1.3)	1					1 (0.6)	1
Psychiatric disorders	0	0	1 (2.4)	1			1 (0.6)	1
Insomnia			1 (2.4)	1			1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.9.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse events	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	6 (7.7)	6	3 (7.1)	4	3 (7.5)	3	4 (26.7)	9	16 (9.1)	22
Mild	6 (7.7)	6	3 (7.1)	4	2 (5.0)	2	3 (20.0)	7	14 (8.0)	19
Moderate	0	0	0	0	1 (2.5)	1	1 (6.7)	2	2 (1.1)	3
Severe	0	0	0	0	0	0	0	0	0	0
Investigations	5 (6.4)	5	2 (4.8)	3	1 (2.5)	1	1 (6.7)	3	9 (5.1)	12
Neutrophil count decreased	3 (3.8)	3	1 (2.4)	1	1 (2.5)	1	0	0	5 (2.9)	5
Mild	3 (3.8)	3	1 (2.4)	1	1 (2.5)	1			5 (2.9)	5
Moderate	0	0	0	0	0	0			0	0
Severe	0	0	0	0	0	0			0	0
Blood triglycerides increased	2 (2.6)	2	0	0	0	0	0	0	2 (1.1)	2
Mild	2 (2.6)	2							2 (1.1)	2
Moderate	0	0							0	0
Severe	0	0							0	0

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood cholesterol increased	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Mild			1 (2.4)	1					1 (0.6)	1
Moderate			0	0					0	0
Severe			0	0					0	0
C-reactive protein increased	0	0	0	0	0	0	1 (6.7)	1	1 (0.6)	1
Mild							1 (6.7)	1	1 (0.6)	1
Moderate							0	0	0	0
Severe							0	0	0	0
Neutrophil count increased	0	0	0	0	0	0	1 (6.7)	1	1 (0.6)	1
Mild							0	0	0	0
Moderate							1 (6.7)	1	1 (0.6)	1
Severe							0	0	0	0
White blood cell count decreased	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Mild			1 (2.4)	1					1 (0.6)	1
Moderate			0	0					0	0
Severe			0	0					0	0

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
White blood cell count increased	0	0	0	0	0	0	1 (6.7)	1	1 (0.6)	1
Mild							0	0	0	0
Moderate							1 (6.7)	1	1 (0.6)	1
Severe							0	0	0	0

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Infections and infestations	0	0	0	0	1 (2.5)	1	2 (13.3)	2	3 (1.7)	3
Nasopharyngitis					0	0	1 (6.7)	1	1 (0.6)	1
Mild							1 (6.7)	1	1 (0.6)	1
Moderate							0	0	0	0
Severe							0	0	0	0
Parotitis					1 (2.5)	1	0	0	1 (0.6)	1
Mild					0	0			0	0
Moderate					1 (2.5)	1			1 (0.6)	1
Severe					0	0			0	0
Pharyngitis					0	0	1 (6.7)	1	1 (0.6)	1
Mild							1 (6.7)	1	1 (0.6)	1
Moderate							0	0	0	0
Severe							0	0	0	0

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Nervous system disorders	0	0	0	0	0	0	2 (13.3)	2	2 (1.1)	2
Headache							2 (13.3)	2	2 (1.1)	2
Mild							2 (13.3)	2	2 (1.1)	2
Moderate							0	0	0	0
Severe							0	0	0	0
Blood and lymphatic system disorders	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Anaemia			1 (2.4)	1					1 (0.6)	1
Mild			1 (2.4)	1					1 (0.6)	1
Moderate			0	0					0	0
Severe			0	0					0	0

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Gastrointestinal disorders	0	0	0	0	0	0	1 (6.7)	1	1 (0.6)	1
Nausea							1 (6.7)	1	1 (0.6)	1
Mild							1 (6.7)	1	1 (0.6)	1
Moderate							0	0	0	0
Severe							0	0	0	0
General disorders and administration site conditions	0	0	0	0	1 (2.5)	1	0	0	1 (0.6)	1
Hunger					1 (2.5)	1			1 (0.6)	1
Mild					1 (2.5)	1			1 (0.6)	1
Moderate					0	0			0	0
Severe					0	0			0	0

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Psychiatric disorders	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Dysphoria	1 (1.3)	1							1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1
Moderate	0	0							0	0
Severe	0	0							0	0
Vascular disorders	0	0	0	0	0	0	1 (6.7)	1	1 (0.6)	1
Hypotension							1 (6.7)	1	1 (0.6)	1
Mild							1 (6.7)	1	1 (0.6)	1
Moderate							0	0	0	0
Severe							0	0	0	0

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	32 (41.0)	49	14 (33.3)	22	14 (35.0)	22	60 (37.5)	93
Mild	32 (41.0)	49	13 (31.0)	21	13 (32.5)	21	58 (36.3)	91
Moderate	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Severe	0	0	0	0	0	0	0	0
Investigations	24 (30.8)	33	8 (19.0)	12	10 (25.0)	13	42 (26.3)	58
Haemoglobin decreased	11 (14.1)	13	3 (7.1)	5	3 (7.5)	4	17 (10.6)	22
Mild	11 (14.1)	13	3 (7.1)	5	3 (7.5)	4	17 (10.6)	22
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Neutrophil count decreased	5 (6.4)	5	1 (2.4)	1	2 (5.0)	2	8 (5.0)	8
Mild	5 (6.4)	5	1 (2.4)	1	2 (5.0)	2	8 (5.0)	8
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood triglycerides increased	3 (3.8)	4	1 (2.4)	1	2 (5.0)	2	6 (3.8)	7
Mild	3 (3.8)	4	1 (2.4)	1	2 (5.0)	2	6 (3.8)	7
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
White blood cell count decreased	2 (2.6)	2	0	0	1 (2.5)	1	3 (1.9)	3
Mild	2 (2.6)	2			1 (2.5)	1	3 (1.9)	3
Moderate	0	0			0	0	0	0
Severe	0	0			0	0	0	0
Alanine aminotransferase increased	1 (1.3)	1	0	0	1 (2.5)	1	2 (1.3)	2
Mild	1 (1.3)	1			1 (2.5)	1	2 (1.3)	2
Moderate	0	0			0	0	0	0
Severe	0	0			0	0	0	0
Gamma-glutamyltransferase increased	2 (2.6)	2	0	0	0	0	2 (1.3)	2
Mild	2 (2.6)	2					2 (1.3)	2
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Protein urine present	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Mild			1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Moderate			0	0	0	0	0	0
Severe			0	0	0	0	0	0
Aspartate aminotransferase increased	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0
Blood bilirubin increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Blood cholesterol increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood creatinine increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Blood glucose increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Eosinophil count increased	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0
Glucose urine present	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Lymphocyte count decreased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Lymphocyte count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
Neutrophil count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
Protein total decreased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
White blood cell count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
Infections and infestations	6 (7.7)	7	3 (7.1)	3	3 (7.5)	3	12 (7.5)	13
Nasopharyngitis	3 (3.8)	3	1 (2.4)	1	2 (5.0)	2	6 (3.8)	6
Mild	3 (3.8)	3	1 (2.4)	1	2 (5.0)	2	6 (3.8)	6
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Hordeolum	1 (1.3)	1	1 (2.4)	1	0	0	2 (1.3)	2
Mild	1 (1.3)	1	1 (2.4)	1			2 (1.3)	2
Moderate	0	0	0	0			0	0
Severe	0	0	0	0			0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Pharyngitis	1 (1.3)	2	1 (2.4)	1	0	0	2 (1.3)	3
Mild	1 (1.3)	2	1 (2.4)	1			2 (1.3)	3
Moderate	0	0	0	0			0	0
Severe	0	0	0	0			0	0
Periodontitis	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Mild					0	0	0	0
Moderate					1 (2.5)	1	1 (0.6)	1
Severe					0	0	0	0
Rhinitis	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Gastrointestinal disorders	4 (5.1)	5	2 (4.8)	2	1 (2.5)	1	7 (4.4)	8

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Constipation	2 (2.6)	2	1 (2.4)	1	1 (2.5)	1	4 (2.5)	4
Mild	2 (2.6)	2	1 (2.4)	1	1 (2.5)	1	4 (2.5)	4
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dental caries	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Diarrhoea	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Rectal prolapse	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Toothache	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Injury, poisoning and procedural complications	2 (2.6)	2	0	0	1 (2.5)	1	3 (1.9)	3
Hand fracture	0	0			1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0
Scar	1 (1.3)	1			0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Tooth fracture	1 (1.3)	1			0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Ear and labyrinth disorders	0	0	0	0	2 (5.0)	2	2 (1.3)	2
Vertigo					2 (5.0)	2	2 (1.3)	2
Mild					2 (5.0)	2	2 (1.3)	2
Moderate					0	0	0	0
Severe					0	0	0	0
Psychiatric disorders	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Insomnia			1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Mild			1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Moderate			0	0	0	0	0	0
Severe			0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood and lymphatic system disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Anaemia			1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
General disorders and administration site conditions	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Pyrexia					1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Musculoskeletal and connective tissue disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Intervertebral disc protrusion			1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Uterine leiomyoma			1 (2.4)	1			1 (0.6)	1
Mild			0	0			0	0
Moderate			1 (2.4)	1			1 (0.6)	1
Severe			0	0			0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Nervous system disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Headache			1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
Respiratory, thoracic and mediastinal disorders	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Oropharyngeal pain	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Skin and subcutaneous tissue disorders	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Eczema	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	6 (7.7)	9	1 (2.4)	2	8 (20.0)	10	15 (9.4)	21
Mild	6 (7.7)	9	1 (2.4)	2	7 (17.5)	9	14 (8.8)	20
Moderate	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Severe	0	0	0	0	0	0	0	0
Investigations	3 (3.8)	4	1 (2.4)	1	2 (5.0)	3	6 (3.8)	8
White blood cell count decreased	1 (1.3)	1	0	0	1 (2.5)	1	2 (1.3)	2
Mild	1 (1.3)	1			1 (2.5)	1	2 (1.3)	2
Moderate	0	0			0	0	0	0
Severe	0	0			0	0	0	0
Alanine aminotransferase increased	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Aspartate aminotransferase increased	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0
Blood bilirubin increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Blood triglycerides increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Haemoglobin decreased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Neutrophil count decreased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Gastrointestinal disorders	2 (2.6)	3	1 (2.4)	1	1 (2.5)	1	4 (2.5)	5
Constipation	1 (1.3)	1	1 (2.4)	1	1 (2.5)	1	3 (1.9)	3
Mild	1 (1.3)	1	1 (2.4)	1	1 (2.5)	1	3 (1.9)	3
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Diarrhoea	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Rectal prolapse	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Infections and infestations	1 (1.3)	1	0	0	2 (5.0)	2	3 (1.9)	3
Hordeolum	1 (1.3)	1			0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Nasopharyngitis	0	0			1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0
Periodontitis	0	0			1 (2.5)	1	1 (0.6)	1
Mild					0	0	0	0
Moderate					1 (2.5)	1	1 (0.6)	1
Severe					0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Ear and labyrinth disorders	0	0	0	0	2 (5.0)	2	2 (1.3)	2
Vertigo					2 (5.0)	2	2 (1.3)	2
Mild					2 (5.0)	2	2 (1.3)	2
Moderate					0	0	0	0
Severe					0	0	0	0
General disorders and administration site conditions	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Pyrexia					1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Injury, poisoning and procedural complications	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Scar	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Psychiatric disorders	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Insomnia					1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	29 (37.2)	40	14 (33.3)	20	9 (22.5)	12	52 (32.5)	72
Mild	29 (37.2)	40	13 (31.0)	19	9 (22.5)	12	51 (31.9)	71
Moderate	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Severe	0	0	0	0	0	0	0	0
Investigations	23 (29.5)	29	8 (19.0)	11	8 (20.0)	10	39 (24.4)	50
Haemoglobin decreased	11 (14.1)	13	3 (7.1)	4	3 (7.5)	4	17 (10.6)	21
Mild	11 (14.1)	13	3 (7.1)	4	3 (7.5)	4	17 (10.6)	21
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Neutrophil count decreased	4 (5.1)	4	1 (2.4)	1	2 (5.0)	2	7 (4.4)	7
Mild	4 (5.1)	4	1 (2.4)	1	2 (5.0)	2	7 (4.4)	7
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood triglycerides increased	3 (3.8)	3	1 (2.4)	1	2 (5.0)	2	6 (3.8)	6
Mild	3 (3.8)	3	1 (2.4)	1	2 (5.0)	2	6 (3.8)	6
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Gamma-glutamyltransferase increased	2 (2.6)	2	0	0	0	0	2 (1.3)	2
Mild	2 (2.6)	2					2 (1.3)	2
Moderate	0	0					0	0
Severe	0	0					0	0
Protein urine present	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Mild			1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Moderate			0	0	0	0	0	0
Severe			0	0	0	0	0	0
Alanine aminotransferase increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood cholesterol increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Blood creatinine increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Blood glucose increased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Eosinophil count increased	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Glucose urine present	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Lymphocyte count decreased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Lymphocyte count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
Neutrophil count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Protein total decreased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
White blood cell count decreased	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
White blood cell count increased	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
Infections and infestations	5 (6.4)	6	3 (7.1)	3	1 (2.5)	1	9 (5.6)	10

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Nasopharyngitis	3 (3.8)	3	1 (2.4)	1	1 (2.5)	1	5 (3.1)	5
Mild	3 (3.8)	3	1 (2.4)	1	1 (2.5)	1	5 (3.1)	5
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Pharyngitis	1 (1.3)	2	1 (2.4)	1	0	0	2 (1.3)	3
Mild	1 (1.3)	2	1 (2.4)	1			2 (1.3)	3
Moderate	0	0	0	0			0	0
Severe	0	0	0	0			0	0
Hordeolum	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
Rhinitis	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Gastrointestinal disorders	2 (2.6)	2	1 (2.4)	1	0	0	3 (1.9)	3
Constipation	1 (1.3)	1	0	0			1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Dental caries	1 (1.3)	1	0	0			1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Toothache	0	0	1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Injury, poisoning and procedural complications	1 (1.3)	1	0	0	1 (2.5)	1	2 (1.3)	2
Hand fracture	0	0			1 (2.5)	1	1 (0.6)	1
Mild					1 (2.5)	1	1 (0.6)	1
Moderate					0	0	0	0
Severe					0	0	0	0
Tooth fracture	1 (1.3)	1			0	0	1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Blood and lymphatic system disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Anaemia			1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Musculoskeletal and connective tissue disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Intervertebral disc protrusion			1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Uterine leiomyoma			1 (2.4)	1			1 (0.6)	1
Mild			0	0			0	0
Moderate			1 (2.4)	1			1 (0.6)	1
Severe			0	0			0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Nervous system disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Headache			1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0
Psychiatric disorders	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Insomnia			1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0	0			0	0
Severe			0	0			0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Respiratory, thoracic and mediastinal disorders	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Oropharyngeal pain	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0
Skin and subcutaneous tissue disorders	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Eczema	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0	0					0	0
Severe	0	0					0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.10.1 Summary of Adverse Events by System Organ Class, Preferred Term and Severity - Safety Population****Safety Time Period: Safety Follow-up**

System Organ Class Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any adverse event	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)			
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events	26 (36.6)	32	3 (60.0)	8	14 (34.1)	20	9 (23.7)	12	0	0
Mild	26 (36.6)	32	3 (60.0)	8	13 (31.7)	19	9 (23.7)	12		
Moderate	0	0	0	0	1 (2.4)	1	0	0		
Severe	0	0	0	0	0	0	0	0		
Investigations	20 (28.2)	25	3 (60.0)	4	8 (19.5)	11	8 (21.1)	10		
Haemoglobin decreased	9 (12.7)	11	2 (40.0)	2	3 (7.3)	4	3 (7.9)	4		
Mild	9 (12.7)	11	2 (40.0)	2	3 (7.3)	4	3 (7.9)	4		
Moderate	0	0	0	0	0	0	0	0		
Severe	0	0	0	0	0	0	0	0		
Neutrophil count decreased	4 (5.6)	4	0	0	1 (2.4)	1	2 (5.3)	2		
Mild	4 (5.6)	4			1 (2.4)	1	2 (5.3)	2		
Moderate	0	0			0	0	0	0		
Severe	0	0			0	0	0	0		

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)			
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood triglycerides increased	3 (4.2)	3	0	0	1 (2.4)	1	2 (5.3)	2		
Mild	3 (4.2)	3			1 (2.4)	1	2 (5.3)	2		
Moderate	0	0			0	0	0	0		
Severe	0	0			0	0	0	0		
Gamma-glutamyltransferase increased	1 (1.4)	1	1 (20.0)	1	0	0	0	0		
Mild	1 (1.4)	1	1 (20.0)	1						
Moderate	0	0	0	0						
Severe	0	0	0	0						
Protein urine present	0	0	0	0	1 (2.4)	1	1 (2.6)	1		
Mild					1 (2.4)	1	1 (2.6)	1		
Moderate					0	0	0	0		
Severe					0	0	0	0		

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)			
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Alanine aminotransferase increased	0	0	1 (20.0)	1	0	0	0	0		
Mild			1 (20.0)	1						
Moderate			0	0						
Severe			0	0						
Blood cholesterol increased	1 (1.4)	1	0	0	0	0	0	0		
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								
Blood creatinine increased	1 (1.4)	1	0	0	0	0	0	0		
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood glucose increased	1 (1.4)	1	0	0	0	0	0	0		
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								
Eosinophil count increased	0	0	0	0	0	0	1 (2.6)	1		
Mild							1 (2.6)	1		
Moderate							0	0		
Severe							0	0		
Glucose urine present	1 (1.4)	1	0	0	0	0	0	0		
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Lymphocyte count decreased	1 (1.4)	1	0	0	0	0	0	0		
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								
Lymphocyte count increased	0	0	0	0	1 (2.4)	1	0	0		
Mild					1 (2.4)	1				
Moderate					0	0				
Severe					0	0				
Neutrophil count increased	0	0	0	0	1 (2.4)	1	0	0		
Mild					1 (2.4)	1				
Moderate					0	0				
Severe					0	0				

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Protein total decreased	0	0	0	0	1 (2.4)	1	0	0		
Mild					1 (2.4)	1				
Moderate					0	0				
Severe					0	0				
White blood cell count decreased	1 (1.4)	1	0	0	0	0	0	0		
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								
White blood cell count increased	0	0	0	0	1 (2.4)	1	0	0		
Mild					1 (2.4)	1				
Moderate					0	0				
Severe					0	0				

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)			
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Infections and infestations	3 (4.2)	3	2 (40.0)	3	3 (7.3)	3	1 (2.6)	1		
Nasopharyngitis	2 (2.8)	2	1 (20.0)	1	1 (2.4)	1	1 (2.6)	1		
Mild	2 (2.8)	2	1 (20.0)	1	1 (2.4)	1	1 (2.6)	1		
Moderate	0	0	0	0	0	0	0	0		
Severe	0	0	0	0	0	0	0	0		
Pharyngitis	0	0	1 (20.0)	2	1 (2.4)	1	0	0		
Mild			1 (20.0)	2	1 (2.4)	1				
Moderate			0	0	0	0				
Severe			0	0	0	0				
Hordeolum	0	0	0	0	1 (2.4)	1	0	0		
Mild					1 (2.4)	1				
Moderate					0	0				
Severe					0	0				

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)			
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Rhinitis	1 (1.4)	1	0	0	0	0	0	0		
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Gastrointestinal disorders	1 (1.4)	1	1 (20.0)	1	1 (2.4)	1	0	0		
Constipation	1 (1.4)	1	0	0	0	0				
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								
Dental caries	0	0	1 (20.0)	1	0	0				
Mild			1 (20.0)	1						
Moderate			0	0						
Severe			0	0						
Toothache	0	0	0	0	1 (2.4)	1				
Mild					1 (2.4)	1				
Moderate					0	0				
Severe					0	0				

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)			
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Injury, poisoning and procedural complications	1 (1.4)	1	0	0	0	0	1 (2.6)	1		
Hand fracture	0	0					1 (2.6)	1		
Mild							1 (2.6)	1		
Moderate							0	0		
Severe							0	0		
Tooth fracture	1 (1.4)	1					0	0		
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood and lymphatic system disorders	0	0	0	0	1 (2.4)	1	0	0		
Anaemia					1 (2.4)	1				
Mild					1 (2.4)	1				
Moderate					0	0				
Severe					0	0				
Musculoskeletal and connective tissue disorders	0	0	0	0	1 (2.4)	1	0	0		
Intervertebral disc protrusion					1 (2.4)	1				
Mild					1 (2.4)	1				
Moderate					0	0				
Severe					0	0				

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	0	1 (2.4)	1	0	0		
Uterine leiomyoma					1 (2.4)	1				
Mild					0	0				
Moderate					1 (2.4)	1				
Severe					0	0				
Nervous system disorders	0	0	0	0	1 (2.4)	1	0	0		
Headache					1 (2.4)	1				
Mild					1 (2.4)	1				
Moderate					0	0				
Severe					0	0				

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Psychiatric disorders	0	0	0	0	1 (2.4)	1	0	0		
Insomnia					1 (2.4)	1				
Mild					1 (2.4)	1				
Moderate					0	0				
Severe					0	0				
Respiratory, thoracic and mediastinal disorders	1 (1.4)	1	0	0	0	0	0	0		
Oropharyngeal pain	1 (1.4)	1								
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.11.1 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)		Predominantly Abstinent (N=1)	
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Skin and subcutaneous tissue disorders	1 (1.4)	1	0	0	0	0	0	0		
Eczema	1 (1.4)	1								
Mild	1 (1.4)	1								
Moderate	0	0								
Severe	0	0								

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.12.1 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=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Serious adverse events	0	0	0	0	0	0	0	0	0	0

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.12.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Serious adverse events	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.13.1 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=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Adverse events leading to discontinuation	0	0	0	0	0	0	2 (13.3)	2	2 (1.1)	2
Infections and infestations							1 (6.7)	1	1 (0.6)	1
Nasopharyngitis							1 (6.7)	1	1 (0.6)	1
Vascular disorders							1 (6.7)	1	1 (0.6)	1
Hypotension							1 (6.7)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.13.1 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Adverse events leading to discontinuation	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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 15.2.6.14.1 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	THSm2.2 (N=78)				mCC (N=42)		SA (N=40)			
	THS 2.2 (N=71)		Not Abstinent (N=5)		CC (N=41)		Abstinent (N=38)		Predominantly Abstinent (N=1)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
	0	0	0	0	0	0	0	0	0	0
Adverse Events Leading to Discontinuation										

Note: Only subjects randomized are summarized in post-randomization tables.

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

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

Note: No AE was observed in 3 subjects discontinued during confinement (N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.

**Table 15.2.6.15.1 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Pre-Randomization**

	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Device events	1 (1.3)	1	4 (9.5)	4	5 (12.5)	5	0	0	10 (5.7)	10
Not Related to AE	1 (1.3)	1	4 (9.5)	4	5 (12.5)	5			10 (5.7)	10
Device events by severity										
Major	1 (1.3)	1	4 (9.5)	4	5 (12.5)	5			10 (5.7)	10
CH DOES NOT CHARGE WHEN INSERTED INTO THE MOBIL UNIT	0	0	3 (7.1)	3	5 (12.5)	5			8 (4.6)	8
BATTERY MALFUNCTION	1 (1.3)	1	1 (2.4)	1	0	0			2 (1.1)	2

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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 15.2.6.15.1 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Post-Randomization**

	THSm2.2 (N=78)	
	n (%)	Events
Device events	53 (67.9)	144
Not Related to AE	53 (67.9)	144
Device events by severity		
Major	53 (67.9)	144
CH HEATER BROKEN (LED BLINKING RED)	32 (41.0)	50
CH DOES NOT CHARGE WHEN INSERTED INTO THE MOBIL UNIT	23 (29.5)	40
BATTERY MALFUNCTION	17 (21.8)	26
CH STOPS HEATING BEFORE END OF SMOKING EXPERIENCE	5 (6.4)	5
SMOKING EXPERIENCE DOES NOT START WHEN PRESSING THE BUTTON	4 (5.1)	4
THE DEVICE HAS CHARGING FAILURE DUE TO BAD ELECTRICAL CONTACT BETWEEN CHARGER AND HOLDER.	4 (5.1)	4
THE SUBJECT LOST IT.	3 (3.8)	4
ELECTRONIC MALFUNCTION DURING THE SMOKING EXPERIENCE	2 (2.6)	3
A COVER OF THE LED DISPLAY WAS FALLEN OFF.	1 (1.3)	1
SUBJECT INFORMED THAT SHE LOST THE HOLDER VIA TELEPHONE ON 25/SEP.NEW HOLDER WAS SHIPPED ON 25/SEP.WE CONFIRMED SHE RECEIVED NEW HOLDER AND INSTRUCTED HER NOT TO LOSE IT VIA TELEPH	1 (1.3)	1

Note: Only subjects randomized are summarized in post-randomization tables.

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 15.2.6.15.1 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Post-Randomization**

	THSm2.2 (N=78)	
	n (%)	Events
THE COVER OF CHARGER DOESN'T CLOSE.	1 (1.3)	1
THE PATIENT DROPPED THE DEVICE INTO WATER AND DESTROYED IT	1 (1.3)	1
THE PATIENT LOST THE DEVICE.	1 (1.3)	2
THE SUBJECT LOST THIS DEVICE.	1 (1.3)	2

Note: Only subjects randomized are summarized in post-randomization tables.

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 15.2.6.15.1 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Confinement**

	THSm2.2 (N=78)	
	n (%)	Events
Device events	26 (33.3)	39
Not Related to AE	26 (33.3)	39
Device events by severity		
Major	26 (33.3)	39
CH DOES NOT CHARGE WHEN INSERTED INTO THE MOBIL UNIT	9 (11.5)	10
CH HEATER BROKEN (LED BLINKING RED)	9 (11.5)	9
BATTERY MALFUNCTION	8 (10.3)	11
CH STOPS HEATING BEFORE END OF SMOKING EXPERIENCE	4 (5.1)	4
SMOKING EXPERIENCE DOES NOT START WHEN PRESSING THE BUTTON	2 (2.6)	2
THE DEVICE HAS CHARGING FAILURE DUE TO BAD ELECTRICAL CONTACT BETWEEN CHARGER AND HOLDER.	2 (2.6)	2
THE COVER OF CHARGER DOESN'T CLOSE.	1 (1.3)	1

Note: Only subjects randomized are summarized in post-randomization tables.

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 15.2.6.15.1 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Ambulatory**

	THSm2.2 (N=78)	
	n (%)	Events
Device events	44 (56.4)	105
Not Related to AE	44 (56.4)	105
Device events by severity		
Major	44 (56.4)	105
CH HEATER BROKEN (LED BLINKING RED)	27 (34.6)	41
CH DOES NOT CHARGE WHEN INSERTED INTO THE MOBIL UNIT	16 (20.5)	30
BATTERY MALFUNCTION	12 (15.4)	15
THE SUBJECT LOST IT.	3 (3.8)	4
ELECTRONIC MALFUNCTION DURING THE SMOKING EXPERIENCE	2 (2.6)	3
SMOKING EXPERIENCE DOES NOT START WHEN PRESSING THE BUTTON	2 (2.6)	2
THE DEVICE HAS CHARGING FAILURE DUE TO BAD ELECTRICAL CONTACT BETWEEN CHARGER AND HOLDER.	2 (2.6)	2
A COVER OF THE LED DISPLAY WAS FALLEN OFF.	1 (1.3)	1
CH STOPS HEATING BEFORE END OF SMOKING EXPERIENCE	1 (1.3)	1
SUBJECT INFORMED THAT SHE LOST THE HOLDER VIA TELEPHONE ON 25/SEP.NEW HOLDER WAS SHIPPED ON 25/SEP.WE CONFIRMED SHE RECEIVED NEW HOLDER AND INSTRUCTED HER NOT TO LOSE IT VIA TELEPH	1 (1.3)	1

Note: Only subjects randomized are summarized in post-randomization tables.

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 15.2.6.15.1 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Ambulatory**

	THSm2.2 (N=78)	
	n (%)	Events
THE PATIENT DROPPED THE DEVICE INTO WATER AND DESTROYED IT	1 (1.3)	1
THE PATIENT LOST THE DEVICE.	1 (1.3)	2
THE SUBJECT LOST THIS DEVICE.	1 (1.3)	2

Note: Only subjects randomized are summarized in post-randomization tables.

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 15.2.6.15.1 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Safety Follow-up**

	THSm2.2 (N=78)	
	n (%)	Events
Any device events	0	0

Note: Only subjects randomized are summarized in post-randomization tables.

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: 15.3.6.2

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**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Alanine Aminotransferase (IU/L)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	21.8 (9.87)	19.3 (8.95)	18.2 (8.34)	19.5 (9.31)	20.2 (9.31)
		Median	19.0	16.5	16.0	18.0	18.0
		Min, Max	7, 49	9, 54	7, 44	9, 41	7, 54
		Normal value – n (%)	76 (97.4)	41 (97.6)	40 (100)	15 (100)	172 (98.3)
		High value – n (%)	2 (2.6)	1 (2.4)	0	0	3 (1.7)
		Abnormal NCS – n (%)	2 (2.6)	1 (2.4)	0	0	3 (1.7)
		ALT increased					
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	40 (100)	15 (100)	172 (98.3)
		Grade 1 - n(%)	2 (2.6)	1 (2.4)	0	0	3 (1.7)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Alanine Aminotransferase (IU/L)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	20.2 (9.64)	17.0 (8.77)	15.9 (7.20)	16.8 (6.15)	18.2 (8.93)
		Median	18.0	14.0	13.0	16.0	15.0
		Min, Max	6, 51	7, 49	9, 38	12, 27	6, 51
		Normal value – n (%)	73 (93.6)	40 (95.2)	40 (100)	5 (33.3)	158 (90.3)
		High value – n (%)	5 (6.4)	2 (4.8)	0	0	7 (4.0)
		Abnormal NCS – n (%)	5 (6.4)	2 (4.8)	0	0	7 (4.0)
		ALT increased					
		Grade 0 - n(%)	73 (93.6)	40 (95.2)	40 (100)	5 (33.3)	158 (90.3)
		Grade 1 - n(%)	5 (6.4)	2 (4.8)	0	0	7 (4.0)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Aspartate Aminotransferase (IU/L)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	23.0 (6.62)	22.1 (6.08)	21.2 (5.23)	22.2 (5.24)	22.3 (6.08)
		Median	22.0	21.0	20.0	21.0	21.0
		Min, Max	13, 53	15, 47	14, 38	15, 35	13, 53
		Normal value – n (%)	75 (96.2)	41 (97.6)	40 (100)	15 (100)	171 (97.7)
		High value – n (%)	3 (3.8)	1 (2.4)	0	0	4 (2.3)
		Abnormal NCS – n (%)	3 (3.8)	1 (2.4)	0	0	4 (2.3)
		AST increased					
		Grade 0 - n(%)	75 (96.2)	41 (97.6)	40 (100)	15 (100)	171 (97.7)
		Grade 1 - n(%)	3 (3.8)	1 (2.4)	0	0	4 (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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Aspartate Aminotransferase (IU/L)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	19.1 (4.51)	18.6 (5.42)	17.9 (6.15)	21.4 (4.67)	18.7 (5.18)
		Median	18.0	17.0	16.0	22.0	18.0
		Min, Max	9, 30	11, 34	11, 43	16, 28	9, 43
		Normal value – n (%)	78 (100)	42 (100)	39 (97.5)	5 (33.3)	164 (93.7)
		High value – n (%)	0	0	1 (2.5)	0	1 (0.6)
		Abnormal NCS – n (%)	0	0	1 (2.5)	0	1 (0.6)
		AST increased					
		Grade 0 - n(%)	78 (100)	42 (100)	39 (97.5)	5 (33.3)	164 (93.7)
		Grade 1 - n(%)	0	0	1 (2.5)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]	Study Day	Statistic	(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Bilirubin (mg/dL) [0.2-1.2]	Screening	n	78	42	40	15	175
		Mean (SD)	0.78 (0.242)	0.77 (0.260)	0.73 (0.229)	0.75 (0.224)	0.77 (0.241)
		Median	0.70	0.70	0.70	0.70	0.70
		Min, Max	0.4, 1.3	0.4, 1.5	0.3, 1.3	0.4, 1.3	0.3, 1.5
		Normal value – n (%)	72 (92.3)	39 (92.9)	39 (97.5)	14 (93.3)	164 (93.7)
		High value – n (%)	6 (7.7)	3 (7.1)	1 (2.5)	1 (6.7)	11 (6.3)
		Abnormal NCS – n (%)	6 (7.7)	3 (7.1)	1 (2.5)	1 (6.7)	11 (6.3)
		Blood bilirubin increased					
		Grade 0 - n(%)	72 (92.3)	39 (92.9)	39 (97.5)	14 (93.3)	164 (93.7)
		Grade 1 - n(%)	6 (7.7)	3 (7.1)	1 (2.5)	1 (6.7)	11 (6.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Bilirubin (mg/dL) [0.2-1.2]	Day 0	n	78	42	40	5	165
		Mean (SD)	0.66 (0.230)	0.60 (0.220)	0.62 (0.197)	0.68 (0.278)	0.64 (0.221)
		Median	0.60	0.55	0.60	0.60	0.60
		Min, Max	0.3, 1.5	0.2, 1.2	0.3, 1.2	0.4, 1.1	0.2, 1.5
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	5 (33.3)	164 (93.7)
		High value – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Blood bilirubin increased					
		Grade 0 - n(%)	77 (98.7)	42 (100)	40 (100)	5 (33.3)	164 (93.7)
		Grade 1 - n(%)	1 (1.3)	0	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Study Day	Statistic						
Direct Bilirubin (mg/dL)							
Screening	n		78	42	40	15	175
	Mean (SD)		0.137 (0.0606)	0.143 (0.0704)	0.145 (0.0678)	0.133 (0.0488)	0.140 (0.0635)
	Median		0.100	0.100	0.100	0.100	0.100
	Min, Max		0.10, 0.30	0.00, 0.30	0.00, 0.30	0.10, 0.20	0.00, 0.30
	Normal value – n (%)		78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
Day 0	n		78	42	40	5	165
	BLOQ, n (%)		2 (2.6)	3 (7.1)	1 (2.5)	0	6 (3.4)
	Mean (SD)		0.169 (0.0536)	0.158 (0.0671)	0.184 (0.0604)	0.180 (0.0837)	0.170 (0.0600)
	Median		0.200	0.200	0.200	0.200	0.200
	Min, Max		0.05, 0.30	0.05, 0.30	0.05, 0.30	0.10, 0.30	0.05, 0.30
	Normal value – n (%)		78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Alkaline Phosphatase (IU/L) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	207.8 (57.85)	209.6 (48.38)	208.6 (56.21)	194.2 (56.88)	207.3 (54.93)
		Median	197.0	201.0	193.5	184.0	197.0
		Min, Max	112, 386	137, 372	115, 333	100, 318	100, 386
		Normal value – n (%)	75 (96.2)	41 (97.6)	37 (92.5)	15 (100)	168 (96.0)
		High value – n (%)	3 (3.8)	1 (2.4)	3 (7.5)	0	7 (4.0)
		Abnormal NCS – n (%)	3 (3.8)	1 (2.4)	3 (7.5)	0	7 (4.0)
		Alkaline phosphatase increased					
		Grade 0 - n(%)	75 (96.2)	41 (97.6)	37 (92.5)	15 (100)	168 (96.0)
		Grade 1 - n(%)	3 (3.8)	1 (2.4)	3 (7.5)	0	7 (4.0)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Alkaline Phosphatase (IU/L) [¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	58.2 (15.76)	59.6 (14.35)	58.3 (16.31)	52.4 (9.02)	58.4 (15.33)
		Median	55.0	57.0	54.5	50.0	56.0
		Min, Max	32, 120	39, 99	32, 100	43, 65	32, 120
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Alkaline phosphatase increased					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Gamma Glutamyl Transferase (IU/L) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	26.1 (15.05)	23.0 (15.49)	19.9 (9.12)	24.7 (9.92)	23.8 (13.77)
		Median	23.0	18.5	17.0	23.0	20.0
		Min, Max	9, 78	7, 73	8, 46	13, 41	7, 78
		Normal value – n (%)	76 (97.4)	42 (100)	40 (100)	14 (93.3)	172 (98.3)
		High value – n (%)	2 (2.6)	0	0	1 (6.7)	3 (1.7)
		Abnormal NCS – n (%)	2 (2.6)	0	0	1 (6.7)	3 (1.7)
		GGT increased					
		Grade 0 - n(%)	76 (97.4)	42 (100)	40 (100)	14 (93.3)	172 (98.3)
		Grade 1 - n(%)	2 (2.6)	0	0	1 (6.7)	3 (1.7)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Gamma Glutamyl Transferase (IU/L)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	21.1 (13.11)	17.7 (10.21)	15.6 (7.69)	18.4 (6.11)	18.8 (11.27)
		Median	17.0	15.5	13.5	18.0	16.0
		Min, Max	6, 61	5, 50	8, 42	10, 27	5, 61
		Low value – n (%)	2 (2.6)	1 (2.4)	2 (5.0)	0	5 (2.9)
		Normal value – n (%)	76 (97.4)	41 (97.6)	38 (95.0)	5 (33.3)	160 (91.4)
		Abnormal NCS – n (%)	2 (2.6)	1 (2.4)	2 (5.0)	0	5 (2.9)
		GGT increased					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Lactate Dehydrogenase (IU/L)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	163.8 (32.59)	158.3 (20.71)	157.7 (25.05)	167.2 (33.00)	161.4 (28.46)
		Median	158.0	152.5	159.0	166.0	157.0
		Min, Max	106, 276	114, 199	116, 225	118, 230	106, 276
		Low value – n (%)	3 (3.8)	1 (2.4)	2 (5.0)	1 (6.7)	7 (4.0)
		Normal value – n (%)	72 (92.3)	41 (97.6)	38 (95.0)	14 (93.3)	165 (94.3)
		High value – n (%)	3 (3.8)	0	0	0	3 (1.7)
		Abnormal NCS – n (%)	6 (7.7)	1 (2.4)	2 (5.0)	1 (6.7)	10 (5.7)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]	Study Day	Statistic	(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Lactate Dehydrogenase (IU/L)							
[¹]	Day 0	n	78	42	38	5	163
		Mean (SD)	146.1 (27.97)	143.1 (19.26)	140.8 (19.90)	162.2 (36.44)	144.6 (24.57)
		Median	141.0	140.0	138.0	143.0	140.0
		Min, Max	102, 233	104, 189	103, 206	125, 208	102, 233
		Normal value – n (%)	78 (100)	42 (100)	38 (95.0)	5 (33.3)	163 (93.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Glucose (mg/dL) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	86.3 (7.03)	87.0 (5.24)	85.5 (6.58)	86.3 (7.19)	86.3 (6.52)
		Median	85.5	87.5	84.5	84.0	86.0
		Min, Max	71, 102	75, 96	76, 100	76, 99	71, 102
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		Hyperglycemia					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		Hypoglycemia					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]	Study Day	Statistic	(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Glucose (mg/dL)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	85.1 (7.84)	85.6 (5.87)	85.1 (7.34)	91.2 (5.64)	85.4 (7.22)
		Median	85.0	85.0	85.0	94.0	85.0
		Min, Max	70, 110	72, 101	74, 101	83, 97	70, 110
		Normal value – n (%)	76 (97.4)	42 (100)	40 (100)	5 (33.3)	163 (93.1)
		High value – n (%)	2 (2.6)	0	0	0	2 (1.1)
		Abnormal NCS – n (%)	2 (2.6)	0	0	0	2 (1.1)
		Hyperglycemia					
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	38 (95.0)	5 (33.3)	160 (91.4)
		Grade 1 - n(%)	2 (2.6)	1 (2.4)	2 (5.0)	0	5 (2.9)
		Hypoglycemia					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Creatinine (mg/dL) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	0.678 (0.1309)	0.697 (0.1279)	0.702 (0.1571)	0.751 (0.1615)	0.695 (0.1396)
		Median	0.675	0.680	0.705	0.730	0.690
		Min, Max	0.29, 0.96	0.47, 1.04	0.39, 1.18	0.57, 1.23	0.29, 1.23
		Low value – n (%)	5 (6.4)	1 (2.4)	3 (7.5)	0	9 (5.1)
		Normal value – n (%)	73 (93.6)	41 (97.6)	36 (90.0)	14 (93.3)	164 (93.7)
		High value – n (%)	0	0	1 (2.5)	1 (6.7)	2 (1.1)
		Abnormal NCS – n (%)	5 (6.4)	1 (2.4)	4 (10.0)	1 (6.7)	11 (6.3)
		Creatinine increased					
		Grade 0 - n(%)	78 (100)	42 (100)	39 (97.5)	14 (93.3)	173 (98.9)
		Grade 1 - n(%)	0	0	1 (2.5)	1 (6.7)	2 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Creatinine (mg/dL) [¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	0.764 (0.1433)	0.786 (0.1407)	0.773 (0.1519)	0.740 (0.1141)	0.771 (0.1432)
		Median	0.800	0.800	0.800	0.700	0.800
		Min, Max	0.40, 1.10	0.60, 1.00	0.50, 1.10	0.60, 0.90	0.40, 1.10
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Creatinine increased					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]			(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Study Day	Statistic						
Protein (g/dL) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	7.28 (0.441)	7.28 (0.396)	7.24 (0.358)	7.13 (0.514)	7.26 (0.418)
		Median	7.30	7.30	7.20	7.00	7.20
		Min, Max	6.2, 8.5	6.4, 8.2	6.6, 8.3	6.3, 7.9	6.2, 8.5
		Low value – n (%)	5 (6.4)	3 (7.1)	1 (2.5)	2 (13.3)	11 (6.3)
		Normal value – n (%)	70 (89.7)	39 (92.9)	39 (97.5)	13 (86.7)	161 (92.0)
		High value – n (%)	3 (3.8)	0	0	0	3 (1.7)
		Abnormal NCS – n (%)	8 (10.3)	3 (7.1)	1 (2.5)	2 (13.3)	14 (8.0)
		Hypoproteinemia					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]	Study Day	Statistic	(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Protein (g/dL) [¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	6.85 (0.405)	6.88 (0.551)	6.78 (0.430)	6.78 (0.606)	6.84 (0.456)
		Median	6.85	6.85	6.80	6.80	6.80
		Min, Max	5.9, 7.8	5.8, 8.9	6.0, 7.5	6.1, 7.6	5.8, 8.9
		Low value – n (%)	3 (3.8)	2 (4.8)	2 (5.0)	0	7 (4.0)
		Normal value – n (%)	75 (96.2)	39 (92.9)	38 (95.0)	5 (33.3)	157 (89.7)
		High value – n (%)	0	1 (2.4)	0	0	1 (0.6)
		Abnormal NCS – n (%)	3 (3.8)	3 (7.1)	2 (5.0)	0	8 (4.6)
		Hypoproteinemia					
		Grade 0 - n(%)	75 (96.2)	40 (95.2)	38 (95.0)	5 (33.3)	158 (90.3)
		Grade 1 - n(%)	3 (3.8)	2 (4.8)	2 (5.0)	0	7 (4.0)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Blood Urea Nitrogen (mg/dL)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	11.2 (2.90)	11.4 (2.78)	11.9 (3.85)	11.9 (2.94)	11.5 (3.11)
		Median	11.0	11.0	11.0	11.0	11.0
		Min, Max	3, 18	6, 18	6, 24	8, 19	3, 24
		Low value – n (%)	6 (7.7)	4 (9.5)	3 (7.5)	0	13 (7.4)
		Normal value – n (%)	72 (92.3)	38 (90.5)	36 (90.0)	15 (100)	161 (92.0)
		High value – n (%)	0	0	1 (2.5)	0	1 (0.6)
		Abnormal NCS – n (%)	6 (7.7)	4 (9.5)	4 (10.0)	0	14 (8.0)
		Blood Urea Nitrogen					
		Grade 0 - n(%)	78 (100)	42 (100)	39 (97.5)	15 (100)	174 (99.4)
		Grade 1 - n(%)	0	0	1 (2.5)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Blood Urea Nitrogen (mg/dL)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	11.3 (2.42)	11.6 (2.26)	11.5 (2.42)	12.4 (1.82)	11.5 (2.35)
		Median	11.0	11.0	11.5	13.0	11.0
		Min, Max	6, 19	7, 17	6, 17	10, 14	6, 19
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Blood Urea Nitrogen Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Triglycerides							
(mg/dL)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	103.7 (59.64)	96.2 (46.20)	88.3 (52.15)	95.6 (47.83)	97.7 (53.93)
		Median	90.0	74.0	70.0	86.0	83.0
		Min, Max	37, 304	38, 206	30, 263	36, 198	30, 304
		Normal value – n (%)	65 (83.3)	34 (81.0)	35 (87.5)	13 (86.7)	147 (84.0)
		High value – n (%)	13 (16.7)	8 (19.0)	5 (12.5)	2 (13.3)	28 (16.0)
		Abnormal NCS – n (%)	12 (15.4)	8 (19.0)	5 (12.5)	2 (13.3)	27 (15.4)
		Abnormal CS – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Hypertriglyceridemia					
		Grade 0 - n(%)	65 (83.3)	34 (81.0)	35 (87.5)	13 (86.7)	147 (84.0)
		Grade 1 - n(%)	12 (15.4)	8 (19.0)	5 (12.5)	2 (13.3)	27 (15.4)
		Grade 2 - n(%)	1 (1.3)	0	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Triglycerides							
(mg/dL)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	143.4 (72.94)	130.5 (50.88)	109.9 (42.10)	115.2 (37.40)	131.2 (61.56)
		Median	124.5	114.5	101.5	99.0	118.0
		Min, Max	54, 421	53, 236	54, 226	79, 176	53, 421
		Normal value – n (%)	74 (94.9)	41 (97.6)	39 (97.5)	5 (33.3)	159 (90.9)
		High value – n (%)	4 (5.1)	1 (2.4)	1 (2.5)	0	6 (3.4)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	0	3 (1.7)
		Abnormal CS – n (%)	3 (3.8)	0	0	0	3 (1.7)
		Hypertriglyceridemia					
		Grade 0 - n(%)	52 (66.7)	29 (69.0)	32 (80.0)	4 (26.7)	117 (66.9)
		Grade 1 - n(%)	23 (29.5)	13 (31.0)	8 (20.0)	1 (6.7)	45 (25.7)
		Grade 2 - n(%)	3 (3.8)	0	0	0	3 (1.7)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Cholesterol (mg/dL)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	200.2 (36.18)	201.0 (40.51)	192.2 (32.07)	207.3 (34.89)	199.2 (36.23)
		Median	198.5	199.0	194.5	206.0	198.0
		Min, Max	111, 288	127, 287	129, 245	145, 273	111, 288
		Low value – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value – n (%)	55 (70.5)	25 (59.5)	32 (80.0)	11 (73.3)	123 (70.3)
		High value – n (%)	22 (28.2)	17 (40.5)	8 (20.0)	4 (26.7)	51 (29.1)
		Abnormal NCS – n (%)	22 (28.2)	17 (40.5)	8 (20.0)	4 (26.7)	51 (29.1)
		Abnormal CS – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Cholesterol high					
		Grade 0 - n(%)	56 (71.8)	25 (59.5)	32 (80.0)	11 (73.3)	124 (70.9)
		Grade 1 - n(%)	22 (28.2)	17 (40.5)	8 (20.0)	4 (26.7)	51 (29.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Cholesterol (mg/dL)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	197.6 (35.01)	200.1 (42.06)	182.9 (28.45)	209.8 (32.05)	195.0 (35.88)
		Median	195.5	193.5	182.0	218.0	191.0
		Min, Max	131, 290	131, 343	131, 245	170, 247	131, 343
		Low value – n (%)	5 (6.4)	1 (2.4)	2 (5.0)	0	8 (4.6)
		Normal value – n (%)	71 (91.0)	40 (95.2)	38 (95.0)	4 (26.7)	153 (87.4)
		High value – n (%)	2 (2.6)	1 (2.4)	0	1 (6.7)	4 (2.3)
		Abnormal NCS – n (%)	7 (9.0)	1 (2.4)	2 (5.0)	1 (6.7)	11 (6.3)
		Abnormal CS – n (%)	0	1 (2.4)	0	0	1 (0.6)
		Cholesterol high					
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	40 (100)	4 (26.7)	161 (92.0)
		Grade 1 - n(%)	2 (2.6)	0	0	1 (6.7)	3 (1.7)
		Grade 2 - n(%)	0	1 (2.4)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Albumin (g/L) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	46.7 (2.70)	46.4 (2.75)	46.5 (2.38)	45.5 (3.16)	46.5 (2.68)
		Median	46.5	46.0	46.0	45.0	46.0
		Min, Max	41, 53	39, 52	42, 55	40, 50	39, 55
		Normal value – n (%)	78 (100)	42 (100)	39 (97.5)	15 (100)	174 (99.4)
		High value – n (%)	0	0	1 (2.5)	0	1 (0.6)
		Abnormal NCS – n (%)	0	0	1 (2.5)	0	1 (0.6)
		Hypoalbuminemia Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Albumin (g/L)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	42.7 (3.39)	42.4 (3.84)	41.9 (3.13)	41.0 (4.31)	42.4 (3.47)
		Median	43.0	42.0	42.5	42.0	43.0
		Min, Max	36, 52	34, 50	36, 48	36, 45	34, 52
		Normal value – n (%)	76 (97.4)	41 (97.6)	40 (100)	5 (33.3)	162 (92.6)
		High value – n (%)	2 (2.6)	1 (2.4)	0	0	3 (1.7)
		Abnormal NCS – n (%)	2 (2.6)	1 (2.4)	0	0	3 (1.7)
		Hypoalbuminemia					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Sodium (mmol/L)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	140.7 (1.59)	140.7 (1.91)	141.2 (2.00)	141.1 (1.49)	140.9 (1.76)
		Median	141.0	141.0	141.5	141.0	141.0
		Min, Max	138, 144	136, 145	136, 146	139, 144	136, 146
		Low value – n (%)	0	2 (4.8)	1 (2.5)	0	3 (1.7)
		Normal value – n (%)	78 (100)	40 (95.2)	39 (97.5)	15 (100)	172 (98.3)
		Abnormal NCS – n (%)	0	2 (4.8)	1 (2.5)	0	3 (1.7)
		Hypernatremia					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		Hyponatremia					
		Grade 0 - n(%)	78 (100)	40 (95.2)	39 (97.5)	15 (100)	172 (98.3)
		Grade 1 - n(%)	0	2 (4.8)	1 (2.5)	0	3 (1.7)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Sodium (mmol/L)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	140.1 (1.73)	140.5 (1.68)	140.1 (2.03)	139.8 (1.79)	140.2 (1.79)
		Median	140.0	141.0	140.0	140.0	140.0
		Min, Max	137, 145	137, 144	136, 144	137, 142	136, 145
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Hypernatremia					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Hyponatremia					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Potassium (mmol/L) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	4.17 (0.319)	4.28 (0.365)	4.22 (0.397)	4.34 (0.293)	4.22 (0.349)
		Median	4.15	4.30	4.20	4.40	4.20
		Min, Max	3.6, 5.0	3.6, 5.3	3.5, 5.2	3.9, 4.8	3.5, 5.3
		Normal value – n (%)	78 (100)	41 (97.6)	37 (92.5)	15 (100)	171 (97.7)
		High value – n (%)	0	1 (2.4)	3 (7.5)	0	4 (2.3)
		Abnormal NCS – n (%)	0	1 (2.4)	3 (7.5)	0	4 (2.3)
		Hyperkalemia					
		Grade 0 - n(%)	78 (100)	41 (97.6)	37 (92.5)	15 (100)	171 (97.7)
		Grade 1 - n(%)	0	1 (2.4)	3 (7.5)	0	4 (2.3)
		Hypokalemia					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
[Reference range]	Study Day	Statistic					
Potassium (mmol/L)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	4.19 (0.348)	4.27 (0.323)	4.21 (0.405)	4.26 (0.231)	4.22 (0.352)
		Median	4.20	4.20	4.20	4.20	4.20
		Min, Max	3.6, 5.5	3.7, 5.2	3.6, 5.3	4.0, 4.5	3.6, 5.5
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	5 (33.3)	164 (93.7)
		High value – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Hyperkalemia					
		Grade 0 - n(%)	77 (98.7)	42 (100)	40 (100)	5 (33.3)	164 (93.7)
		Grade 1 - n(%)	1 (1.3)	0	0	0	1 (0.6)
		Hypokalemia					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alanine						
Aminotransferase (IU/L)						
[¹]	Baseline	n	78	42	40	160
		Mean (SD)	20.2 (9.64)	17.0 (8.77)	15.9 (7.20)	18.3 (9.02)
		Median	18.0	14.0	13.0	15.0
		Min, Max	6, 51	7, 49	9, 38	6, 51
		Normal value – n (%)	73 (93.6)	40 (95.2)	40 (100)	153 (95.6)
		High value – n (%)	5 (6.4)	2 (4.8)	0	7 (4.4)
		Abnormal NCS – n (%)	5 (6.4)	2 (4.8)	0	7 (4.4)
		ALT increased				
		Grade 0 - n(%)	73 (93.6)	40 (95.2)	40 (100)	153 (95.6)
		Grade 1 - n(%)	5 (6.4)	2 (4.8)	0	7 (4.4)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alanine						
Aminotransferase (IU/L)						
[¹]	Day 6	n	78	42	40	160
		Mean (SD)	27.0 (13.45)	23.0 (9.79)	24.4 (21.22)	25.3 (15.03)
		Median	24.0	22.0	16.0	22.0
		Min, Max	10, 91	12, 62	8, 117	8, 117
		Normal value – n (%)	66 (84.6)	40 (95.2)	34 (85.0)	140 (87.5)
		High value – n (%)	12 (15.4)	2 (4.8)	6 (15.0)	20 (12.5)
		Abnormal NCS – n (%)	12 (15.4)	2 (4.8)	5 (12.5)	19 (11.9)
		Abnormal CS – n (%)	0	0	1 (2.5)	1 (0.6)
		ALT increased				
		Grade 0 - n(%)	66 (84.6)	40 (95.2)	34 (85.0)	140 (87.5)
		Grade 1 - n(%)	12 (15.4)	2 (4.8)	6 (15.0)	20 (12.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alanine						
Aminotransferase (IU/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	6.8 (10.40)	5.9 (7.17)	8.6 (18.98)	7.0 (12.45)
		Median	6.0	5.5	2.0	4.0
		Min, Max	-12, 66	-9, 24	-6, 98	-12, 98
	Shift in Normality	Normal to High, NCS - n(%)	8 (10.3)	1 (2.4)	5 (12.5)	14 (8.8)
		Normal to High, CS - n(%)	0	0	1 (2.5)	1 (0.6)
		High, NCS to Normal - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
	Shift in Toxicity	ALT increased				
		0 to 1 - n(%)	8 (10.3)	1 (2.4)	6 (15.0)	15 (9.4)
		1 to 0 - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alanine						
Aminotransferase (IU/L)						
[¹]	Day 30	n	77	41	38	156
		Mean (SD)	19.7 (13.65)	17.0 (13.84)	21.3 (17.64)	19.4 (14.75)
		Median	16.0	13.0	14.0	15.0
		Min, Max	9, 111	8, 83	5, 85	5, 111
		Low value – n (%)	0	0	1 (2.5)	1 (0.6)
		Normal value – n (%)	76 (97.4)	39 (92.9)	34 (85.0)	149 (93.1)
		High value – n (%)	1 (1.3)	2 (4.8)	3 (7.5)	6 (3.8)
		Abnormal NCS – n (%)	0	2 (4.8)	4 (10.0)	6 (3.8)
		Abnormal CS – n (%)	1 (1.3)	0	0	1 (0.6)
		ALT increased				
		Grade 0 - n(%)	76 (97.4)	39 (92.9)	35 (87.5)	150 (93.8)
		Grade 1 - n(%)	0	2 (4.8)	3 (7.5)	5 (3.1)
		Grade 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alanine Aminotransferase (IU/L)						
[¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.1 (12.42)	0.2 (6.88)	5.2 (12.37)	1.3 (11.37)
		Median	-1.0	0.0	1.0	0.0
		Min, Max	-17, 89	-12, 34	-7, 49	-17, 89
	Shift in Normality	Normal to High, NCS - n(%)	0	0	3 (7.5)	3 (1.9)
		Normal to High, CS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
		High, NCS to Normal - n(%)	4 (5.1)	0	0	4 (2.5)
	Shift in Toxicity	ALT increased				
		0 to 1 - n(%)	0	0	3 (7.5)	3 (1.9)
		0 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n(%)	4 (5.1)	0	0	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alanine						
Aminotransferase (IU/L)						
[¹]	Day 60	n	77	41	39	157
		Mean (SD)	18.2 (9.87)	17.8 (10.35)	17.0 (8.26)	17.8 (9.58)
		Median	16.0	15.0	14.0	15.0
		Min, Max	7, 65	8, 67	9, 41	7, 67
		Normal value – n (%)	75 (96.2)	40 (95.2)	39 (97.5)	154 (96.3)
		High value – n (%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		Abnormal NCS – n (%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		ALT increased				
		Grade 0 - n(%)	75 (96.2)	40 (95.2)	39 (97.5)	154 (96.3)
		Grade 1 - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alanine						
Aminotransferase (IU/L) [¹]	Change from Baseline	n	77	41	39	157
		Mean (SD)	-1.6 (6.76)	1.0 (8.90)	1.0 (5.76)	-0.3 (7.23)
		Median	-2.0	0.0	0.0	-1.0
		Min, Max	-20, 18	-20, 41	-15, 16	-20, 41
	Shift in Normality	Normal to High, NCS - n(%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n(%)	2 (2.6)	2 (4.8)	0	4 (2.5)
	Shift in Toxicity	ALT increased				
		0 to 1 - n(%)	0	1 (2.4)	0	1 (0.6)
		1 to 0 - n(%)	2 (2.6)	2 (4.8)	0	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alanine						
Aminotransferase (IU/L)						
[¹]	Day 91	n	77	41	38	156
		Mean (SD)	17.7 (9.94)	16.0 (9.47)	16.3 (8.91)	16.9 (9.55)
		Median	15.0	13.0	13.0	14.0
		Min, Max	6, 52	6, 53	7, 39	6, 53
		Normal value – n (%)	75 (96.2)	39 (92.9)	38 (95.0)	152 (95.0)
		High value – n (%)	2 (2.6)	2 (4.8)	0	4 (2.5)
		Abnormal NCS – n (%)	2 (2.6)	2 (4.8)	0	4 (2.5)
		ALT increased				
		Grade 0 - n(%)	75 (96.2)	39 (92.9)	38 (95.0)	152 (95.0)
		Grade 1 - n(%)	2 (2.6)	2 (4.8)	0	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alanine Aminotransferase (IU/L)						
[¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-2.2 (7.50)	-0.8 (8.86)	0.2 (6.41)	-1.2 (7.66)
		Median	-3.0	-3.0	-1.0	-2.5
		Min, Max	-22, 16	-24, 29	-9, 25	-24, 29
	Shift in Normality	Normal to High, NCS - n(%)	0	2 (4.8)	0	2 (1.3)
		High, NCS to Normal - n(%)	2 (2.6)	2 (4.8)	0	4 (2.5)
	Shift in Toxicity	ALT increased				
		0 to 1 - n(%)	0	2 (4.8)	0	2 (1.3)
		1 to 0 - n(%)	2 (2.6)	2 (4.8)	0	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Aspartate						
Aminotransferase (IU/L)						
[¹]	Baseline	n	78	42	40	160
		Mean (SD)	19.1 (4.51)	18.6 (5.42)	17.9 (6.15)	18.7 (5.19)
		Median	18.0	17.0	16.0	18.0
		Min, Max	9, 30	11, 34	11, 43	9, 43
		Normal value – n (%)	78 (100)	42 (100)	39 (97.5)	159 (99.4)
		High value – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal NCS – n (%)	0	0	1 (2.5)	1 (0.6)
		AST increased				
		Grade 0 - n(%)	78 (100)	42 (100)	39 (97.5)	159 (99.4)
		Grade 1 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Aspartate Aminotransferase (IU/L)						
[¹]	Day 6	n	78	42	40	160
		Mean (SD)	23.3 (4.97)	22.7 (5.53)	22.6 (12.02)	23.0 (7.44)
		Median	22.5	21.0	18.5	21.0
		Min, Max	14, 40	16, 40	13, 83	13, 83
		Normal value – n (%)	77 (98.7)	41 (97.6)	37 (92.5)	155 (96.9)
		High value – n (%)	1 (1.3)	1 (2.4)	3 (7.5)	5 (3.1)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	2 (5.0)	4 (2.5)
		Abnormal CS – n (%)	0	0	1 (2.5)	1 (0.6)
		AST increased				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	37 (92.5)	155 (96.9)
		Grade 1 - n(%)	1 (1.3)	1 (2.4)	3 (7.5)	5 (3.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Aspartate						
Aminotransferase (IU/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	4.2 (4.74)	4.1 (3.79)	4.7 (12.15)	4.3 (7.13)
		Median	4.0	4.0	2.5	3.0
		Min, Max	-8, 17	-3, 15	-21, 67	-21, 67
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	1 (2.4)	2 (5.0)	4 (2.5)
		Normal to High, CS - n(%)	0	0	1 (2.5)	1 (0.6)
		High, NCS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
	Shift in Toxicity	AST increased				
		0 to 1 - n(%)	1 (1.3)	1 (2.4)	3 (7.5)	5 (3.1)
		1 to 0 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Aspartate						
Aminotransferase (IU/L)						
[¹]	Day 30	n	77	41	38	156
		Mean (SD)	19.3 (6.03)	19.0 (7.51)	20.4 (7.97)	19.5 (6.91)
		Median	18.0	17.0	18.5	18.0
		Min, Max	12, 50	10, 57	13, 50	10, 57
		Normal value – n (%)	76 (97.4)	40 (95.2)	36 (90.0)	152 (95.0)
		High value – n (%)	1 (1.3)	1 (2.4)	2 (5.0)	4 (2.5)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	2 (5.0)	4 (2.5)
		AST increased				
		Grade 0 - n(%)	76 (97.4)	40 (95.2)	36 (90.0)	152 (95.0)
		Grade 1 - n(%)	1 (1.3)	1 (2.4)	2 (5.0)	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Aspartate Aminotransferase (IU/L)						
[¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.3 (5.14)	0.7 (4.48)	2.3 (5.77)	0.9 (5.17)
		Median	0.0	0.0	1.5	0.5
		Min, Max	-10, 27	-6, 23	-9, 21	-10, 27
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	1 (2.4)	2 (5.0)	4 (2.5)
		High, NCS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
	Shift in Toxicity	AST increased				
		0 to 1 - n(%)	1 (1.3)	1 (2.4)	2 (5.0)	4 (2.5)
		1 to 0 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Aspartate						
Aminotransferase (IU/L)						
[¹]	Day 60	n	77	41	39	157
		Mean (SD)	18.4 (5.49)	18.4 (5.43)	17.7 (3.67)	18.3 (5.06)
		Median	17.0	17.0	17.0	17.0
		Min, Max	12, 46	9, 36	12, 28	9, 46
		Low value – n (%)	0	1 (2.4)	0	1 (0.6)
		Normal value – n (%)	76 (97.4)	39 (92.9)	39 (97.5)	154 (96.3)
		High value – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Abnormal NCS – n (%)	1 (1.3)	2 (4.8)	0	3 (1.9)
		AST increased				
		Grade 0 - n(%)	76 (97.4)	40 (95.2)	39 (97.5)	155 (96.9)
		Grade 1 - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Aspartate						
Aminotransferase (IU/L) [¹]	Change from Baseline	n	77	41	39	157
		Mean (SD)	-0.5 (3.81)	0.1 (4.38)	-0.3 (4.98)	-0.3 (4.26)
		Median	-1.0	0.0	0.0	-1.0
		Min, Max	-13, 16	-14, 12	-19, 12	-19, 16
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Normal to Low, NCS - n(%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
	Shift in Toxicity	AST increased				
		0 to 1 - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		1 to 0 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Aspartate						
Aminotransferase (IU/L)						
[¹]	Day 91	n	77	41	38	156
		Mean (SD)	18.5 (5.69)	17.7 (5.61)	17.8 (3.97)	18.1 (5.29)
		Median	18.0	16.0	17.0	17.0
		Min, Max	11, 38	10, 38	13, 29	10, 38
		Normal value – n (%)	74 (94.9)	40 (95.2)	38 (95.0)	152 (95.0)
		High value – n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Abnormal NCS – n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		AST increased				
		Grade 0 - n(%)	74 (94.9)	40 (95.2)	38 (95.0)	152 (95.0)
		Grade 1 - n(%)	3 (3.8)	1 (2.4)	0	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Aspartate						
Aminotransferase (IU/L) [¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.4 (3.91)	-0.6 (4.57)	-0.3 (3.86)	-0.4 (4.06)
		Median	0.0	-1.0	0.0	0.0
		Min, Max	-11, 14	-15, 14	-14, 7	-15, 14
	Shift in Normality	Normal to High, NCS - n(%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		High, NCS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
	Shift in Toxicity	AST increased				
		0 to 1 - n(%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		1 to 0 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Baseline	n	78	42	40	160
		Mean (SD)	0.66 (0.230)	0.60 (0.220)	0.62 (0.197)	0.63 (0.220)
		Median	0.60	0.55	0.60	0.60
		Min, Max	0.3, 1.5	0.2, 1.2	0.3, 1.2	0.2, 1.5
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)
		Blood bilirubin increased				
		Grade 0 - n(%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		Grade 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 6	n	78	42	40	160
		BLOQ, n (%)	0	0	1 (2.5)	1 (0.6)
		Mean (SD)	0.63 (0.213)	0.55 (0.208)	0.45 (0.165)	0.56 (0.212)
		Median	0.60	0.50	0.40	0.50
		Min, Max	0.3, 1.6	0.2, 1.1	0.1, 1.0	0.1, 1.6
		Low value – n (%)	0	0	1 (2.5)	1 (0.6)
		Normal value – n (%)	77 (98.7)	42 (100)	39 (97.5)	158 (98.8)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal CS – n (%)	1 (1.3)	0	0	1 (0.6)
		Blood bilirubin increased				
		Grade 0 - n(%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		Grade 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.03 (0.199)	-0.05 (0.166)	-0.17 (0.135)	-0.07 (0.185)
		Median	0.00	0.00	-0.10	-0.10
		Min, Max	-0.8, 0.5	-0.4, 0.3	-0.5, 0.0	-0.8, 0.5
	Shift in Normality	Normal to High, CS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
		High, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Blood bilirubin increased				
		0 to 1 - n(%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 30	n	77	41	38	156
		BLOQ, n (%)	0	2 (4.8)	0	2 (1.3)
		Mean (SD)	0.62 (0.215)	0.56 (0.237)	0.62 (0.225)	0.60 (0.223)
		Median	0.60	0.50	0.60	0.60
		Min, Max	0.2, 1.2	0.1, 0.9	0.3, 1.1	0.1, 1.2
		Low value – n (%)	0	2 (4.8)	0	2 (1.3)
		Normal value – n (%)	77 (98.7)	39 (92.9)	38 (95.0)	154 (96.3)
		Abnormal NCS – n (%)	0	2 (4.8)	0	2 (1.3)
		Blood bilirubin increased Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.03 (0.170)	-0.03 (0.157)	-0.01 (0.147)	-0.03 (0.161)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-0.4, 0.4	-0.5, 0.2	-0.3, 0.3	-0.5, 0.4
	Shift in Normality	Normal to Low, NCS - n(%)	0	2 (4.8)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 60	n	77	41	39	157
		Mean (SD)	0.61 (0.221)	0.50 (0.175)	0.59 (0.296)	0.58 (0.235)
		Median	0.60	0.50	0.50	0.50
		Min, Max	0.2, 1.3	0.2, 0.9	0.2, 1.7	0.2, 1.7
		Normal value – n (%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		High value – n (%)	1 (1.3)	0	1 (2.5)	2 (1.3)
		Abnormal NCS – n (%)	1 (1.3)	0	1 (2.5)	2 (1.3)
		Blood bilirubin increased				
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		Grade 1 - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Change from Baseline	n	77	41	39	157
		Mean (SD)	-0.04 (0.172)	-0.10 (0.149)	-0.03 (0.211)	-0.05 (0.178)
		Median	0.00	-0.10	0.00	0.00
		Min, Max	-0.5, 0.3	-0.5, 0.1	-0.4, 0.5	-0.5, 0.5
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)
		Blood bilirubin increased 0 to 1 - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)
	Shift in Toxicity					

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 91	n	77	41	38	156
		BLOQ, n (%)	0	1 (2.4)	0	1 (0.6)
		Mean (SD)	0.60 (0.199)	0.51 (0.187)	0.53 (0.168)	0.56 (0.192)
		Median	0.60	0.50	0.50	0.50
		Min, Max	0.3, 1.2	0.1, 0.9	0.3, 1.1	0.1, 1.2
		Low value – n (%)	0	1 (2.4)	0	1 (0.6)
		Normal value – n (%)	77 (98.7)	40 (95.2)	38 (95.0)	155 (96.9)
		Abnormal NCS – n (%)	0	1 (2.4)	0	1 (0.6)
		Blood bilirubin increased Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.05 (0.180)	-0.08 (0.169)	-0.09 (0.144)	-0.07 (0.169)
		Median	0.00	-0.10	-0.10	-0.10
		Min, Max	-0.4, 0.4	-0.5, 0.2	-0.4, 0.3	-0.5, 0.4
	Shift in Normality	Normal to Low, NCS - n(%)	0	1 (2.4)	0	1 (0.6)
Direct Bilirubin (mg/dL) [¹]	Baseline	n	78	42	40	160
		BLOQ, n (%)	2 (2.6)	3 (7.1)	1 (2.5)	6 (3.8)
		Mean (SD)	0.169 (0.0536)	0.158 (0.0671)	0.184 (0.0604)	0.170 (0.0594)
		Median	0.200	0.200	0.200	0.200
		Min, Max	0.05, 0.30	0.05, 0.30	0.05, 0.30	0.05, 0.30
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Direct Bilirubin (mg/dL) [¹]	Day 6	n	78	42	40	160
		BLOQ, n (%)	7 (9.0)	10 (23.8)	9 (22.5)	26 (16.3)
		Mean (SD)	0.151 (0.0653)	0.131 (0.0707)	0.114 (0.0589)	0.136 (0.0666)
		Median	0.200	0.100	0.100	0.100
		Min, Max	0.05, 0.40	0.05, 0.30	0.05, 0.30	0.05, 0.40
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.019 (0.0666)	-0.027 (0.0576)	-0.070 (0.0659)	-0.034 (0.0672)
		Median	0.000	0.000	-0.100	0.000
		Min, Max	-0.15, 0.20	-0.15, 0.10	-0.20, 0.10	-0.20, 0.20

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Direct Bilirubin (mg/dL) [¹]	Day 30	n	77	41	38	156
		BLOQ, n (%)	9 (11.5)	10 (23.8)	6 (15.0)	25 (15.6)
		Mean (SD)	0.147 (0.0607)	0.134 (0.0647)	0.150 (0.0658)	0.145 (0.0629)
		Median	0.200	0.100	0.200	0.200
		Min, Max	0.05, 0.30	0.05, 0.20	0.05, 0.30	0.05, 0.30
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.020 (0.0496)	-0.023 (0.0435)	-0.033 (0.0596)	-0.024 (0.0507)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.10, 0.10	-0.10, 0.10	-0.15, 0.10	-0.15, 0.10

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Direct Bilirubin (mg/dL) [¹]	Day 60	n	77	41	39	157
		BLOQ, n (%)	4 (5.1)	6 (14.3)	7 (17.5)	17 (10.6)
		Mean (SD)	0.164 (0.0658)	0.137 (0.0633)	0.158 (0.0808)	0.155 (0.0697)
		Median	0.200	0.100	0.200	0.200
		Min, Max	0.05, 0.40	0.05, 0.30	0.05, 0.40	0.05, 0.40
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
	Change from Baseline	n	77	41	39	157
		Mean (SD)	-0.004 (0.0567)	-0.021 (0.0536)	-0.026 (0.0688)	-0.014 (0.0596)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.10, 0.10	-0.15, 0.10	-0.15, 0.10	-0.15, 0.10

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Direct Bilirubin (mg/dL) [¹]	Day 91	n	77	41	38	156
		BLOQ, n (%)	4 (5.1)	8 (19.0)	4 (10.0)	16 (10.0)
		Mean (SD)	0.156 (0.0585)	0.139 (0.0667)	0.145 (0.0666)	0.149 (0.0628)
		Median	0.200	0.100	0.100	0.200
		Min, Max	0.05, 0.30	0.05, 0.30	0.05, 0.30	0.05, 0.30
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.012 (0.0562)	-0.018 (0.0458)	-0.038 (0.0620)	-0.020 (0.0559)
		Median	0.000	0.000	-0.025	0.000
		Min, Max	-0.15, 0.10	-0.15, 0.10	-0.10, 0.10	-0.15, 0.10

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alkaline Phosphatase (IU/L)						
[¹]	Baseline	n	78	42	40	160
		Mean (SD)	58.2 (15.76)	59.6 (14.35)	58.3 (16.31)	58.6 (15.46)
		Median	55.0	57.0	54.5	56.0
		Min, Max	32, 120	39, 99	32, 100	32, 120
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Alkaline phosphatase increased Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alkaline Phosphatase (IU/L)						
[¹]	Day 6	n	78	42	40	160
		Mean (SD)	64.1 (18.06)	64.9 (15.72)	61.8 (18.62)	63.8 (17.55)
		Median	60.0	64.5	59.5	61.0
		Min, Max	36, 140	41, 101	31, 113	31, 140
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)
		Alkaline phosphatase increased				
		Grade 0 - n(%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		Grade 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alkaline Phosphatase (IU/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	5.9 (4.38)	5.3 (5.47)	3.5 (5.85)	5.2 (5.13)
		Median	6.0	5.0	2.0	5.0
		Min, Max	-5, 20	-6, 23	-9, 19	-9, 23
	Shift in Normality	Normal to High, NCS - n(%)		0	0	1 (0.6)
	Shift in Toxicity	Alkaline phosphatase increased				
		0 to 1 - n(%)		0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alkaline Phosphatase (IU/L)						
[¹]	Day 30	n	77	41	38	156
		Mean (SD)	58.5 (14.98)	59.0 (14.65)	57.1 (18.03)	58.3 (15.60)
		Median	57.0	58.0	55.0	56.5
		Min, Max	31, 100	36, 99	32, 98	31, 100
		Low value – n (%)	0	0	1 (2.5)	1 (0.6)
		Normal value – n (%)	77 (98.7)	41 (97.6)	37 (92.5)	155 (96.9)
		Abnormal NCS – n (%)	0	0	1 (2.5)	1 (0.6)
		Alkaline phosphatase increased Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.6 (9.51)	-0.9 (5.44)	-0.9 (5.23)	-0.2 (7.68)
		Median	-1.0	0.0	-2.0	-1.0
		Min, Max	-20, 62	-16, 14	-14, 10	-20, 62

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alkaline Phosphatase (IU/L) [¹]	Shift in Normality	Normal to Low, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
	Day 60	n	77	41	39	157
		Mean (SD)	56.9 (14.71)	58.8 (15.36)	58.9 (17.78)	57.9 (15.61)
		Median	54.0	55.0	55.0	55.0
		Min, Max	33, 105	34, 104	40, 122	33, 122
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Alkaline phosphatase increased Grade 0 - n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
	Change from Baseline	n	77	41	39	157
		Mean (SD)	-1.0 (6.66)	-1.1 (5.35)	0.5 (7.34)	-0.6 (6.52)
		Median	-1.0	-1.0	0.0	-1.0
		Min, Max	-29, 15	-14, 10	-12, 28	-29, 28

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Alkaline Phosphatase (IU/L)						
[¹]	Day 91	n	77	41	38	156
		Mean (SD)	56.5 (14.36)	59.5 (16.74)	56.6 (16.71)	57.3 (15.55)
		Median	55.0	58.0	51.5	54.5
		Min, Max	33, 99	34, 110	32, 113	32, 113
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Alkaline phosphatase increased				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-1.4 (6.08)	-0.4 (7.95)	-1.3 (6.05)	-1.1 (6.58)
		Median	-1.0	-1.0	-1.5	-1.0
		Min, Max	-22, 17	-22, 22	-15, 19	-22, 22

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Gamma Glutamyl Transferase (IU/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	21.1 (13.11)	17.7 (10.21)	15.6 (7.69)	18.8 (11.41)
		Median	17.0	15.5	13.5	15.0
		Min, Max	6, 61	5, 50	8, 42	5, 61
		Low value – n (%)	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
		Normal value – n (%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		Abnormal NCS – n (%)	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
		GGT increased				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Gamma Glutamyl Transferase (IU/L) [¹]	Day 6	n	78	42	40	160
		BLOQ, n (%)	0	1 (2.4)	0	1 (0.6)
		Mean (SD)	20.8 (11.72)	17.5 (11.02)	15.2 (7.99)	18.5 (10.91)
		Median	17.0	14.0	13.0	15.0
		Min, Max	7, 55	2, 55	7, 39	2, 55
		Low value – n (%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)
		Normal value – n (%)	77 (98.7)	40 (95.2)	39 (97.5)	156 (97.5)
		Abnormal NCS – n (%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)
		GGT increased Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Gamma Glutamyl Transferase (IU/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.3 (3.46)	-0.1 (3.79)	-0.4 (2.89)	-0.3 (3.40)
		Median	0.5	0.0	-1.0	0.0
		Min, Max	-13, 8	-9, 16	-5, 12	-13, 16
	Shift in Normality	Normal to Low, NCS - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Gamma Glutamyl Transferase (IU/L) [¹]	Day 30	n	77	41	38	156
		Mean (SD)	22.1 (17.63)	17.7 (12.52)	17.8 (12.39)	19.9 (15.31)
		Median	16.0	14.0	15.0	15.0
		Min, Max	7, 130	6, 62	8, 74	6, 130
		Low value – n (%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		Normal value – n (%)	73 (93.6)	39 (92.9)	37 (92.5)	149 (93.1)
		High value – n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		Abnormal NCS – n (%)	3 (3.8)	2 (4.8)	1 (2.5)	6 (3.8)
		Abnormal CS – n (%)	1 (1.3)	0	0	1 (0.6)
		GGT increased				
		Grade 0 - n(%)	75 (96.2)	40 (95.2)	37 (92.5)	152 (95.0)
		Grade 1 - n(%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Grade 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Gamma Glutamyl Transferase (IU/L) [¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	1.2 (14.97)	-0.1 (4.53)	1.9 (6.41)	1.1 (11.20)
		Median	0.0	-1.0	1.0	0.0
		Min, Max	-18, 113	-10, 15	-5, 32	-18, 113
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Normal to High, CS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
		Low, NCS to Normal - n(%)	1 (1.3)	0	2 (5.0)	3 (1.9)
	Shift in Toxicity	GGT increased				
		0 to 1 - n(%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		0 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Gamma Glutamyl Transferase (IU/L) [¹]	Day 60	n	77	41	39	157
		Mean (SD)	20.4 (13.72)	17.1 (10.71)	16.5 (8.39)	18.6 (11.90)
		Median	16.0	14.0	14.0	15.0
		Min, Max	7, 85	6, 54	7, 51	6, 85
		Low value – n (%)	2 (2.6)	2 (4.8)	3 (7.5)	7 (4.4)
		Normal value – n (%)	73 (93.6)	39 (92.9)	36 (90.0)	148 (92.5)
		High value – n (%)	2 (2.6)	0	0	2 (1.3)
		Abnormal NCS – n (%)	4 (5.1)	2 (4.8)	3 (7.5)	9 (5.6)
		GGT increased				
		Grade 0 - n(%)	75 (96.2)	41 (97.6)	39 (97.5)	155 (96.9)
		Grade 1 - n(%)	2 (2.6)	0	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Gamma Glutamyl Transferase (IU/L) [¹]	Change from Baseline	n	77	41	39	157
		Mean (SD)	-0.5 (8.75)	-0.6 (5.91)	0.7 (4.22)	-0.2 (7.14)
		Median	0.0	-1.0	0.0	0.0
		Min, Max	-28, 41	-17, 26	-11, 15	-28, 41
	Shift in Normality	Normal to High, NCS - n(%)	2 (2.6)	0	0	2 (1.3)
		Normal to Low, NCS - n(%)	0	1 (2.4)	2 (5.0)	3 (1.9)
		Low, NCS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
	Shift in Toxicity	GGT increased				
		0 to 1 - n(%)	2 (2.6)	0	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Gamma Glutamyl Transferase (IU/L) [¹]	Day 91	n	77	41	38	156
		BLOQ, n (%)	0	1 (2.4)	0	1 (0.6)
		Mean (SD)	20.4 (15.20)	17.6 (14.32)	16.8 (8.00)	18.8 (13.57)
		Median	16.0	15.0	15.0	15.0
		Min, Max	6, 96	2, 86	5, 38	2, 96
		Low value – n (%)	2 (2.6)	2 (4.8)	0	4 (2.5)
		Normal value – n (%)	73 (93.6)	38 (90.5)	38 (95.0)	149 (93.1)
		High value – n (%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		Abnormal NCS – n (%)	3 (3.8)	3 (7.1)	0	6 (3.8)
		Abnormal CS – n (%)	1 (1.3)	0	0	1 (0.6)
		GGT increased				
		Grade 0 - n(%)	75 (96.2)	40 (95.2)	38 (95.0)	153 (95.6)
		Grade 1 - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Gamma Glutamyl Transferase (IU/L) [¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.5 (10.31)	-0.1 (10.69)	0.8 (4.34)	-0.1 (9.30)
		Median	0.0	-1.0	1.0	0.0
		Min, Max	-26, 57	-18, 58	-14, 10	-26, 58
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Normal to High, CS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Low, NCS to Normal - n(%)	1 (1.3)	0	2 (5.0)	3 (1.9)
	Shift in Toxicity	GGT increased				
		0 to 1 - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lactate Dehydrogenase (IU/L)						
[¹]	Baseline	n	78	42	38	158
		Mean (SD)	146.1 (27.97)	143.1 (19.26)	140.8 (19.90)	144.0 (24.05)
		Median	141.0	140.0	138.0	140.0
		Min, Max	102, 233	104, 189	103, 206	102, 233
		Normal value – n (%)	78 (100)	42 (100)	38 (95.0)	158 (98.8)
	Day 6	n	76	42	40	158
		Mean (SD)	148.4 (24.26)	145.5 (19.74)	136.9 (21.05)	144.7 (22.70)
		Median	143.0	145.0	135.0	141.5
		Min, Max	101, 231	100, 189	101, 195	100, 231
		Normal value – n (%)	76 (97.4)	42 (100)	40 (100)	158 (98.8)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lactate Dehydrogenase (IU/L)						
[¹]	Change from Baseline	n	76	42	38	156
		Mean (SD)	1.6 (12.18)	2.3 (10.97)	-4.1 (17.08)	0.4 (13.41)
		Median	3.0	1.5	-8.5	0.5
		Min, Max	-32, 36	-19, 27	-46, 39	-46, 39
	Day 30	n	77	41	38	156
		Mean (SD)	144.8 (27.70)	138.3 (18.72)	135.6 (17.22)	140.9 (23.53)
		Median	141.0	132.0	134.0	137.5
		Min, Max	94, 265	97, 183	107, 179	94, 265
		Normal value – n (%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lactate Dehydrogenase (IU/L)						
[¹]	Change from Baseline	n	77	41	36	154
		Mean (SD)	-1.7 (17.78)	-5.4 (11.40)	-5.4 (13.30)	-3.6 (15.33)
		Median	-2.0	-6.0	-3.0	-3.0
		Min, Max	-40, 94	-34, 15	-53, 16	-53, 94
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
	Day 60	n	77	41	39	157
		Mean (SD)	144.9 (25.66)	140.8 (20.16)	140.0 (21.23)	142.6 (23.23)
		Median	142.0	136.0	140.0	140.0
		Min, Max	91, 227	105, 207	96, 203	91, 227
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lactate Dehydrogenase (IU/L)						
[¹]	Change from Baseline	n	77	41	37	155
		Mean (SD)	-1.7 (17.63)	-3.0 (13.73)	-0.4 (19.63)	-1.7 (17.13)
		Median	-1.0	-3.0	-1.0	-1.0
		Min, Max	-41, 52	-37, 20	-63, 52	-63, 52
	Day 91	n	76	40	38	154
		Mean (SD)	144.9 (24.94)	140.7 (17.81)	139.8 (17.57)	142.6 (21.59)
		Median	139.0	138.5	140.0	139.0
		Min, Max	101, 224	93, 186	105, 176	93, 224
		Normal value – n (%)	76 (97.4)	40 (95.2)	38 (95.0)	154 (96.3)
	Change from Baseline	n	76	40	36	152
		Mean (SD)	-1.9 (17.84)	-2.7 (13.06)	-0.1 (15.30)	-1.7 (16.04)
		Median	0.0	-3.5	-0.5	-1.0
		Min, Max	-52, 47	-31, 22	-54, 33	-54, 47

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (mg/dL) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	85.1 (7.84)	85.6 (5.87)	85.1 (7.34)	85.2 (7.21)
		Median	85.0	85.0	85.0	85.0
		Min, Max	70, 110	72, 101	74, 101	70, 110
		Normal value – n (%)	76 (97.4)	42 (100)	40 (100)	158 (98.8)
		High value – n (%)	2 (2.6)	0	0	2 (1.3)
		Abnormal NCS – n (%)	2 (2.6)	0	0	2 (1.3)
		Hyperglycemia				
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		Grade 1 - n(%)	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
		Hypoglycemia				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (mg/dL) [¹]	Day 6	n	66	37	34	137
		Mean (SD)	83.7 (7.80)	85.1 (5.25)	82.3 (5.22)	83.7 (6.64)
		Median	85.0	86.0	83.0	85.0
		Min, Max	67, 103	67, 92	68, 90	67, 103
		Low value – n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		Normal value – n (%)	63 (80.8)	36 (85.7)	33 (82.5)	132 (82.5)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)
		Hyperglycemia				
		Grade 0 - n(%)	63 (80.8)	37 (88.1)	34 (85.0)	134 (83.8)
		Grade 1 - n(%)	3 (3.8)	0	0	3 (1.9)
		Hypoglycemia				
		Grade 0 - n(%)	64 (82.1)	36 (85.7)	33 (82.5)	133 (83.1)
		Grade 1 - n(%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (mg/dL) [¹]	Change from Baseline	n	66	37	34	137
		Mean (SD)	-1.4 (6.24)	-0.1 (6.81)	-2.3 (7.14)	-1.3 (6.63)
		Median	-2.0	0.0	-0.5	-1.0
		Min, Max	-16, 16	-21, 12	-22, 11	-22, 16
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		High, NCS to Normal - n(%)	2 (2.6)	0	0	2 (1.3)
	Shift in Toxicity	Hyperglycemia				
		0 to 1 - n(%)	2 (2.6)	0	0	2 (1.3)
		1 to 0 - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)
		Hypoglycemia				
		0 to 1 - n(%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (mg/dL) [¹]	Day 30	n	78	42	40	160
		Mean (SD)	90.2 (7.00)	92.0 (8.05)	91.5 (9.89)	91.0 (8.07)
		Median	90.0	92.0	88.0	90.0
		Min, Max	77, 113	74, 126	77, 117	74, 126
		Normal value – n (%)	70 (89.7)	39 (92.9)	34 (85.0)	143 (89.4)
		High value – n (%)	8 (10.3)	3 (7.1)	6 (15.0)	17 (10.6)
		Abnormal NCS – n (%)	8 (10.3)	3 (7.1)	6 (15.0)	17 (10.6)
		Hyperglycemia				
		Grade 0 - n(%)	67 (85.9)	37 (88.1)	29 (72.5)	133 (83.1)
		Grade 1 - n(%)	10 (12.8)	4 (9.5)	9 (22.5)	23 (14.4)
		Hypoglycemia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (mg/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	5.1 (5.34)	6.5 (7.00)	6.4 (8.06)	5.8 (6.54)
		Median	5.0	5.0	6.0	5.0
		Min, Max	-7, 18	-5, 41	-15, 27	-15, 41
	Shift in Normality	Normal to High, NCS - n(%)	6 (7.7)	3 (7.1)	6 (15.0)	15 (9.4)
	Shift in Toxicity	Hyperglycemia				
		0 to 1 - n(%)	8 (10.3)	3 (7.1)	7 (17.5)	18 (11.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (mg/dL) [¹]	Day 60	n	78	42	40	160
		Mean (SD)	90.0 (7.64)	92.5 (5.92)	88.0 (6.53)	90.2 (7.09)
		Median	90.0	92.0	88.0	90.0
		Min, Max	70, 117	83, 108	77, 108	70, 117
		Normal value – n (%)	73 (93.6)	39 (92.9)	39 (97.5)	151 (94.4)
		High value – n (%)	5 (6.4)	3 (7.1)	1 (2.5)	9 (5.6)
		Abnormal NCS – n (%)	5 (6.4)	3 (7.1)	1 (2.5)	9 (5.6)
		Hyperglycemia				
		Grade 0 - n(%)	69 (88.5)	37 (88.1)	36 (90.0)	142 (88.8)
		Grade 1 - n(%)	8 (10.3)	4 (9.5)	2 (5.0)	14 (8.8)
Hypoglycemia		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (mg/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	4.9 (6.51)	6.9 (5.28)	2.9 (6.99)	4.9 (6.46)
		Median	4.5	7.0	2.5	4.5
		Min, Max	-14, 29	0, 23	-11, 23	-14, 29
	Shift in Normality	Normal to High, NCS - n(%)	3 (3.8)	3 (7.1)	1 (2.5)	7 (4.4)
	Shift in Toxicity	Hyperglycemia				
		0 to 1 - n(%)	6 (7.7)	3 (7.1)	2 (5.0)	11 (6.9)
		1 to 0 - n(%)	0	0	2 (5.0)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (mg/dL) [¹]	Day 91	n	78	42	40	160
		Mean (SD)	90.2 (8.42)	91.1 (6.12)	87.4 (7.32)	89.8 (7.69)
		Median	88.0	90.0	87.0	88.0
		Min, Max	76, 119	79, 106	72, 104	72, 119
		Normal value – n (%)	72 (92.3)	40 (95.2)	39 (97.5)	151 (94.4)
		High value – n (%)	6 (7.7)	2 (4.8)	1 (2.5)	9 (5.6)
		Abnormal NCS – n (%)	5 (6.4)	2 (4.8)	1 (2.5)	8 (5.0)
		Abnormal CS – n (%)	1 (1.3)	0	0	1 (0.6)
		Hyperglycemia				
		Grade 0 - n(%)	68 (87.2)	37 (88.1)	36 (90.0)	141 (88.1)
		Grade 1 - n(%)	8 (10.3)	4 (9.5)	2 (5.0)	14 (8.8)
		Hypoglycemia				
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (mg/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	5.1 (6.68)	5.6 (5.84)	2.4 (6.56)	4.5 (6.53)
		Median	5.0	5.0	2.0	5.0
		Min, Max	-9, 22	-8, 20	-13, 19	-13, 22
	Shift in Normality	Normal to High, NCS - n(%)	3 (3.8)	2 (4.8)	1 (2.5)	6 (3.8)
		Normal to High, CS - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Hyperglycemia				
		0 to 1 - n(%)	6 (7.7)	3 (7.1)	1 (2.5)	10 (6.3)
		1 to 0 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Creatinine (mg/dL) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	0.764 (0.1433)	0.786 (0.1407)	0.773 (0.1519)	0.772 (0.1442)
		Median	0.800	0.800	0.800	0.800
		Min, Max	0.40, 1.10	0.60, 1.00	0.50, 1.10	0.40, 1.10
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Creatinine increased Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Creatinine (mg/dL) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	0.849 (0.1602)	0.838 (0.1431)	0.815 (0.1407)	0.838 (0.1508)
		Median	0.800	0.800	0.800	0.800
		Min, Max	0.50, 1.20	0.60, 1.10	0.60, 1.20	0.50, 1.20
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Creatinine increased				
		Grade 0 - n(%)	27 (34.6)	18 (42.9)	23 (57.5)	68 (42.5)
		Grade 1 - n(%)	51 (65.4)	24 (57.1)	17 (42.5)	92 (57.5)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.085 (0.0870)	0.052 (0.0672)	0.043 (0.0844)	0.066 (0.0833)
		Median	0.100	0.100	0.000	0.100
		Min, Max	-0.10, 0.30	-0.10, 0.20	-0.10, 0.30	-0.10, 0.30

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Creatinine (mg/dL) [¹]	Shift in Toxicity	Creatinine increased 0 to 1 - n(%)	51 (65.4)	24 (57.1)	17 (42.5)	92 (57.5)
	Day 30	n	77	41	38	156
		Mean (SD)	0.788 (0.1386)	0.793 (0.1312)	0.784 (0.1242)	0.788 (0.1325)
		Median	0.800	0.800	0.800	0.800
		Min, Max	0.40, 1.10	0.60, 1.10	0.60, 1.10	0.40, 1.10
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Creatinine increased				
		Grade 0 - n(%)	46 (59.0)	29 (69.0)	29 (72.5)	104 (65.0)
		Grade 1 - n(%)	31 (39.7)	12 (28.6)	9 (22.5)	52 (32.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Creatinine (mg/dL) [¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.025 (0.0891)	0.012 (0.0679)	0.011 (0.0728)	0.018 (0.0800)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.20, 0.20	-0.10, 0.10	-0.20, 0.20	-0.20, 0.20
	Shift in Toxicity	Creatinine increased 0 to 1 - n(%)	31 (39.7)	12 (28.6)	9 (22.5)	52 (32.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Creatinine (mg/dL) [¹]	Day 60	n	77	41	39	157
		Mean (SD)	0.768 (0.1410)	0.761 (0.1302)	0.764 (0.1496)	0.765 (0.1396)
		Median	0.800	0.800	0.800	0.800
		Min, Max	0.40, 1.00	0.50, 1.10	0.50, 1.10	0.40, 1.10
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Creatinine increased				
		Grade 0 - n(%)	54 (69.2)	36 (85.7)	32 (80.0)	122 (76.3)
		Grade 1 - n(%)	23 (29.5)	5 (11.9)	7 (17.5)	35 (21.9)
	Change from Baseline	n	77	41	39	157
		Mean (SD)	0.004 (0.0752)	-0.020 (0.0679)	-0.013 (0.0732)	-0.006 (0.0732)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.10, 0.10	-0.20, 0.10	-0.20, 0.10	-0.20, 0.10

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Creatinine (mg/dL) [¹]	Shift in Toxicity	Creatinine increased 0 to 1 - n(%)	23 (29.5)	5 (11.9)	7 (17.5)	35 (21.9)
	Day 91	n	77	41	38	156
		Mean (SD)	0.779 (0.1464)	0.780 (0.1309)	0.805 (0.1414)	0.786 (0.1408)
		Median	0.800	0.700	0.800	0.800
		Min, Max	0.40, 1.10	0.50, 1.00	0.60, 1.10	0.40, 1.10
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Creatinine increased				
		Grade 0 - n(%)	51 (65.4)	30 (71.4)	23 (57.5)	104 (65.0)
		Grade 1 - n(%)	25 (32.1)	11 (26.2)	15 (37.5)	51 (31.9)
		Grade 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Creatinine (mg/dL) [¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.016 (0.0961)	-0.000 (0.0775)	0.032 (0.0702)	0.015 (0.0859)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.20, 0.40	-0.20, 0.10	-0.10, 0.20	-0.20, 0.40
	Shift in Toxicity	Creatinine increased				
		0 to 1 - n(%)	25 (32.1)	11 (26.2)	15 (37.5)	51 (31.9)
		0 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (g/dL) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	6.85 (0.405)	6.88 (0.551)	6.78 (0.430)	6.84 (0.453)
		Median	6.85	6.85	6.80	6.80
		Min, Max	5.9, 7.8	5.8, 8.9	6.0, 7.5	5.8, 8.9
		Low value – n (%)	3 (3.8)	2 (4.8)	2 (5.0)	7 (4.4)
		Normal value – n (%)	75 (96.2)	39 (92.9)	38 (95.0)	152 (95.0)
		High value – n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal NCS – n (%)	3 (3.8)	3 (7.1)	2 (5.0)	8 (5.0)
		Hypoproteinemia				
		Grade 0 - n(%)	75 (96.2)	40 (95.2)	38 (95.0)	153 (95.6)
		Grade 1 - n(%)	3 (3.8)	2 (4.8)	2 (5.0)	7 (4.4)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (g/dL) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	7.25 (0.363)	7.15 (0.453)	6.78 (0.398)	7.11 (0.439)
		Median	7.30	7.20	6.80	7.10
		Min, Max	6.4, 8.3	6.1, 7.9	6.0, 7.9	6.0, 8.3
		Low value – n (%)	0	0	2 (5.0)	2 (1.3)
		Normal value – n (%)	78 (100)	42 (100)	38 (95.0)	158 (98.8)
		Abnormal NCS – n (%)	0	0	2 (5.0)	2 (1.3)
		Hypoproteinemia				
		Grade 0 - n(%)	78 (100)	42 (100)	38 (95.0)	158 (98.8)
		Grade 1 - n(%)	0	0	2 (5.0)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (g/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.39 (0.382)	0.27 (0.485)	0.00 (0.346)	0.26 (0.431)
		Median	0.40	0.30	0.00	0.25
		Min, Max	-0.7, 1.3	-1.6, 1.2	-0.8, 0.7	-1.6, 1.3
	Shift in Normality	Normal to Low, NCS - n(%)	0	0	2 (5.0)	2 (1.3)
		High, NCS to Normal - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n(%)	3 (3.8)	2 (4.8)	2 (5.0)	7 (4.4)
	Shift in Toxicity	Hypoproteinemia				
		0 to 1 - n(%)	0	0	2 (5.0)	2 (1.3)
		1 to 0 - n(%)	3 (3.8)	2 (4.8)	2 (5.0)	7 (4.4)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (g/dL) [¹]	Day 30	n	77	41	38	156
		Mean (SD)	6.74 (0.401)	6.62 (0.385)	6.53 (0.377)	6.66 (0.398)
		Median	6.70	6.70	6.50	6.60
		Min, Max	5.9, 7.9	5.4, 7.4	5.6, 7.4	5.4, 7.9
		Low value – n (%)	1 (1.3)	2 (4.8)	4 (10.0)	7 (4.4)
		Normal value – n (%)	76 (97.4)	39 (92.9)	34 (85.0)	149 (93.1)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	4 (10.0)	6 (3.8)
		Abnormal CS – n (%)	0	1 (2.4)	0	1 (0.6)
		Hypoproteinemia				
		Grade 0 - n(%)	76 (97.4)	39 (92.9)	34 (85.0)	149 (93.1)
		Grade 1 - n(%)	1 (1.3)	1 (2.4)	4 (10.0)	6 (3.8)
		Grade 2 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (g/dL) [¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.12 (0.328)	-0.26 (0.428)	-0.22 (0.285)	-0.18 (0.352)
		Median	-0.20	-0.20	-0.20	-0.20
		Min, Max	-0.8, 0.8	-2.1, 0.6	-0.9, 0.4	-2.1, 0.8
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	0	3 (7.5)	4 (2.5)
		Normal to Low, CS - n(%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n(%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)
	Shift in Toxicity	Hypoproteinemia				
		0 to 1 - n(%)	1 (1.3)	0	3 (7.5)	4 (2.5)
		0 to 2 - n(%)	0	1 (2.4)	0	1 (0.6)
		1 to 0 - n(%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (g/dL) [¹]	Day 60	n	77	41	39	157
		Mean (SD)	6.78 (0.362)	6.65 (0.412)	6.62 (0.430)	6.70 (0.397)
		Median	6.80	6.70	6.60	6.70
		Min, Max	5.9, 7.5	5.6, 7.4	5.8, 7.7	5.6, 7.7
		Low value – n (%)	1 (1.3)	4 (9.5)	4 (10.0)	9 (5.6)
		Normal value – n (%)	76 (97.4)	37 (88.1)	35 (87.5)	148 (92.5)
		Abnormal NCS – n (%)	1 (1.3)	4 (9.5)	4 (10.0)	9 (5.6)
		Hypoproteinemia				
		Grade 0 - n(%)	76 (97.4)	37 (88.1)	35 (87.5)	148 (92.5)
		Grade 1 - n(%)	1 (1.3)	4 (9.5)	4 (10.0)	9 (5.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (g/dL) [¹]	Change from Baseline	n	77	41	39	157
		Mean (SD)	-0.08 (0.353)	-0.23 (0.453)	-0.14 (0.392)	-0.14 (0.393)
		Median	-0.10	-0.20	-0.20	-0.20
		Min, Max	-0.8, 0.7	-2.1, 0.6	-0.8, 1.3	-2.1, 1.3
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	2 (4.8)	3 (7.5)	6 (3.8)
		High, NCS to Normal - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n(%)	3 (3.8)	0	1 (2.5)	4 (2.5)
	Shift in Toxicity	Hypoproteinemia				
		0 to 1 - n(%)	1 (1.3)	2 (4.8)	3 (7.5)	6 (3.8)
		1 to 0 - n(%)	3 (3.8)	0	1 (2.5)	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (g/dL) [¹]	Day 91	n	77	41	38	156
		Mean (SD)	6.71 (0.357)	6.62 (0.376)	6.59 (0.425)	6.66 (0.381)
		Median	6.70	6.60	6.60	6.60
		Min, Max	6.1, 7.6	5.7, 7.4	5.7, 7.9	5.7, 7.9
		Low value – n (%)	0	3 (7.1)	4 (10.0)	7 (4.4)
		Normal value – n (%)	77 (98.7)	38 (90.5)	34 (85.0)	149 (93.1)
		Abnormal NCS – n (%)	0	3 (7.1)	4 (10.0)	7 (4.4)
		Hypoproteinemia				
		Grade 0 - n(%)	77 (98.7)	38 (90.5)	34 (85.0)	149 (93.1)
		Grade 1 - n(%)	0	3 (7.1)	4 (10.0)	7 (4.4)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (g/dL) [¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.15 (0.358)	-0.26 (0.426)	-0.16 (0.376)	-0.18 (0.382)
		Median	-0.20	-0.30	-0.20	-0.20
		Min, Max	-1.0, 0.7	-1.9, 0.7	-1.0, 0.6	-1.9, 0.7
	Shift in Normality	Normal to Low, NCS - n(%)	0	2 (4.8)	4 (10.0)	6 (3.8)
		High, NCS to Normal - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n(%)	3 (3.8)	1 (2.4)	2 (5.0)	6 (3.8)
	Shift in Toxicity	Hypoproteinemia				
		0 to 1 - n(%)	0	2 (4.8)	4 (10.0)	6 (3.8)
		1 to 0 - n(%)	3 (3.8)	1 (2.4)	2 (5.0)	6 (3.8)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Blood Urea Nitrogen (mg/dL)						
[¹]	Baseline	n	78	42	40	160
		Mean (SD)	11.3 (2.42)	11.6 (2.26)	11.5 (2.42)	11.5 (2.37)
		Median	11.0	11.0	11.5	11.0
		Min, Max	6, 19	7, 17	6, 17	6, 19
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Blood Urea Nitrogen Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Blood Urea Nitrogen (mg/dL)						
[¹]	Day 6	n	78	42	40	160
		Mean (SD)	11.9 (2.15)	11.8 (2.30)	12.0 (2.54)	11.9 (2.28)
		Median	12.0	11.0	11.0	12.0
		Min, Max	7, 18	8, 17	8, 18	7, 18
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Blood Urea Nitrogen Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.6 (1.85)	0.2 (1.57)	0.5 (2.00)	0.5 (1.82)
		Median	0.5	0.0	0.5	0.0
		Min, Max	-5, 4	-4, 4	-5, 5	-5, 5

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Blood Urea Nitrogen (mg/dL)						
[¹]	Day 30	n	77	41	38	156
		Mean (SD)	12.2 (2.36)	11.6 (2.56)	12.8 (2.50)	12.2 (2.47)
		Median	12.0	11.0	13.0	12.0
		Min, Max	6, 19	7, 17	6, 18	6, 19
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Blood Urea Nitrogen Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.9 (1.96)	0.1 (1.88)	1.2 (1.79)	0.7 (1.93)
		Median	1.0	0.0	1.0	1.0
		Min, Max	-8, 5	-4, 4	-3, 5	-8, 5

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Blood Urea Nitrogen (mg/dL)						
[¹]	Day 60	n	77	41	39	157
		Mean (SD)	12.2 (2.28)	11.8 (2.58)	12.8 (2.43)	12.2 (2.41)
		Median	12.0	12.0	13.0	12.0
		Min, Max	8, 18	6, 20	7, 17	6, 20
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Blood Urea Nitrogen Grade 0 - n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
	Change from Baseline	n	77	41	39	157
		Mean (SD)	0.9 (2.09)	0.2 (1.91)	1.3 (1.96)	0.8 (2.04)
		Median	1.0	0.0	1.0	1.0
		Min, Max	-6, 7	-4, 5	-3, 6	-6, 7

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Blood Urea Nitrogen (mg/dL)						
[¹]	Day 91	n	77	41	38	156
		Mean (SD)	11.6 (2.34)	11.9 (2.58)	12.7 (2.57)	12.0 (2.49)
		Median	11.0	11.0	13.0	12.0
		Min, Max	7, 19	7, 19	7, 18	7, 19
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Blood Urea Nitrogen Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.4 (2.27)	0.3 (1.83)	1.1 (1.99)	0.5 (2.11)
		Median	0.0	1.0	1.0	1.0
		Min, Max	-7, 6	-3, 4	-3, 5	-7, 6

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Triglycerides (mg/dL) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	143.4 (72.94)	130.5 (50.88)	109.9 (42.10)	131.7 (62.17)
		Median	124.5	114.5	101.5	118.5
		Min, Max	54, 421	53, 236	54, 226	53, 421
		Normal value – n (%)	74 (94.9)	41 (97.6)	39 (97.5)	154 (96.3)
		High value – n (%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Abnormal CS – n (%)	3 (3.8)	0	0	3 (1.9)
		Hypertriglyceridemia				
		Grade 0 - n(%)	52 (66.7)	29 (69.0)	32 (80.0)	113 (70.6)
		Grade 1 - n(%)	23 (29.5)	13 (31.0)	8 (20.0)	44 (27.5)
		Grade 2 - n(%)	3 (3.8)	0	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Triglycerides (mg/dL) [¹]	Day 6	n	66	37	34	137
		Mean (SD)	137.0 (66.36)	137.9 (59.75)	109.6 (42.41)	130.4 (60.25)
		Median	124.5	110.0	101.0	114.0
		Min, Max	56, 380	50, 254	53, 203	50, 380
		Normal value – n (%)	62 (79.5)	34 (81.0)	33 (82.5)	129 (80.6)
		High value – n (%)	4 (5.1)	3 (7.1)	1 (2.5)	8 (5.0)
		Abnormal NCS – n (%)	1 (1.3)	3 (7.1)	1 (2.5)	5 (3.1)
		Abnormal CS – n (%)	3 (3.8)	0	0	3 (1.9)
		Hypertriglyceridemia				
		Grade 0 - n(%)	44 (56.4)	25 (59.5)	26 (65.0)	95 (59.4)
		Grade 1 - n(%)	19 (24.4)	12 (28.6)	8 (20.0)	39 (24.4)
		Grade 2 - n(%)	3 (3.8)	0	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Triglycerides (mg/dL) [¹]	Change from Baseline	n	66	37	34	137
		Mean (SD)	-8.6 (40.42)	6.5 (34.83)	0.4 (40.39)	-2.3 (39.24)
		Median	-6.0	-3.0	-3.5	-4.0
		Min, Max	-164, 125	-69, 79	-128, 77	-164, 125
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	3 (7.1)	0	4 (2.5)
		Normal to High, CS - 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, CS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Hypertriglyceridemia				
		0 to 1 - n(%)	7 (9.0)	2 (4.8)	5 (12.5)	14 (8.8)
		1 to 0 - n(%)	6 (7.7)	2 (4.8)	3 (7.5)	11 (6.9)
		1 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)
		2 to 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Triglycerides (mg/dL) [¹]	Day 30	n	78	42	40	160
		Mean (SD)	151.4 (75.01)	137.7 (47.73)	127.5 (61.36)	141.8 (65.85)
		Median	131.5	138.0	113.5	125.5
		Min, Max	50, 421	61, 229	44, 314	44, 421
		Normal value – n (%)	72 (92.3)	39 (92.9)	38 (95.0)	149 (93.1)
		High value – n (%)	6 (7.7)	3 (7.1)	2 (5.0)	11 (6.9)
		Abnormal NCS – n (%)	4 (5.1)	3 (7.1)	2 (5.0)	9 (5.6)
		Abnormal CS – n (%)	2 (2.6)	0	0	2 (1.3)
		Hypertriglyceridemia				
		Grade 0 - n(%)	48 (61.5)	25 (59.5)	27 (67.5)	100 (62.5)
		Grade 1 - n(%)	26 (33.3)	16 (38.1)	10 (25.0)	52 (32.5)
		Grade 2 - n(%)	3 (3.8)	0	1 (2.5)	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Triglycerides (mg/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	7.9 (44.68)	7.2 (29.17)	17.6 (49.04)	10.2 (42.36)
		Median	8.5	6.5	8.0	7.5
		Min, Max	-166, 174	-49, 95	-86, 194	-166, 194
	Shift in Normality	Normal to High, NCS - n(%)	3 (3.8)	2 (4.8)	1 (2.5)	6 (3.8)
		High, CS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Hypertriglyceridemia				
		0 to 1 - n(%)	10 (12.8)	3 (7.1)	4 (10.0)	17 (10.6)
		0 to 2 - n(%)	0	0	1 (2.5)	1 (0.6)
		1 to 0 - n(%)	6 (7.7)	0	2 (5.0)	8 (5.0)
		1 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)
		2 to 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Triglycerides (mg/dL) [¹]	Day 60	n	78	42	40	160
		Mean (SD)	144.2 (64.90)	149.0 (66.13)	124.5 (51.57)	140.5 (62.53)
		Median	127.5	138.5	121.5	126.5
		Min, Max	66, 368	52, 359	52, 267	52, 368
		Low value – n (%)	0	0	1 (2.5)	1 (0.6)
		Normal value – n (%)	74 (94.9)	41 (97.6)	38 (95.0)	153 (95.6)
		High value – n (%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
		Abnormal NCS – n (%)	1 (1.3)	0	2 (5.0)	3 (1.9)
		Abnormal CS – n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Hypertriglyceridemia				
		Grade 0 - n(%)	49 (62.8)	25 (59.5)	25 (62.5)	99 (61.9)
		Grade 1 - n(%)	25 (32.1)	15 (35.7)	13 (32.5)	53 (33.1)
		Grade 2 - n(%)	3 (3.8)	1 (2.4)	0	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Triglycerides (mg/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.8 (41.24)	18.5 (56.00)	14.6 (40.43)	8.9 (45.81)
		Median	3.5	17.0	8.5	8.0
		Min, Max	-143, 134	-105, 252	-68, 150	-143, 252
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)
		Normal to High, CS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Normal to Low, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
		High, NCS to Normal - n(%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		High, CS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
[Reference range]	Study Day	Statistic				
Triglycerides (mg/dL) [¹]	Shift in Toxicity	Hypertriglyceridemia				
		0 to 1 - n(%)	9 (11.5)	5 (11.9)	7 (17.5)	21 (13.1)
		0 to 2 - n(%)	0	1 (2.4)	0	1 (0.6)
		1 to 0 - n(%)	6 (7.7)	3 (7.1)	2 (5.0)	11 (6.9)
		1 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)
		2 to 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Triglycerides (mg/dL) [¹]	Day 91	n	78	42	40	160
		Mean (SD)	142.7 (83.30)	136.0 (45.29)	129.7 (67.27)	137.7 (70.91)
		Median	120.0	131.5	108.0	123.5
		Min, Max	49, 491	57, 236	53, 353	49, 491
		Normal value – n (%)	73 (93.6)	41 (97.6)	38 (95.0)	152 (95.0)
		High value – n (%)	5 (6.4)	1 (2.4)	2 (5.0)	8 (5.0)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Abnormal CS – n (%)	4 (5.1)	0	1 (2.5)	5 (3.1)
		Hypertriglyceridemia				
		Grade 0 - n(%)	53 (67.9)	26 (61.9)	24 (60.0)	103 (64.4)
		Grade 1 - n(%)	18 (23.1)	15 (35.7)	13 (32.5)	46 (28.8)
		Grade 2 - n(%)	5 (6.4)	0	1 (2.5)	6 (3.8)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Triglycerides (mg/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.7 (41.54)	5.5 (35.30)	19.8 (40.30)	6.0 (40.32)
		Median	0.0	4.0	3.0	2.0
		Min, Max	-111, 110	-84, 87	-30, 150	-111, 150
	Shift in Normality	Normal to High, NCS - n(%)	0	1 (2.4)	0	1 (0.6)
		Normal to High, CS - n(%)	2 (2.6)	0	1 (2.5)	3 (1.9)
		High, NCS to Normal - n(%)	0	1 (2.4)	0	1 (0.6)
		High, CS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Hypertriglyceridemia				
		0 to 1 - n(%)	5 (6.4)	5 (11.9)	6 (15.0)	16 (10.0)
		1 to 0 - n(%)	7 (9.0)	3 (7.1)	0	10 (6.3)
		1 to 2 - n(%)	2 (2.6)	0	1 (2.5)	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cholesterol (mg/dL) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	197.6 (35.01)	200.1 (42.06)	182.9 (28.45)	194.6 (35.99)
		Median	195.5	193.5	182.0	190.5
		Min, Max	131, 290	131, 343	131, 245	131, 343
		Low value – n (%)	5 (6.4)	1 (2.4)	2 (5.0)	8 (5.0)
		Normal value – n (%)	71 (91.0)	40 (95.2)	38 (95.0)	149 (93.1)
		High value – n (%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		Abnormal NCS – n (%)	7 (9.0)	1 (2.4)	2 (5.0)	10 (6.3)
		Abnormal CS – n (%)	0	1 (2.4)	0	1 (0.6)
		Cholesterol high				
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	40 (100)	157 (98.1)
		Grade 1 - n(%)	2 (2.6)	0	0	2 (1.3)
		Grade 2 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cholesterol (mg/dL) [¹]	Day 6	n	66	37	34	137
		Mean (SD)	198.0 (34.09)	198.2 (34.10)	175.2 (28.95)	192.4 (34.13)
		Median	198.0	204.0	177.0	192.0
		Min, Max	130, 293	131, 276	125, 255	125, 293
		Low value – n (%)	4 (5.1)	0	4 (10.0)	8 (5.0)
		Normal value – n (%)	61 (78.2)	36 (85.7)	30 (75.0)	127 (79.4)
		High value – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Abnormal NCS – n (%)	5 (6.4)	1 (2.4)	4 (10.0)	10 (6.3)
		Cholesterol high				
		Grade 0 - n(%)	65 (83.3)	36 (85.7)	34 (85.0)	135 (84.4)
		Grade 1 - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cholesterol (mg/dL) [¹]	Change from Baseline	n	66	37	34	137
		Mean (SD)	-0.7 (20.82)	-2.1 (21.94)	-5.3 (20.51)	-2.2 (20.98)
		Median	0.0	2.0	-2.5	0.0
		Min, Max	-61, 39	-67, 52	-51, 31	-67, 52
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	0	0	2 (5.0)	2 (1.3)
		High, NCS to Normal - n(%)	2 (2.6)	0	0	2 (1.3)
		High, CS to High, NCS - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
	Shift in Toxicity	Cholesterol high				
		0 to 1 - n(%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n(%)	2 (2.6)	0	0	2 (1.3)
		2 to 1 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cholesterol (mg/dL) [¹]	Day 30	n	78	42	40	160
		Mean (SD)	195.3 (33.37)	192.8 (32.19)	187.8 (33.76)	192.8 (33.10)
		Median	191.5	192.5	182.5	189.0
		Min, Max	133, 291	121, 254	125, 256	121, 291
		Low value – n (%)	3 (3.8)	2 (4.8)	3 (7.5)	8 (5.0)
		Normal value – n (%)	75 (96.2)	40 (95.2)	36 (90.0)	151 (94.4)
		High value – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal NCS – n (%)	3 (3.8)	2 (4.8)	4 (10.0)	9 (5.6)
		Cholesterol high				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	37 (92.5)	155 (96.9)
		Grade 1 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cholesterol (mg/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-2.3 (16.03)	-7.3 (25.28)	4.9 (19.51)	-1.8 (20.05)
		Median	-1.0	-6.5	7.5	0.0
		Min, Max	-42, 29	-94, 69	-46, 43	-94, 69
	Shift in Normality	Normal to High, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
		Normal to Low, NCS - n(%)	0	2 (4.8)	3 (7.5)	5 (3.1)
		High, NCS to Normal - n(%)	2 (2.6)	0	0	2 (1.3)
		High, CS to Normal - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n(%)	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
	Shift in Toxicity	Cholesterol high				
		0 to 1 - n(%)	0	0	1 (2.5)	1 (0.6)
		1 to 0 - n(%)	2 (2.6)	0	0	2 (1.3)
		2 to 0 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cholesterol (mg/dL) [¹]	Day 60	n	78	42	40	160
		Mean (SD)	194.8 (37.19)	194.1 (34.01)	189.1 (34.15)	193.2 (35.49)
		Median	188.0	189.5	189.0	188.5
		Min, Max	132, 311	130, 261	125, 263	125, 311
		Low value – n (%)	8 (10.3)	1 (2.4)	3 (7.5)	12 (7.5)
		Normal value – n (%)	68 (87.2)	41 (97.6)	35 (87.5)	144 (90.0)
		High value – n (%)	2 (2.6)	0	2 (5.0)	4 (2.5)
		Abnormal NCS – n (%)	9 (11.5)	1 (2.4)	5 (12.5)	15 (9.4)
		Abnormal CS – n (%)	1 (1.3)	0	0	1 (0.6)
		Cholesterol high				
		Grade 0 - n(%)	75 (96.2)	41 (97.6)	36 (90.0)	152 (95.0)
		Grade 1 - n(%)	1 (1.3)	0	2 (5.0)	3 (1.9)
		Grade 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cholesterol (mg/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-2.8 (21.47)	-6.0 (25.22)	6.2 (20.32)	-1.4 (22.58)
		Median	-2.5	-1.5	4.5	-1.0
		Min, Max	-42, 48	-103, 42	-36, 55	-103, 55
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	2 (5.0)	3 (1.9)
		Normal to High, CS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	3 (3.8)	1 (2.4)	2 (5.0)	6 (3.8)
		High, NCS to Normal - n(%)	2 (2.6)	0	0	2 (1.3)
		High, CS to Normal - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n(%)	0	1 (2.4)	1 (2.5)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
[Reference range]	Study Day	Statistic				
Cholesterol (mg/dL) [¹]	Shift in Toxicity	Cholesterol high				
		0 to 1 - n(%)	1 (1.3)	0	2 (5.0)	3 (1.9)
		0 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n(%)	2 (2.6)	0	0	2 (1.3)
		2 to 0 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cholesterol (mg/dL) [¹]	Day 91	n	78	42	40	160
		Mean (SD)	189.9 (37.73)	191.1 (32.76)	187.2 (28.82)	189.5 (34.24)
		Median	186.5	183.5	190.0	187.0
		Min, Max	133, 311	125, 274	125, 252	125, 311
		Low value – n (%)	7 (9.0)	2 (4.8)	2 (5.0)	11 (6.9)
		Normal value – n (%)	67 (85.9)	39 (92.9)	37 (92.5)	143 (89.4)
		High value – n (%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
		Abnormal NCS – n (%)	10 (12.8)	3 (7.1)	3 (7.5)	16 (10.0)
		Abnormal CS – n (%)	1 (1.3)	0	0	1 (0.6)
		Cholesterol high				
		Grade 0 - n(%)	72 (92.3)	40 (95.2)	37 (92.5)	149 (93.1)
		Grade 1 - n(%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)
		Grade 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cholesterol (mg/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-7.7 (23.38)	-9.0 (29.73)	4.3 (18.38)	-5.1 (24.60)
		Median	-9.5	-8.0	1.0	-5.0
		Min, Max	-80, 61	-119, 85	-33, 39	-119, 85
	Shift in Normality	Normal to High, NCS - n(%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		Normal to High, CS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	3 (3.8)	2 (4.8)	2 (5.0)	7 (4.4)
		High, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
		High, CS to Normal - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n(%)	1 (1.3)	1 (2.4)	2 (5.0)	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
[Reference range]	Study Day	Statistic				
Cholesterol (mg/dL) [¹]	Shift in Toxicity	Cholesterol high				
		0 to 1 - n(%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		0 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n(%)	1 (1.3)	0	0	1 (0.6)
		2 to 0 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Albumin (g/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	42.7 (3.39)	42.4 (3.84)	41.9 (3.13)	42.5 (3.45)
		Median	43.0	42.0	42.5	43.0
		Min, Max	36, 52	34, 50	36, 48	34, 52
		Normal value – n (%)	76 (97.4)	41 (97.6)	40 (100)	157 (98.1)
		High value – n (%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		Abnormal NCS – n (%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		Hypoalbuminemia Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Albumin (g/L) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	44.8 (2.59)	43.8 (3.36)	41.4 (3.25)	43.7 (3.27)
		Median	44.5	44.0	41.0	44.0
		Min, Max	39, 54	38, 53	36, 51	36, 54
		Normal value – n (%)	77 (98.7)	40 (95.2)	39 (97.5)	156 (97.5)
		High value – n (%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)
		Abnormal NCS – n (%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)
		Hypoalbuminemia Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	2.1 (2.31)	1.4 (2.68)	-0.5 (2.41)	1.3 (2.64)
		Median	2.0	2.0	-0.5	1.0
		Min, Max	-5, 7	-6, 7	-6, 4	-6, 7

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Albumin (g/L) [¹]	Shift in Normality	Normal to High, NCS - n(%)	0	1 (2.4)	1 (2.5)	2 (1.3)
		High, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
	Day 30	n	77	41	38	156
		Mean (SD)	41.5 (2.84)	40.3 (2.48)	39.8 (2.72)	40.7 (2.80)
		Median	42.0	41.0	39.5	41.0
		Min, Max	37, 50	35, 44	33, 46	33, 50
		Normal value – n (%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)
		Hypoalbuminemia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Albumin (g/L) [¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-1.3 (2.37)	-2.0 (2.41)	-2.1 (2.03)	-1.6 (2.32)
		Median	-2.0	-2.0	-2.0	-2.0
		Min, Max	-6, 5	-9, 3	-6, 2	-9, 5
	Shift in Normality					
		High, NCS to Normal - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Albumin (g/L) [¹]	Day 60	n	77	41	39	157
		Mean (SD)	41.3 (2.97)	40.0 (2.68)	39.9 (2.92)	40.6 (2.94)
		Median	42.0	40.0	40.0	40.0
		Min, Max	34, 48	32, 46	35, 47	32, 48
		Low value – n (%)	0	1 (2.4)	0	1 (0.6)
		Normal value – n (%)	77 (98.7)	40 (95.2)	39 (97.5)	156 (97.5)
		Abnormal NCS – n (%)	0	1 (2.4)	0	1 (0.6)
		Hypoalbuminemia				
		Grade 0 - n(%)	77 (98.7)	40 (95.2)	39 (97.5)	156 (97.5)
		Grade 1 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Albumin (g/L) [¹]	Change from Baseline	n	77	41	39	157
		Mean (SD)	-1.4 (2.37)	-2.2 (2.75)	-1.9 (2.32)	-1.7 (2.47)
		Median	-1.0	-2.0	-2.0	-2.0
		Min, Max	-8, 6	-10, 4	-7, 4	-10, 6
	Shift in Normality	Normal to Low, NCS - n(%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)
	Shift in Toxicity	Hypoalbuminemia				
		0 to 1 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Albumin (g/L) [¹]	Day 91	n	77	41	38	156
		Mean (SD)	41.0 (2.65)	39.8 (2.52)	39.9 (2.84)	40.4 (2.70)
		Median	41.0	40.0	40.0	40.0
		Min, Max	36, 48	33, 45	36, 47	33, 48
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hypoalbuminemia Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-1.8 (2.54)	-2.5 (2.75)	-1.9 (2.17)	-2.0 (2.52)
		Median	-2.0	-2.0	-2.0	-2.0
		Min, Max	-7, 5	-8, 4	-6, 5	-8, 5
	Shift in Normality					
		High, NCS to Normal - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Sodium (mmol/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	140.1 (1.73)	140.5 (1.68)	140.1 (2.03)	140.2 (1.79)
		Median	140.0	141.0	140.0	140.0
		Min, Max	137, 145	137, 144	136, 144	136, 145
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Hypernatremia				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Hyponatremia				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Sodium (mmol/L) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	139.3 (1.67)	138.9 (2.18)	139.3 (2.15)	139.2 (1.94)
		Median	139.0	139.5	139.5	139.0
		Min, Max	135, 144	135, 142	135, 144	135, 144
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Hypernatremia				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Hyponatremia				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.8 (1.85)	-1.6 (1.84)	-0.8 (2.29)	-1.0 (1.98)
		Median	-1.0	-1.0	0.0	-1.0
		Min, Max	-5, 4	-6, 2	-7, 4	-7, 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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Sodium (mmol/L) [¹]	Day 30	n	77	41	38	156
		Mean (SD)	139.5 (1.71)	139.6 (1.90)	139.7 (2.31)	139.6 (1.91)
		Median	140.0	140.0	140.0	140.0
		Min, Max	136, 143	136, 143	135, 143	135, 143
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hypernatremia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hyponatremia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.6 (1.82)	-0.8 (1.68)	-0.4 (1.81)	-0.6 (1.78)
		Median	-1.0	0.0	0.0	0.0
		Min, Max	-7, 3	-5, 2	-6, 3	-7, 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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Sodium (mmol/L) [¹]	Day 60	n	77	41	39	157
		Mean (SD)	139.6 (1.61)	139.9 (1.98)	140.3 (1.34)	139.8 (1.67)
		Median	139.0	140.0	140.0	140.0
		Min, Max	136, 143	136, 144	137, 143	136, 144
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Hypernatremia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Hyponatremia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
	Change from Baseline	n	77	41	39	157
		Mean (SD)	-0.5 (1.70)	-0.6 (1.62)	0.2 (1.57)	-0.4 (1.67)
		Median	0.0	-1.0	0.0	0.0
		Min, Max	-5, 2	-4, 2	-3, 4	-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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Sodium (mmol/L) [¹]	Day 91	n	77	41	38	156
		Mean (SD)	140.0 (1.54)	139.5 (1.37)	140.4 (1.61)	139.9 (1.54)
		Median	140.0	140.0	140.0	140.0
		Min, Max	135, 143	137, 142	137, 143	135, 143
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hypernatremia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hyponatremia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.2 (1.68)	-1.0 (1.57)	0.3 (1.44)	-0.3 (1.65)
		Median	0.0	-1.0	0.0	0.0
		Min, Max	-5, 3	-4, 3	-3, 3	-5, 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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Potassium (mmol/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	4.19 (0.348)	4.27 (0.323)	4.21 (0.405)	4.22 (0.356)
		Median	4.20	4.20	4.20	4.20
		Min, Max	3.6, 5.5	3.7, 5.2	3.6, 5.3	3.6, 5.5
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)
		Hyperkalemia				
		Grade 0 - n(%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		Grade 1 - n(%)	1 (1.3)	0	0	1 (0.6)
		Hypokalemia				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Potassium (mmol/L) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	4.23 (0.330)	4.25 (0.416)	4.30 (0.348)	4.25 (0.357)
		Median	4.20	4.20	4.30	4.20
		Min, Max	3.7, 5.5	3.5, 5.3	3.7, 5.3	3.5, 5.5
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)
		Hyperkalemia				
		Grade 0 - n(%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		Grade 1 - n(%)	1 (1.3)	0	0	1 (0.6)
		Hypokalemia				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Potassium (mmol/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.04 (0.351)	-0.02 (0.406)	0.08 (0.306)	0.04 (0.356)
		Median	0.00	-0.05	0.10	0.00
		Min, Max	-1.0, 1.0	-1.1, 1.3	-0.9, 0.6	-1.1, 1.3
	Shift in Normality	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)
	Shift in Toxicity	Hyperkalemia				
		0 to 1 - n(%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Potassium (mmol/L) [¹]	Day 30	n	77	41	38	156
		Mean (SD)	4.28 (0.320)	4.23 (0.245)	4.23 (0.263)	4.26 (0.288)
		Median	4.20	4.20	4.20	4.20
		Min, Max	3.7, 5.2	3.7, 4.7	3.7, 4.9	3.7, 5.2
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hyperkalemia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hypokalemia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.09 (0.307)	-0.03 (0.330)	0.00 (0.300)	0.03 (0.314)
		Median	0.10	-0.10	0.00	0.00
		Min, Max	-0.5, 1.1	-1.1, 0.6	-0.9, 0.7	-1.1, 1.1

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Potassium (mmol/L) [¹]	Shift in Normality	High, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Hyperkalemia 1 to 0 - n(%)	1 (1.3)	0	0	1 (0.6)
	Day 60	n	77	41	39	157
		Mean (SD)	4.28 (0.342)	4.26 (0.325)	4.20 (0.242)	4.25 (0.315)
		Median	4.20	4.10	4.20	4.20
		Min, Max	3.7, 5.4	3.7, 5.1	3.7, 4.7	3.7, 5.4
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Hyperkalemia Grade 0 - n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Hypokalemia Grade 0 - n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Potassium (mmol/L) [¹]	Change from Baseline	n	77	41	39	157
		Mean (SD)	0.08 (0.306)	-0.01 (0.438)	-0.03 (0.331)	0.03 (0.352)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-0.7, 0.8	-1.1, 1.1	-0.8, 0.6	-1.1, 1.1
	Shift in Normality	High, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
		Shift in Toxicity Hyperkalemia 1 to 0 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Potassium (mmol/L) [¹]	Day 91	n	77	41	38	156
		Mean (SD)	4.19 (0.311)	4.17 (0.316)	4.23 (0.330)	4.19 (0.315)
		Median	4.10	4.10	4.10	4.10
		Min, Max	3.6, 5.1	3.6, 5.0	3.7, 5.0	3.6, 5.1
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hyperkalemia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hypokalemia				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.01 (0.278)	-0.10 (0.338)	0.00 (0.303)	-0.03 (0.302)
		Median	0.00	-0.10	0.00	0.00
		Min, Max	-0.5, 0.7	-1.1, 0.7	-0.6, 0.8	-1.1, 0.8

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.16.1 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Potassium (mmol/L) [¹]	Shift in Normality	High, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Hyperkalemia 1 to 0 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.4

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Erythrocytes (T/L) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	4.626 (0.4462)	4.663 (0.4697)	4.553 (0.4265)	4.405 (0.4896)	4.599 (0.4530)
		Median	4.625	4.665	4.585	4.440	4.610
		Min, Max	3.58, 5.43	3.54, 5.72	3.86, 5.46	3.72, 5.15	3.54, 5.72
		Low value – n (%)	5 (6.4)	3 (7.1)	3 (7.5)	4 (26.7)	15 (8.6)
		Normal value – n (%)	72 (92.3)	38 (90.5)	37 (92.5)	11 (73.3)	158 (90.3)
		High value – n (%)	1 (1.3)	1 (2.4)	0	0	2 (1.1)
		Abnormal NCS – n (%)	6 (7.7)	4 (9.5)	3 (7.5)	4 (26.7)	17 (9.7)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Erythrocytes (T/L) [¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	4.732 (0.4967)	4.721 (0.5035)	4.635 (0.4336)	4.520 (0.5168)	4.699 (0.4827)
		Median	4.700	4.750	4.700	4.400	4.700
		Min, Max	3.60, 5.70	3.60, 5.80	3.80, 5.60	4.00, 5.20	3.60, 5.80
		Low value – n (%)	9 (11.5)	5 (11.9)	5 (12.5)	2 (13.3)	21 (12.0)
		Normal value – n (%)	69 (88.5)	37 (88.1)	35 (87.5)	3 (20.0)	144 (82.3)
		Abnormal NCS – n (%)	9 (11.5)	5 (11.9)	5 (12.5)	2 (13.3)	21 (12.0)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Hemoglobin (g/dL)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	14.41 (1.424)	14.33 (1.316)	14.26 (1.337)	14.03 (1.212)	14.32 (1.355)
		Median	14.50	14.40	14.20	14.10	14.30
		Min, Max	11.3, 16.9	11.5, 16.6	11.9, 16.9	11.9, 16.1	11.3, 16.9
		Low value – n (%)	3 (3.8)	0	1 (2.5)	3 (20.0)	7 (4.0)
		Normal value – n (%)	72 (92.3)	42 (100)	39 (97.5)	12 (80.0)	165 (94.3)
		High value – n (%)	3 (3.8)	0	0	0	3 (1.7)
		Abnormal NCS – n (%)	6 (7.7)	0	1 (2.5)	3 (20.0)	10 (5.7)
		Hemoglobin increase					
		Grade 0 - n(%)	75 (96.2)	42 (100)	40 (100)	15 (100)	172 (98.3)
		Grade 1 - n(%)	3 (3.8)	0	0	0	3 (1.7)
		Hemoglobin decreased					
		Grade 0 - n(%)	73 (93.6)	38 (90.5)	38 (95.0)	11 (73.3)	160 (91.4)
		Grade 1 - n(%)	5 (6.4)	4 (9.5)	2 (5.0)	4 (26.7)	15 (8.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Hemoglobin (g/dL) [¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	14.39 (1.632)	14.16 (1.505)	14.20 (1.391)	13.78 (1.280)	14.27 (1.528)
		Median	14.50	14.35	14.30	13.30	14.40
		Min, Max	11.0, 17.4	10.8, 17.3	11.6, 17.3	12.7, 15.6	10.8, 17.4
		Low value – n (%)	4 (5.1)	2 (4.8)	0	0	6 (3.4)
		Normal value – n (%)	74 (94.9)	40 (95.2)	40 (100)	5 (33.3)	159 (90.9)
		Abnormal NCS – n (%)	4 (5.1)	1 (2.4)	0	0	5 (2.9)
		Abnormal CS – n (%)	0	1 (2.4)	0	0	1 (0.6)
		Hemoglobin increase					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Hemoglobin decreased					
		Grade 0 - n(%)	67 (85.9)	37 (88.1)	36 (90.0)	4 (26.7)	144 (82.3)
		Grade 1 - n(%)	11 (14.1)	4 (9.5)	4 (10.0)	1 (6.7)	20 (11.4)
		Grade 2 - n(%)	0	1 (2.4)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Hematocrit (%)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	42.59 (3.939)	42.42 (3.571)	42.37 (3.705)	41.60 (3.605)	42.41 (3.750)
		Median	42.80	42.35	42.60	41.80	42.40
		Min, Max	34.1, 49.1	34.2, 48.7	36.3, 49.7	35.2, 47.8	34.1, 49.7
		Low value – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	1 (6.7)	4 (2.3)
		Normal value – n (%)	76 (97.4)	41 (97.6)	39 (97.5)	14 (93.3)	170 (97.1)
		High value – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal NCS – n (%)	2 (2.6)	1 (2.4)	1 (2.5)	1 (6.7)	5 (2.9)
	Day 0	n	78	42	40	5	165
		Mean (SD)	44.01 (4.637)	43.45 (4.244)	43.38 (4.259)	42.20 (3.421)	43.66 (4.399)
		Median	44.00	43.50	43.00	42.00	44.00
		Min, Max	34.0, 53.0	34.0, 53.0	36.0, 54.0	39.0, 47.0	34.0, 54.0
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Leukocytes (GI/L) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	6.815 (1.4465)	6.545 (1.1856)	6.980 (1.5895)	7.107 (1.6264)	6.813 (1.4378)
		Median	6.700	6.750	6.900	6.900	6.800
		Min, Max	4.10, 9.60	4.30, 9.50	4.00, 9.50	3.80, 10.10	3.80, 10.10
		Normal value – n (%)	70 (89.7)	41 (97.6)	35 (87.5)	13 (86.7)	159 (90.9)
		High value – n (%)	8 (10.3)	1 (2.4)	5 (12.5)	2 (13.3)	16 (9.1)
		Abnormal NCS – n (%)	8 (10.3)	1 (2.4)	5 (12.5)	2 (13.3)	16 (9.1)
		WBC Increase					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		WBC Decrease					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Leukocytes (GI/L) [¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	5.918 (1.1804)	5.763 (1.3366)	6.501 (1.9268)	5.580 (1.4773)	6.010 (1.4564)
		Median	5.950	5.660	6.360	5.090	5.860
		Min, Max	3.10, 8.68	2.99, 9.52	3.34, 12.40	4.31, 8.13	2.99, 12.40
		Low value – n (%)	5 (6.4)	2 (4.8)	1 (2.5)	0	8 (4.6)
		Normal value – n (%)	73 (93.6)	40 (95.2)	38 (95.0)	5 (33.3)	156 (89.1)
		High value – n (%)	0	0	1 (2.5)	0	1 (0.6)
		Abnormal NCS – n (%)	5 (6.4)	1 (2.4)	1 (2.5)	0	7 (4.0)
		Abnormal CS – n (%)	0	1 (2.4)	1 (2.5)	0	2 (1.1)
		WBC Increase					
		Grade 0 - n(%)	78 (100)	42 (100)	39 (97.5)	5 (33.3)	164 (93.7)
		Grade 1 - n(%)	0	0	1 (2.5)	0	1 (0.6)
		WBC Decrease					
		Grade 0 - n(%)	73 (93.6)	40 (95.2)	39 (97.5)	5 (33.3)	157 (89.7)
		Grade 1 - n(%)	5 (6.4)	1 (2.4)	1 (2.5)	0	7 (4.0)
		Grade 2 - n(%)	0	1 (2.4)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test Overall Safety (N=15)	Overall Safety (N=175)
Neutrophils (G/L) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	4.074 (1.2206)	3.936 (0.8977)	4.173 (1.3691)	4.247 (1.0790)	4.078 (1.1715)
		Median	3.900	4.050	4.050	4.300	4.000
		Min, Max	1.80, 6.90	2.30, 6.00	2.00, 6.90	2.40, 5.80	1.80, 6.90
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		Neutrophils Decrease Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Neutrophils (GI/L)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	3.391 (1.0306)	3.226 (0.9336)	3.846 (1.7008)	3.480 (1.3755)	3.462 (1.2261)
		Median	3.360	3.035	3.640	3.060	3.240
		Min, Max	1.17, 6.20	1.47, 5.63	1.37, 9.73	2.36, 5.81	1.17, 9.73
		Low value – n (%)	6 (7.7)	2 (4.8)	3 (7.5)	0	11 (6.3)
		Normal value – n (%)	72 (92.3)	40 (95.2)	36 (90.0)	5 (33.3)	153 (87.4)
		High value – n (%)	0	0	1 (2.5)	0	1 (0.6)
		Abnormal NCS – n (%)	3 (3.8)	1 (2.4)	2 (5.0)	0	6 (3.4)
		Abnormal CS – n (%)	3 (3.8)	1 (2.4)	2 (5.0)	0	6 (3.4)
		Neutrophils Decrease					
		Grade 0 - n(%)	72 (92.3)	40 (95.2)	37 (92.5)	5 (33.3)	154 (88.0)
		Grade 1 - n(%)	3 (3.8)	1 (2.4)	2 (5.0)	0	6 (3.4)
		Grade 2 - n(%)	3 (3.8)	1 (2.4)	1 (2.5)	0	5 (2.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test Overall Safety (N=15)	Overall Safety (N=175)
Neutrophils/Leukocytes (%)							
[40-75]	Screening	n	78	42	40	15	175
		Mean (SD)	59.10 (8.652)	60.00 (7.651)	58.80 (7.824)	59.69 (7.107)	59.30 (8.057)
		Median	58.70	60.80	59.70	58.30	59.10
		Min, Max	34.7, 79.9	44.6, 73.6	45.4, 74.5	49.3, 78.0	34.7, 79.9
		Low value – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value – n (%)	75 (96.2)	42 (100)	40 (100)	14 (93.3)	171 (97.7)
		High value – n (%)	2 (2.6)	0	0	1 (6.7)	3 (1.7)
		Abnormal NCS – n (%)	3 (3.8)	0	0	1 (6.7)	4 (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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test Overall Safety (N=15)	Overall Safety (N=175)
Lymphocytes (GI/L) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	2.099 (0.5323)	1.952 (0.6197)	2.155 (0.4669)	2.273 (0.6934)	2.091 (0.5585)
		Median	2.000	1.800	2.150	2.300	2.000
		Min, Max	1.00, 3.60	0.80, 3.80	1.20, 3.20	1.00, 3.80	0.80, 3.80
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		Lymphocytes Increase Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		Lymphocytes Decrease Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Lymphocytes (GI/L) [¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	2.069 (0.5019)	2.026 (0.5560)	2.148 (0.4866)	1.758 (0.4703)	2.068 (0.5120)
		Median	2.040	1.895	2.090	1.790	2.020
		Min, Max	1.01, 3.39	1.24, 3.40	1.36, 3.14	1.27, 2.31	1.01, 3.40
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Lymphocytes Increase Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Lymphocytes Decrease Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Lymphocytes/Leukocytes (%)							
[18-49]	Screening	n	78	42	40	15	175
		Mean (SD)	31.47 (7.658)	29.96 (7.350)	31.90 (7.449)	31.84 (7.034)	31.23 (7.459)
		Median	31.50	29.40	31.85	31.80	31.50
		Min, Max	14.4, 50.4	13.2, 44.9	17.0, 44.9	14.5, 41.9	13.2, 50.4
		Low value – n (%)	3 (3.8)	1 (2.4)	2 (5.0)	1 (6.7)	7 (4.0)
		Normal value – n (%)	74 (94.9)	41 (97.6)	38 (95.0)	14 (93.3)	167 (95.4)
		High value – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal NCS – n (%)	4 (5.1)	1 (2.4)	2 (5.0)	1 (6.7)	8 (4.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test Overall Safety (N=15)	Overall Safety (N=175)
Monocytes (GI/L)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	0.406 (0.1173)	0.393 (0.1191)	0.403 (0.1317)	0.415 (0.1469)	0.403 (0.1229)
		Median	0.390	0.360	0.375	0.360	0.380
		Min, Max	0.17, 0.80	0.18, 0.67	0.19, 0.74	0.28, 0.85	0.17, 0.85
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
	Day 0	n	78	42	40	5	165
		Mean (SD)	0.286 (0.0802)	0.289 (0.0879)	0.324 (0.1187)	0.248 (0.0934)	0.295 (0.0940)
		Median	0.290	0.275	0.300	0.230	0.290
		Min, Max	0.12, 0.51	0.14, 0.55	0.16, 0.68	0.13, 0.39	0.12, 0.68
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]	Study Day	Statistic	(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Monocytes/Leukocytes							
(%)							
[2-10]	Screening	n	78	42	40	15	175
		Mean (SD)	6.03 (1.518)	6.10 (1.738)	5.88 (1.691)	5.90 (1.578)	6.00 (1.606)
		Median	5.90	6.50	5.95	5.50	6.00
		Min, Max	3.5, 9.9	3.0, 10.2	2.0, 11.8	4.0, 9.1	2.0, 11.8
		Normal value – n (%)	78 (100)	41 (97.6)	39 (97.5)	15 (100)	173 (98.9)
		High value – n (%)	0	1 (2.4)	1 (2.5)	0	2 (1.1)
		Abnormal NCS – n (%)	0	1 (2.4)	1 (2.5)	0	2 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test Overall Safety (N=15)	Overall Safety (N=175)
Eosinophils (GI/L) [¹]	Screening	n	78	42	40	15	175
		Mean (SD)	0.195 (0.1762)	0.228 (0.1228)	0.208 (0.1624)	0.157 (0.1622)	0.202 (0.1603)
		Median	0.165	0.250	0.150	0.090	0.170
		Min, Max	0.02, 1.41	0.02, 0.50	0.05, 0.69	0.00, 0.46	0.00, 1.41
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		Eosinophils					
		Grade 0 - n(%)	77 (98.7)	42 (100)	39 (97.5)	15 (100)	173 (98.9)
		Grade 1 - n(%)	1 (1.3)	0	1 (2.5)	0	2 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test Overall Safety (N=15)	Overall Safety (N=175)
Eosinophils (GI/L) [¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	0.125 (0.0698)	0.169 (0.0934)	0.134 (0.0693)	0.056 (0.0289)	0.136 (0.0785)
		Median	0.100	0.160	0.120	0.060	0.110
		Min, Max	0.04, 0.37	0.04, 0.38	0.03, 0.28	0.03, 0.10	0.03, 0.38
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Eosinophils Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Eosinophils/Leukocytes (%)							
[0-8]	Screening	n	78	42	40	15	175
		Mean (SD)	2.85 (2.363)	3.44 (1.753)	2.84 (1.836)	2.11 (1.982)	2.93 (2.096)
		Median	2.35	3.60	2.65	1.10	2.60
		Min, Max	0.4, 17.8	0.3, 7.8	0.6, 8.0	0.0, 6.1	0.0, 17.8
		Normal value – n (%)	76 (97.4)	42 (100)	40 (100)	15 (100)	173 (98.9)
		High value – n (%)	2 (2.6)	0	0	0	2 (1.1)
		Abnormal NCS – n (%)	2 (2.6)	0	0	0	2 (1.1)
Basophils (GI/L)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	0.04 (0.031)	0.03 (0.030)	0.04 (0.029)	0.03 (0.041)	0.04 (0.031)
		Median	0.03	0.02	0.03	0.02	0.03
		Min, Max	0.0, 0.2	0.0, 0.1	0.0, 0.1	0.0, 0.2	0.0, 0.2
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Basophils (GI/L)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	0.05 (0.018)	0.05 (0.023)	0.05 (0.026)	0.04 (0.016)	0.05 (0.022)
		Median	0.05	0.05	0.05	0.04	0.05
		Min, Max	0.0, 0.1	0.0, 0.1	0.0, 0.1	0.0, 0.1	0.0, 0.1
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
Basophils/Leukocytes (%)							
[0-2]	Screening	n	78	42	40	15	175
		Mean (SD)	0.55 (0.421)	0.51 (0.388)	0.59 (0.390)	0.46 (0.616)	0.54 (0.424)
		Median	0.40	0.40	0.50	0.40	0.40
		Min, Max	0.0, 2.2	0.0, 1.8	0.0, 1.9	0.0, 2.5	0.0, 2.5
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	14 (93.3)	173 (98.9)
		High value – n (%)	1 (1.3)	0	0	1 (6.7)	2 (1.1)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (6.7)	2 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test Overall Safety (N=15)	Overall Safety (N=175)
Platelets (GI/L)							
[¹]	Screening	n	78	42	40	15	175
			239.58	239.31	246.28	222.07	
		Mean (SD)	(47.968)	(55.181)	(47.769)	(50.455)	239.54 (49.887)
		Median	236.50	245.00	243.00	230.00	238.00
		Min, Max	149.0, 355.0	142.0, 355.0	165.0, 382.0	127.0, 316.0	127.0, 382.0
		Low value – n (%)	0	0	0	1 (6.7)	1 (0.6)
		Normal value – n (%)	77 (98.7)	40 (95.2)	37 (92.5)	14 (93.3)	168 (96.0)
		High value – n (%)	1 (1.3)	2 (4.8)	3 (7.5)	0	6 (3.4)
		Abnormal NCS – n (%)	1 (1.3)	2 (4.8)	3 (7.5)	1 (6.7)	7 (4.0)
		Platelets Decrease					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	14 (93.3)	174 (99.4)
		Grade 1 - n(%)	0	0	0	1 (6.7)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Platelets (GI/L) [¹]	Day 0	n	78	42	40	5	165
			225.54	228.05	239.30	223.80	
		Mean (SD)	(53.759)	(50.048)	(45.052)	(60.194)	229.46 (50.858)
		Median	221.50	220.00	233.00	202.00	223.00
		Min, Max	140.0, 448.0	147.0, 363.0	167.0, 335.0	176.0, 329.0	140.0, 448.0
		Normal value – n (%)	76 (97.4)	42 (100)	40 (100)	5 (33.3)	163 (93.1)
		High value – n (%)	2 (2.6)	0	0	0	2 (1.1)
		Abnormal NCS – n (%)	2 (2.6)	0	0	0	2 (1.1)
		Platelets Decrease Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]	Study Day	Statistic	(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Ery. Mean Corpuscular Hemoglobin (pg)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	31.19 (1.626)	30.80 (1.809)	31.37 (1.571)	32.01 (2.023)	31.21 (1.710)
		Median	31.50	31.10	31.25	31.90	31.40
		Min, Max	24.1, 33.9	24.9, 34.4	25.4, 33.8	26.3, 34.8	24.1, 34.8
		Low value – n (%)	3 (3.8)	4 (9.5)	1 (2.5)	1 (6.7)	9 (5.1)
		Normal value – n (%)	75 (96.2)	37 (88.1)	39 (97.5)	12 (80.0)	163 (93.1)
		High value – n (%)	0	1 (2.4)	0	2 (13.3)	3 (1.7)
		Abnormal NCS – n (%)	3 (3.8)	5 (11.9)	1 (2.5)	3 (20.0)	12 (6.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test Overall Safety (N=15)	Overall Safety (N=175)
Ery. Mean Corpuscular Hemoglobin (pg)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	30.51 (1.666)	30.07 (1.773)	30.83 (1.518)	30.80 (2.775)	30.48 (1.703)
		Median	31.00	30.00	31.00	32.00	31.00
		Min, Max	24.0, 34.0	25.0, 34.0	25.0, 34.0	26.0, 33.0	24.0, 34.0
		Low value – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	0	3 (1.7)
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	5 (33.3)	162 (92.6)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	0	3 (1.7)
Ery. Mean Corpuscular HGB Concentration (g/dL)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	33.82 (0.548)	33.75 (0.581)	33.64 (0.570)	33.73 (0.378)	33.76 (0.549)
		Median	33.80	33.70	33.60	33.70	33.80
		Min, Max	32.4, 35.1	32.3, 34.8	32.1, 34.8	33.0, 34.3	32.1, 35.1
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]	Study Day	Statistic	(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Ery. Mean Corpuscular							
HGB Concentration							
(g/dL)							
[1]							
	Day 0	n	78	42	40	5	165
		Mean (SD)	32.79 (0.945)	32.64 (1.008)	32.95 (0.960)	32.80 (0.448)	32.79 (0.954)
		Median	33.00	33.00	33.00	33.00	33.00
		Min, Max	30.0, 35.0	30.0, 35.0	31.0, 35.0	32.0, 33.0	30.0, 35.0
		Low value – n (%)	4 (5.1)	1 (2.4)	1 (2.5)	0	6 (3.4)
		Normal value – n (%)	74 (94.9)	41 (97.6)	39 (97.5)	5 (33.3)	159 (90.9)
		Abnormal NCS – n (%)	4 (5.1)	1 (2.4)	1 (2.5)	0	6 (3.4)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test Overall Safety (N=15)	Overall Safety (N=175)
Ery. Mean Corpuscular Volume (fL)							
[¹]	Screening	n	78	42	40	15	175
		Mean (SD)	92.21 (4.299)	91.21 (4.751)	93.18 (4.145)	94.80 (5.672)	92.41 (4.575)
		Median	93.00	92.00	93.00	95.00	93.00
		Min, Max	74.0, 99.0	77.0, 100.0	79.0, 101.0	79.0, 102.0	74.0, 102.0
		Low value – n (%)	4 (5.1)	4 (9.5)	1 (2.5)	1 (6.7)	10 (5.7)
		Normal value – n (%)	74 (94.9)	38 (90.5)	39 (97.5)	14 (93.3)	165 (94.3)
		Abnormal NCS – n (%)	4 (5.1)	4 (9.5)	1 (2.5)	1 (6.7)	10 (5.7)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]	Study Day	Statistic	(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Ery. Mean Corpuscular							
Volume (fL)							
[¹]	Day 0	n	78	42	40	5	165
		Mean (SD)	93.01 (4.186)	92.40 (4.295)	93.75 (3.888)	93.40 (7.830)	93.05 (4.262)
		Median	94.00	92.50	94.00	97.00	93.00
		Min, Max	76.0, 101.0	82.0, 103.0	80.0, 101.0	80.0, 99.0	76.0, 103.0
		Low value – n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value – n (%)	66 (84.6)	37 (88.1)	32 (80.0)	3 (20.0)	138 (78.9)
		High value – n (%)	11 (14.1)	5 (11.9)	8 (20.0)	2 (13.3)	26 (14.9)
		Abnormal NCS – n (%)	12 (15.4)	5 (11.9)	8 (20.0)	2 (13.3)	27 (15.4)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Erythrocytes (T/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	4.732 (0.4967)	4.721 (0.5035)	4.635 (0.4336)	4.705 (0.4823)
		Median	4.700	4.750	4.700	4.700
		Min, Max	3.60, 5.70	3.60, 5.80	3.80, 5.60	3.60, 5.80
		Low value – n (%)	9 (11.5)	5 (11.9)	5 (12.5)	19 (11.9)
		Normal value – n (%)	69 (88.5)	37 (88.1)	35 (87.5)	141 (88.1)
		Abnormal NCS – n (%)	9 (11.5)	5 (11.9)	5 (12.5)	19 (11.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Erythrocytes (T/L) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	4.779 (0.4725)	4.726 (0.4910)	4.513 (0.4497)	4.699 (0.4817)
		Median	4.800	4.700	4.500	4.700
		Min, Max	3.70, 6.00	3.60, 5.80	3.70, 5.40	3.60, 6.00
		Low value – n (%)	6 (7.7)	5 (11.9)	14 (35.0)	25 (15.6)
		Normal value – n (%)	72 (92.3)	37 (88.1)	26 (65.0)	135 (84.4)
		Abnormal NCS – n (%)	6 (7.7)	5 (11.9)	14 (35.0)	25 (15.6)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.047 (0.1871)	0.005 (0.2141)	-0.123 (0.2007)	-0.006 (0.2086)
		Median	0.050	0.000	-0.150	0.000
		Min, Max	-0.40, 0.50	-0.60, 0.40	-0.50, 0.40	-0.60, 0.50
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	1 (2.4)	9 (22.5)	11 (6.9)
		Low, NCS to Normal - n(%)	4 (5.1)	1 (2.4)	0	5 (3.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Erythrocytes (T/L) [¹]	Day 30	n	77	41	38	156
		Mean (SD)	4.542 (0.4411)	4.544 (0.4605)	4.413 (0.4282)	4.511 (0.4439)
		Median	4.500	4.600	4.450	4.500
		Min, Max	3.50, 5.60	3.60, 5.40	3.60, 5.40	3.50, 5.60
		Low value – n (%)	15 (19.2)	10 (23.8)	14 (35.0)	39 (24.4)
		Normal value – n (%)	62 (79.5)	31 (73.8)	24 (60.0)	117 (73.1)
		Abnormal NCS – n (%)	15 (19.2)	10 (23.8)	14 (35.0)	39 (24.4)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.190 (0.1896)	-0.166 (0.2266)	-0.195 (0.1470)	-0.185 (0.1902)
		Median	-0.200	-0.100	-0.200	-0.200
		Min, Max	-0.60, 0.30	-0.80, 0.30	-0.50, 0.20	-0.80, 0.30
	Shift in Normality	Normal to Low, NCS - n(%)	7 (9.0)	6 (14.3)	9 (22.5)	22 (13.8)
		Low, NCS to Normal - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Erythrocytes (T/L) [¹]	Day 60	n	77	41	39	157
		Mean (SD)	4.587 (0.4491)	4.602 (0.4699)	4.518 (0.4026)	4.574 (0.4421)
		Median	4.600	4.700	4.500	4.600
		Min, Max	3.60, 5.50	3.50, 5.50	3.80, 5.50	3.50, 5.50
		Low value – n (%)	15 (19.2)	8 (19.0)	8 (20.0)	31 (19.4)
		Normal value – n (%)	62 (79.5)	33 (78.6)	31 (77.5)	126 (78.8)
		Abnormal NCS – n (%)	15 (19.2)	8 (19.0)	8 (20.0)	31 (19.4)
	Change from Baseline	n	77	41	39	157
		Mean (SD)	-0.144 (0.2119)	-0.107 (0.2602)	-0.115 (0.2278)	-0.127 (0.2284)
		Median	-0.100	-0.100	-0.100	-0.100
		Min, Max	-0.70, 0.30	-0.70, 0.40	-0.60, 0.40	-0.70, 0.40
	Shift in Normality	Normal to Low, NCS - n(%)	7 (9.0)	5 (11.9)	4 (10.0)	16 (10.0)
		Low, NCS to Normal - n(%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Erythrocytes (T/L) [¹]	Day 91	n	77	41	38	156
		Mean (SD)	4.547 (0.4781)	4.617 (0.4284)	4.492 (0.4600)	4.552 (0.4604)
		Median	4.500	4.700	4.350	4.500
		Min, Max	3.50, 5.50	3.70, 5.60	3.70, 5.60	3.50, 5.60
		Low value – n (%)	17 (21.8)	7 (16.7)	11 (27.5)	35 (21.9)
		Normal value – n (%)	60 (76.9)	34 (81.0)	27 (67.5)	121 (75.6)
		Abnormal NCS – n (%)	17 (21.8)	7 (16.7)	11 (27.5)	35 (21.9)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.184 (0.2272)	-0.093 (0.2328)	-0.116 (0.2225)	-0.144 (0.2298)
		Median	-0.200	-0.100	-0.100	-0.100
		Min, Max	-0.70, 0.40	-0.60, 0.50	-0.60, 0.30	-0.70, 0.50
	Shift in Normality	Normal to Low, NCS - n(%)	9 (11.5)	4 (9.5)	7 (17.5)	20 (12.5)
		Low, NCS to Normal - n(%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hemoglobin (g/dL) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	14.39 (1.632)	14.16 (1.505)	14.20 (1.391)	14.29 (1.536)
		Median	14.50	14.35	14.30	14.40
		Min, Max	11.0, 17.4	10.8, 17.3	11.6, 17.3	10.8, 17.4
		Low value – n (%)	4 (5.1)	2 (4.8)	0	6 (3.8)
		Normal value – n (%)	74 (94.9)	40 (95.2)	40 (100)	154 (96.3)
		Abnormal NCS – n (%)	4 (5.1)	1 (2.4)	0	5 (3.1)
		Abnormal CS – n (%)	0	1 (2.4)	0	1 (0.6)
		Hemoglobin increase				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Hemoglobin decreased				
		Grade 0 - n(%)	67 (85.9)	37 (88.1)	36 (90.0)	140 (87.5)
		Grade 1 - n(%)	11 (14.1)	4 (9.5)	4 (10.0)	19 (11.9)
		Grade 2 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hemoglobin (g/dL) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	14.66 (1.498)	14.36 (1.489)	13.89 (1.301)	14.39 (1.474)
		Median	14.70	14.65	13.85	14.45
		Min, Max	11.5, 17.3	10.2, 16.8	11.5, 16.2	10.2, 17.3
		Low value – n (%)	2 (2.6)	2 (4.8)	1 (2.5)	5 (3.1)
		Normal value – n (%)	76 (97.4)	40 (95.2)	39 (97.5)	155 (96.9)
		Abnormal NCS – n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		Abnormal CS – n (%)	0	1 (2.4)	0	1 (0.6)
		Hemoglobin increase				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Hemoglobin decreased				
		Grade 0 - n(%)	49 (62.8)	28 (66.7)	11 (27.5)	88 (55.0)
		Grade 1 - n(%)	29 (37.2)	12 (28.6)	29 (72.5)	70 (43.8)
		Grade 2 - n(%)	0	2 (4.8)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hemoglobin (g/dL) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.27 (0.628)	0.19 (0.607)	-0.31 (0.651)	0.10 (0.670)
		Median	0.20	0.20	-0.40	0.15
		Min, Max	-1.4, 2.0	-1.6, 1.3	-1.5, 1.2	-1.6, 2.0
	Shift in Normality	Normal to Low, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
		Low, NCS to Normal - n(%)	2 (2.6)	0	0	2 (1.3)
	Shift in Toxicity	Hemoglobin decreased				
		0 to 1 - n(%)	24 (30.8)	10 (23.8)	26 (65.0)	60 (37.5)
		0 to 2 - n(%)	0	1 (2.4)	0	1 (0.6)
		1 to 0 - n(%)	6 (7.7)	2 (4.8)	1 (2.5)	9 (5.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hemoglobin (g/dL) [¹]	Day 30	n	77	41	38	156
		Mean (SD)	13.81 (1.397)	13.69 (1.401)	13.56 (1.285)	13.71 (1.367)
		Median	14.10	13.90	13.75	13.90
		Min, Max	10.2, 16.5	9.6, 15.6	11.3, 16.3	9.6, 16.5
		Low value – n (%)	6 (7.7)	3 (7.1)	4 (10.0)	13 (8.1)
		Normal value – n (%)	71 (91.0)	38 (90.5)	34 (85.0)	143 (89.4)
		Abnormal NCS – n (%)	5 (6.4)	1 (2.4)	4 (10.0)	10 (6.3)
		Abnormal CS – n (%)	1 (1.3)	2 (4.8)	0	3 (1.9)
		Hemoglobin increase				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hemoglobin decreased				
		Grade 0 - n(%)	17 (21.8)	9 (21.4)	8 (20.0)	34 (21.3)
		Grade 1 - n(%)	55 (70.5)	29 (69.0)	29 (72.5)	113 (70.6)
		Grade 2 - n(%)	3 (3.8)	2 (4.8)	1 (2.5)	6 (3.8)
		Grade 3 - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hemoglobin (g/dL) [¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.57 (0.610)	-0.44 (0.618)	-0.56 (0.518)	-0.53 (0.590)
		Median	-0.50	-0.30	-0.65	-0.50
		Min, Max	-2.5, 0.9	-2.4, 0.8	-1.6, 0.6	-2.5, 0.9
	Shift in Normality	Normal to Low, NCS - n(%)	2 (2.6)	1 (2.4)	4 (10.0)	7 (4.4)
		Normal to Low, CS - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Low, CS - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Hemoglobin decreased				
		0 to 1 - n(%)	48 (61.5)	26 (61.9)	25 (62.5)	99 (61.9)
		0 to 2 - n(%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		0 to 3 - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		1 to 0 - n(%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		1 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hemoglobin (g/dL) [¹]	Day 60	n	77	41	39	157
		Mean (SD)	13.99 (1.557)	13.90 (1.619)	13.81 (1.343)	13.92 (1.516)
		Median	14.20	14.40	14.00	14.20
		Min, Max	10.8, 17.1	9.4, 16.2	11.0, 16.3	9.4, 17.1
		Low value – n (%)	8 (10.3)	5 (11.9)	1 (2.5)	14 (8.8)
		Normal value – n (%)	69 (88.5)	36 (85.7)	38 (95.0)	143 (89.4)
		Abnormal NCS – n (%)	4 (5.1)	2 (4.8)	1 (2.5)	7 (4.4)
		Abnormal CS – n (%)	4 (5.1)	3 (7.1)	0	7 (4.4)
		Hemoglobin increase				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Hemoglobin decreased				
		Grade 0 - n(%)	22 (28.2)	17 (40.5)	10 (25.0)	49 (30.6)
		Grade 1 - n(%)	50 (64.1)	21 (50.0)	28 (70.0)	99 (61.9)
		Grade 2 - n(%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		Grade 3 - n(%)	3 (3.8)	2 (4.8)	0	5 (3.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hemoglobin (g/dL) [¹]	Change from Baseline	n	77	41	39	157
		Mean (SD)	-0.39 (0.671)	-0.22 (0.796)	-0.39 (0.645)	-0.34 (0.699)
		Median	-0.30	-0.10	-0.40	-0.30
		Min, Max	-2.4, 1.1	-2.6, 1.2	-1.8, 1.0	-2.6, 1.2
	Shift in Normality	Normal to Low, NCS - n(%)	3 (3.8)	2 (4.8)	1 (2.5)	6 (3.8)
		Normal to Low, CS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Low, NCS to Low, CS - n(%)	3 (3.8)	1 (2.4)	0	4 (2.5)
	Shift in Toxicity	Hemoglobin decreased				
		0 to 1 - n(%)	46 (59.0)	19 (45.2)	24 (60.0)	89 (55.6)
		0 to 2 - n(%)	0	0	1 (2.5)	1 (0.6)
		0 to 3 - n(%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		1 to 0 - n(%)	5 (6.4)	1 (2.4)	0	6 (3.8)
		1 to 2 - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		2 to 3 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hemoglobin (g/dL) [¹]	Day 91	n	77	41	38	156
		Mean (SD)	13.91 (1.524)	13.95 (1.461)	13.83 (1.385)	13.90 (1.466)
		Median	14.10	14.30	13.55	14.05
		Min, Max	10.7, 17.0	8.7, 16.4	11.2, 17.3	8.7, 17.3
		Low value – n (%)	5 (6.4)	1 (2.4)	1 (2.5)	7 (4.4)
		Normal value – n (%)	72 (92.3)	40 (95.2)	37 (92.5)	149 (93.1)
		Abnormal NCS – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal CS – n (%)	5 (6.4)	1 (2.4)	0	6 (3.8)
		Hemoglobin increase				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Hemoglobin decreased				
		Grade 0 - n(%)	21 (26.9)	19 (45.2)	13 (32.5)	53 (33.1)
		Grade 1 - n(%)	46 (59.0)	20 (47.6)	23 (57.5)	89 (55.6)
		Grade 2 - n(%)	7 (9.0)	1 (2.4)	1 (2.5)	9 (5.6)
		Grade 3 - n(%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hemoglobin (g/dL) [¹]	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.47 (0.723)	-0.17 (0.708)	-0.29 (0.719)	-0.35 (0.724)
		Median	-0.40	-0.10	-0.20	-0.30
		Min, Max	-2.6, 0.8	-2.1, 1.6	-2.4, 0.8	-2.6, 1.6
	Shift in Normality	Normal to Low, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
		Normal to Low, CS - n(%)	2 (2.6)	0	0	2 (1.3)
		Low, NCS to Normal - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Low, NCS to Low, CS - n(%)	3 (3.8)	0	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hemoglobin (g/dL) [¹]	Shift in Toxicity	Hemoglobin decreased				
		0 to 1 - n(%)	43 (55.1)	18 (42.9)	21 (52.5)	82 (51.3)
		0 to 2 - n(%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)
		0 to 3 - n(%)	3 (3.8)	0	1 (2.5)	4 (2.5)
		1 to 0 - n(%)	4 (5.1)	2 (4.8)	2 (5.0)	8 (5.0)
		1 to 2 - n(%)	4 (5.1)	0	0	4 (2.5)
		2 to 3 - n(%)	0	1 (2.4)	0	1 (0.6)
Hematocrit (%) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	44.01 (4.637)	43.45 (4.244)	43.38 (4.259)	43.71 (4.427)
		Median	44.00	43.50	43.00	44.00
		Min, Max	34.0, 53.0	34.0, 53.0	36.0, 54.0	34.0, 54.0
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hematocrit (%) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	44.54 (3.796)	43.69 (4.003)	42.08 (3.612)	43.70 (3.914)
		Median	44.00	44.00	42.00	44.00
		Min, Max	37.0, 52.0	35.0, 53.0	36.0, 50.0	35.0, 53.0
		Low value – n (%)	0	0	1 (2.5)	1 (0.6)
		Normal value – n (%)	78 (100)	42 (100)	39 (97.5)	159 (99.4)
		Abnormal NCS – n (%)	0	0	1 (2.5)	1 (0.6)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.53 (2.278)	0.24 (2.207)	-1.30 (1.951)	-0.01 (2.298)
		Median	0.00	0.00	-1.00	0.00
		Min, Max	-5.0, 5.0	-6.0, 4.0	-5.0, 4.0	-6.0, 5.0
	Shift in Normality	Normal to Low, NCS - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hematocrit (%) [¹]	Day 30	n	77	41	38	156
		Mean (SD)	42.38 (3.826)	42.22 (3.844)	41.55 (3.501)	42.13 (3.746)
		Median	42.00	43.00	42.00	42.00
		Min, Max	33.0, 50.0	33.0, 48.0	35.0, 49.0	33.0, 50.0
		Low value – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Normal value – n (%)	76 (97.4)	40 (95.2)	38 (95.0)	154 (96.3)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-1.62 (2.116)	-1.12 (2.472)	-1.61 (1.499)	-1.49 (2.087)
		Median	-1.00	-1.00	-2.00	-1.00
		Min, Max	-7.0, 4.0	-9.0, 5.0	-5.0, 1.0	-9.0, 5.0
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hematocrit (%) [¹]	Day 60	n	77	41	39	157
		Mean (SD)	42.58 (3.761)	42.34 (4.121)	42.41 (3.386)	42.48 (3.748)
		Median	43.00	43.00	42.00	43.00
		Min, Max	34.0, 51.0	32.0, 49.0	36.0, 51.0	32.0, 51.0
		Low value – n (%)	0	1 (2.4)	0	1 (0.6)
		Normal value – n (%)	77 (98.7)	40 (95.2)	39 (97.5)	156 (97.5)
		Abnormal NCS – n (%)	0	1 (2.4)	0	1 (0.6)
	Change from Baseline	n	77	41	39	157
		Mean (SD)	-1.42 (2.370)	-1.00 (2.627)	-1.03 (2.390)	-1.21 (2.437)
		Median	-1.00	0.00	-1.00	-1.00
		Min, Max	-7.0, 3.0	-8.0, 4.0	-7.0, 5.0	-8.0, 5.0
	Shift in Normality	Normal to Low, NCS - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Hematocrit (%) [¹]	Day 91	n	77	41	38	156
		Mean (SD)	41.99 (3.999)	42.32 (3.725)	42.08 (4.083)	42.10 (3.927)
		Median	42.00	43.00	41.50	42.00
		Min, Max	33.0, 49.0	31.0, 49.0	35.0, 53.0	31.0, 53.0
		Low value – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Normal value – n (%)	76 (97.4)	40 (95.2)	38 (95.0)	154 (96.3)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-2.01 (2.309)	-1.02 (2.495)	-1.08 (2.174)	-1.53 (2.363)
		Median	-2.00	-1.00	-1.00	-1.00
		Min, Max	-9.0, 3.0	-7.0, 5.0	-7.0, 2.0	-9.0, 5.0
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Leukocytes (GI/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	5.918 (1.1804)	5.763 (1.3366)	6.501 (1.9268)	6.023 (1.4584)
		Median	5.950	5.660	6.360	5.905
		Min, Max	3.10, 8.68	2.99, 9.52	3.34, 12.40	2.99, 12.40
		Low value – n (%)	5 (6.4)	2 (4.8)	1 (2.5)	8 (5.0)
		Normal value – n (%)	73 (93.6)	40 (95.2)	38 (95.0)	151 (94.4)
		High value – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal NCS – n (%)	5 (6.4)	1 (2.4)	1 (2.5)	7 (4.4)
		Abnormal CS – n (%)	0	1 (2.4)	1 (2.5)	2 (1.3)
		WBC Increase				
		Grade 0 - n(%)	78 (100)	42 (100)	39 (97.5)	159 (99.4)
		Grade 1 - n(%)	0	0	1 (2.5)	1 (0.6)
		WBC Decrease				
		Grade 0 - n(%)	73 (93.6)	40 (95.2)	39 (97.5)	152 (95.0)
		Grade 1 - n(%)	5 (6.4)	1 (2.4)	1 (2.5)	7 (4.4)
		Grade 2 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Leukocytes (GI/L) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	6.191 (1.2212)	6.101 (1.3616)	6.006 (1.6369)	6.122 (1.3650)
		Median	6.170	6.215	5.805	6.070
		Min, Max	2.96, 9.04	3.47, 9.92	2.50, 10.30	2.50, 10.30
		Low value – n (%)	1 (1.3)	3 (7.1)	1 (2.5)	5 (3.1)
		Normal value – n (%)	77 (98.7)	39 (92.9)	39 (97.5)	155 (96.9)
		Abnormal NCS – n (%)	0	2 (4.8)	0	2 (1.3)
		Abnormal CS – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		WBC Increase				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		WBC Decrease				
		Grade 0 - n(%)	77 (98.7)	39 (92.9)	39 (97.5)	155 (96.9)
		Grade 1 - n(%)	0	3 (7.1)	0	3 (1.9)
		Grade 2 - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Leukocytes (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.273 (0.9786)	0.339 (0.7330)	-0.495 (1.4777)	0.098 (1.1210)
		Median	0.385	0.410	-0.470	0.305
		Min, Max	-3.18, 2.55	-1.14, 1.77	-3.32, 4.28	-3.32, 4.28
	Shift in Normality	Normal to Low, NCS - n(%)	0	2 (4.8)	0	2 (1.3)
		High, CS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
		Low, NCS to Normal - n(%)	4 (5.1)	1 (2.4)	0	5 (3.1)
		Low, NCS to Low, CS - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
[Reference range]	Study Day	Statistic				
Leukocytes (GI/L) [¹]	Shift in Toxicity	WBC Increase				
		1 to 0 - n(%)	0	0	1 (2.5)	1 (0.6)
		WBC Decrease				
		0 to 1 - n(%)	0	2 (4.8)	0	2 (1.3)
		1 to 0 - n(%)	4 (5.1)	1 (2.4)	0	5 (3.1)
		1 to 2 - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)
		2 to 1 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Leukocytes (GI/L) [¹]	Day 30	n	78	42	40	160
		Mean (SD)	5.641 (1.1427)	5.788 (1.3653)	6.059 (1.5452)	5.784 (1.3144)
		Median	5.565	5.810	5.745	5.700
		Min, Max	3.07, 8.00	2.85, 9.88	3.90, 10.04	2.85, 10.04
		Low value – n (%)	4 (5.1)	3 (7.1)	0	7 (4.4)
		Normal value – n (%)	74 (94.9)	39 (92.9)	40 (100)	153 (95.6)
		Abnormal NCS – n (%)	3 (3.8)	2 (4.8)	0	5 (3.1)
		Abnormal CS – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		WBC Increase				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		WBC Decrease				
		Grade 0 - n(%)	73 (93.6)	38 (90.5)	38 (95.0)	149 (93.1)
		Grade 1 - n(%)	4 (5.1)	2 (4.8)	0	6 (3.8)
		Grade 2 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Leukocytes (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.278 (0.9520)	0.025 (0.7563)	-0.442 (1.8534)	-0.239 (1.2077)
		Median	-0.150	-0.015	-0.095	-0.090
		Min, Max	-3.19, 1.34	-1.63, 2.02	-7.58, 2.79	-7.58, 2.79
	Shift in Normality	Normal to Low, NCS - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		High, CS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
		Low, NCS to Normal - n(%)	3 (3.8)	0	1 (2.5)	4 (2.5)
		Low, NCS to Low, CS - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	WBC Increase 1 to 0 - n(%)	0	0	1 (2.5)	1 (0.6)
		WBC Decrease 0 to 1 - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		1 to 0 - n(%)	3 (3.8)	0	1 (2.5)	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Leukocytes (GI/L) [¹]	Day 60	n	78	42	40	160
		Mean (SD)	5.654 (1.3344)	5.828 (1.5777)	6.076 (1.6210)	5.805 (1.4760)
		Median	5.695	5.615	6.105	5.695
		Min, Max	2.88, 11.78	2.75, 10.84	3.16, 11.05	2.75, 11.78
		Low value – n (%)	5 (6.4)	4 (9.5)	1 (2.5)	10 (6.3)
		Normal value – n (%)	72 (92.3)	37 (88.1)	38 (95.0)	147 (91.9)
		High value – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Abnormal NCS – n (%)	3 (3.8)	3 (7.1)	2 (5.0)	8 (5.0)
		Abnormal CS – n (%)	3 (3.8)	2 (4.8)	0	5 (3.1)
		WBC Increase				
		Grade 0 - n(%)	76 (97.4)	40 (95.2)	38 (95.0)	154 (96.3)
		Grade 1 - n(%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		WBC Decrease				
		Grade 0 - n(%)	72 (92.3)	37 (88.1)	38 (95.0)	147 (91.9)
		Grade 1 - n(%)	4 (5.1)	3 (7.1)	1 (2.5)	8 (5.0)
		Grade 2 - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Leukocytes (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.265 (1.2558)	0.065 (1.2607)	-0.425 (1.8151)	-0.218 (1.4194)
		Median	-0.180	-0.125	-0.045	-0.130
		Min, Max	-4.73, 3.86	-1.94, 5.29	-6.71, 2.28	-6.71, 5.29
	Shift in Normality	Normal to High, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
		Normal to High, CS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Normal to Low, NCS - n(%)	1 (1.3)	2 (4.8)	0	3 (1.9)
		Normal to Low, CS - n(%)	1 (1.3)	0	0	1 (0.6)
		High, CS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
		Low, NCS to Normal - n(%)	2 (2.6)	0	0	2 (1.3)
		Low, NCS to Low, CS - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Leukocytes (GI/L) [¹]	Shift in Toxicity	WBC Increase				
		0 to 1 - n(%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		1 to 0 - n(%)	0	0	1 (2.5)	1 (0.6)
		WBC Decrease				
		0 to 1 - n(%)	1 (1.3)	2 (4.8)	0	3 (1.9)
		0 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n(%)	2 (2.6)	0	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Leukocytes (GI/L) [¹]	Day 91	n	78	42	40	160
		Mean (SD)	5.650 (1.3157)	6.030 (1.5507)	6.050 (1.5159)	5.850 (1.4354)
		Median	5.625	5.675	6.045	5.705
		Min, Max	2.75, 9.38	2.83, 10.23	3.01, 10.11	2.75, 10.23
		Low value – n (%)	4 (5.1)	4 (9.5)	3 (7.5)	11 (6.9)
		Normal value – n (%)	74 (94.9)	38 (90.5)	37 (92.5)	149 (93.1)
		Abnormal NCS – n (%)	2 (2.6)	3 (7.1)	2 (5.0)	7 (4.4)
		Abnormal CS – n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		WBC Increase				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		WBC Decrease				
		Grade 0 - n(%)	73 (93.6)	37 (88.1)	35 (87.5)	145 (90.6)
		Grade 1 - n(%)	2 (2.6)	3 (7.1)	3 (7.5)	8 (5.0)
		Grade 2 - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Leukocytes (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.269 (1.2273)	0.268 (1.1399)	-0.451 (1.9524)	-0.173 (1.4404)
		Median	-0.355	0.080	-0.330	-0.210
		Min, Max	-4.69, 4.16	-1.34, 3.37	-7.73, 3.86	-7.73, 4.16
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	2 (4.8)	2 (5.0)	5 (3.1)
		Normal to Low, CS - n(%)	1 (1.3)	0	0	1 (0.6)
		High, CS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
		Low, NCS to Normal - n(%)	3 (3.8)	0	0	3 (1.9)
		Low, NCS to Low, CS - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
[Reference range]	Study Day	Statistic				
Leukocytes (GI/L) [¹]	Shift in Toxicity	WBC Increase				
		1 to 0 - n(%)	0	0	1 (2.5)	1 (0.6)
		WBC Decrease				
		0 to 1 - n(%)	1 (1.3)	2 (4.8)	2 (5.0)	5 (3.1)
		0 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n(%)	3 (3.8)	0	0	3 (1.9)
		1 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neutrophils (GI/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	3.391 (1.0306)	3.226 (0.9336)	3.846 (1.7008)	3.461 (1.2260)
		Median	3.360	3.035	3.640	3.270
		Min, Max	1.17, 6.20	1.47, 5.63	1.37, 9.73	1.17, 9.73
		Low value – n (%)	6 (7.7)	2 (4.8)	3 (7.5)	11 (6.9)
		Normal value – n (%)	72 (92.3)	40 (95.2)	36 (90.0)	148 (92.5)
		High value – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal NCS – n (%)	3 (3.8)	1 (2.4)	2 (5.0)	6 (3.8)
		Abnormal CS – n (%)	3 (3.8)	1 (2.4)	2 (5.0)	6 (3.8)
		Neutrophils Decrease				
		Grade 0 - n(%)	72 (92.3)	40 (95.2)	37 (92.5)	149 (93.1)
		Grade 1 - n(%)	3 (3.8)	1 (2.4)	2 (5.0)	6 (3.8)
		Grade 2 - n(%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neutrophils (GI/L) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	3.388 (0.9399)	3.531 (1.0350)	3.613 (1.5107)	3.482 (1.1283)
		Median	3.420	3.545	3.330	3.415
		Min, Max	1.47, 5.74	1.64, 6.09	1.05, 7.98	1.05, 7.98
		Low value – n (%)	4 (5.1)	2 (4.8)	2 (5.0)	8 (5.0)
		Normal value – n (%)	74 (94.9)	40 (95.2)	36 (90.0)	150 (93.8)
		High value – n (%)	0	0	2 (5.0)	2 (1.3)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	3 (7.5)	5 (3.1)
		Abnormal CS – n (%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)
		Neutrophils Decrease				
		Grade 0 - n(%)	74 (94.9)	40 (95.2)	38 (95.0)	152 (95.0)
		Grade 1 - n(%)	3 (3.8)	2 (4.8)	1 (2.5)	6 (3.8)
		Grade 2 - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neutrophils (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.002 (0.8238)	0.304 (0.6386)	-0.234 (1.3039)	0.020 (0.9426)
		Median	0.085	0.345	-0.165	0.115
		Min, Max	-3.46, 1.97	-1.01, 1.70	-2.82, 3.94	-3.46, 3.94
	Shift in Normality	Normal to High, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
		Normal to Low, NCS - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)
		Normal to Low, CS - n(%)	1 (1.3)	0	0	1 (0.6)
		High, CS to High, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
		Low, NCS to Normal - n(%)	3 (3.8)	0	2 (5.0)	5 (3.1)
		Low, CS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
[Reference range]	Study Day	Statistic				
Neutrophils (GI/L) [¹]	Shift in Toxicity	Neutrophils Decrease				
		0 to 1 - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)
		0 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n(%)	3 (3.8)	0	2 (5.0)	5 (3.1)
		2 to 0 - n(%)	1 (1.3)	0	0	1 (0.6)
		2 to 1 - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neutrophils (GI/L) [¹]	Day 30	n	78	42	40	160
		Mean (SD)	3.042 (0.9609)	3.146 (0.9746)	3.417 (1.3811)	3.163 (1.0879)
		Median	3.000	3.005	3.010	3.005
		Min, Max	1.19, 5.51	1.21, 5.20	1.94, 7.79	1.19, 7.79
		Low value – n (%)	11 (14.1)	3 (7.1)	2 (5.0)	16 (10.0)
		Normal value – n (%)	67 (85.9)	39 (92.9)	37 (92.5)	143 (89.4)
		High value – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal NCS – n (%)	7 (9.0)	1 (2.4)	3 (7.5)	11 (6.9)
		Abnormal CS – n (%)	4 (5.1)	2 (4.8)	0	6 (3.8)
		Neutrophils Decrease				
		Grade 0 - n(%)	66 (84.6)	38 (90.5)	36 (90.0)	140 (87.5)
		Grade 1 - n(%)	7 (9.0)	1 (2.4)	2 (5.0)	10 (6.3)
		Grade 2 - n(%)	4 (5.1)	2 (4.8)	0	6 (3.8)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neutrophils (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.349 (0.8791)	-0.080 (0.6900)	-0.429 (1.7644)	-0.298 (1.1309)
		Median	-0.190	-0.065	-0.215	-0.180
		Min, Max	-4.37, 1.75	-1.08, 1.88	-7.31, 4.23	-7.31, 4.23
	Shift in Normality	Normal to High, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
		Normal to Low, NCS - n(%)	5 (6.4)	1 (2.4)	1 (2.5)	7 (4.4)
		Normal to Low, CS - n(%)	2 (2.6)	0	0	2 (1.3)
		High, CS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
		Low, NCS to Normal - n(%)	1 (1.3)	0	2 (5.0)	3 (1.9)
		Low, NCS to Low, CS - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, CS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
		Low, CS to Low, NCS - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
[Reference range]	Study Day	Statistic				
Neutrophils (GI/L) [¹]	Shift in Toxicity	Neutrophils Decrease				
		0 to 1 - n(%)	5 (6.4)	1 (2.4)	1 (2.5)	7 (4.4)
		0 to 2 - n(%)	2 (2.6)	0	0	2 (1.3)
		1 to 0 - n(%)	1 (1.3)	0	2 (5.0)	3 (1.9)
		1 to 2 - n(%)	0	1 (2.4)	0	1 (0.6)
		2 to 0 - n(%)	1 (1.3)	0	0	1 (0.6)
		2 to 1 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neutrophils (GI/L) [¹]	Day 60	n	78	42	40	160
		Mean (SD)	3.090 (1.1944)	3.270 (1.2365)	3.369 (1.3274)	3.207 (1.2376)
		Median	3.025	3.085	3.085	3.040
		Min, Max	1.01, 9.46	1.10, 8.07	1.40, 7.63	1.01, 9.46
		Low value – n (%)	9 (11.5)	3 (7.1)	2 (5.0)	14 (8.8)
		Normal value – n (%)	67 (85.9)	38 (90.5)	37 (92.5)	142 (88.8)
		High value – n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		Abnormal NCS – n (%)	7 (9.0)	1 (2.4)	2 (5.0)	10 (6.3)
		Abnormal CS – n (%)	4 (5.1)	3 (7.1)	1 (2.5)	8 (5.0)
		Neutrophils Decrease				
		Grade 0 - n(%)	68 (87.2)	38 (90.5)	37 (92.5)	143 (89.4)
		Grade 1 - n(%)	6 (7.7)	1 (2.4)	1 (2.5)	8 (5.0)
		Grade 2 - n(%)	3 (3.8)	2 (4.8)	1 (2.5)	6 (3.8)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neutrophils (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.300 (1.1882)	0.044 (1.0507)	-0.477 (1.6481)	-0.254 (1.2929)
		Median	-0.160	-0.185	-0.305	-0.185
		Min, Max	-4.55, 5.16	-1.40, 4.70	-6.92, 2.28	-6.92, 5.16
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	1 (2.5)	2 (1.3)
		Normal to High, CS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Normal to Low, NCS - n(%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
		Normal to Low, CS - n(%)	2 (2.6)	0	0	2 (1.3)
		High, CS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
		Low, NCS to Normal - n(%)	2 (2.6)	0	2 (5.0)	4 (2.5)
		Low, NCS to Low, CS - n(%)	0	1 (2.4)	0	1 (0.6)
		Low, CS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
		Low, CS to Low, NCS - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
[Reference range]	Study Day	Statistic				
Neutrophils (GI/L) [¹]	Shift in Toxicity	Neutrophils Decrease				
		0 to 1 - n(%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
		0 to 2 - n(%)	2 (2.6)	0	0	2 (1.3)
		1 to 0 - n(%)	2 (2.6)	0	2 (5.0)	4 (2.5)
		1 to 2 - n(%)	0	1 (2.4)	0	1 (0.6)
		2 to 0 - n(%)	1 (1.3)	0	0	1 (0.6)
		2 to 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neutrophils (GI/L) [¹]	Day 91	n	78	42	40	160
		Mean (SD)	3.064 (1.1445)	3.360 (1.2497)	3.288 (1.2633)	3.198 (1.2027)
		Median	2.975	2.985	3.220	3.030
		Min, Max	1.32, 7.42	1.17, 6.72	1.17, 6.84	1.17, 7.42
		Low value – n (%)	10 (12.8)	3 (7.1)	4 (10.0)	17 (10.6)
		Normal value – n (%)	67 (85.9)	39 (92.9)	36 (90.0)	142 (88.8)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	8 (10.3)	2 (4.8)	1 (2.5)	11 (6.9)
		Abnormal CS – n (%)	3 (3.8)	1 (2.4)	3 (7.5)	7 (4.4)
		Neutrophils Decrease				
		Grade 0 - n(%)	67 (85.9)	38 (90.5)	34 (85.0)	139 (86.9)
		Grade 1 - n(%)	7 (9.0)	2 (4.8)	1 (2.5)	10 (6.3)
		Grade 2 - n(%)	3 (3.8)	1 (2.4)	3 (7.5)	7 (4.4)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neutrophils (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.326 (1.1220)	0.134 (1.0499)	-0.559 (1.7917)	-0.264 (1.3217)
		Median	-0.405	0.050	-0.380	-0.265
		Min, Max	-4.17, 4.39	-1.45, 3.67	-7.43, 3.58	-7.43, 4.39
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
		Normal to Low, CS - n(%)	2 (2.6)	0	1 (2.5)	3 (1.9)
		High, CS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)
		Low, NCS to Normal - n(%)	2 (2.6)	0	1 (2.5)	3 (1.9)
		Low, NCS to Low, CS - n(%)	0	0	1 (2.5)	1 (0.6)
		Low, CS to Low, NCS - n(%)	2 (2.6)	0	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
[Reference range]	Study Day	Statistic				
Neutrophils (GI/L) [¹]	Shift in Toxicity	Neutrophils Decrease				
		0 to 1 - n(%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
		0 to 2 - n(%)	2 (2.6)	0	1 (2.5)	3 (1.9)
		1 to 0 - n(%)	2 (2.6)	0	1 (2.5)	3 (1.9)
		1 to 2 - n(%)	0	0	1 (2.5)	1 (0.6)
		2 to 1 - n(%)	2 (2.6)	0	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neutrophils/Leukocytes (%)						
[40-75]	Baseline	n	78	42	40	160
		Mean (SD)	59.10 (8.652)	60.00 (7.651)	58.80 (7.824)	59.26 (8.159)
		Median	58.70	60.80	59.70	59.15
		Min, Max	34.7, 79.9	44.6, 73.6	45.4, 74.5	34.7, 79.9
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	75 (96.2)	42 (100)	40 (100)	157 (98.1)
		High value – n (%)	2 (2.6)	0	0	2 (1.3)
		Abnormal NCS – n (%)	3 (3.8)	0	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lymphocytes (GI/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	2.069 (0.5019)	2.026 (0.5560)	2.148 (0.4866)	2.078 (0.5116)
		Median	2.040	1.895	2.090	2.030
		Min, Max	1.01, 3.39	1.24, 3.40	1.36, 3.14	1.01, 3.40
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Lymphocytes Increase Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Lymphocytes Decrease Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lymphocytes (GI/L) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	2.323 (0.5398)	2.042 (0.4925)	1.949 (0.4029)	2.156 (0.5208)
		Median	2.260	1.945	1.885	2.100
		Min, Max	1.24, 3.94	1.28, 3.21	1.09, 2.76	1.09, 3.94
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Lymphocytes Increase Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Lymphocytes Decrease Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.254 (0.4263)	0.016 (0.2489)	-0.199 (0.5792)	0.078 (0.4709)
		Median	0.240	0.010	-0.145	0.095
		Min, Max	-1.20, 1.23	-0.57, 0.49	-1.27, 0.90	-1.27, 1.23

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lymphocytes (GI/L) [¹]	Day 30	n	78	42	40	160
		Mean (SD)	2.132 (0.4970)	2.094 (0.6780)	2.138 (0.3965)	2.124 (0.5264)
		Median	2.080	1.980	2.130	2.060
		Min, Max	0.70, 3.38	1.09, 4.38	1.32, 3.05	0.70, 4.38
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	77 (98.7)	41 (97.6)	40 (100)	158 (98.8)
		High value – n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Lymphocytes Increase				
		Grade 0 - n(%)	77 (98.7)	40 (95.2)	38 (95.0)	155 (96.9)
		Grade 2 - n(%)	0	1 (2.4)	0	1 (0.6)
		Lymphocytes Decrease				
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		Grade 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lymphocytes (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.063 (0.3927)	0.068 (0.4303)	-0.011 (0.5398)	0.046 (0.4416)
		Median	0.040	0.010	0.090	0.040
		Min, Max	-1.14, 0.94	-0.60, 1.31	-1.42, 1.20	-1.42, 1.31
	Shift in Normality	Normal to High, CS - n(%)	0	1 (2.4)	0	1 (0.6)
		Normal to Low, CS - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Lymphocytes Increase 0 to 2 - n(%)	0	1 (2.4)	0	1 (0.6)
		Lymphocytes Decrease 0 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lymphocytes (GI/L) [¹]	Day 60	n	78	42	40	160
		Mean (SD)	2.104 (0.5300)	2.005 (0.5177)	2.185 (0.4788)	2.098 (0.5153)
		Median	2.035	1.910	2.205	2.055
		Min, Max	0.83, 3.46	1.08, 3.43	1.49, 3.18	0.83, 3.46
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		Abnormal CS – n (%)	1 (1.3)	0	0	1 (0.6)
		Lymphocytes Increase				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Lymphocytes Decrease				
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	39 (97.5)	156 (97.5)
		Grade 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lymphocytes (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.036 (0.4508)	-0.022 (0.4722)	0.036 (0.5400)	0.021 (0.4776)
		Median	0.065	0.005	0.020	0.045
		Min, Max	-1.55, 0.95	-1.70, 1.13	-1.13, 1.13	-1.70, 1.13
	Shift in Normality	Normal to Low, CS - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Lymphocytes Decrease 0 to 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lymphocytes (GI/L) [¹]	Day 91	n	78	42	40	160
		Mean (SD)	2.117 (0.5244)	2.076 (0.5671)	2.252 (0.4689)	2.140 (0.5240)
		Median	2.065	2.010	2.165	2.060
		Min, Max	0.91, 3.32	1.09, 3.44	1.49, 3.42	0.91, 3.44
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Lymphocytes Increase Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Lymphocytes Decrease Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.048 (0.4671)	0.050 (0.3874)	0.104 (0.4886)	0.062 (0.4511)
		Median	0.055	0.055	0.055	0.055
		Min, Max	-1.01, 1.34	-0.64, 1.18	-0.78, 1.51	-1.01, 1.51

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lymphocytes/Leukocytes (%)						
[18-49]	Baseline	n	78	42	40	160
		Mean (SD)	31.47 (7.658)	29.96 (7.350)	31.90 (7.449)	31.18 (7.517)
		Median	31.50	29.40	31.85	31.40
		Min, Max	14.4, 50.4	13.2, 44.9	17.0, 44.9	13.2, 50.4
		Low value – n (%)	3 (3.8)	1 (2.4)	2 (5.0)	6 (3.8)
		Normal value – n (%)	74 (94.9)	41 (97.6)	38 (95.0)	153 (95.6)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	4 (5.1)	1 (2.4)	2 (5.0)	7 (4.4)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Monocytes (GI/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	0.286 (0.0802)	0.289 (0.0879)	0.324 (0.1187)	0.296 (0.0939)
		Median	0.290	0.275	0.300	0.290
		Min, Max	0.12, 0.51	0.14, 0.55	0.16, 0.68	0.12, 0.68
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Day 6	n	78	42	40	160
		Mean (SD)	0.313 (0.1097)	0.309 (0.0785)	0.274 (0.0777)	0.302 (0.0957)
		Median	0.300	0.300	0.275	0.290
		Min, Max	0.14, 0.67	0.13, 0.57	0.09, 0.45	0.09, 0.67
		Low value – n (%)	0	0	2 (5.0)	2 (1.3)
		Normal value – n (%)	78 (100)	42 (100)	38 (95.0)	158 (98.8)
		Abnormal NCS – n (%)	0	0	2 (5.0)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Monocytes (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.027 (0.1017)	0.021 (0.0856)	-0.050 (0.0855)	0.006 (0.0987)
		Median	0.025	0.030	-0.045	0.010
		Min, Max	-0.20, 0.35	-0.14, 0.29	-0.34, 0.09	-0.34, 0.35
	Shift in Normality	Normal to Low, NCS - n(%)	0	0	2 (5.0)	2 (1.3)
	Day 30	n	78	42	40	160
		Mean (SD)	0.289 (0.0934)	0.309 (0.1108)	0.305 (0.1042)	0.298 (0.1007)
		Median	0.280	0.280	0.290	0.280
		Min, Max	0.10, 0.52	0.10, 0.55	0.13, 0.72	0.10, 0.72
		Low value – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Normal value – n (%)	77 (98.7)	41 (97.6)	40 (100)	158 (98.8)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Monocytes (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.003 (0.0833)	0.021 (0.0718)	-0.019 (0.1077)	0.002 (0.0879)
		Median	0.000	0.015	-0.010	0.000
		Min, Max	-0.17, 0.17	-0.14, 0.26	-0.35, 0.21	-0.35, 0.26
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
	Day 60	n	78	42	40	160
		Mean (SD)	0.280 (0.0903)	0.315 (0.1228)	0.284 (0.0949)	0.290 (0.1013)
		Median	0.270	0.290	0.270	0.280
		Min, Max	0.11, 0.64	0.16, 0.76	0.14, 0.64	0.11, 0.76
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Monocytes (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.006 (0.0805)	0.027 (0.0836)	-0.040 (0.1224)	-0.006 (0.0959)
		Median	-0.035	0.015	-0.025	-0.010
		Min, Max	-0.16, 0.26	-0.15, 0.23	-0.38, 0.39	-0.38, 0.39
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
	Day 91	n	78	42	40	160
		Mean (SD)	0.298 (0.0982)	0.347 (0.1364)	0.301 (0.1074)	0.311 (0.1129)
		Median	0.290	0.320	0.290	0.300
		Min, Max	0.10, 0.63	0.12, 0.77	0.12, 0.64	0.10, 0.77
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Monocytes (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.012 (0.0835)	0.059 (0.0988)	-0.023 (0.1300)	0.015 (0.1045)
		Median	0.010	0.040	-0.015	0.010
		Min, Max	-0.17, 0.31	-0.10, 0.36	-0.42, 0.21	-0.42, 0.36
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
Monocytes/Leukocytes (%) [2-10]	Baseline	n	78	42	40	160
		Mean (SD)	6.03 (1.518)	6.10 (1.738)	5.88 (1.691)	6.01 (1.613)
		Median	5.90	6.50	5.95	6.00
		Min, Max	3.5, 9.9	3.0, 10.2	2.0, 11.8	2.0, 11.8
		Normal value – n (%)	78 (100)	41 (97.6)	39 (97.5)	158 (98.8)
		High value – n (%)	0	1 (2.4)	1 (2.5)	2 (1.3)
		Abnormal NCS – n (%)	0	1 (2.4)	1 (2.5)	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Eosinophils (GI/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	0.125 (0.0698)	0.169 (0.0934)	0.134 (0.0693)	0.139 (0.0783)
		Median	0.100	0.160	0.120	0.115
		Min, Max	0.04, 0.37	0.04, 0.38	0.03, 0.28	0.03, 0.38
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Eosinophils Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Eosinophils (GI/L) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	0.113 (0.0589)	0.163 (0.0776)	0.123 (0.0599)	0.128 (0.0675)
		Median	0.100	0.145	0.115	0.120
		Min, Max	0.04, 0.32	0.05, 0.33	0.03, 0.29	0.03, 0.33
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Eosinophils Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.012 (0.0447)	-0.006 (0.0561)	-0.012 (0.0473)	-0.010 (0.0483)
		Median	-0.010	0.005	-0.010	-0.005
		Min, Max	-0.19, 0.09	-0.19, 0.08	-0.14, 0.09	-0.19, 0.09

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Eosinophils (GI/L) [¹]	Day 30	n	78	42	40	160
		Mean (SD)	0.127 (0.0619)	0.189 (0.0849)	0.154 (0.0948)	0.150 (0.0810)
		Median	0.120	0.185	0.130	0.130
		Min, Max	0.04, 0.33	0.06, 0.36	0.03, 0.53	0.03, 0.53
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		Eosinophils Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.003 (0.0494)	0.020 (0.0463)	0.020 (0.0834)	0.011 (0.0593)
		Median	0.005	0.010	0.010	0.010
		Min, Max	-0.14, 0.13	-0.09, 0.13	-0.18, 0.43	-0.18, 0.43

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Eosinophils (GI/L) [¹]	Day 60	n	78	42	40	160
		Mean (SD)	0.131 (0.0791)	0.188 (0.1040)	0.193 (0.2808)	0.162 (0.1614)
		Median	0.120	0.165	0.130	0.130
		Min, Max	0.03, 0.53	0.05, 0.42	0.03, 1.84	0.03, 1.84
		Normal value – n (%)	78 (100)	42 (100)	39 (97.5)	159 (99.4)
		High value – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal CS – n (%)	0	0	1 (2.5)	1 (0.6)
		Eosinophils				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Grade 2 - n(%)	0	0	1 (2.5)	1 (0.6)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.007 (0.0608)	0.019 (0.0660)	0.059 (0.2790)	0.023 (0.1499)
		Median	0.000	0.020	0.010	0.010
		Min, Max	-0.15, 0.19	-0.17, 0.22	-0.13, 1.74	-0.17, 1.74

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Eosinophils (GI/L) [¹]	Shift in Normality	Normal to High, CS - n(%)	0	0	1 (2.5)	1 (0.6)
	Shift in Toxicity	Eosinophils 0 to 2 - n(%)	0	0	1 (2.5)	1 (0.6)
	Day 91	n	78	42	40	160
		Mean (SD)	0.126 (0.0655)	0.195 (0.1128)	0.158 (0.1409)	0.152 (0.1051)
		Median	0.110	0.170	0.120	0.120
		Min, Max	0.03, 0.36	0.05, 0.52	0.03, 0.90	0.03, 0.90
		Normal value – n (%)	78 (100)	42 (100)	39 (97.5)	159 (99.4)
		High value – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal NCS – n (%)	0	0	1 (2.5)	1 (0.6)
		Eosinophils				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	37 (92.5)	155 (96.9)
		Grade 1 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Eosinophils (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.002 (0.0520)	0.026 (0.0672)	0.024 (0.1421)	0.014 (0.0870)
		Median	0.010	0.020	-0.005	0.010
		Min, Max	-0.13, 0.21	-0.12, 0.23	-0.20, 0.80	-0.20, 0.80
	Shift in Normality	Normal to High, NCS - n(%)	0	0	1 (2.5)	1 (0.6)
	Shift in Toxicity	Eosinophils 0 to 1 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Eosinophils/Leukocytes (%)						
[0-8]	Baseline	n	78	42	40	160
		Mean (SD)	2.85 (2.363)	3.44 (1.753)	2.84 (1.836)	3.00 (2.096)
		Median	2.35	3.60	2.65	2.75
		Min, Max	0.4, 17.8	0.3, 7.8	0.6, 8.0	0.3, 17.8
		Normal value – n (%)	76 (97.4)	42 (100)	40 (100)	158 (98.8)
		High value – n (%)	2 (2.6)	0	0	2 (1.3)
		Abnormal NCS – n (%)	2 (2.6)	0	0	2 (1.3)
Basophils (GI/L)						
[¹]	Baseline	n	78	42	40	160
		Mean (SD)	0.05 (0.018)	0.05 (0.023)	0.05 (0.026)	0.05 (0.022)
		Median	0.05	0.05	0.05	0.05
		Min, Max	0.0, 0.1	0.0, 0.1	0.0, 0.1	0.0, 0.1
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Basophils (GI/L) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	0.05 (0.022)	0.06 (0.022)	0.05 (0.019)	0.05 (0.021)
		Median	0.05	0.05	0.05	0.05
		Min, Max	0.0, 0.1	0.0, 0.1	0.0, 0.1	0.0, 0.1
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.01 (0.017)	0.00 (0.022)	-0.00 (0.017)	0.00 (0.019)
		Median	0.01	0.00	0.00	0.00
		Min, Max	-0.0, 0.1	-0.1, 0.1	-0.0, 0.0	-0.1, 0.1
	Day 30	n	78	42	40	160
		Mean (SD)	0.05 (0.019)	0.05 (0.025)	0.05 (0.019)	0.05 (0.021)
		Median	0.05	0.05	0.05	0.05
		Min, Max	0.0, 0.1	0.0, 0.1	0.0, 0.1	0.0, 0.1
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Basophils (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.00 (0.017)	0.00 (0.029)	-0.00 (0.023)	0.00 (0.022)
		Median	0.00	0.00	-0.01	0.00
		Min, Max	-0.0, 0.1	-0.1, 0.1	-0.0, 0.1	-0.1, 0.1
	Day 60	n	78	42	40	160
		Mean (SD)	0.05 (0.016)	0.05 (0.025)	0.05 (0.026)	0.05 (0.021)
		Median	0.04	0.05	0.04	0.04
		Min, Max	0.0, 0.1	0.0, 0.2	0.0, 0.1	0.0, 0.2
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.00 (0.015)	-0.00 (0.031)	-0.00 (0.026)	-0.00 (0.023)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-0.0, 0.0	-0.1, 0.2	-0.1, 0.1	-0.1, 0.2

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Basophils (GI/L) [¹]	Day 91	n	78	42	40	160
		Mean (SD)	0.04 (0.016)	0.05 (0.038)	0.05 (0.023)	0.05 (0.025)
		Median	0.04	0.05	0.05	0.04
		Min, Max	0.0, 0.1	0.0, 0.3	0.0, 0.1	0.0, 0.3
		Normal value – n (%)	78 (100)	41 (97.6)	40 (100)	159 (99.4)
		High value – n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal NCS – n (%)	0	1 (2.4)	0	1 (0.6)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.00 (0.016)	0.00 (0.047)	0.00 (0.022)	-0.00 (0.029)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-0.0, 0.0	-0.1, 0.3	-0.1, 0.1	-0.1, 0.3
	Shift in Normality	Normal to High, NCS - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Basophils/Leukocytes (%)						
[0-2]	Baseline	n	78	42	40	160
		Mean (SD)	0.55 (0.421)	0.51 (0.388)	0.59 (0.390)	0.55 (0.404)
		Median	0.40	0.40	0.50	0.40
		Min, Max	0.0, 2.2	0.0, 1.8	0.0, 1.9	0.0, 2.2
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Platelets (GI/L) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	225.54 (53.759)	228.05 (50.048)	239.30 (45.052)	229.64 (50.752)
		Median	221.50	220.00	233.00	224.00
		Min, Max	140.0, 448.0	147.0, 363.0	167.0, 335.0	140.0, 448.0
		Normal value – n (%)	76 (97.4)	42 (100)	40 (100)	158 (98.8)
		High value – n (%)	2 (2.6)	0	0	2 (1.3)
		Abnormal NCS – n (%)	2 (2.6)	0	0	2 (1.3)
		Platelets Decrease				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Platelets (GI/L) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	237.74 (53.577)	231.14 (45.981)	235.48 (50.296)	235.44 (50.629)
		Median	231.50	234.50	227.00	232.00
		Min, Max	141.0, 465.0	144.0, 344.0	146.0, 386.0	141.0, 465.0
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)
		Platelets Decrease				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	12.21 (21.338)	3.10 (20.714)	-3.83 (25.393)	5.81 (23.123)
		Median	13.00	6.50	-4.00	7.00
		Min, Max	-60.0, 72.0	-40.0, 44.0	-67.0, 79.0	-67.0, 79.0
	Shift in Normality	High, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Platelets (GI/L) [¹]	Day 30	n	78	42	40	160
		Mean (SD)	235.23 (49.927)	236.93 (51.117)	241.50 (46.044)	237.24 (49.066)
		Median	227.50	230.50	227.50	229.00
		Min, Max	149.0, 402.0	153.0, 335.0	161.0, 365.0	149.0, 402.0
		Normal value – n (%)	77 (98.7)	42 (100)	40 (100)	159 (99.4)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	0	0	1 (0.6)
		Platelets Decrease				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	9.69 (29.157)	8.88 (26.092)	2.20 (20.530)	7.61 (26.468)
		Median	9.00	8.00	2.00	8.00
		Min, Max	-101.0, 96.0	-58.0, 59.0	-61.0, 54.0	-101.0, 96.0
	Shift in Normality	High, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Platelets (GI/L) [¹]	Day 60	n	78	42	40	160
		Mean (SD)	246.91 (58.491)	240.31 (50.943)	250.15 (45.586)	245.99 (53.376)
		Median	234.50	245.00	245.00	239.50
		Min, Max	129.0, 448.0	146.0, 353.0	164.0, 357.0	129.0, 448.0
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	75 (96.2)	42 (100)	40 (100)	157 (98.1)
		High value – n (%)	2 (2.6)	0	0	2 (1.3)
		Abnormal NCS – n (%)	3 (3.8)	0	0	3 (1.9)
		Platelets Decrease				
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	39 (97.5)	156 (97.5)
		Grade 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Platelets (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	21.37 (41.061)	12.26 (39.772)	10.85 (33.493)	16.35 (39.038)
		Median	16.50	6.00	6.50	8.00
		Min, Max	-76.0, 178.0	-55.0, 106.0	-48.0, 117.0	-76.0, 178.0
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Platelets Decrease				
		0 to 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Platelets (GI/L) [¹]	Day 91	n	78	42	40	160
		Mean (SD)	252.27 (56.658)	245.00 (49.272)	246.75 (40.748)	248.98 (50.977)
		Median	238.00	250.50	243.00	243.50
		Min, Max	135.0, 459.0	145.0, 361.0	162.0, 347.0	135.0, 459.0
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	75 (96.2)	42 (100)	40 (100)	157 (98.1)
		High value – n (%)	2 (2.6)	0	0	2 (1.3)
		Abnormal NCS – n (%)	3 (3.8)	0	0	3 (1.9)
		Platelets Decrease				
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		Grade 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Platelets (GI/L) [¹]	Change from Baseline	n	78	42	40	160
		Mean (SD)	26.73 (40.159)	16.95 (40.659)	7.45 (34.224)	19.34 (39.477)
		Median	23.50	16.50	5.00	16.50
		Min, Max	-70.0, 162.0	-66.0, 104.0	-64.0, 87.0	-70.0, 162.0
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	Platelets Decrease				
		0 to 1 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	30.51 (1.666)	30.07 (1.773)	30.83 (1.518)	30.48 (1.671)
		Median	31.00	30.00	31.00	31.00
		Min, Max	24.0, 34.0	25.0, 34.0	25.0, 34.0	24.0, 34.0
		Low value – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [1]						
	Day 6	n	78	42	40	160
		Mean (SD)	30.73 (1.857)	30.45 (2.039)	30.90 (1.646)	30.70 (1.853)
		Median	31.00	30.00	31.00	31.00
		Min, Max	23.0, 34.0	24.0, 35.0	25.0, 34.0	23.0, 35.0
		Low value – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Normal value – n (%)	77 (98.7)	40 (95.2)	39 (97.5)	156 (97.5)
		High value – n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.22 (0.907)	0.38 (0.825)	0.08 (0.859)	0.23 (0.876)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-2.0, 2.0	-1.0, 2.0	-2.0, 1.0	-2.0, 2.0
	Shift in Normality	Normal to High, NCS - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [1]						
	Day 30	n	77	41	38	156
		Mean (SD)	30.55 (1.698)	30.27 (1.858)	30.84 (1.701)	30.54 (1.743)
		Median	31.00	30.00	31.00	31.00
		Min, Max	23.0, 34.0	25.0, 35.0	24.0, 34.0	23.0, 35.0
		Low value – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Normal value – n (%)	76 (97.4)	39 (92.9)	37 (92.5)	152 (95.0)
		High value – n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal NCS – n (%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.06 (0.817)	0.22 (0.759)	0.03 (0.822)	0.10 (0.802)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-2.0, 2.0	-1.0, 2.0	-2.0, 2.0	-2.0, 2.0
	Shift in Normality	Normal to High, NCS - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [¹]	Day 60	n	77	41	39	157
		Mean (SD)	30.60 (1.929)	30.34 (1.825)	30.64 (1.709)	30.54 (1.842)
		Median	31.00	31.00	31.00	31.00
		Min, Max	22.0, 35.0	24.0, 33.0	24.0, 34.0	22.0, 35.0
		Low value – n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		Normal value – n (%)	74 (94.9)	40 (95.2)	38 (95.0)	152 (95.0)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS – n (%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)
	Change from Baseline	n	77	41	39	157
		Mean (SD)	0.12 (1.051)	0.29 (0.902)	-0.18 (0.791)	0.09 (0.964)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-2.0, 3.0	-2.0, 2.0	-2.0, 1.0	-2.0, 3.0
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [1]						
	Day 91	n	77	41	38	156
		Mean (SD)	30.71 (1.762)	30.41 (2.037)	31.00 (1.644)	30.71 (1.812)
		Median	31.00	31.00	31.00	31.00
		Min, Max	24.0, 34.0	22.0, 33.0	25.0, 34.0	22.0, 34.0
		Low value – n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
		Normal value – n (%)	75 (96.2)	40 (95.2)	37 (92.5)	152 (95.0)
		Abnormal NCS – n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.23 (1.012)	0.37 (1.179)	0.18 (0.897)	0.26 (1.028)
		Median	0.00	1.00	0.00	0.00
		Min, Max	-2.0, 2.0	-3.0, 2.0	-2.0, 2.0	-3.0, 2.0
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [¹]	Baseline	n	78	42	40	160
		Mean (SD)	32.79 (0.945)	32.64 (1.008)	32.95 (0.960)	32.79 (0.966)
		Median	33.00	33.00	33.00	33.00
		Min, Max	30.0, 35.0	30.0, 35.0	31.0, 35.0	30.0, 35.0
		Low value – n (%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
		Normal value – n (%)	74 (94.9)	41 (97.6)	39 (97.5)	154 (96.3)
		Abnormal NCS – n (%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL)						
[¹]	Day 6	n	78	42	40	160
		Mean (SD)	32.92 (1.298)	32.83 (1.306)	33.03 (1.121)	32.93 (1.252)
		Median	33.00	33.00	33.00	33.00
		Min, Max	30.0, 36.0	29.0, 36.0	31.0, 35.0	29.0, 36.0
		Low value – n (%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
		Normal value – n (%)	74 (94.9)	41 (97.6)	39 (97.5)	154 (96.3)
		Abnormal NCS – n (%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.13 (1.012)	0.19 (0.969)	0.08 (0.829)	0.13 (0.953)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-2.0, 2.0	-2.0, 2.0	-2.0, 2.0	-2.0, 2.0
	Shift in Normality	Normal to Low, NCS - n(%)	2 (2.6)	0	0	2 (1.3)
		Low, NCS to Normal - n(%)	2 (2.6)	0	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL)						
[¹]	Day 30	n	77	41	38	156
		Mean (SD)	32.62 (1.065)	32.44 (1.097)	32.74 (1.108)	32.60 (1.082)
		Median	33.00	33.00	33.00	33.00
		Min, Max	30.0, 35.0	29.0, 35.0	30.0, 35.0	29.0, 35.0
		Low value – n (%)	5 (6.4)	2 (4.8)	1 (2.5)	8 (5.0)
		Normal value – n (%)	72 (92.3)	39 (92.9)	37 (92.5)	148 (92.5)
		Abnormal NCS – n (%)	5 (6.4)	2 (4.8)	1 (2.5)	8 (5.0)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.14 (0.870)	-0.20 (0.873)	-0.18 (0.834)	-0.17 (0.857)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-2.0, 2.0	-2.0, 1.0	-2.0, 1.0	-2.0, 2.0
	Shift in Normality	Normal to Low, NCS - n(%)	2 (2.6)	1 (2.4)	0	3 (1.9)
		Low, NCS to Normal - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL)						
[¹]	Day 60	n	77	41	39	157
		Mean (SD)	32.91 (1.416)	32.83 (1.139)	32.64 (1.159)	32.82 (1.284)
		Median	33.00	33.00	33.00	33.00
		Min, Max	28.0, 35.0	29.0, 35.0	30.0, 35.0	28.0, 35.0
		Low value – n (%)	4 (5.1)	2 (4.8)	2 (5.0)	8 (5.0)
		Normal value – n (%)	73 (93.6)	39 (92.9)	37 (92.5)	149 (93.1)
		Abnormal NCS – n (%)	4 (5.1)	2 (4.8)	2 (5.0)	8 (5.0)
	Change from Baseline	n	77	41	39	157
		Mean (SD)	0.14 (1.345)	0.20 (1.078)	-0.26 (1.070)	0.06 (1.221)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-3.0, 3.0	-2.0, 2.0	-2.0, 2.0	-3.0, 3.0
	Shift in Normality	Normal to Low, NCS - n(%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)
		Low, NCS to Normal - n(%)	3 (3.8)	0	0	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL)						
[¹]	Day 91	n	77	41	38	156
		Mean (SD)	33.25 (1.138)	33.10 (1.020)	32.92 (0.942)	33.13 (1.064)
		Median	33.00	33.00	33.00	33.00
		Min, Max	30.0, 36.0	29.0, 35.0	30.0, 35.0	29.0, 36.0
		Low value – n (%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)
		Normal value – n (%)	74 (94.9)	40 (95.2)	37 (92.5)	151 (94.4)
		Abnormal NCS – n (%)	3 (3.8)	1 (2.4)	1 (2.5)	5 (3.1)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.48 (1.047)	0.46 (1.143)	0.00 (0.987)	0.36 (1.072)
		Median	1.00	0.00	0.00	0.00
		Min, Max	-2.0, 3.0	-2.0, 3.0	-2.0, 2.0	-2.0, 3.0
	Shift in Normality	Normal to Low, NCS - n(%)	1 (1.3)	0	0	1 (0.6)
		Low, NCS to Normal - n(%)	2 (2.6)	0	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Volume (fL)						
[¹]	Baseline	n	78	42	40	160
		Mean (SD)	93.01 (4.186)	92.40 (4.295)	93.75 (3.888)	93.04 (4.145)
		Median	94.00	92.50	94.00	93.00
		Min, Max	76.0, 101.0	82.0, 103.0	80.0, 101.0	76.0, 103.0
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	66 (84.6)	37 (88.1)	32 (80.0)	135 (84.4)
		High value – n (%)	11 (14.1)	5 (11.9)	8 (20.0)	24 (15.0)
		Abnormal NCS – n (%)	12 (15.4)	5 (11.9)	8 (20.0)	25 (15.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Volume (fL) [¹]	Day 6	n	78	42	40	160
		Mean (SD)	93.27 (4.205)	92.69 (4.599)	93.70 (3.811)	93.23 (4.209)
		Median	94.00	92.00	94.00	93.00
		Min, Max	78.0, 101.0	83.0, 102.0	81.0, 102.0	78.0, 102.0
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	64 (82.1)	37 (88.1)	35 (87.5)	136 (85.0)
		High value – n (%)	13 (16.7)	5 (11.9)	5 (12.5)	23 (14.4)
		Abnormal NCS – n (%)	14 (17.9)	5 (11.9)	5 (12.5)	24 (15.0)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.26 (1.951)	0.29 (1.942)	-0.05 (1.961)	0.19 (1.944)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-4.0, 4.0	-3.0, 4.0	-3.0, 3.0	-4.0, 4.0
	Shift in Normality	Normal to High, NCS - n(%)	6 (7.7)	1 (2.4)	1 (2.5)	8 (5.0)
		High, NCS to Normal - n(%)	4 (5.1)	1 (2.4)	4 (10.0)	9 (5.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Volume (fL)						
[¹]	Day 30	n	77	41	38	156
		Mean (SD)	93.53 (4.084)	93.15 (4.264)	94.26 (3.992)	93.61 (4.103)
		Median	94.00	93.00	95.00	94.00
		Min, Max	77.0, 102.0	83.0, 102.0	80.0, 102.0	77.0, 102.0
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	66 (84.6)	35 (83.3)	31 (77.5)	132 (82.5)
		High value – n (%)	10 (12.8)	6 (14.3)	7 (17.5)	23 (14.4)
		Abnormal NCS – n (%)	11 (14.1)	6 (14.3)	7 (17.5)	24 (15.0)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.55 (1.578)	0.76 (1.446)	0.45 (1.267)	0.58 (1.469)
		Median	0.00	1.00	0.00	0.50
		Min, Max	-3.0, 4.0	-2.0, 4.0	-2.0, 3.0	-3.0, 4.0
	Shift in Normality	Normal to High, NCS - n(%)	4 (5.1)	2 (4.8)	1 (2.5)	7 (4.4)
		High, NCS to Normal - n(%)	5 (6.4)	1 (2.4)	1 (2.5)	7 (4.4)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Volume (fL) [¹]	Day 60	n	77	41	39	157
		Mean (SD)	93.16 (4.056)	92.56 (4.627)	94.15 (3.711)	93.25 (4.146)
		Median	93.00	93.00	95.00	93.00
		Min, Max	78.0, 101.0	81.0, 101.0	81.0, 101.0	78.0, 101.0
		Low value – n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	66 (84.6)	37 (88.1)	32 (80.0)	135 (84.4)
		High value – n (%)	10 (12.8)	4 (9.5)	7 (17.5)	21 (13.1)
		Abnormal NCS – n (%)	11 (14.1)	4 (9.5)	7 (17.5)	22 (13.8)
	Change from Baseline	n	77	41	39	157
		Mean (SD)	0.17 (1.909)	0.17 (1.949)	0.26 (1.728)	0.19 (1.865)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-5.0, 4.0	-3.0, 4.0	-3.0, 4.0	-5.0, 4.0
	Shift in Normality	Normal to High, NCS - n(%)	4 (5.1)	1 (2.4)	1 (2.5)	6 (3.8)
		High, NCS to Normal - n(%)	5 (6.4)	2 (4.8)	2 (5.0)	9 (5.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Volume (fL)						
[¹]	Day 91	n	77	41	38	156
		Mean (SD)	92.43 (3.824)	91.80 (4.622)	93.89 (3.826)	92.62 (4.095)
		Median	93.00	92.00	94.00	93.00
		Min, Max	77.0, 101.0	77.0, 100.0	81.0, 101.0	77.0, 101.0
		Low value – n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Normal value – n (%)	72 (92.3)	37 (88.1)	31 (77.5)	140 (87.5)
		High value – n (%)	4 (5.1)	3 (7.1)	7 (17.5)	14 (8.8)
		Abnormal NCS – n (%)	5 (6.4)	4 (9.5)	7 (17.5)	16 (10.0)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.56 (1.944)	-0.59 (2.086)	0.08 (1.851)	-0.41 (1.968)
		Median	-1.00	0.00	0.00	0.00
		Min, Max	-5.0, 6.0	-6.0, 5.0	-4.0, 4.0	-6.0, 6.0

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.17.1 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Ery. Mean Corpuscular Volume (fL) [¹]	Shift in Normality	Normal to High, NCS - n(%)	0	1 (2.4)	2 (5.0)	3 (1.9)
		Normal to Low, NCS - n(%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n(%)	7 (9.0)	3 (7.1)	2 (5.0)	12 (7.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.5

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Study Day	Statistic						
pH [5-8]	Screening	n	78	42	40	15	175
		Mean (SD)	6.01 (0.584)	6.31 (0.584)	6.05 (0.451)	6.03 (0.668)	6.09 (0.573)
		Median	6.00	6.00	6.00	6.00	6.00
		Min, Max	5.0, 7.5	5.5, 7.5	5.5, 7.0	5.0, 7.0	5.0, 7.5
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
	Day 0	n	78	42	40	5	165
		Mean (SD)	6.12 (0.395)	6.00 (0.247)	6.11 (0.310)	5.90 (0.224)	6.08 (0.341)
		Median	6.00	6.00	6.00	6.00	6.00
		Min, Max	5.0, 7.0	5.5, 6.5	5.5, 7.0	5.5, 6.0	5.0, 7.0
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Study Day	Statistic						
Specific Gravity							
Screening	n		78	42	40	15	175
			1.0174	1.0166	1.0161	1.0165	1.0169
		Mean (SD)	(0.00907)	(0.00936)	(0.00877)	(0.00951)	(0.00905)
		Median	1.0170	1.0185	1.0165	1.0160	1.0170
		Min, Max	1.001, 1.038	1.002, 1.034	1.003, 1.030	1.002, 1.031	1.001, 1.038
		Low value – n (%)	2 (2.6)	0	0	0	2 (1.1)
		Normal value – n (%)	74 (94.9)	41 (97.6)	40 (100)	14 (93.3)	169 (96.6)
		High value – n (%)	2 (2.6)	1 (2.4)	0	1 (6.7)	4 (2.3)
		Abnormal NCS – n (%)	4 (5.1)	1 (2.4)	0	1 (6.7)	6 (3.4)
Day 0	n		78	42	40	5	165
			1.0132	1.0154	1.0134	1.0136	1.0138
		Mean (SD)	(0.00511)	(0.00528)	(0.00383)	(0.00404)	(0.00490)
		Median	1.0120	1.0155	1.0135	1.0130	1.0130
		Min, Max	1.005, 1.024	1.007, 1.027	1.007, 1.021	1.009, 1.020	1.005, 1.027
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]	Study Day	Statistic	(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Bilirubin (Urine)							
[¹]	Screening	n	78	42	40	15	175
		Negative	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
	Day 0	n	78	42	40	5	165
		Negative	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
Glucose (Urine)							
[¹]	Screening	n	78	42	40	15	175
		Negative	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (100)
		U.Glucose increase					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units)			THSm2.2	mCC	SA	Product Test	Overall Safety
[Reference range]	Study Day	Statistic	(N=78)	(N=42)	(N=40)	(N=15)	(N=175)
Glucose (Urine)							
[¹]	Day 0	n	78	42	40	5	165
		Normal	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		U.Glucose increase					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
Nitrite							
[¹]	Screening	n	78	42	40	15	175
		Negative	78 (100)	42 (100)	39 (97.5)	15 (100)	174 (99.4)
		Positive	0	0	1 (2.5)	0	1 (0.6)
		Normal value – n (%)	78 (100)	42 (100)	39 (97.5)	15 (100)	174 (99.4)
		Abnormal value – n (%)	0	0	1 (2.5)	0	1 (0.6)
		Abnormal NCS – n (%)	0	0	1 (2.5)	0	1 (0.6)
	Day 0	n	78	42	40	5	165
		Negative	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	5 (33.3)	165 (94.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range]			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Study Day	Statistic						
Erythrocytes (Urine)							
[-]	Day 0	n	78	42	40	5	165
		Negative	78 (100)	42 (100)	38 (95.0)	5 (33.3)	163 (93.1)
		1+	0	0	1 (2.5)	0	1 (0.6)
		Trace	0	0	1 (2.5)	0	1 (0.6)
		Normal value – n (%)	78 (100)	42 (100)	39 (97.5)	5 (33.3)	164 (93.7)
		High value – n (%)	0	0	1 (2.5)	0	1 (0.6)
		Abnormal NCS – n (%)	0	0	1 (2.5)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range] Study Day Statistic			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Protein (Urine) [¹]	Screening	n	78	42	40	15	175
		Negative	74 (94.9)	40 (95.2)	40 (100)	13 (86.7)	167 (95.4)
		Trace	4 (5.1)	2 (4.8)	0	2 (13.3)	8 (4.6)
		Normal value – n (%)	74 (94.9)	40 (95.2)	40 (100)	13 (86.7)	167 (95.4)
		Abnormal value – n (%)	4 (5.1)	2 (4.8)	0	2 (13.3)	8 (4.6)
		Abnormal NCS – n (%)	4 (5.1)	2 (4.8)	0	2 (13.3)	8 (4.6)
		U.Protein increase					
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	15 (100)	175 (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 are based on the number of subjects indicated in the column header (N).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomization**

Parameter (units) [Reference range] Study Day Statistic			THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Protein (Urine) [¹]	Day 0	n	78	42	40	5	165
		Negative	59 (75.6)	25 (59.5)	30 (75.0)	4 (26.7)	118 (67.4)
		1+	3 (3.8)	1 (2.4)	0	0	4 (2.3)
		Trace	16 (20.5)	16 (38.1)	10 (25.0)	1 (6.7)	43 (24.6)
		Normal value – n (%)	59 (75.6)	25 (59.5)	30 (75.0)	4 (26.7)	118 (67.4)
		High value – n (%)	19 (24.4)	17 (40.5)	10 (25.0)	1 (6.7)	47 (26.9)
		Abnormal NCS – n (%)	19 (24.4)	17 (40.5)	10 (25.0)	1 (6.7)	47 (26.9)
		U.Protein increase					
		Grade 0 - n(%)	75 (96.2)	41 (97.6)	40 (100)	5 (33.3)	161 (92.0)
		Grade 1 - n(%)	3 (3.8)	1 (2.4)	0	0	4 (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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
pH [5-8]	Baseline	n	78	42	40	160
		Mean (SD)	6.12 (0.395)	6.00 (0.247)	6.11 (0.310)	6.08 (0.343)
		Median	6.00	6.00	6.00	6.00
		Min, Max	5.0, 7.0	5.5, 6.5	5.5, 7.0	5.0, 7.0
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Day 6	n	78	42	40	160
		Mean (SD)	5.87 (0.367)	5.96 (0.357)	6.14 (0.409)	5.96 (0.389)
		Median	6.00	6.00	6.00	6.00
		Min, Max	5.5, 7.0	5.5, 7.0	5.5, 7.0	5.5, 7.0
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	-0.25 (0.455)	-0.04 (0.357)	0.03 (0.438)	-0.13 (0.442)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-1.0, 0.5	-0.5, 1.0	-1.0, 1.0	-1.0, 1.0

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
pH [5-8]	Day 30	n	77	41	38	156
		Mean (SD)	5.98 (0.358)	6.02 (0.316)	6.09 (0.326)	6.02 (0.341)
		Median	6.00	6.00	6.00	6.00
		Min, Max	5.5, 7.0	5.5, 6.5	5.5, 6.5	5.5, 7.0
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	-0.14 (0.436)	0.04 (0.304)	-0.03 (0.402)	-0.07 (0.402)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-1.0, 1.0	-0.5, 0.5	-0.5, 1.0	-1.0, 1.0
	Day 60	n	77	41	39	157
		Mean (SD)	6.06 (0.372)	6.12 (0.312)	6.06 (0.348)	6.08 (0.350)
		Median	6.00	6.00	6.00	6.00
		Min, Max	5.5, 7.0	5.5, 6.5	5.5, 7.0	5.5, 7.0
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
pH [5-8]	Change from Baseline	n	77	41	39	157
		Mean (SD)	-0.06 (0.490)	0.13 (0.336)	-0.05 (0.394)	-0.01 (0.437)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-1.0, 1.0	-0.5, 0.5	-1.0, 1.0	-1.0, 1.0
	Day 91	n	77	41	38	156
		Mean (SD)	6.12 (0.508)	6.09 (0.370)	6.17 (0.469)	6.13 (0.464)
		Median	6.00	6.00	6.00	6.00
		Min, Max	5.5, 8.0	5.5, 7.0	5.5, 7.5	5.5, 8.0
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.00 (0.551)	0.10 (0.340)	0.05 (0.462)	0.04 (0.481)
		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: 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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Specific Gravity						
[¹]	Baseline	n	78	42	40	160
		Mean (SD)	1.0132 (0.00511)	1.0154 (0.00528)	1.0134 (0.00383)	1.0138 (0.00493)
		Median	1.0120	1.0155	1.0135	1.0130
		Min, Max	1.005, 1.024	1.007, 1.027	1.007, 1.021	1.005, 1.027
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Day 6	n	78	42	40	160
		Mean (SD)	1.0168 (0.00574)	1.0168 (0.00607)	1.0139 (0.00609)	1.0161 (0.00602)
		Median	1.0175	1.0170	1.0140	1.0160
		Min, Max	1.004, 1.028	1.003, 1.029	1.003, 1.030	1.003, 1.030
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Change from Baseline	n	78	42	40	160
		Mean (SD)	0.0036 (0.00590)	0.0015 (0.00598)	0.0005 (0.00616)	0.0022 (0.00610)
		Median	0.0035	0.0015	-0.0005	0.0030
		Min, Max	-0.011, 0.016	-0.015, 0.015	-0.009, 0.022	-0.015, 0.022

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Specific Gravity [¹]	Day 30	n	77	41	38	156
		Mean (SD)	1.0150 (0.00473)	1.0153 (0.00427)	1.0140 (0.00443)	1.0148 (0.00454)
		Median	1.0140	1.0150	1.0140	1.0140
		Min, Max	1.007, 1.029	1.007, 1.030	1.005, 1.023	1.005, 1.030
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.0019 (0.00539)	0.0002 (0.00576)	0.0006 (0.00519)	0.0012 (0.00547)
		Median	0.0020	0.0000	0.0010	0.0010
		Min, Max	-0.011, 0.018	-0.012, 0.012	-0.011, 0.010	-0.012, 0.018
	Day 60	n	77	41	39	157
		Mean (SD)	1.0145 (0.00518)	1.0139 (0.00516)	1.0150 (0.00517)	1.0144 (0.00515)
		Median	1.0140	1.0130	1.0150	1.0140
		Min, Max	1.003, 1.026	1.004, 1.027	1.005, 1.025	1.003, 1.027
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Specific Gravity [¹]	Change from Baseline	n	77	41	39	157
		Mean (SD)	0.0014 (0.00577)	-0.0012 (0.00584)	0.0016 (0.00517)	0.0007 (0.00574)
		Median	0.0000	0.0000	0.0020	0.0000
		Min, Max	-0.011, 0.017	-0.014, 0.013	-0.011, 0.014	-0.014, 0.017
	Day 91	n	77	41	38	156
		Mean (SD)	1.0151 (0.00481)	1.0138 (0.00449)	1.0150 (0.00553)	1.0147 (0.00492)
		Median	1.0150	1.0130	1.0140	1.0140
		Min, Max	1.005, 1.024	1.005, 1.023	1.005, 1.026	1.005, 1.026
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Change from Baseline	n	77	41	38	156
		Mean (SD)	0.0020 (0.00596)	-0.0013 (0.00526)	0.0016 (0.00639)	0.0010 (0.00603)
		Median	0.0020	-0.0030	0.0020	0.0005
		Min, Max	-0.011, 0.017	-0.008, 0.016	-0.010, 0.018	-0.011, 0.018

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (Urine) [¹]	Baseline	n	78	42	40	160
		Negative	78 (100)	42 (100)	40 (100)	160 (100)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Day 6	n	78	42	40	160
		Negative	78 (100)	42 (100)	40 (100)	160 (100)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Day 30	n	77	41	38	156
		Negative	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Day 60	n	77	41	39	157
		Negative	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Bilirubin (Urine) [¹]	Day 91	n	77	41	38	156
		Negative	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
Glucose (Urine) [¹]	Baseline	n	78	42	40	160
		Normal	78 (100)	42 (100)	40 (100)	160 (100)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		U.Glucose increase				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)
	Day 6	n	78	42	40	160
		Normal	78 (100)	42 (100)	40 (100)	160 (100)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
		U.Glucose increase				
		Grade 0 - n(%)	78 (100)	42 (100)	40 (100)	160 (100)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (Urine) [¹]	Day 30	n	77	41	38	156
		Normal	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal value – n (%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		U.Glucose increase				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
	Day 60	n	77	41	39	157
		Normal	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		U.Glucose increase				
		Grade 0 - n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Glucose (Urine) [¹]	Day 91	n	77	41	38	156
		Normal	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		1+	1 (1.3)	0	0	1 (0.6)
		Normal value – n (%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		High value – n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS – n (%)	1 (1.3)	0	0	1 (0.6)
		U.Glucose increase				
		Grade 0 - n(%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		Grade 2 - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Normality	Normal to High, CS - n(%)	1 (1.3)	0	0	1 (0.6)
	Shift in Toxicity	U.Glucose increase 0 to 2 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Nitrite [¹]	Baseline	n	78	42	40	160
		Negative	78 (100)	42 (100)	40 (100)	160 (100)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Day 6	n	78	42	40	160
		Negative	78 (100)	42 (100)	40 (100)	160 (100)
		Normal value – n (%)	78 (100)	42 (100)	40 (100)	160 (100)
	Day 30	n	77	41	38	156
		Negative	77 (98.7)	40 (95.2)	38 (95.0)	155 (96.9)
		1+	0	1 (2.4)	0	1 (0.6)
		Normal value – n (%)	77 (98.7)	40 (95.2)	38 (95.0)	155 (96.9)
		High value – n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal NCS – n (%)	0	1 (2.4)	0	1 (0.6)
		Shift in Normality				
		Normal to High, NCS - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Nitrite [¹]	Day 60	n	77	41	39	157
		Negative	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
	Day 91	n	77	41	38	156
		Negative	77 (98.7)	41 (97.6)	37 (92.5)	155 (96.9)
		2+	0	0	1 (2.5)	1 (0.6)
		Normal value – n (%)	77 (98.7)	41 (97.6)	37 (92.5)	155 (96.9)
		High value – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal NCS – n (%)	0	0	1 (2.5)	1 (0.6)
	Shift in Normality	Normal to High, NCS - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Erythrocytes (Urine) [-]	Baseline	n	78	42	40	160
		Negative	78 (100)	42 (100)	38 (95.0)	158 (98.8)
		1+	0	0	1 (2.5)	1 (0.6)
		Trace	0	0	1 (2.5)	1 (0.6)
		Normal value – n (%)	78 (100)	42 (100)	39 (97.5)	159 (99.4)
		High value – n (%)	0	0	1 (2.5)	1 (0.6)
		Abnormal NCS – n (%)	0	0	1 (2.5)	1 (0.6)
	Day 6	n	78	42	40	160
		Negative	75 (96.2)	41 (97.6)	38 (95.0)	154 (96.3)
		1+	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Trace	2 (2.6)	0	1 (2.5)	3 (1.9)
		Normal value – n (%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		High value – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Abnormal NCS – n (%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Erythrocytes (Urine) [-]	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
	Day 30	n	77	41	38	156
		Negative	75 (96.2)	41 (97.6)	35 (87.5)	151 (94.4)
		1+	1 (1.3)	0	0	1 (0.6)
		2+	1 (1.3)	0	0	1 (0.6)
		3+	0	0	1 (2.5)	1 (0.6)
		Trace	0	0	2 (5.0)	2 (1.3)
		Normal value – n (%)	75 (96.2)	41 (97.6)	36 (90.0)	152 (95.0)
		High value – n (%)	2 (2.6)	0	2 (5.0)	4 (2.5)
		Abnormal NCS – n (%)	2 (2.6)	0	2 (5.0)	4 (2.5)
	Shift in Normality	Normal to High, NCS - n(%)	2 (2.6)	0	2 (5.0)	4 (2.5)
		High, NCS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Erythrocytes (Urine) [-]	Day 60	n	77	41	39	157
		Negative	74 (94.9)	39 (92.9)	36 (90.0)	149 (93.1)
		1+	1 (1.3)	1 (2.4)	0	2 (1.3)
		2+	0	0	1 (2.5)	1 (0.6)
		3+	0	1 (2.4)	0	1 (0.6)
		Trace	2 (2.6)	0	2 (5.0)	4 (2.5)
		Normal value – n (%)	76 (97.4)	39 (92.9)	38 (95.0)	153 (95.6)
		High value – n (%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)
		Abnormal NCS – n (%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)
	Shift in Normality	Normal to High, NCS - n(%)	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)
		High, NCS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Erythrocytes (Urine) [-]	Day 91	n	77	41	38	156
		Negative	72 (92.3)	39 (92.9)	35 (87.5)	146 (91.3)
		1+	2 (2.6)	0	0	2 (1.3)
		2+	2 (2.6)	0	1 (2.5)	3 (1.9)
		3+	0	0	1 (2.5)	1 (0.6)
		Trace	1 (1.3)	2 (4.8)	1 (2.5)	4 (2.5)
		Normal value – n (%)	73 (93.6)	41 (97.6)	36 (90.0)	150 (93.8)
		High value – n (%)	4 (5.1)	0	2 (5.0)	6 (3.8)
		Abnormal NCS – n (%)	4 (5.1)	0	2 (5.0)	6 (3.8)
	Shift in Normality	Normal to High, NCS - n(%)	4 (5.1)	0	2 (5.0)	6 (3.8)
		High, NCS to Normal - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (Urine) [¹]	Baseline	n	78	42	40	160
		Negative	59 (75.6)	25 (59.5)	30 (75.0)	114 (71.3)
		1+	3 (3.8)	1 (2.4)	0	4 (2.5)
		Trace	16 (20.5)	16 (38.1)	10 (25.0)	42 (26.3)
		Normal value – n (%)	59 (75.6)	25 (59.5)	30 (75.0)	114 (71.3)
		High value – n (%)	19 (24.4)	17 (40.5)	10 (25.0)	46 (28.8)
		Abnormal NCS – n (%)	19 (24.4)	17 (40.5)	10 (25.0)	46 (28.8)
		U.Protein increase				
		Grade 0 - n(%)	75 (96.2)	41 (97.6)	40 (100)	156 (97.5)
		Grade 1 - n(%)	3 (3.8)	1 (2.4)	0	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (Urine) [¹]	Day 6	n	78	42	40	160
		Negative	30 (38.5)	16 (38.1)	25 (62.5)	71 (44.4)
		1+	12 (15.4)	5 (11.9)	4 (10.0)	21 (13.1)
		Trace	36 (46.2)	21 (50.0)	11 (27.5)	68 (42.5)
		Normal value – n (%)	30 (38.5)	16 (38.1)	25 (62.5)	71 (44.4)
		High value – n (%)	48 (61.5)	26 (61.9)	15 (37.5)	89 (55.6)
		Abnormal NCS – n (%)	48 (61.5)	26 (61.9)	15 (37.5)	89 (55.6)
		U.Protein increase				
		Grade 0 - n(%)	66 (84.6)	37 (88.1)	36 (90.0)	139 (86.9)
		Grade 1 - n(%)	12 (15.4)	5 (11.9)	4 (10.0)	21 (13.1)
	Shift in Normality	Normal to High, NCS - n(%)	33 (42.3)	12 (28.6)	9 (22.5)	54 (33.8)
		High, NCS to Normal - n(%)	4 (5.1)	3 (7.1)	4 (10.0)	11 (6.9)
	Shift in Toxicity	U.Protein increase				
		0 to 1 - n(%)	10 (12.8)	4 (9.5)	4 (10.0)	18 (11.3)
		1 to 0 - n(%)	1 (1.3)	0	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (Urine) [¹]	Day 30	n	77	41	38	156
		Negative	62 (79.5)	30 (71.4)	30 (75.0)	122 (76.3)
		1+	2 (2.6)	0	0	2 (1.3)
		Trace	13 (16.7)	11 (26.2)	8 (20.0)	32 (20.0)
		Normal value – n (%)	62 (79.5)	30 (71.4)	30 (75.0)	122 (76.3)
		High value – n (%)	15 (19.2)	11 (26.2)	8 (20.0)	34 (21.3)
		Abnormal NCS – n (%)	15 (19.2)	11 (26.2)	8 (20.0)	34 (21.3)
		U.Protein increase				
		Grade 0 - n(%)	75 (96.2)	41 (97.6)	38 (95.0)	154 (96.3)
		Grade 1 - n(%)	2 (2.6)	0	0	2 (1.3)
	Shift in Normality	Normal to High, NCS - n(%)	8 (10.3)	7 (16.7)	4 (10.0)	19 (11.9)
		High, NCS to Normal - n(%)	11 (14.1)	12 (28.6)	6 (15.0)	29 (18.1)
	Shift in Toxicity	U.Protein increase				
		0 to 1 - n(%)	2 (2.6)	0	0	2 (1.3)
		1 to 0 - n(%)	3 (3.8)	1 (2.4)	0	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (Urine) [¹]	Day 60	n	77	41	39	157
		Negative	55 (70.5)	29 (69.0)	25 (62.5)	109 (68.1)
		1+	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
		2+	0	1 (2.4)	0	1 (0.6)
		Trace	20 (25.6)	10 (23.8)	12 (30.0)	42 (26.3)
		Normal value – n (%)	55 (70.5)	29 (69.0)	25 (62.5)	109 (68.1)
		High value – n (%)	22 (28.2)	12 (28.6)	14 (35.0)	48 (30.0)
		Abnormal NCS – n (%)	22 (28.2)	11 (26.2)	14 (35.0)	47 (29.4)
		Abnormal CS – n (%)	0	1 (2.4)	0	1 (0.6)
		U.Protein increase				
		Grade 0 - n(%)	75 (96.2)	39 (92.9)	37 (92.5)	151 (94.4)
		Grade 1 - n(%)	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
		Grade 2 - n(%)	0	1 (2.4)	0	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (Urine) [¹]	Shift in Normality	Normal to High, NCS - n(%)	13 (16.7)	2 (4.8)	7 (17.5)	22 (13.8)
		Normal to High, CS - n(%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n(%)	9 (11.5)	7 (16.7)	3 (7.5)	19 (11.9)
	Shift in Toxicity U.Protein increase	0 to 1 - n(%)	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
		0 to 2 - n(%)	0	1 (2.4)	0	1 (0.6)
		1 to 0 - n(%)	3 (3.8)	1 (2.4)	0	4 (2.5)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (Urine) [¹]	Day 91	n	77	41	38	156
		Negative	44 (56.4)	26 (61.9)	23 (57.5)	93 (58.1)
		1+	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
		2+	0	0	1 (2.5)	1 (0.6)
		Trace	31 (39.7)	14 (33.3)	12 (30.0)	57 (35.6)
		Normal value – n (%)	44 (56.4)	26 (61.9)	23 (57.5)	93 (58.1)
		High value – n (%)	33 (42.3)	15 (35.7)	15 (37.5)	63 (39.4)
		Abnormal NCS – n (%)	33 (42.3)	15 (35.7)	14 (35.0)	62 (38.8)
		Abnormal CS – n (%)	0	0	1 (2.5)	1 (0.6)
		U.Protein increase				
		Grade 0 - n(%)	75 (96.2)	40 (95.2)	35 (87.5)	150 (93.8)
		Grade 1 - n(%)	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)
		Grade 2 - n(%)	0	0	1 (2.5)	1 (0.6)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**Table 15.2.6.18.1 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Parameter (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Protein (Urine) [¹]	Shift in Normality	Normal to High, NCS - n(%)	22 (28.2)	7 (16.7)	8 (20.0)	37 (23.1)
		Normal to High, CS - n(%)	0	0	1 (2.5)	1 (0.6)
		High, NCS to Normal - n(%)	7 (9.0)	8 (19.0)	4 (10.0)	19 (11.9)
	Shift in Toxicity U.Protein increase	0 to 1 - n(%)	1 (1.3)	0	2 (5.0)	3 (1.9)
		0 to 2 - n(%)	0	0	1 (2.5)	1 (0.6)
		1 to 0 - n(%)	2 (2.6)	0	0	2 (1.3)

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).

Note: 1: Normality ranges are provided in Appendix 15.3.6.6

**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=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	0	0	0	0	0	0	1 (6.7)	2	1 (0.6)	2
Alimentary Tract And Metabolism							1 (6.7)	1	1 (0.6)	1
Stomatological Preparations							1 (6.7)	1	1 (0.6)	1
Nervous System							1 (6.7)	1	1 (0.6)	1
Analgesics							1 (6.7)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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: Post-Randomization**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	11 (14.1)	22	5 (11.9)	11	5 (12.5)	16	21 (13.1)	49
Nervous System	3 (3.8)	3	3 (7.1)	3	3 (7.5)	3	9 (5.6)	9
Analgesics	3 (3.8)	3	3 (7.1)	3	3 (7.5)	3	9 (5.6)	9

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Post-Randomization**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Alimentary Tract And Metabolism	3 (3.8)	3	2 (4.8)	3	2 (5.0)	2	7 (4.4)	8
Drugs For Acid Related Disorders	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Stomatological Preparations	1 (1.3)	1	1 (2.4)	2	0	0	2 (1.3)	3
Antidiarrheals, Intestinal	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Antiinflammatory/Anti-infective Agents								
Drugs For Constipation	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Other Alimentary Tract And Metabolism Products	1 (1.3)	1	0	0	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Post-Randomization**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Antiinfectives For Systemic Use	3 (3.8)	3	1 (2.4)	1	3 (7.5)	6	7 (4.4)	10
Antibacterials For Systemic Use	3 (3.8)	3	1 (2.4)	1	3 (7.5)	6	7 (4.4)	10
Respiratory System	5 (6.4)	7	0	0	1 (2.5)	2	6 (3.8)	9
Cough And Cold Preparations	2 (2.6)	2			1 (2.5)	2	3 (1.9)	4
Throat Preparations	3 (3.8)	3			0	0	3 (1.9)	3
Antihistamines For Systemic Use	1 (1.3)	1			0	0	1 (0.6)	1
Nasal Preparations	1 (1.3)	1			0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Post-Randomization**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood And Blood Forming Organs	0	0	2 (4.8)	2	2 (5.0)	2	4 (2.5)	4
Antianemic Preparations			2 (4.8)	2	0	0	2 (1.3)	2
Antihemorrhagics			0	0	2 (5.0)	2	2 (1.3)	2
Musculo-Skeletal System	2 (2.6)	2	1 (2.4)	1	1 (2.5)	1	4 (2.5)	4
Antiinflammatory And Antirheumatic Products	1 (1.3)	1	1 (2.4)	1	1 (2.5)	1	3 (1.9)	3
Topical Products For Joint And Muscular Pain	1 (1.3)	1	0	0	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Post-Randomization**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Cardiovascular System	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Lipid Modifying Agents			1 (2.4)	1			1 (0.6)	1
Dermatologicals	1 (1.3)	2	0	0	0	0	1 (0.6)	2
Anti-Acne Preparations	1 (1.3)	1					1 (0.6)	1
Corticosteroids, Dermatological Preparations	1 (1.3)	1					1 (0.6)	1
Sensory Organs	1 (1.3)	2	0	0	0	0	1 (0.6)	2
Ophthalmologicals	1 (1.3)	2					1 (0.6)	2

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Confinement**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	2 (2.6)	3	0	0	3 (7.5)	4	5 (3.1)	7
Antiinfectives For Systemic Use	0	0			2 (5.0)	2	2 (1.3)	2
Antibacterials For Systemic Use					2 (5.0)	2	2 (1.3)	2
Nervous System	0	0			2 (5.0)	2	2 (1.3)	2
Analgesics					2 (5.0)	2	2 (1.3)	2
Alimentary Tract And Metabolism	1 (1.3)	1			0	0	1 (0.6)	1
Drugs For Constipation	1 (1.3)	1					1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Confinement**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Sensory Organs	1 (1.3)	2			0	0	1 (0.6)	2
Ophthalmologicals	1 (1.3)	2					1 (0.6)	2

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Ambulatory**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	9 (11.5)	19	5 (11.9)	11	3 (7.5)	12	17 (10.6)	42
Nervous System	3 (3.8)	3	3 (7.1)	3	1 (2.5)	1	7 (4.4)	7
Analgesics	3 (3.8)	3	3 (7.1)	3	1 (2.5)	1	7 (4.4)	7

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Ambulatory**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Alimentary Tract And Metabolism	2 (2.6)	2	2 (4.8)	3	2 (5.0)	2	6 (3.8)	7
Drugs For Acid Related Disorders	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Stomatological Preparations	1 (1.3)	1	1 (2.4)	2	0	0	2 (1.3)	3
Antidiarrheals, Intestinal	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Antiinflammatory/Antiinfective Agents								
Other Alimentary Tract And Metabolism Products	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Antiinfectives For Systemic Use	3 (3.8)	3	1 (2.4)	1	2 (5.0)	4	6 (3.8)	8
Antibacterials For Systemic Use	3 (3.8)	3	1 (2.4)	1	2 (5.0)	4	6 (3.8)	8

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Ambulatory**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Respiratory System	5 (6.4)	7	0	0	1 (2.5)	2	6 (3.8)	9
Cough And Cold Preparations	2 (2.6)	2			1 (2.5)	2	3 (1.9)	4
Throat Preparations	3 (3.8)	3			0	0	3 (1.9)	3
Antihistamines For Systemic Use	1 (1.3)	1			0	0	1 (0.6)	1
Nasal Preparations	1 (1.3)	1			0	0	1 (0.6)	1
Blood And Blood Forming Organs	0	0	2 (4.8)	2	2 (5.0)	2	4 (2.5)	4
Antianemic Preparations			2 (4.8)	2	0	0	2 (1.3)	2
Antihemorrhagics			0	0	2 (5.0)	2	2 (1.3)	2

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Ambulatory**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Musculo-Skeletal System	2 (2.6)	2	1 (2.4)	1	1 (2.5)	1	4 (2.5)	4
Antiinflammatory And Antirheumatic Products	1 (1.3)	1	1 (2.4)	1	1 (2.5)	1	3 (1.9)	3
Topical Products For Joint And Muscular Pain	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Cardiovascular System	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Lipid Modifying Agents			1 (2.4)	1			1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Ambulatory**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Dermatologicals	1 (1.3)	2	0	0	0	0	1 (0.6)	2
Anti-Acne Preparations	1 (1.3)	1					1 (0.6)	1
Corticosteroids, Dermatological Preparations	1 (1.3)	1					1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Safety Follow-up**

ATC1 ATC2	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any medications	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	0	0	0	0	0	0	1 (6.7)	2	1 (0.6)	2
Paracetamol							1 (6.7)	1	1 (0.6)	1
Povidone-Iodine							1 (6.7)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THSm2.2 on Day -2 but were not randomized. "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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	11 (14.1)	22	5 (11.9)	11	5 (12.5)	16	21 (13.1)	49
Paracetamol	3 (3.8)	3	2 (4.8)	2	3 (7.5)	3	8 (5.0)	8
Loxoprofen Sodium	1 (1.3)	1	1 (2.4)	1	1 (2.5)	1	3 (1.9)	3
Carbocisteine	1 (1.3)	1	0	0	1 (2.5)	1	2 (1.3)	2
Clarithromycin	0	0	0	0	2 (5.0)	2	2 (1.3)	2
Rebamipide	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Tranexamic Acid	0	0	0	0	2 (5.0)	2	2 (1.3)	2
Amoxicillin Trihydrate	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Amoxicillin W/Clavulanate Potassium	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Benzethonium Chloride	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Bisacodyl	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Cefaclor	1 (1.3)	1	0	0	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Cefditoren Pivoxil	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Cefteram Pivoxil	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Clostridium Butyricum	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Dextromethorphan Hydrobromide	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Diclofenac	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Diflucortolone Valerate	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Epinastine Hydrochloride	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Ferrous Sodium Citrate	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Fluorometholone	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Garenoxacin Mesilate	0	0	0	0	1 (2.5)	1	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Heparinoid	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Ketotifen Fumarate	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Lac-B Granular Powder N	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Levofloxacin	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Mecobalamin	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Nadifloxacin	1 (1.3)	1	0	0	0	0	1 (0.6)	1
New Lulu A	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Other Agents For Local Oral Treatment	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Pabron S Gold	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Povidone-Iodine	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Spektramox	0	0	0	0	1 (2.5)	1	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Stomatologicals, Mouth Preparations	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Sultamicillin Tosilate	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Tocopheryl Nicotinate	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Xylestesin	1 (1.3)	1	0	0	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Confinement**

Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	2 (2.6)	3	0	0	3 (7.5)	4	5 (3.1)	7
Paracetamol	0	0			2 (5.0)	2	2 (1.3)	2
Amoxicillin W/Clavulanate Potassium	0	0			1 (2.5)	1	1 (0.6)	1
Bisacodyl	1 (1.3)	1			0	0	1 (0.6)	1
Fluorometholone	1 (1.3)	1			0	0	1 (0.6)	1
Levofloxacin	1 (1.3)	1			0	0	1 (0.6)	1
Spektramox	0	0			1 (2.5)	1	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Ambulatory**

Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	9 (11.5)	19	5 (11.9)	11	3 (7.5)	12	17 (10.6)	42
Paracetamol	3 (3.8)	3	2 (4.8)	2	1 (2.5)	1	6 (3.8)	6
Loxoprofen Sodium	1 (1.3)	1	1 (2.4)	1	1 (2.5)	1	3 (1.9)	3
Carbocisteine	1 (1.3)	1	0	0	1 (2.5)	1	2 (1.3)	2
Clarithromycin	0	0	0	0	2 (5.0)	2	2 (1.3)	2
Rebamipide	0	0	1 (2.4)	1	1 (2.5)	1	2 (1.3)	2
Tranexamic Acid	0	0	0	0	2 (5.0)	2	2 (1.3)	2
Amoxicillin Trihydrate	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Benzethonium Chloride	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Cefaclor	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Cefditoren Pivoxil	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Ceferam Pivoxil	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Clostridium Butyricum	1 (1.3)	1	0	0	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Ambulatory**

Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Dextromethorphan Hydrobromide	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Diclofenac	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Difluocortolone Valerate	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Epinastine Hydrochloride	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Ferrous Sodium Citrate	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Garenoxacin Mesilate	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Heparinoid	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Ketotifen Fumarate	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Lac-B Granular Powder N	0	0	0	0	1 (2.5)	1	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Ambulatory**

Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Mecobalamin	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Nadifloxacin	1 (1.3)	1	0	0	0	0	1 (0.6)	1
New Lulu A	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Other Agents For Local Oral Treatment	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Pabron S Gold	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Povidone-Iodine	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Stomatologicals, Mouth Preparations	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Sultamicillin Tosilate	0	0	0	0	1 (2.5)	1	1 (0.6)	1
Tocopheryl Nicotinate	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Xylestesin	1 (1.3)	1	0	0	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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: Safety Follow-up**

Preferred Term	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	0	0	0	0	0	0	0	0

Note: The Overall Safety refers to all subjects exposed to THSm2.2. Only subjects randomized are summarized in post-randomization tables.

Note: mCC = Menthol conventional cigarettes; SA = Smoking 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**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Systolic Blood Pressure (mmHg)										
	Baseline	n	78		42		40		160	
		Mean	110.1		111.4		104.5		109.0	
		(SD)	(11.12)		(10.05)		(7.55)		(10.35)	
		Median	110.0		112.0		103.0		108.0	
		Min,	90.0,		94.0,		91.0,		90.0,	
		Max	136.0		133.0		125.0		136.0	
	Day 1	n	78	78	42	42	40	40	160	160
		Mean	106.5	-3.7	108.7	-2.6	102.2	-2.3	106.0	-3.1
		(SD)	(9.47)	(8.64)	(11.91)	(9.1)	(8.29)	(6.07)	(10.13)	(8.18)
		Median	106.0	-4.0	107.0	-2.0	101.0	-3.0	105.0	-3.0
		Min,	87.0,	-28.0,	90.0,	-33.0,	90.0,	-17.0,	87.0,	-33.0,
		Max	128.0	21.0	135.0	14.0	119.0	13.0	135.0	21.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Systolic Blood Pressure (mmHg)										
	Day 2	n	77	77	41	41	40	40	158	158
		Mean	105.8	-4.5	107.6	-3.4	102.3	-2.2	105.4	-3.6
		(SD)	(10.31)	(8.44)	(10.85)	(8.42)	(8.54)	(7.24)	(10.17)	(8.15)
		Median	105.0	-4.0	105.0	-4.0	103.0	-3.0	104.0	-3.5
		Min,	90.0,	-29.0,	90.0,	-18.0,	90.0,	-19.0,	90.0,	-29.0,
		Max	140.0	13.0	132.0	21.0	121.0	17.0	140.0	21.0
	Day 3	n	77	77	41	41	40	40	158	158
		Mean	107.4	-2.9	109.1	-1.9	101.9	-2.6	106.4	-2.6
		(SD)	(10.44)	(8.12)	(12.71)	(9.92)	(7.44)	(7.69)	(10.74)	(8.47)
		Median	106.0	-3.0	107.0	-3.0	102.0	-3.0	105.0	-3.0
		Min,	91.0,	-25.0,	88.0,	-23.0,	91.0,	-25.0,	88.0,	-25.0,
		Max	130.0	16.0	137.0	21.0	121.0	13.0	137.0	21.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Systolic Blood Pressure (mmHg)										
	Day 4	n	77	77	41	41	39	39	157	157
		Mean	106.1	-4.1	108.9	-2.1	101.2	-3.2	105.6	-3.4
		(SD)	(10.43)	(9.39)	(11.69)	(7.85)	(7.4)	(6.74)	(10.45)	(8.4)
		Median	105.0	-4.0	107.0	-4.0	101.0	-3.0	105.0	-4.0
		Min,	90.0,	-26.0,	91.0,	-15.0,	90.0,	-15.0,	90.0,	-26.0,
		Max	131.0	19.0	136.0	14.0	116.0	10.0	136.0	19.0
	Day 5	n	77	77	41	41	39	39	157	157
		Mean	108.8	-1.4	108.7	-2.3	103.1	-1.3	107.4	-1.6
		(SD)	(10.59)	(8.49)	(11.46)	(8.72)	(9.77)	(10.16)	(10.85)	(8.94)
		Median	108.0	-1.0	105.0	-2.0	101.0	-3.0	106.0	-2.0
		Min,	91.0,	-19.0,	90.0,	-18.0,	90.0,	-16.0,	90.0,	-19.0,
		Max	133.0	23.0	136.0	13.0	139.0	39.0	139.0	39.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Systolic Blood Pressure (mmHg)										
	Day 6	n	77	77	41	41	39	39	157	157
		Mean	109.4	-0.9	108.8	-2.2	103.1	-1.3	107.7	-1.3
		(SD)	(10.05)	(9.34)	(10.64)	(9.14)	(7.08)	(6.39)	(9.88)	(8.61)
		Median	109.0	-2.0	108.0	-4.0	102.0	-2.0	107.0	-2.0
		Min,	90.0,	-19.0,	90.0,	-23.0,	90.0,	-11.0,	90.0,	-23.0,
		Max	136.0	27.0	131.0	22.0	118.0	17.0	136.0	27.0
	Day 30	n	77	77	41	41	38	38	156	156
		Mean	108.6	-1.7	110.0	-1.0	103.9	-0.5	107.8	-1.2
		(SD)	(10.86)	(9.87)	(11.82)	(8.43)	(9.23)	(7.84)	(10.93)	(9)
		Median	109.0	-3.0	109.0	-3.0	103.5	0.0	107.0	-2.0
		Min,	90.0,	-34.0,	90.0,	-20.0,	90.0,	-16.0,	90.0,	-34.0,
		Max	134.0	18.0	134.0	20.0	126.0	26.0	134.0	26.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Systolic Blood Pressure (mmHg)										
	Day 60	n	77	77	41	41	39	39	157	157
		Mean	108.3	-2.0	109.4	-1.7	104.0	-0.4	107.5	-1.5
		(SD)	(10.58)	(8.99)	(10.83)	(11.65)	(8.38)	(6.75)	(10.3)	(9.26)
		Median	107.0	-3.0	111.0	-1.0	104.0	-2.0	106.0	-2.0
		Min,	91.0,	-27.0,	92.0,	-27.0,	91.0,	-9.0,	91.0,	-27.0,
		Max	132.0	25.0	138.0	21.0	127.0	20.0	138.0	25.0
	Day 91	n	77	77	41	41	38	38	156	156
		Mean	104.4	-5.9	105.5	-5.5	101.9	-2.4	104.1	-5.0
		(SD)	(10.81)	(8.53)	(13.01)	(12.35)	(8.74)	(7.32)	(10.99)	(9.48)
		Median	104.0	-5.0	103.0	-7.0	100.0	-3.5	103.0	-5.0
		Min,	85.0,	-27.0,	83.0,	-30.0,	87.0,	-13.0,	83.0,	-30.0,
		Max	137.0	20.0	142.0	35.0	129.0	17.0	142.0	35.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diastolic Blood Pressure (mmHg)										
	Baseline	n	78		42		40		160	
		Mean	66.6		67.5		63.9		66.2	
		(SD)	(8.94)		(7.08)		(5.79)		(7.86)	
		Median	66.5		66.5		62.5		65.5	
		Min,	50.0,		56.0,		55.0,		50.0,	
		Max	88.0		84.0		80.0		88.0	
	Day 1	n	78	78	42	42	40	40	160	160
		Mean	63.7	-2.9	64.8	-2.6	61.3	-2.6	63.4	-2.8
		(SD)	(7.29)	(6.82)	(7.03)	(5.11)	(6.32)	(5.59)	(7.08)	(6.08)
		Median	62.5	-3.0	64.0	-3.0	60.0	-2.5	62.5	-3.0
		Min,	52.0,	-18.0,	52.0,	-12.0,	52.0,	-15.0,	52.0,	-18.0,
		Max	83.0	11.0	81.0	11.0	80.0	13.0	83.0	13.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diastolic Blood Pressure (mmHg)										
	Day 2	n	77	77	41	41	40	40	158	158
		Mean	63.0	-3.8	63.2	-4.3	59.5	-4.4	62.2	-4.1
		(SD)	(7.87)	(6.37)	(8.13)	(5.53)	(6.29)	(5.86)	(7.69)	(6)
		Median	62.0	-3.0	62.0	-4.0	58.5	-3.5	61.0	-4.0
		Min,	50.0,	-21.0,	52.0,	-14.0,	45.0,	-16.0,	45.0,	-21.0,
		Max	81.0	7.0	83.0	15.0	72.0	7.0	83.0	15.0
	Day 3	n	77	77	41	41	40	40	158	158
		Mean	65.1	-1.6	63.7	-3.8	59.8	-4.1	63.4	-2.8
		(SD)	(8.44)	(7.07)	(8.8)	(6.84)	(5.96)	(5.63)	(8.24)	(6.73)
		Median	64.0	-2.0	62.0	-3.0	59.5	-3.5	62.0	-3.0
		Min,	51.0,	-20.0,	49.0,	-16.0,	51.0,	-16.0,	49.0,	-20.0,
		Max	88.0	16.0	89.0	13.0	75.0	8.0	89.0	16.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diastolic Blood Pressure (mmHg)										
	Day 4	n	77	77	41	41	39	39	157	157
		Mean	63.2	-3.5	64.8	-2.7	59.7	-4.2	62.8	-3.5
		(SD)	(7.54)	(7.08)	(7.48)	(6.25)	(5.89)	(6.13)	(7.35)	(6.62)
		Median	63.0	-4.0	63.0	-3.0	59.0	-4.0	62.0	-3.0
		Min,	50.0,	-18.0,	54.0,	-16.0,	50.0,	-17.0,	50.0,	-18.0,
		Max	90.0	19.0	81.0	11.0	71.0	8.0	90.0	19.0
	Day 5	n	77	77	41	41	39	39	157	157
		Mean	65.0	-1.8	64.6	-2.9	59.5	-4.4	63.5	-2.8
		(SD)	(7.57)	(6.67)	(7.5)	(7.08)	(6.5)	(8.21)	(7.62)	(7.22)
		Median	65.0	-1.0	65.0	-3.0	59.0	-5.0	63.0	-3.0
		Min,	50.0,	-24.0,	50.0,	-21.0,	47.0,	-26.0,	47.0,	-26.0,
		Max	83.0	17.0	86.0	11.0	84.0	25.0	86.0	25.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diastolic Blood Pressure (mmHg)										
	Day 6	n	77	77	41	41	39	39	157	157
		Mean	70.3	3.5	68.5	1.0	65.0	1.1	68.5	2.3
		(SD)	(7.55)	(6.74)	(7.4)	(5.95)	(5.56)	(5.86)	(7.34)	(6.41)
		Median	69.0	3.0	68.0	1.0	64.0	2.0	68.0	2.0
		Min,	53.0,	-10.0,	51.0,	-13.0,	54.0,	-12.0,	51.0,	-13.0,
		Max	88.0	21.0	84.0	14.0	80.0	11.0	88.0	21.0
	Day 30	n	77	77	41	41	38	38	156	156
		Mean	65.2	-1.6	65.6	-1.9	61.2	-2.7	64.3	-1.9
		(SD)	(8.83)	(6.98)	(7.8)	(5.09)	(6.94)	(5.11)	(8.28)	(6.08)
		Median	64.0	-2.0	64.0	-2.0	60.5	-3.0	63.0	-2.0
		Min,	48.0,	-23.0,	51.0,	-13.0,	51.0,	-12.0,	48.0,	-23.0,
		Max	90.0	13.0	88.0	11.0	79.0	9.0	90.0	13.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diastolic Blood Pressure (mmHg)										
	Day 60	n	77	77	41	41	39	39	157	157
		Mean	65.5	-1.3	66.7	-0.7	62.2	-1.7	65.0	-1.2
		(SD)	(8.51)	(6)	(8.7)	(7.38)	(6.34)	(7.06)	(8.21)	(6.62)
		Median	64.0	-2.0	64.0	0.0	62.0	-3.0	63.0	-2.0
		Min,	52.0,	-17.0,	56.0,	-23.0,	49.0,	-18.0,	49.0,	-23.0,
		Max	84.0	15.0	95.0	14.0	82.0	13.0	95.0	15.0
	Day 91	n	77	77	41	41	38	38	156	156
		Mean	62.9	-3.8	63.9	-3.6	62.4	-1.5	63.1	-3.2
		(SD)	(8.55)	(6.85)	(9.05)	(7.53)	(6.67)	(5.43)	(8.24)	(6.75)
		Median	62.0	-4.0	62.0	-4.0	63.0	-1.0	62.0	-4.0
		Min,	48.0,	-22.0,	50.0,	-16.0,	52.0,	-11.0,	48.0,	-22.0,
		Max	89.0	14.0	91.0	20.0	80.0	10.0	91.0	20.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Pulse Rate (beats/min)										
	Baseline	n	78		42		40		160	
		Mean	66.4		67.5		67.7		67.0	
		(SD)	(8.43)		(7.58)		(7.45)		(7.95)	
		Median	65.5		66.5		67.0		67.0	
		Min,	50.0,		54.0,		54.0,		50.0,	
		Max	93.0		89.0		86.0		93.0	
	Day 1	n	78	78	42	42	40	40	160	160
		Mean	65.3	-1.1	68.1	0.6	63.2	-4.5	65.5	-1.5
		(SD)	(8.23)	(7.7)	(7.44)	(6.16)	(5.93)	(5.09)	(7.67)	(6.95)
		Median	65.0	0.0	67.5	0.5	64.0	-4.0	65.0	-2.0
		Min,	51.0,	-32.0,	55.0,	-12.0,	48.0,	-19.0,	48.0,	-32.0,
		Max	88.0	21.0	85.0	19.0	80.0	6.0	88.0	21.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Pulse Rate (beats/min)										
	Day 2	n	77	77	41	41	40	40	158	158
		Mean	65.9	-0.6	68.2	0.8	61.5	-6.2	65.4	-1.6
		(SD)	(8.72)	(7.5)	(7.61)	(6.46)	(6.12)	(6.36)	(8.18)	(7.43)
		Median	65.0	-1.0	67.0	1.0	60.5	-7.0	65.0	-2.0
		Min,	48.0,	-19.0,	54.0,	-16.0,	48.0,	-17.0,	48.0,	-19.0,
		Max	90.0	23.0	84.0	18.0	81.0	15.0	90.0	23.0
	Day 3	n	77	77	41	41	40	40	158	158
		Mean	66.1	-0.4	66.9	-0.6	61.1	-6.6	65.0	-2.0
		(SD)	(8.13)	(7.78)	(6.43)	(5.68)	(6.17)	(5.79)	(7.59)	(7.28)
		Median	66.0	-1.0	67.0	0.0	61.0	-7.0	65.0	-2.0
		Min,	49.0,	-22.0,	56.0,	-15.0,	48.0,	-18.0,	48.0,	-22.0,
		Max	90.0	22.0	81.0	13.0	74.0	9.0	90.0	22.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Pulse Rate (beats/min)										
	Day 4	n	77	77	41	41	39	39	157	157
		Mean	65.2	-1.4	67.6	0.1	61.0	-6.7	64.8	-2.3
		(SD)	(7.66)	(8.03)	(7.2)	(7.29)	(6.2)	(7.31)	(7.55)	(8.05)
		Median	65.0	-1.0	67.0	0.0	60.0	-6.0	64.0	-2.0
		Min,	50.0,	-25.0,	53.0,	-15.0,	46.0,	-26.0,	46.0,	-26.0,
		Max	83.0	21.0	82.0	16.0	80.0	16.0	83.0	21.0
	Day 5	n	77	77	41	41	39	39	157	157
		Mean	65.8	-0.8	67.9	0.5	59.9	-7.7	64.9	-2.2
		(SD)	(8.2)	(7.95)	(7.66)	(5.77)	(8.05)	(7.38)	(8.51)	(7.95)
		Median	65.0	0.0	67.0	0.0	59.0	-8.0	65.0	-2.0
		Min,	48.0,	-24.0,	54.0,	-13.0,	48.0,	-24.0,	48.0,	-24.0,
		Max	87.0	15.0	94.0	15.0	92.0	15.0	94.0	15.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Pulse Rate (beats/min)										
	Day 6	n	77	77	41	41	39	39	157	157
		Mean	61.1	-5.5	63.1	-4.3	55.3	-12.3	60.2	-6.9
		(SD)	(8.39)	(8.31)	(7.82)	(6.66)	(6.42)	(7.61)	(8.28)	(8.32)
		Median	59.0	-6.0	63.0	-5.0	55.0	-11.0	60.0	-8.0
		Min,	42.0,	-27.0,	48.0,	-17.0,	43.0,	-31.0,	42.0,	-31.0,
		Max	81.0	13.0	80.0	18.0	66.0	4.0	81.0	18.0
	Day 30	n	77	77	41	41	38	38	156	156
		Mean	65.4	-1.1	66.6	-0.8	64.5	-3.2	65.5	-1.6
		(SD)	(7.75)	(7.95)	(7.11)	(8.42)	(6.62)	(6.92)	(7.32)	(7.85)
		Median	64.0	0.0	65.0	0.0	65.0	-2.5	65.0	-1.0
		Min,	53.0,	-31.0,	54.0,	-18.0,	48.0,	-22.0,	48.0,	-31.0,
		Max	87.0	20.0	83.0	16.0	77.0	7.0	87.0	20.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Pulse Rate (beats/min)										
	Day 60	n	77	77	41	41	39	39	157	157
		Mean	63.8	-2.8	65.9	-1.5	62.7	-5.0	64.1	-3.0
		(SD)	(8.24)	(8.46)	(6.57)	(8.09)	(6.84)	(6.11)	(7.55)	(7.9)
		Median	64.0	-2.0	65.0	-1.0	62.0	-5.0	64.0	-3.0
		Min,	49.0,	-38.0,	48.0,	-21.0,	50.0,	-18.0,	48.0,	-38.0,
		Max	92.0	25.0	81.0	11.0	77.0	10.0	92.0	25.0
	Day 91	n	77	77	41	41	38	38	156	156
		Mean	57.9	-8.7	59.1	-8.3	60.7	-7.0	58.9	-8.2
		(SD)	(6.78)	(7.53)	(7.55)	(9.46)	(7.01)	(5.84)	(7.09)	(7.71)
		Median	58.0	-8.0	58.0	-10.0	60.5	-6.5	59.0	-8.0
		Min,	46.0,	-36.0,	46.0,	-24.0,	42.0,	-18.0,	42.0,	-36.0,
		Max	74.0	8.0	81.0	17.0	79.0	7.0	81.0	17.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Respiratory Rate (breaths/min)										
	Baseline	n	78		42		40		160	
		Mean	16.8		17.1		17.0		16.9	
		(SD)	(1.7)		(1.8)		(1.77)		(1.74)	
		Median	16.0		16.5		16.0		16.0	
		Min,	15.0,		15.0,		15.0,		15.0,	
		Max	20.0		20.0		20.0		20.0	
	Day 1	n	78	78	42	42	40	40	160	160
		Mean	16.8	-0.0	17.0	-0.1	16.8	-0.1	16.9	-0.1
		(SD)	(1.67)	(2.31)	(1.72)	(2.17)	(1.64)	(2.36)	(1.67)	(2.27)
		Median	16.0	0.0	16.5	0.0	16.0	0.0	16.0	0.0
		Min,	15.0,	-5.0,	15.0,	-5.0,	15.0,	-4.0,	15.0,	-5.0,
		Max	20.0	5.0	20.0	5.0	20.0	5.0	20.0	5.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		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	41	41	40	40	158	158
		Mean	16.7	-0.1	16.1	-1.0	16.5	-0.4	16.5	-0.4
		(SD)	(1.67)	(2.16)	(1.43)	(1.77)	(1.93)	(2.43)	(1.69)	(2.16)
		Median	16.0	0.0	16.0	0.0	16.0	0.0	16.0	0.0
		Min,	15.0,	-5.0,	15.0,	-5.0,	10.0,	-6.0,	10.0,	-6.0,
		Max	20.0	5.0	20.0	2.0	20.0	5.0	20.0	5.0
	Day 3	n	77	77	41	41	40	40	158	158
		Mean	16.9	0.1	16.6	-0.6	17.1	0.1	16.8	-0.1
		(SD)	(1.72)	(1.98)	(1.77)	(2.42)	(1.76)	(2.54)	(1.74)	(2.25)
		Median	16.0	0.0	16.0	0.0	17.0	0.0	16.0	0.0
		Min,	15.0,	-5.0,	15.0,	-5.0,	15.0,	-5.0,	15.0,	-5.0,
		Max	20.0	4.0	20.0	4.0	20.0	5.0	20.0	5.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Respiratory Rate (breaths/min)										
	Day 4	n	77	77	41	41	39	39	157	157
		Mean	16.6	-0.2	16.4	-0.7	16.8	-0.2	16.6	-0.3
		(SD)	(1.57)	(2.04)	(1.66)	(2.11)	(1.67)	(2.34)	(1.62)	(2.14)
		Median	16.0	0.0	16.0	0.0	16.0	0.0	16.0	0.0
		Min,	15.0,	-5.0,	15.0,	-5.0,	15.0,	-4.0,	15.0,	-5.0,
		Max	20.0	4.0	20.0	4.0	20.0	5.0	20.0	5.0
	Day 5	n	77	77	41	41	39	39	157	157
		Mean	16.6	-0.2	16.6	-0.6	17.2	0.2	16.7	-0.2
		(SD)	(1.72)	(2.18)	(1.74)	(2.43)	(1.78)	(2.53)	(1.74)	(2.34)
		Median	16.0	0.0	16.0	0.0	16.0	0.0	16.0	0.0
		Min,	12.0,	-5.0,	15.0,	-5.0,	15.0,	-4.0,	12.0,	-5.0,
		Max	20.0	5.0	20.0	3.0	20.0	5.0	20.0	5.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Respiratory Rate (breaths/min)										
	Day 6	n	77	77	41	41	39	39	157	157
		Mean	17.0	0.1	16.6	-0.5	17.0	0.0	16.9	-0.1
		(SD)	(1.71)	(2.45)	(1.58)	(2.26)	(1.55)	(2.17)	(1.64)	(2.34)
		Median	16.0	0.0	16.0	0.0	17.0	0.0	16.0	0.0
		Min,	15.0,	-5.0,	15.0,	-4.0,	15.0,	-5.0,	15.0,	-5.0,
		Max	20.0	5.0	20.0	3.0	20.0	4.0	20.0	5.0
	Day 30	n	77	77	41	41	38	38	156	156
		Mean	17.0	0.2	17.0	-0.1	16.6	-0.3	16.9	-0.0
		(SD)	(1.47)	(2.26)	(1.65)	(2.05)	(1.2)	(2.22)	(1.46)	(2.2)
		Median	16.0	0.0	17.0	0.0	16.0	0.0	16.0	0.0
		Min,	15.0,	-5.0,	15.0,	-4.0,	15.0,	-5.0,	15.0,	-5.0,
		Max	20.0	4.0	20.0	4.0	20.0	4.0	20.0	4.0

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 15.2.6.20 Summary of Supine Vital Signs - Safety Population**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Respiratory Rate (breaths/min)										
	Day 60	n	77	77	41	41	39	39	157	157
		Mean	16.8	0.0	16.4	-0.7	16.9	-0.1	16.8	-0.2
		(SD)	(1.65)	(2.3)	(1.4)	(1.99)	(1.53)	(2.02)	(1.56)	(2.17)
		Median	16.0	0.0	16.0	-1.0	16.0	0.0	16.0	0.0
		Min,	15.0,	-5.0,	15.0,	-4.0,	15.0,	-4.0,	15.0,	-5.0,
		Max	20.0	5.0	20.0	4.0	20.0	4.0	20.0	5.0
	Day 91	n	77	77	41	41	38	38	156	156
		Mean	16.9	0.1	17.0	-0.1	16.3	-0.6	16.8	-0.2
		(SD)	(1.69)	(2.52)	(1.74)	(2.1)	(1.23)	(2.12)	(1.62)	(2.32)
		Median	16.0	0.0	16.0	0.0	16.0	0.0	16.0	0.0
		Min,	15.0,	-5.0,	15.0,	-4.0,	15.0,	-5.0,	15.0,	-5.0,
		Max	20.0	5.0	20.0	5.0	20.0	4.0	20.0	5.0

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 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation	Baseline	n	78	42	40	160
		Normal	75 (96.2%)	34 (81.0%)	36 (90.0%)	145 (90.6%)
		Abnormal NCS	3 (3.8%)	8 (19.0%)	4 (10.0%)	15 (9.4%)
		Abnormal CS	0	0	0	0
	Day 6	n	78	42	40	160
		Normal	70 (89.7%)	36 (85.7%)	37 (92.5%)	143 (89.4%)
		Abnormal NCS	8 (10.3%)	6 (14.3%)	3 (7.5%)	17 (10.6%)
		Abnormal CS	0	0	0	0
	Day 30	n	77	41	38	156
		Normal	67 (87.0%)	32 (78.0%)	38 (100%)	137 (87.8%)
		Abnormal NCS	10 (13.0%)	9 (22.0%)	0	19 (12.2%)
		Abnormal CS	0	0	0	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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation	Day 60	n	77	41	39	157
		Normal	69 (89.6%)	35 (85.4%)	37 (94.9%)	141 (89.8%)
		Abnormal NCS	8 (10.4%)	6 (14.6%)	2 (5.1%)	16 (10.2%)
		Abnormal CS	0	0	0	0
	Day 91	n	77	41	38	156
		Normal	70 (90.9%)	33 (80.5%)	36 (94.7%)	139 (89.1%)
		Abnormal NCS	7 (9.1%)	8 (19.5%)	2 (5.3%)	17 (10.9%)
		Abnormal CS	0	0	0	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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Heart Rate (Beats/min)	Baseline	n	78		42		40		160	
		Mean	56.6		58.9		56.4		57.1	
		(SD)	7.74		7.39		6.96		7.49	
		Median	55.5		58.0		56.0		57.0	
		Min,	40		43		42		40	
		Max	78		76		75		78	
	Day 6	n	78	78	42	42	40	40	160	160
		Mean	58.0	1.4	59.5	0.6	53.6	-2.8	57.3	0.1
		(SD)	7.81	6.87	6.79	8.33	6.35	6.84	7.50	7.42
		Median	57.0	1.5	59.0	0.5	53.5	-3.0	57.0	0.0
		Min,	40	-21	48	-13	42	-14	40	-21
		Max	77	17	78	32	66	10	78	32

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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		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	41	41	38	38	156	156
		Mean	62.2	5.5	65.0	6.2	62.3	6.3	63.0	5.9
		(SD)	6.58	6.68	6.69	7.14	6.48	8.52	6.66	7.25
		Median	61.0	6.0	65.0	5.0	62.0	7.0	62.0	6.0
		Min,	51	-25	50	-9	48	-15	48	-25
		Max	83	23	85	25	74	23	85	25
	Day 60	n	77	77	41	41	39	39	157	157
		Mean	61.2	4.5	63.2	4.4	61.8	5.6	61.9	4.8
		(SD)	7.70	7.33	7.06	5.18	7.06	6.24	7.38	6.54
		Median	62.0	4.0	63.0	5.0	61.0	6.0	62.0	5.0
		Min,	45	-25	46	-7	44	-8	44	-25
		Max	80	21	83	13	79	23	83	23

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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Heart Rate (Beats/min)	Day 91	n	77	77	41	41	38	38	156	156
		Mean	55.8	-0.9	57.5	-1.2	60.2	4.1	57.3	0.3
		(SD)	5.86	7.24	6.92	7.58	7.40	7.64	6.75	7.71
		Median	55.0	0.0	58.0	-1.0	60.0	4.0	57.0	1.0
		Min,	47	-28	46	-16	44	-11	44	-28
		Max	72	14	73	12	82	22	82	22
PR Duration (msec)	Baseline	n	78		42		40		160	
		Mean	162.5		162.6		161.6		162.3	
		(SD)	18.32		24.40		18.18		19.93	
		Median	160.0		158.0		164.0		160.0	
		Min,	128		126		116		116	
		Max	208		250		196		250	

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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
PR Duration (msec)	Day 6	n	78	78	42	42	40	40	160	160
		Mean	164.7	2.2	162.8	0.2	162.6	1.0	163.7	1.4
		(SD)	18.75	11.13	20.54	12.72	21.67	12.49	19.88	11.86
		Median	165.0	2.0	160.0	2.0	166.0	2.0	162.0	2.0
		Min,	122	-28	122	-58	118	-40	118	-58
		Max	210	28	208	16	200	38	210	38
	Day 30	n	77	77	41	41	38	38	156	156
		Mean	158.7	-3.8	161.8	-1.0	159.7	-1.6	159.8	-2.5
		(SD)	18.19	10.36	20.37	12.37	15.22	12.47	18.06	11.44
		Median	160.0	-4.0	164.0	-2.0	162.0	-3.0	161.0	-4.0
		Min,	120	-30	122	-56	114	-26	114	-56
		Max	204	30	208	20	186	38	208	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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
PR Duration (msec)	Day 60	n	77	77	41	41	39	39	157	157
		Mean	160.8	-1.7	158.8	-4.0	156.9	-4.7	159.3	-3.1
		(SD)	18.53	12.26	20.81	11.39	17.26	14.37	18.80	12.59
		Median	160.0	-2.0	160.0	-4.0	160.0	-4.0	160.0	-2.0
		Min,	126	-32	118	-54	114	-58	114	-58
		Max	208	36	196	18	188	20	208	36
	Day 91	n	77	77	41	41	38	38	156	156
		Mean	159.0	-3.6	158.6	-4.2	154.6	-6.7	157.8	-4.5
		(SD)	18.55	12.31	19.29	12.86	14.59	11.05	17.86	12.16
		Median	156.0	-4.0	156.0	-2.0	159.0	-6.0	157.0	-4.0
		Min,	120	-34	116	-62	112	-26	112	-62
		Max	200	38	194	16	178	32	200	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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QT Duration (msec)	Baseline	n	78		42		40		160	
		Mean	426.4		419.3		429.9		425.4	
		(SD)	32.38		24.91		25.50		29.03	
		Median	424.0		417.0		430.0		423.0	
		Min,	356		380		380		356	
		Max	508		476		492		508	
	Day 6	n	78	78	42	42	40	40	160	160
		Mean	418.5	-7.9	411.5	-7.8	434.7	4.9	420.7	-4.7
		(SD)	28.08	18.68	22.64	19.96	22.72	18.77	26.74	19.72
		Median	417.0	-6.0	413.0	-5.0	430.0	8.0	420.0	-4.0
		Min,	358	-56	366	-56	394	-36	358	-56
		Max	500	32	472	28	486	36	500	36

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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QT Duration (msec)	Day 30	n	77	77	41	41	38	38	156	156
		Mean	404.6	-21.8	398.5	-21.1	409.4	-21.5	404.2	-21.6
		(SD)	25.24	18.68	19.66	16.81	24.40	20.93	23.86	18.67
		Median	402.0	-24.0	400.0	-22.0	407.0	-27.0	402.0	-23.0
		Min,	342	-80	362	-56	368	-58	342	-80
		Max	470	48	438	8	480	24	480	48
	Day 60	n	77	77	41	41	39	39	157	157
		Mean	403.9	-22.5	401.4	-18.2	410.5	-19.6	404.9	-20.6
		(SD)	26.29	20.19	22.73	16.35	25.67	17.73	25.32	18.63
		Median	404.0	-22.0	404.0	-18.0	414.0	-20.0	404.0	-22.0
		Min,	350	-76	364	-62	358	-48	350	-76
		Max	486	46	446	18	494	20	494	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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QT Duration (msec)	Day 91	n	77	77	41	41	38	38	156	156
		Mean	416.5	-9.9	411.0	-8.6	409.0	-21.9	413.2	-12.5
		(SD)	27.58	21.06	22.21	20.25	25.77	21.15	25.88	21.43
		Median	414.0	-8.0	410.0	-12.0	401.0	-18.0	411.0	-12.0
		Min,	362	-62	368	-44	374	-80	362	-80
		Max	484	40	462	40	480	16	484	40
QTcB - Bazett's Correction Formula (msec)	Baseline	n	78		42		40		160	
		Mean	413.26		414.40		416.13		414.28	
		(SD)	21.833		19.872		19.055		20.570	
		Median	413.50		416.00		415.50		415.00	
		Min,	362.0		361.0		376.0		361.0	
		Max	446.0		446.0		447.0		447.0	

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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QTcB - Bazett's Correction Formula (msec)	Day 6	n	78	78	42	42	40	40	160	160
		Mean	410.68	-2.58	409.19	-5.21	410.45	-5.68	410.23	-4.04
		(SD)	24.545	14.383	20.121	15.116	17.951	12.735	21.808	14.176
		Median	408.50	-1.00	408.50	-4.50	410.50	-5.50	409.00	-2.00
		Min,	347.0	-36.0	366.0	-34.0	381.0	-38.0	347.0	-38.0
		Max	454.0	27.0	446.0	48.0	449.0	23.0	454.0	48.0
	Day 30	n	77	77	41	41	38	38	156	156
		Mean	411.79	-1.53	414.80	0.41	416.89	0.71	413.83	-0.47
		(SD)	21.991	13.893	21.066	12.502	16.893	16.779	20.601	14.258
		Median	409.00	-2.00	417.00	1.00	415.50	0.00	414.50	-1.00
		Min,	367.0	-32.0	358.0	-24.0	387.0	-39.0	358.0	-39.0
		Max	464.0	32.0	460.0	37.0	446.0	39.0	464.0	39.0

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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QTcB - Bazett's Correction Formula (msec)	Day 60	n	77	77	41	41	39	39	157	157
		Mean	407.32	-6.00	411.63	-2.76	416.46	0.54	410.72	-3.53
		(SD)	21.417	14.962	21.590	14.896	18.496	13.900	20.987	14.844
		Median	409.00	-6.00	412.00	-4.00	417.00	2.00	411.00	-4.00
		Min,	357.0	-46.0	357.0	-34.0	374.0	-34.0	357.0	-46.0
		Max	448.0	35.0	451.0	41.0	447.0	35.0	451.0	41.0
	Day 91	n	77	77	41	41	38	38	156	156
		Mean	401.56	-11.77	402.37	-12.02	409.21	-6.97	403.63	-10.67
		(SD)	22.489	12.344	20.115	14.681	19.123	17.488	21.210	14.414
		Median	402.00	-11.00	401.00	-13.00	410.50	-5.50	404.00	-10.00
		Min,	352.0	-52.0	356.0	-38.0	364.0	-52.0	352.0	-52.0
		Max	449.0	16.0	444.0	24.0	447.0	39.0	449.0	39.0

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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QTcF - Fridericia's Correction										
Formula (msec)	Baseline	n	78		42		40		160	
		Mean	416.39		415.22		419.56		416.87	
		(SD)	22.040		18.056		17.410		19.907	
		Median	414.91		413.40		421.87		417.16	
		Min,	367.8		377.5		383.8		367.8	
		Max	464.9		450.9		446.0		464.9	
	Day 6	n	78	78	42	42	40	40	160	160
		Mean	412.20	-4.19	409.20	-6.02	417.44	-2.12	412.72	-4.15
		(SD)	22.027	10.892	18.026	10.908	15.565	8.995	19.677	10.486
		Median	410.04	-3.85	407.13	-5.56	416.62	-0.95	411.00	-3.74
		Min,	354.7	-35.5	377.6	-26.9	392.9	-21.8	354.7	-35.5
		Max	460.9	20.8	450.2	16.6	444.8	15.8	460.9	20.8

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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		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	41	41	38	38	156	156
		Mean	408.49	-7.94	408.53	-6.80	413.56	-6.32	409.74	-7.25
		(SD)	20.913	11.079	18.320	8.923	16.912	12.067	19.341	10.770
		Median	405.04	-6.96	408.46	-5.45	410.07	-6.05	407.62	-6.50
		Min,	361.8	-34.5	359.8	-32.3	382.2	-27.6	359.8	-34.5
		Max	450.7	15.9	446.4	14.6	445.6	20.7	450.7	20.7
	Day 60	n	77	77	41	41	39	39	157	157
		Mean	405.17	-11.26	407.42	-7.92	413.41	-6.08	407.80	-9.10
		(SD)	19.841	12.198	19.300	12.831	17.909	11.247	19.410	12.266
		Median	404.11	-11.04	406.98	-8.80	412.87	-5.85	407.71	-9.84
		Min,	358.0	-52.9	363.0	-41.8	367.7	-38.3	358.0	-52.9
		Max	454.3	15.4	441.5	26.5	445.5	19.8	454.3	26.5

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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QTcF - Fridericia's Correction Formula (msec)	Day 91	n	77	77	41	41	38	38	156	156
		Mean	405.50	-10.93	404.11	-11.23	408.09	-11.79	405.77	-11.22
		(SD)	22.089	10.123	17.416	11.809	18.091	13.910	19.943	11.513
		Median	406.82	-11.84	402.99	-14.13	406.35	-10.26	404.70	-11.88
		Min,	365.8	-37.5	367.6	-31.0	369.9	-51.5	365.8	-51.5
		Max	452.4	12.3	448.8	20.8	442.4	25.9	452.4	25.9
QRS Duration (msec)	Baseline	n	78		42		40		160	
		Mean	94.3		94.1		93.5		94.1	
		(SD)	9.71		11.63		9.45		10.13	
		Median	92.0		92.0		93.0		92.0	
		Min,	74		78		72		72	
		Max	126		138		112		138	

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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QRS Duration (msec)	Day 6	n	78	78	42	42	40	40	160	160
		Mean	94.2	-0.1	94.0	-0.1	93.2	-0.4	93.9	-0.2
		(SD)	9.92	5.59	12.09	3.81	9.65	3.74	10.41	4.73
		Median	94.0	0.0	92.0	0.0	92.0	0.0	92.0	0.0
		Min,	74	-18	78	-8	76	-10	74	-18
		Max	122	26	138	14	116	6	138	26
	Day 30	n	77	77	41	41	38	38	156	156
		Mean	93.6	-0.7	93.6	-0.2	92.3	-1.0	93.3	-0.7
		(SD)	9.92	3.90	11.90	3.47	9.37	3.69	10.30	3.73
		Median	92.0	0.0	94.0	0.0	90.0	-1.0	92.0	0.0
		Min,	70	-12	76	-12	72	-10	70	-12
		Max	122	8	138	6	114	6	138	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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.21 Summary of ECG Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Visit Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QRS Duration (msec)	Day 60	n	77	77	41	41	39	39	157	157
		Mean	93.1	-1.2	93.4	-0.5	92.8	-1.0	93.1	-1.0
		(SD)	9.83	4.41	12.46	3.40	9.38	4.21	10.41	4.10
		Median	92.0	-2.0	92.0	0.0	92.0	0.0	92.0	0.0
		Min,	72	-14	76	-6	74	-12	72	-14
		Max	122	10	140	8	114	8	140	10
	Day 91	n	77	77	41	41	38	38	156	156
		Mean	93.5	-0.8	93.0	-0.8	92.3	-1.1	93.1	-0.9
		(SD)	10.30	4.35	13.04	4.52	9.80	4.51	10.91	4.41
		Median	92.0	0.0	90.0	-2.0	93.0	-2.0	92.0	-2.0
		Min,	72	-18	74	-14	72	-10	72	-18
		Max	122	8	140	8	112	8	140	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.

Note: Interpretation refers to the interpretation of the parameter results as normal, or abnormal; NCS = not clinically significant, CS = clinically significant.

**Table 15.2.6.22 Summary of Spirometry Results - Safety Population****Safety Time Period: Pre-randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
			Raw value	Raw value	Raw value	Raw value	Raw value
Clinically Significance (with bronchodilator)	Screening	n	78	42	40	15	175
		Normal	78 (100%)	42 (100%)	40 (100%)	15 (100%)	175 (100%)
Clinically Significance	Screening	n	78	42	40	15	175
		Normal	78 (100%)	42 (100%)	40 (100%)	15 (100%)	175 (100%)
	Day 0	n	78	42	40		160
		Normal	76 (97.4%)	41 (97.6%)	37 (92.5%)		154 (96.3%)
		Abnormal NCS	2 (2.6%)	1 (2.4%)	3 (7.5%)		6 (3.8%)

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: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Pre-randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
			Raw value	Raw value	Raw value	Raw value	Raw value
Best measured FEV1 value (with bronchodilator) (L)	Screening	n	78	42	40	15	175
		Mean	3.312	3.342	3.221	3.205	3.289
		SD	0.723	0.790	0.687	0.816	0.735
		Median	3.415	3.305	3.385	3.400	3.390
		Min	2.00	1.53	1.94	1.76	1.53
		Max	5.06	4.80	4.47	4.63	5.06
Best measured FEV1 value (L)	Screening	n	78	42	40	15	175
		Mean	3.210	3.234	3.114	3.062	3.181
		SD	0.709	0.762	0.638	0.755	0.707
		Median	3.275	3.250	3.190	3.180	3.230
		Min	1.83	1.51	1.88	1.64	1.51
		Max	4.77	4.53	4.23	4.45	4.77

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: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Pre-randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
			Raw value	Raw value	Raw value	Raw value	Raw value
Best measured FEV1 value (L)	Day 0	n	78	42	40		160
		Mean	3.187	3.216	3.085		3.169
		SD	0.711	0.767	0.663		0.712
		Median	3.280	3.225	3.260		3.260
		Min	1.82	1.52	1.74		1.52
		Max	4.84	4.53	4.06		4.84
Best measured FVC value (with bronchodilator) (L)	Screening	n	78	42	40	15	175
		Mean	3.913	3.922	3.887	4.135	3.928
		SD	0.798	0.858	0.782	1.038	0.826
		Median	4.005	3.915	3.970	4.140	3.980
		Min	2.24	2.02	2.53	2.46	2.02
		Max	5.72	5.29	5.63	5.52	5.72

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: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Pre-randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
			Raw value	Raw value	Raw value	Raw value	Raw value
Best measured FVC value (L)	Screening	n	78	42	40	15	175
		Mean	3.882	3.879	3.836	4.023	3.883
		SD	0.813	0.836	0.747	1.029	0.818
		Median	3.925	3.845	3.825	3.990	3.890
		Min	2.27	2.05	2.45	2.28	2.05
		Max	5.76	5.29	5.53	5.45	5.76
	Day 0	n	78	42	40		160
		Mean	3.884	3.919	3.818		3.877
		SD	0.792	0.836	0.779		0.797
		Median	3.930	3.920	3.875		3.885
		Min	2.26	2.14	2.38		2.14
		Max	5.86	5.54	5.48		5.86

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: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Pre-randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
			Raw value	Raw value	Raw value	Raw value	Raw value
Calculated ratio between FEV1/FVC (with bronchodilator) (RATIO)	Screening	n	78	42	40	15	175
		Mean	0.845	0.850	0.828	0.777	0.836
		SD	0.057	0.057	0.050	0.068	0.059
		Median	0.840	0.850	0.830	0.780	0.830
		Min	0.73	0.73	0.71	0.70	0.70
		Max	0.96	0.99	0.92	0.89	0.99
Calculated ratio between FEV1/FVC (RATIO)	Screening	n	78	42	40	15	175
		Mean	0.827	0.831	0.811	0.766	0.819
		SD	0.063	0.060	0.059	0.089	0.066
		Median	0.820	0.830	0.820	0.730	0.820
		Min	0.71	0.74	0.69	0.66	0.66
		Max	1.00	0.98	0.92	0.94	1.00

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: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Pre-randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
			Raw value	Raw value	Raw value	Raw value	Raw value
Percent of predicted FEV1 value (with bronchodilator) (%)	Screening	n	78	42	40	15	175
		Mean	97.74	97.82	96.12	93.73	97.04
		SD	7.83	9.81	9.09	8.27	8.68
		Median	97.45	97.05	95.65	95.20	97.00
		Min	81.7	84.0	80.1	80.8	80.1
		Max	118.4	122.7	119.0	108.4	122.7
Percent of predicted FEV1 value (%)	Screening	n	78	42	40	15	175
		Mean	94.71	94.70	93.22	89.71	93.94
		SD	8.02	9.19	10.35	8.65	8.97
		Median	95.30	95.05	93.20	89.30	93.80
		Min	79.2	75.7	72.7	78.4	72.7
		Max	115.3	112.8	121.0	106.0	121.0

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: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Pre-randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
			Raw value	Raw value	Raw value	Raw value	Raw value
Percent of predicted FEV1 value (%)	Day 0	n	78	42	40		160
		Mean	93.92	94.05	92.10		93.50
		SD	7.34	8.88	9.80		8.40
		Median	93.00	93.75	91.40		93.05
		Min	81.9	76.0	74.4		74.4
		Max	115.6	117.2	113.2		117.2
Percent of predicted FVC value (with bronchodilator) (%)	Screening	n	78	42	40	15	175
		Mean	100.47	99.89	100.98	103.68	100.72
		SD	9.46	10.09	10.11	10.64	9.83
		Median	100.55	98.80	99.65	101.80	99.70
		Min	80.2	84.2	86.3	85.1	80.2
		Max	120.9	127.0	128.3	121.8	128.3

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: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Pre-randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
			Raw value	Raw value	Raw value	Raw value	Raw value
Percent of predicted FVC value (%)	Screening	n	78	42	40	15	175
		Mean	99.66	98.88	99.76	100.81	99.60
		SD	10.35	9.94	9.70	10.97	10.09
		Median	99.85	96.45	98.45	100.30	99.00
		Min	81.3	77.8	85.1	76.8	76.8
		Max	121.0	119.8	125.5	120.8	125.5
	Day 0	n	78	42	40		160
		Mean	99.85	99.95	99.20		99.71
		SD	10.39	10.20	10.29		10.25
		Median	99.25	96.40	98.30		98.40
		Min	81.0	84.6	83.7		81.0
		Max	124.9	125.9	123.4		125.9

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: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Clinically Significance (with bronchodilator)	Baseline	n	78	42	40	160
		Normal	78 (100%)	42 (100%)	40 (100%)	160 (100%)
Clinically Significance	Baseline	n	78	42	40	160
		Normal	76 (97.4%)	41 (97.6%)	37 (92.5%)	154 (96.3%)
		Abnormal NCS	2 (2.6%)	1 (2.4%)	3 (7.5%)	6 (3.8%)
	Day 6	n	78	42	40	160
		Normal	77 (98.7%)	40 (95.2%)	38 (95.0%)	155 (96.9%)
		Abnormal NCS	1 (1.3%)	2 (4.8%)	2 (5.0%)	5 (3.1%)
	Day 91	n	78	42	40	160
		Normal	78 (100%)	41 (97.6%)	39 (97.5%)	158 (98.8%)
		Abnormal NCS		1 (2.4%)	1 (2.5%)	2 (1.3%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Best measured FEV1 value (with bronchodilator) (L)	Baseline	n	78	42	40	160
		Mean	3.312	3.342	3.221	3.297
		SD	0.723	0.790	0.687	0.730
		Median	3.415	3.305	3.385	3.385
		Min	2.00	1.53	1.94	1.53
		Max	5.06	4.80	4.47	5.06
Best measured FEV1 value (L)	Baseline	n	78	42	40	160
		Mean	3.187	3.216	3.085	3.169
		SD	0.711	0.767	0.663	0.712
		Median	3.280	3.225	3.260	3.260
		Min	1.82	1.52	1.74	1.52
		Max	4.84	4.53	4.06	4.84

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Best measured FEV1 value (L)	Day 6	n	78	78	42	42	40	40	160	160
		Mean	3.271	0.084	3.268	0.052	3.169	0.084	3.245	0.076
		SD	0.683	0.148	0.729	0.157	0.665	0.211	0.688	0.168
		Median	3.320	0.085	3.260	0.050	3.215	0.125	3.270	0.080
		Min	1.98	-0.19	1.65	-0.37	1.90	-0.53	1.65	-0.53
		Max	4.69	0.57	4.43	0.57	4.18	0.53	4.69	0.57
	Day 91	n	77	77	41	41	39	39	157	157
		Mean	3.218	0.038	3.159	-0.029	3.148	0.039	3.185	0.021
		SD	0.676	0.168	0.731	0.208	0.672	0.184	0.686	0.184
		Median	3.330	0.050	3.140	-0.010	3.300	0.050	3.290	0.040
		Min	1.94	-0.46	1.64	-0.52	1.57	-0.54	1.57	-0.54
		Max	4.58	0.42	4.45	0.49	4.12	0.46	4.58	0.49

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Best measured FVC value (with bronchodilator) (L)	Baseline	n	78	42	40	160
		Mean	3.913	3.922	3.887	3.909
		SD	0.798	0.858	0.782	0.805
		Median	4.005	3.915	3.970	3.960
		Min	2.24	2.02	2.53	2.02
		Max	5.72	5.29	5.63	5.72
Best measured FVC value (L)	Baseline	n	78	42	40	160
		Mean	3.884	3.919	3.818	3.877
		SD	0.792	0.836	0.779	0.797
		Median	3.930	3.920	3.875	3.885
		Min	2.26	2.14	2.38	2.14
		Max	5.86	5.54	5.48	5.86

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Best measured FVC value (L)	Day 6	n	78	78	42	42	40	40	160	160
		Mean	3.921	0.037	3.926	0.007	3.894	0.076	3.916	0.039
		SD	0.744	0.155	0.767	0.163	0.779	0.202	0.754	0.171
		Median	3.920	0.030	3.915	0.040	3.955	0.085	3.930	0.040
		Min	2.37	-0.43	2.40	-0.39	2.52	-0.60	2.37	-0.60
		Max	5.46	0.43	5.21	0.28	5.71	0.57	5.71	0.57
	Day 91	n	77	77	41	41	39	39	157	157
		Mean	3.916	0.042	3.903	0.002	3.893	0.049	3.907	0.033
		SD	0.759	0.205	0.822	0.247	0.774	0.228	0.774	0.222
		Median	3.920	0.040	3.890	-0.010	3.960	0.080	3.930	0.050
		Min	2.35	-0.59	2.34	-0.57	2.19	-0.62	2.19	-0.62
		Max	5.38	0.51	5.22	0.56	5.46	0.67	5.46	0.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Calculated ratio between FEV1/FVC (with bronchodilator) (RATIO)	Baseline	n	78	42	40	160
		Mean	0.845	0.850	0.828	0.842
		SD	0.057	0.057	0.050	0.056
		Median	0.840	0.850	0.830	0.840
		Min	0.73	0.73	0.71	0.71
		Max	0.96	0.99	0.92	0.99
Calculated ratio between FEV1/FVC (RATIO)	Baseline	n	78	42	40	160
		Mean	0.827	0.831	0.811	0.824
		SD	0.063	0.060	0.059	0.061
		Median	0.820	0.830	0.820	0.820
		Min	0.71	0.74	0.69	0.69
		Max	1.00	0.98	0.92	1.00

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Percent of predicted FEV1 value (with bronchodilator) (%)	Baseline	n	78	42	40	160
		Mean	97.74	97.82	96.12	97.35
		SD	7.83	9.81	9.09	8.68
		Median	97.45	97.05	95.65	97.00
		Min	81.7	84.0	80.1	80.1
		Max	118.4	122.7	119.0	122.7
Percent of predicted FEV1 value (%)	Baseline	n	78	42	40	160
		Mean	93.92	94.05	92.10	93.50
		SD	7.34	8.88	9.80	8.40
		Median	93.00	93.75	91.40	93.05
		Min	81.9	76.0	74.4	74.4
		Max	115.6	117.2	113.2	117.2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Percent of predicted FEV1 value (%)	Day 6	n	78	78	42	42	40	40	160	160
		Mean	96.88	2.96	95.98	1.93	94.85	2.76	96.14	2.64
		SD	7.80	4.60	9.43	4.43	11.19	6.48	9.15	5.08
		Median	96.40	2.75	96.25	1.60	93.05	3.80	96.10	2.70
		Min	81.5	-6.3	78.3	-8.4	72.7	-13.5	72.7	-13.5
		Max	119.7	15.2	121.9	14.4	117.7	17.6	121.9	17.6
	Day 91	n	77	77	41	41	39	39	157	157
		Mean	95.45	1.47	93.46	-0.56	93.80	1.25	94.52	0.89
		SD	7.92	5.02	11.12	6.30	11.53	5.50	9.77	5.53
		Median	95.00	1.40	91.70	-0.30	92.50	1.50	94.00	1.10
		Min	81.4	-13.6	68.9	-16.3	71.1	-14.9	68.9	-16.3
		Max	117.7	15.2	124.3	12.3	119.0	15.7	124.3	15.7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Percent of predicted FVC value (with bronchodilator) (%)	Baseline	n	78	42	40	160
		Mean	100.47	99.89	100.98	100.44
		SD	9.46	10.09	10.11	9.74
		Median	100.55	98.80	99.65	99.65
		Min	80.2	84.2	86.3	80.2
		Max	120.9	127.0	128.3	128.3
Percent of predicted FVC value (%)	Baseline	n	78	42	40	160
		Mean	99.85	99.95	99.20	99.71
		SD	10.39	10.20	10.29	10.25
		Median	99.25	96.40	98.30	98.40
		Min	81.0	84.6	83.7	81.0
		Max	124.9	125.9	123.4	125.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 Spirometry Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Percent of predicted FVC value (%)	Day 6	n	78	78	42	42	40	40	160	160
		Mean	101.11	1.26	100.64	0.69	101.39	2.19	101.05	1.34
		SD	10.88	4.09	11.05	4.34	11.62	5.07	11.05	4.42
		Median	101.25	0.75	99.45	0.85	98.90	2.55	100.10	1.00
		Min	82.3	-8.8	85.9	-8.4	83.4	-12.6	82.3	-12.6
		Max	124.1	12.5	131.4	11.6	125.0	13.1	131.4	13.1
	Day 91	n	77	77	41	41	39	39	157	157
		Mean	101.19	1.34	100.46	0.27	100.88	1.33	100.92	1.06
		SD	11.13	5.07	12.04	6.30	11.19	5.79	11.32	5.57
		Median	101.00	1.00	98.40	-0.30	101.10	2.60	100.60	1.00
		Min	81.7	-12.1	81.3	-15.0	78.6	-14.8	78.6	-15.0
		Max	130.6	11.8	133.2	12.4	123.4	15.4	133.2	15.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS=Not 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 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Head, Eyes, Ears, Nose, Throat	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 6	Normal – n(%)	78 (100)	42 (100)	38 (95.0)	158 (98.8)
		Normal to Normal – n(%)	78 (100)	42 (100)	38 (95.0)	158 (98.8)
		Abnormal NCS – n(%)	0	0	1 (2.5)	1 (0.6)
		Normal to Abnormal NCS – n(%)	0	0	1 (2.5)	1 (0.6)
		Abnormal CS – n(%)	0	0	1 (2.5)	1 (0.6)
		Normal to Abnormal CS – n(%)	0	0	1 (2.5)	1 (0.6)
	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Head, Eyes, Ears, Nose, Throat	Day 60	Normal – n(%)	76 (97.4)	40 (95.2)	39 (97.5)	155 (96.9)
		Normal to Normal – n(%)	76 (97.4)	40 (95.2)	39 (97.5)	155 (96.9)
		Abnormal NCS – n(%)	0	1 (2.4)	0	1 (0.6)
		Normal to Abnormal NCS – n(%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS – n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Abnormal CS – n(%)	1 (1.3)	0	0	1 (0.6)
	Day 91	Normal – n(%)	76 (97.4)	40 (95.2)	38 (95.0)	154 (96.3)
		Normal to Normal – n(%)	76 (97.4)	40 (95.2)	38 (95.0)	154 (96.3)
		Abnormal NCS – n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Normal to Abnormal NCS – n(%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Abnormal CS – n(%)	0	0	0	0
	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Thyroid Gland	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Thyroid Gland	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
Heart	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Heart	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Chest	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Chest	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
Lungs	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lungs	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Lungs	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
Gastrointestinal	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Gastrointestinal	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cardiovascular System	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Cardiovascular System	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
Neurologic	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neurologic	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Neurologic	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
Skin	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Skin	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Back	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Back	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
Musculoskeletal	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Musculoskeletal	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	1 (2.5)	1 (0.6)
		Normal to Abnormal CS – n(%)	0	0	1 (2.5)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Musculoskeletal	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
Abdomen	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 6	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	1 (2.4)	1 (2.5)	2 (1.3)
		Normal to Abnormal NCS – n(%)	0	1 (2.4)	1 (2.5)	2 (1.3)
		Abnormal CS – n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Abnormal 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; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Abdomen	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 60	Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	39 (97.5)	157 (98.1)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 91	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Dentition	Baseline	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 6	Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Normal to Normal – n(%)	78 (100)	42 (100)	40 (100)	160 (100)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 30	Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Normal to Normal – n(%)	77 (98.7)	41 (97.6)	38 (95.0)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Dentition	Day 60	Normal – n(%)	76 (97.4)	41 (97.6)	39 (97.5)	156 (97.5)
		Normal to Normal – n(%)	76 (97.4)	41 (97.6)	39 (97.5)	156 (97.5)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Abnormal CS – n(%)	1 (1.3)	0	0	1 (0.6)
	Day 91	Normal – n(%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		Normal to Normal – n(%)	76 (97.4)	41 (97.6)	38 (95.0)	155 (96.9)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	1 (1.3)	0	0	1 (0.6)
		Normal to Abnormal CS – n(%)	1 (1.3)	0	0	1 (0.6)
Other	Baseline	Normal – n(%)	1 (1.3)	1 (2.4)	1 (2.5)	3 (1.9)
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Other	Day 6	Normal – n(%)	0	0	0	0
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 30	Normal – n(%)	0	0	0	0
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0
	Day 60	Normal – n(%)	0	0	0	0
		Abnormal NCS – n(%)	0	0	0	0
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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 (N=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
Other	Day 91	Normal – n(%)	0	0	0	0
		Abnormal NCS – n(%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS – n(%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; CS=Clinically Significant; NCS=Not 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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Weight (kg)	Baseline	n	78		42		40		160	
		Mean	62.87		61.99		61.36		62.26	
		SD	10.976		10.228		11.090		10.765	
		Median	61.55		63.80		59.95		61.40	
		Min	45.1		43.4		43.7		43.4	
		Max	97.8		84.4		91.8		97.8	
	Day 6	n	78	78	42	42	40	40	160	160
		Mean	62.27	-0.59	61.87	-0.13	61.25	-0.10	61.91	-0.35
		SD	10.650	0.841	9.959	0.798	10.591	1.002	10.401	0.901
		Median	61.40	-0.60	63.30	-0.10	60.20	0.00	61.40	-0.30
		Min	44.8	-3.3	44.2	-1.6	43.4	-3.4	43.4	-3.4
		Max	94.5	1.4	84.4	1.7	88.4	1.4	94.5	1.7

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.

**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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Weight (kg)	Day 30	n	77	77	41	41	38	38	156	156
		Mean	62.98	0.39	62.55	0.54	63.01	1.18	62.88	0.62
		SD	10.795	1.139	10.500	0.999	11.243	1.367	10.761	1.202
		Median	62.00	0.40	63.00	0.50	62.55	1.25	62.40	0.60
		Min	45.1	-2.3	44.2	-1.4	44.6	-2.9	44.2	-2.9
		Max	95.6	3.2	84.9	2.5	88.9	3.4	95.6	3.4
	Day 60	n	77	77	41	41	39	39	157	157
		Mean	63.00	0.41	62.71	0.70	63.26	1.58	62.99	0.78
		SD	10.828	1.417	10.467	1.170	11.015	1.631	10.715	1.485
		Median	61.90	0.30	64.40	0.50	62.60	1.40	62.10	0.60
		Min	45.6	-3.2	43.8	-1.8	45.1	-2.8	43.8	-3.2
		Max	96.6	3.9	84.9	3.9	89.0	4.4	96.6	4.4

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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Weight (kg)	Day 91	n	77	77	41	41	38	38	156	156
		Mean	62.86	0.27	62.41	0.40	63.40	1.58	62.87	0.62
		SD	10.813	1.699	10.422	1.365	11.297	1.885	10.768	1.744
		Median	61.50	0.20	63.40	0.50	62.40	1.50	62.20	0.50
		Min	45.4	-3.7	44.5	-3.1	44.7	-3.5	44.5	-3.7
		Max	96.2	5.2	84.8	2.8	88.3	5.7	96.2	5.7
Body Mass Index (kg/m ²)	Baseline	n	78		42		40		160	
		Mean	22.85		22.44		22.48		22.65	
		SD	2.963		2.876		3.386		3.039	
		Median	22.40		21.90		21.30		21.90	
		Min	18.7		18.9		18.5		18.5	
		Max	32.7		28.4		31.8		32.7	

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.

**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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Body Mass Index (kg/m ²)	Day 6	n	78	78	42	42	40	40	160	160
		Mean	22.64	-0.21	22.40	-0.04	22.44	-0.04	22.53	-0.12
		SD	2.881	0.302	2.817	0.297	3.226	0.366	2.938	0.327
		Median	22.20	-0.20	21.70	0.00	21.25	0.00	21.85	-0.10
		Min	18.3	-1.1	18.8	-0.5	18.7	-1.2	18.3	-1.2
		Max	31.6	0.5	28.2	0.6	30.6	0.5	31.6	0.6
	Day 30	n	77	77	41	41	38	38	156	156
		Mean	22.91	0.14	22.71	0.20	23.00	0.42	22.88	0.22
		SD	2.905	0.415	2.918	0.378	3.503	0.502	3.046	0.441
		Median	22.50	0.10	21.90	0.20	21.85	0.50	22.25	0.20
		Min	18.2	-0.8	18.7	-0.5	18.2	-1.0	18.2	-1.0
		Max	31.9	1.1	29.0	0.9	30.8	1.3	31.9	1.3

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.

**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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Body Mass Index (kg/m ²)	Day 60	n	77	77	41	41	39	39	157	157
		Mean	22.93	0.16	22.77	0.26	23.11	0.57	22.93	0.29
		SD	2.950	0.502	2.880	0.442	3.407	0.612	3.035	0.541
		Median	22.50	0.10	22.00	0.20	22.00	0.50	22.20	0.20
		Min	18.4	-1.1	19.0	-0.7	18.5	-1.0	18.4	-1.1
		Max	32.3	1.5	29.0	1.5	31.4	1.8	32.3	1.8
	Day 91	n	77	77	41	41	38	38	156	156
		Mean	22.88	0.11	22.65	0.14	23.15	0.57	22.89	0.23
		SD	2.948	0.601	2.791	0.517	3.512	0.695	3.041	0.632
		Median	22.60	0.10	21.80	0.20	22.15	0.50	22.10	0.20
		Min	18.5	-1.2	18.6	-1.4	18.4	-1.2	18.4	-1.4
		Max	32.1	1.7	28.6	1.2	31.1	2.2	32.1	2.2

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=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Body Mass Index (Categ.)	Baseline	n	78	42	40	160
		Normal weight	60 (76.9%)	32 (76.2%)	32 (80.0%)	124 (77.5%)
		Overweight	17 (21.8%)	10 (23.8%)	7 (17.5%)	34 (21.3%)
		Obese	1 (1.3%)		1 (2.5%)	2 (1.3%)
	Day 6	n	78	42	40	160
		Underweight	1 (1.3%)			1 (0.6%)
		Normal weight	59 (75.6%)	32 (76.2%)	32 (80.0%)	123 (76.9%)
		Overweight	17 (21.8%)	10 (23.8%)	7 (17.5%)	34 (21.3%)
		Obese	1 (1.3%)		1 (2.5%)	2 (1.3%)

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.

**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=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Body Mass Index (Categ.)	Day 30	n	77	41	38	156
		Underweight	1 (1.3%)		1 (2.6%)	2 (1.3%)
		Normal weight	56 (72.7%)	32 (78.0%)	25 (65.8%)	113 (72.4%)
		Overweight	19 (24.7%)	9 (22.0%)	9 (23.7%)	37 (23.7%)
		Obese	1 (1.3%)		3 (7.9%)	4 (2.6%)
	Day 60	n	77	41	39	157
		Underweight	1 (1.3%)			1 (0.6%)
		Normal weight	57 (74.0%)	30 (73.2%)	28 (71.8%)	115 (73.2%)
		Overweight	18 (23.4%)	11 (26.8%)	8 (20.5%)	37 (23.6%)
		Obese	1 (1.3%)		3 (7.7%)	4 (2.5%)

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=78)	mCC (N=42)	SA (N=40)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Body Mass Index (Categ.)	Day 91	n	77	41	38	156
		Underweight			1 (2.6%)	1 (0.6%)
		Normal weight	57 (74.0%)	30 (73.2%)	26 (68.4%)	113 (72.4%)
		Overweight	19 (24.7%)	11 (26.8%)	8 (21.1%)	38 (24.4%)
		Obese	1 (1.3%)		3 (7.9%)	4 (2.6%)

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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Height (cm)	Baseline	n	78		42		40		160	
		Mean	165.47		166.05		165.00		165.51	
		SD	7.480		10.119		7.809		8.282	
		Median	165.50		166.00		165.00		165.50	
		Min	152.0		147.0		150.0		147.0	
		Max	184.0		188.0		180.0		188.0	
Waist Circumference (cm)	Baseline	n	78		42		40		160	
		Mean	86.8		90.6		85.1		87.4	
		SD	23.81		30.17		24.33		25.67	
		Median	81.5		79.5		77.5		79.5	
		Min	65		64		66		64	
		Max	174		172		167		174	

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=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Waist										
Circumference (cm)	Day 91	n	76	76	41	41	38	38	155	155
		Mean	80.0	-5.6	80.2	-10.8	80.6	-5.1	80.2	-6.8
		SD	8.75	20.46	7.24	28.40	9.70	21.01	8.58	22.92
		Median	78.0	-1.0	80.0	-1.0	78.0	1.0	78.0	-1.0
		Min	66	-96	67	-97	64	-90	64	-97
		Max	109	6	95	7	105	12	109	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 15.2.6.25 Summary of Cough Assessments Over Study - Safety Population****Safety Time Period: Pre-Randomization**

Variable	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Has subject experienced cough in the study period										
Yes	43 (55.1)	71	22 (52.4)	35	20 (50.0)	31	5 (33.3)	5	90 (51.4)	142
No	34 (43.6)	83	20 (47.6)	49	20 (50.0)	49	9 (60.0)	9	83 (47.4)	190
Missing	1 (1.3)	1	0	0	0	0	1 (6.7)	1	2 (1.1)	2
Intensity of cough										
n	43	0	22	0	20	0	5	0	90	0
Very mild	25 (58.1)	45	15 (68.2)	25	10 (50.0)	15	4 (80.0)	4	54 (60.0)	89
Mild	13 (30.2)	17	4 (18.2)	6	7 (35.0)	12	1 (20.0)	1	25 (27.8)	36
Moderate	3 (7.0)	7	3 (13.6)	4	2 (10.0)	3	0	0	8 (8.9)	14
Severe	2 (4.7)	2	0	0	1 (5.0)	1	0	0	3 (3.3)	3
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**

Variable	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Product Test (N=15)		Overall Safety (N=175)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Frequency of cough										
n	43	0	22	0	20	0	5	0	90	0
Rarely	18 (41.9)	32	11 (50.0)	19	6 (30.0)	8	4 (80.0)	4	39 (43.3)	63
Sometimes	21 (48.8)	34	10 (45.5)	15	12 (60.0)	20	1 (20.0)	1	44 (48.9)	70
Fairly often	3 (7.0)	4	1 (4.5)	1	2 (10.0)	3	0	0	6 (6.7)	8
Often	1 (2.3)	1	0	0	0	0	0	0	1 (1.1)	1
Almost always	0	0	0	0	0	0	0	0	0	0
Amount of sputum produced										
n	43	0	22	0	20	0	5	0	90	0
No sputum	22 (51.2)	38	14 (63.6)	20	7 (35.0)	12	5 (100)	5	48 (53.3)	75
A moderate amount of sputum	21 (48.8)	33	8 (36.4)	15	13 (65.0)	19	0	0	42 (46.7)	67
A larger amount of sputum	0	0	0	0	0	0	0	0	0	0
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: Randomized Period**

Variable	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Has subject experienced cough in the study period								
Yes	53 (67.9)	168	24 (57.1)	85	21 (52.5)	76	98 (61.3)	329
No	23 (29.5)	212	17 (40.5)	120	19 (47.5)	121	59 (36.9)	453
Missing	2 (2.6)	2	1 (2.4)	1	0	0	3 (1.9)	3
Intensity of cough								
n	53	0	24	0	21	0	98	0
Very mild	25 (47.2)	84	13 (54.2)	49	8 (38.1)	32	46 (46.9)	165
Mild	19 (35.8)	70	8 (33.3)	31	9 (42.9)	31	36 (36.7)	132
Moderate	9 (17.0)	14	3 (12.5)	5	4 (19.0)	13	16 (16.3)	32
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.

**Table 15.2.6.25 Summary of Cough Assessments Over Study - Safety Population****Safety Time Period: Randomized Period**

Variable	THSm2.2 (N=78)		mCC (N=42)		SA (N=40)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Frequency of cough								
n	53	0	24	0	21	0	98	0
Rarely	26 (49.1)	77	13 (54.2)	45	8 (38.1)	23	47 (48.0)	145
Sometimes	22 (41.5)	84	9 (37.5)	38	9 (42.9)	43	40 (40.8)	165
Fairly often	4 (7.5)	6	2 (8.3)	2	4 (19.0)	10	10 (10.2)	18
Often	1 (1.9)	1	0	0	0	0	1 (1.0)	1
Almost always	0	0	0	0	0	0	0	0
Amount of sputum produced								
n	53	0	24	0	21	0	98	0
No sputum	30 (56.6)	89	14 (58.3)	51	10 (47.6)	32	54 (55.1)	172
A moderate amount of sputum	23 (43.4)	79	10 (41.7)	34	11 (52.4)	44	44 (44.9)	157
A larger 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Pre-Randomization**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Has subject experienced cough in the study period assessed						
Day -1						
Yes	n (%)	32 (41.0)	17 (40.5)	16 (40.0)	5 (33.3)	70 (40.0)
No	n (%)	45 (57.7)	25 (59.5)	24 (60.0)	9 (60.0)	103 (58.9)
Missing	n (%)	1 (1.3)	0	0	1 (6.7)	2 (1.1)
Day 0						
Yes	n (%)	39 (50.0)	18 (42.9)	15 (37.5)	0	72 (41.1)
No	n (%)	38 (48.7)	24 (57.1)	25 (62.5)	0	87 (49.7)
Missing	n (%)	1 (1.3)	0	0	15 (100)	16 (9.1)

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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Pre-Randomization**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
VAS						
Day -1	n	32	17	16	5	70
	Mean (SD)	20.6 (22.98)	14.9 (16.24)	19.6 (20.66)	12.4 (21.25)	18.4 (20.63)
	Median	14.5	11.0	15.0	5.0	12.0
	Min, Max	0, 89	0, 58	0, 76	0, 50	0, 89
Day 0	n	39	18	15	0	72
	Mean (SD)	20.1 (23.39)	15.3 (18.98)	17.2 (19.61)	0	18.3 (21.42)
	Median	10.0	9.5	11.0	0	10.0
	Min, Max	0, 89	0, 69	0, 62	0	0, 89

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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Pre-Randomization**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Intensity of cough						
Day -1						
n	n (%)	32	17	16	5	70
Very mild	n (%)	18 (56.3)	13 (76.5)	7 (43.8)	4 (80.0)	42 (60.0)
Mild	n (%)	10 (31.3)	2 (11.8)	7 (43.8)	1 (20.0)	20 (28.6)
Moderate	n (%)	3 (9.4)	2 (11.8)	1 (6.3)	0	6 (8.6)
Severe	n (%)	1 (3.1)	0	1 (6.3)	0	2 (2.9)
Very severe	n (%)	0	0	0	0	0
Day 0						
n	n (%)	39	18	15	0	72
Very mild	n (%)	27 (69.2)	12 (66.7)	8 (53.3)	0	47 (65.3)
Mild	n (%)	7 (17.9)	4 (22.2)	5 (33.3)	0	16 (22.2)
Moderate	n (%)	4 (10.3)	2 (11.1)	2 (13.3)	0	8 (11.1)
Severe	n (%)	1 (2.6)	0	0	0	1 (1.4)
Very severe	n (%)	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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Pre-Randomization**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Frequency of cough						
Day -1						
n	n (%)	32	17	16	5	70
Rarely	n (%)	14 (43.8)	10 (58.8)	3 (18.8)	4 (80.0)	31 (44.3)
Sometimes	n (%)	15 (46.9)	7 (41.2)	12 (75.0)	1 (20.0)	35 (50.0)
Fairly often	n (%)	3 (9.4)	0	1 (6.3)	0	4 (5.7)
Often	n (%)	0	0	0	0	0
Almost always	n (%)	0	0	0	0	0
Day 0						
n	n (%)	39	18	15	0	72
Rarely	n (%)	18 (46.2)	9 (50.0)	5 (33.3)	0	32 (44.4)
Sometimes	n (%)	19 (48.7)	8 (44.4)	8 (53.3)	0	35 (48.6)
Fairly often	n (%)	1 (2.6)	1 (5.6)	2 (13.3)	0	4 (5.6)
Often	n (%)	1 (2.6)	0	0	0	1 (1.4)
Almost always	n (%)	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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Pre-Randomization**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=40)	Product Test (N=15)	Overall Safety (N=175)
Amount of sputum produced						
Day -1						
n	n (%)	32	17	16	5	70
No sputum	n (%)	16 (50.0)	9 (52.9)	6 (37.5)	5 (100)	36 (51.4)
A moderate amount of sputum	n (%)	16 (50.0)	8 (47.1)	10 (62.5)	0	34 (48.6)
A larger amount of sputum	n (%)	0	0	0	0	0
A very large amount of sputum	n (%)	0	0	0	0	0
Day 0						
n	n (%)	39	18	15	0	72
No sputum	n (%)	22 (56.4)	11 (61.1)	6 (40.0)	0	39 (54.2)
A moderate amount of sputum	n (%)	17 (43.6)	7 (38.9)	9 (60.0)	0	33 (45.8)
A larger amount of sputum	n (%)	0	0	0	0	0
A very large amount of sputum	n (%)	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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Has subject experienced cough in the study period assessed					
Day 1					
Yes	n (%)	34 (43.6)	17 (40.5)	17 (42.5)	68 (42.5)
No	n (%)	42 (53.8)	24 (57.1)	23 (57.5)	89 (55.6)
Missing	n (%)	2 (2.6)	1 (2.4)	0	3 (1.9)
Day 2					
Yes	n (%)	35 (44.9)	19 (45.2)	15 (37.5)	69 (43.1)
No	n (%)	41 (52.6)	22 (52.4)	25 (62.5)	88 (55.0)
Missing	n (%)	2 (2.6)	1 (2.4)	0	3 (1.9)

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Has subject experienced cough in the study period assessed					
Day 3					
Yes	n (%)	37 (47.4)	18 (42.9)	14 (35.0)	69 (43.1)
No	n (%)	39 (50.0)	23 (54.8)	25 (62.5)	87 (54.4)
Missing	n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
Day 4					
Yes	n (%)	29 (37.2)	16 (38.1)	16 (40.0)	61 (38.1)
No	n (%)	47 (60.3)	25 (59.5)	23 (57.5)	95 (59.4)
Missing	n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Has subject experienced cough in the study period assessed					
Day 5					
Yes	n (%)	33 (42.3)	15 (35.7)	14 (35.0)	62 (38.8)
No	n (%)	43 (55.1)	26 (61.9)	25 (62.5)	94 (58.8)
Missing	n (%)	2 (2.6)	1 (2.4)	1 (2.5)	4 (2.5)
Day 30					
Yes	n (%)	23 (29.5)	13 (31.0)	8 (20.0)	44 (27.5)
No	n (%)	54 (69.2)	28 (66.7)	30 (75.0)	112 (70.0)
Missing	n (%)	1 (1.3)	1 (2.4)	2 (5.0)	4 (2.5)

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Has subject experienced cough in the study period assessed					
Day 60					
Yes	n (%)	19 (24.4)	15 (35.7)	9 (22.5)	43 (26.9)
No	n (%)	58 (74.4)	26 (61.9)	29 (72.5)	113 (70.6)
Missing	n (%)	1 (1.3)	1 (2.4)	2 (5.0)	4 (2.5)
Day 90					
Yes	n (%)	15 (19.2)	13 (31.0)	6 (15.0)	34 (21.3)
No	n (%)	61 (78.2)	28 (66.7)	32 (80.0)	121 (75.6)
Missing	n (%)	2 (2.6)	1 (2.4)	2 (5.0)	5 (3.1)

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
VAS					
Day 1	n	34	17	17	68
	Mean (SD)	22.8 (22.14)	16.0 (18.52)	19.3 (21.80)	20.2 (21.10)
	Median	15.5	8.0	8.0	15.0
	Min, Max	0, 78	0, 69	0, 68	0, 78
Day 2	n	35	19	15	69
	Mean (SD)	22.2 (19.90)	16.7 (18.56)	23.1 (24.64)	20.9 (20.52)
	Median	16.0	9.0	15.0	12.0
	Min, Max	0, 64	0, 60	0, 68	0, 68

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
VAS					
Day 3	n	37	18	14	69
	Mean (SD)	21.1 (20.95)	12.9 (18.41)	22.4 (27.64)	19.2 (21.85)
	Median	15.0	6.5	10.0	9.0
	Min, Max	0, 60	0, 69	0, 86	0, 86
Day 4	n	29	16	16	61
	Mean (SD)	23.9 (22.00)	12.9 (15.54)	29.3 (31.16)	22.5 (23.80)
	Median	18.0	7.0	15.5	13.0
	Min, Max	0, 69	0, 56	0, 87	0, 87

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
VAS					
Day 5	n	33	15	14	62
	Mean (SD)	20.9 (20.48)	16.4 (19.76)	25.5 (26.56)	20.9 (21.68)
	Median	16.0	5.0	20.5	13.0
	Min, Max	0, 64	0, 57	0, 69	0, 69
Day 30	n	23	13	8	44
	Mean (SD)	21.3 (21.15)	19.2 (12.43)	25.3 (23.75)	21.4 (19.18)
	Median	18.0	16.0	21.5	17.5
	Min, Max	0, 72	6, 48	0, 75	0, 75

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
VAS					
Day 60	n	19	15	9	43
	Mean (SD)	23.0 (22.24)	17.7 (15.41)	40.3 (26.36)	24.8 (22.24)
	Median	17.0	12.0	38.0	18.0
	Min, Max	1, 88	4, 47	5, 84	1, 88
Day 90	n	15	13	6	34
	Mean (SD)	19.3 (15.93)	21.4 (18.28)	23.8 (17.16)	20.9 (16.63)
	Median	17.0	15.0	20.0	16.0
	Min, Max	0, 52	5, 62	7, 54	0, 62

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Intensity of cough					
Day 1					
n	n (%)	34	17	17	68
Very mild	n (%)	17 (50.0)	9 (52.9)	7 (41.2)	33 (48.5)
Mild	n (%)	12 (35.3)	6 (35.3)	9 (52.9)	27 (39.7)
Moderate	n (%)	5 (14.7)	2 (11.8)	1 (5.9)	8 (11.8)
Severe	n (%)	0	0	0	0
Very severe	n (%)	0	0	0	0
Day 2					
n	n (%)	35	19	15	69
Very mild	n (%)	19 (54.3)	12 (63.2)	6 (40.0)	37 (53.6)
Mild	n (%)	13 (37.1)	7 (36.8)	6 (40.0)	26 (37.7)
Moderate	n (%)	3 (8.6)	0	3 (20.0)	6 (8.7)
Severe	n (%)	0	0	0	0
Very severe	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Intensity of cough					
Day 3					
n	n (%)	37	18	14	69
Very mild	n (%)	21 (56.8)	10 (55.6)	7 (50.0)	38 (55.1)
Mild	n (%)	16 (43.2)	6 (33.3)	4 (28.6)	26 (37.7)
Moderate	n (%)	0	2 (11.1)	3 (21.4)	5 (7.2)
Severe	n (%)	0	0	0	0
Very severe	n (%)	0	0	0	0
Day 4					
n	n (%)	29	16	16	61
Very mild	n (%)	13 (44.8)	8 (50.0)	6 (37.5)	27 (44.3)
Mild	n (%)	13 (44.8)	7 (43.8)	6 (37.5)	26 (42.6)
Moderate	n (%)	3 (10.3)	1 (6.3)	4 (25.0)	8 (13.1)
Severe	n (%)	0	0	0	0
Very severe	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Intensity of cough					
Day 5					
n	n (%)	33	15	14	62
Very mild	n (%)	14 (42.4)	10 (66.7)	6 (42.9)	30 (48.4)
Mild	n (%)	16 (48.5)	5 (33.3)	6 (42.9)	27 (43.5)
Moderate	n (%)	3 (9.1)	0	2 (14.3)	5 (8.1)
Severe	n (%)	0	0	0	0
Very severe	n (%)	0	0	0	0
Day 30					
n	n (%)	23	13	8	44
Very mild	n (%)	10 (43.5)	5 (38.5)	4 (50.0)	19 (43.2)
Mild	n (%)	11 (47.8)	6 (46.2)	3 (37.5)	20 (45.5)
Moderate	n (%)	2 (8.7)	2 (15.4)	1 (12.5)	5 (11.4)
Severe	n (%)	0	0	0	0
Very severe	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Intensity of cough					
Day 60					
n	n (%)	19	15	9	43
Very mild	n (%)	12 (63.2)	4 (26.7)	1 (11.1)	17 (39.5)
Mild	n (%)	5 (26.3)	9 (60.0)	5 (55.6)	19 (44.2)
Moderate	n (%)	1 (5.3)	2 (13.3)	3 (33.3)	6 (14.0)
Severe	n (%)	1 (5.3)	0	0	1 (2.3)
Very severe	n (%)	0	0	0	0
Day 90					
n	n (%)	15	13	6	34
Very mild	n (%)	9 (60.0)	8 (61.5)	4 (66.7)	21 (61.8)
Mild	n (%)	4 (26.7)	3 (23.1)	1 (16.7)	8 (23.5)
Moderate	n (%)	2 (13.3)	2 (15.4)	1 (16.7)	5 (14.7)
Severe	n (%)	0	0	0	0
Very severe	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Frequency of cough					
Day 1					
n	n (%)	34	17	17	68
Rarely	n (%)	15 (44.1)	10 (58.8)	5 (29.4)	30 (44.1)
Sometimes	n (%)	15 (44.1)	7 (41.2)	11 (64.7)	33 (48.5)
Fairly often	n (%)	3 (8.8)	0	1 (5.9)	4 (5.9)
Often	n (%)	1 (2.9)	0	0	1 (1.5)
Almost always	n (%)	0	0	0	0
Day 2					
n	n (%)	35	19	15	69
Rarely	n (%)	14 (40.0)	11 (57.9)	4 (26.7)	29 (42.0)
Sometimes	n (%)	20 (57.1)	8 (42.1)	10 (66.7)	38 (55.1)
Fairly often	n (%)	1 (2.9)	0	1 (6.7)	2 (2.9)
Often	n (%)	0	0	0	0
Almost always	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Frequency of cough					
Day 3					
n	n (%)	37	18	14	69
Rarely	n (%)	20 (54.1)	9 (50.0)	4 (28.6)	33 (47.8)
Sometimes	n (%)	17 (45.9)	9 (50.0)	8 (57.1)	34 (49.3)
Fairly often	n (%)	0	0	2 (14.3)	2 (2.9)
Often	n (%)	0	0	0	0
Almost always	n (%)	0	0	0	0
Day 4					
n	n (%)	29	16	16	61
Rarely	n (%)	13 (44.8)	8 (50.0)	6 (37.5)	27 (44.3)
Sometimes	n (%)	15 (51.7)	7 (43.8)	6 (37.5)	28 (45.9)
Fairly often	n (%)	1 (3.4)	1 (6.3)	4 (25.0)	6 (9.8)
Often	n (%)	0	0	0	0
Almost always	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Frequency of cough					
Day 5					
n	n (%)	33	15	14	62
Rarely	n (%)	15 (45.5)	7 (46.7)	4 (28.6)	26 (41.9)
Sometimes	n (%)	17 (51.5)	7 (46.7)	8 (57.1)	32 (51.6)
Fairly often	n (%)	1 (3.0)	1 (6.7)	2 (14.3)	4 (6.5)
Often	n (%)	0	0	0	0
Almost always	n (%)	0	0	0	0
Day 30					
n	n (%)	23	13	8	44
Rarely	n (%)	8 (34.8)	5 (38.5)	2 (25.0)	15 (34.1)
Sometimes	n (%)	12 (52.2)	8 (61.5)	4 (50.0)	24 (54.5)
Fairly often	n (%)	3 (13.0)	0	2 (25.0)	5 (11.4)
Often	n (%)	0	0	0	0
Almost always	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Frequency of cough					
Day 60					
n	n (%)	19	15	9	43
Rarely	n (%)	4 (21.1)	4 (26.7)	2 (22.2)	10 (23.3)
Sometimes	n (%)	13 (68.4)	9 (60.0)	6 (66.7)	28 (65.1)
Fairly often	n (%)	2 (10.5)	2 (13.3)	1 (11.1)	5 (11.6)
Often	n (%)	0	0	0	0
Almost always	n (%)	0	0	0	0
Day 90					
n	n (%)	15	13	6	34
Rarely	n (%)	7 (46.7)	6 (46.2)	3 (50.0)	16 (47.1)
Sometimes	n (%)	7 (46.7)	6 (46.2)	3 (50.0)	16 (47.1)
Fairly often	n (%)	1 (6.7)	0	0	1 (2.9)
Often	n (%)	0	1 (7.7)	0	1 (2.9)
Almost always	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Amount of sputum produced					
Day 1					
n	n (%)	34	17	17	68
No sputum	n (%)	17 (50.0)	10 (58.8)	9 (52.9)	36 (52.9)
A moderate amount of sputum	n (%)	17 (50.0)	7 (41.2)	8 (47.1)	32 (47.1)
A larger amount of sputum	n (%)	0	0	0	0
A very large amount of sputum	n (%)	0	0	0	0
Day 2					
n	n (%)	35	19	15	69
No sputum	n (%)	15 (42.9)	11 (57.9)	6 (40.0)	32 (46.4)
A moderate amount of sputum	n (%)	20 (57.1)	8 (42.1)	9 (60.0)	37 (53.6)
A larger amount of sputum	n (%)	0	0	0	0
A very large amount of sputum	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Amount of sputum produced					
Day 3					
n	n (%)	37	18	14	69
No sputum	n (%)	23 (62.2)	12 (66.7)	5 (35.7)	40 (58.0)
A moderate amount of sputum	n (%)	14 (37.8)	6 (33.3)	9 (64.3)	29 (42.0)
A larger amount of sputum	n (%)	0	0	0	0
A very large amount of sputum	n (%)	0	0	0	0
Day 4					
n	n (%)	29	16	16	61
No sputum	n (%)	17 (58.6)	9 (56.3)	7 (43.8)	33 (54.1)
A moderate amount of sputum	n (%)	12 (41.4)	7 (43.8)	9 (56.3)	28 (45.9)
A larger amount of sputum	n (%)	0	0	0	0
A very large amount of sputum	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Amount of sputum produced					
Day 5					
n	n (%)	33	15	14	62
No sputum	n (%)	17 (51.5)	9 (60.0)	5 (35.7)	31 (50.0)
A moderate amount of sputum	n (%)	16 (48.5)	6 (40.0)	9 (64.3)	31 (50.0)
A larger amount of sputum	n (%)	0	0	0	0
A very large amount of sputum	n (%)	0	0	0	0
Day 30					
n	n (%)	23	13	8	44
No sputum	n (%)	13 (56.5)	7 (53.8)	3 (37.5)	23 (52.3)
A moderate amount of sputum	n (%)	10 (43.5)	6 (46.2)	5 (62.5)	21 (47.7)
A larger amount of sputum	n (%)	0	0	0	0
A very large amount of sputum	n (%)	0	0	0	0

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 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.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomized Period**

Variable/ Study Day	Statistic	THSm2.2 (N=78)	mCC (N=42)	SA (N=160)	Overall Safety (N=160)
Amount of sputum produced					
Day 60					
n	n (%)	19	15	9	43
No sputum	n (%)	9 (47.4)	11 (73.3)	4 (44.4)	24 (55.8)
A moderate amount of sputum	n (%)	10 (52.6)	4 (26.7)	5 (55.6)	19 (44.2)
A larger amount of sputum	n (%)	0	0	0	0
A very large amount of sputum	n (%)	0	0	0	0
Day 90					
n	n (%)	15	13	6	34
No sputum	n (%)	7 (46.7)	9 (69.2)	4 (66.7)	20 (58.8)
A moderate amount of sputum	n (%)	8 (53.3)	4 (30.8)	2 (33.3)	14 (41.2)
A larger amount of sputum	n (%)	0	0	0	0
A very large amount of sputum	n (%)	0	0	0	0

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 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.