THS 2.2 REGULAR AND SMOOTH MENTHOL FDA FULL LIST OF HPHCs COMPARISON TO COMBUSTIBLE REFERENCE PRODUCT 3R4F ANALYZED BY LABSTAT UCL

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1 Executive Summary

The present study compares the composition of the aerosol of a heated tobacco product (THS 2.2) to the composition of the smoke of a reference combustible cigarette (3R4F) based on the measurement of the full FDA list[1], to complete our previous comparison with our internal PMI-58 list of constituents we have established to compare the performance of heated tobacco products vs. combustible cigarettes.

Based on the levels measured in THS 2.2 and 3R4F, PMI demonstrated an average reduction of total HPHCs of more than 91.9% and 87.8% on a stick basis or nicotine basis respectively for the THS 2.2 Regular and more than 92.6% and 88.8% on a stick basis or nicotine basis respectively for the THS 2.2 Smooth Menthol, both compared to the 3R4F.

The analytical work was performed by Labstat UCL, an independent laboratory.

2 Abbreviations

Abbreviation/Term	Explanation
EDMS	Electronic Document Management System
HPHC	Harmful and Potentially Harmful Constituent
ISO	International Organization for Standardization
LOQ	Limit of Quantification
µg	Microgram
mg	Milligram
ng	Nanogram
PMI	Philip Morris International
SD	Standard Deviation
Stk	Stick
THS	Tobacco Heating System

[1] *Harmful and Potentially Harmful constituents in Tobacco Products and Tobacco Smoke, Established list by Food and Drug Administration on March 4th 2012*

3 Purpose

The present study compares the aerosol composition of a heated tobacco product (THS 2.2) to the composition of the smoke of a reference combustible cigarette (3R4F) based on the measurement of the full FDA list. The objective is also to demonstrate that our PMI-58 internal list is a good proxy to estimate the overall reduction of HPHCs as compared to the reduction we may observed with the full FDA list.

The present study report focuses on the calculation of reduction of HPHCs between the aerosol of the THS 2.2 against the smoke of a reference conventional cigarette (3R4F), based on analytical data measured by an independent Laboratory, Labstat UCL.

4 Research Question

The goal of the study was to demonstrate HPHCs reduction of THS 2.2 heated tobacco product versus the 3R4F reference cigarette.

5 Methods

The detail of the analytical methodology is reported in the Labstat report [1] NS367-H.

6 Results

6.1 Data availability

Data considered in the present report were obtained and reported by Labstat International ULC. Labstat International ULC warrants that all sample(s) were tested in accordance with its standard test procedures and in accordance with its ISO 17025 accreditation.

Table 1: Data considered in the present report.

Product Description	*Labstat Codes*	*Sample numbers*	*Replicates per HPHC*
SMP of B-50593 Batch of SMS.004926.RD(1) Platform 1 – ZRH/THD 2.4/ZRH holder firmware - 1.1.2 (v2.4)/C28/P1 THD V2.4 Holder - White Matte - Marlboro Regular US (HW4- Prior 1- Printed Poly 2) MARLBORO REGULAR	1700175	SMP095215	3 replicates per sample

Product Description	*Labstat Codes*	*Sample numbers*	*Replicates per HPHC*
SMP of B-50594 Batch of SMS.004929.RD(1) Platform 1 – ZRH/THD 2.4/ZRH holder firmware - 1.1.2 (v2.4)/C28/P1 THD V2.4 Holder - Dark Slate - Marlboro Smooth Menthol US (HW4- Prior 1- Printed Poly 2) MARLBORO SMOOTH MENTHOL	1700176	SMP095215	3 replicates per sample

6.2 Comparison of THS 2.2 Regular and 3R4F

Summary statistics and comparisons against the yields of the 3R4F reference combustible cigarette are presented in Table 2 and Table 3. Average reduction on stick basis and on nicotine basis are calculated from Table 3 to exclude the main aerosol deliveries (TPM, nicotine, glycerine and water) from the reduction.

Table 2: Main aerosol deliveries

Aerosol deliveries according to ISO 4387; 8454; 1035	Unit	3R4F			THS 2.2 Regular		
		mean	SD	n	mean	SD	n
Nicotine	mg/stk	1.87	0.09	3	1.23	0.06	3
Nicotine Free Dry Particulate Matter (NFDPM)	mg/stk	28.6	1.5	3	20.0	0.7	3
Total Particulate Matter (TPM)	mg/stk	44.8	3.33	3	54.8	1.96	3
Water[1]	mg/stk	14.3	1.77	3	33.6	1.34	3

[1] *Due to the high water content of the THS 2.2 aerosol, accurate water measurements cannot be obtained with the ISO standard methods. ISO parameters based on water measurements conducted according to ISO standard cannot be considered and in addition they do not account for aerosol formers such as glycerol which constitute a major part of the THS 2.2 aerosol. For this reason the use of terms NFDPM to describe the aerosol collected mass from THS 2.2 may be misleading given the very different constituent make-up in comparison to conventional products. Alternatively accurate water measurements in the THS 2.2 aerosol require the establishment of new analytical methods. Read more in Ghosh, D. & Jeannet, C. (2014). An Improved Cambridge Filter Pad Extraction Methodology to Obtain More Accurate Water and "Tar" Values: In Situ Cambridge Filter Pad Extraction Methodology. Beiträge zur Tabakforschung / Contributions to Tobacco Research, 26(2), pp. 38-49*

Table 3: HPCHs from the FDA full list (excluding main aerosol deliveries reported in Table 2).When results were either below the LOQ or the LOD, results are shown with " < value of LOQ/LOD", and the % of reduction vs. 3R4F was calculated using the LOQ or LOD value respectively for the THS. When both the THS and the 3R4F were below the LOQ/LOD, no reduction can be calculated.

HPHCs	Unit	3R4F			THS 2.2 Regular			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Ammonia	[µg/stk]	31.7	1.13	3	13.14	0.846	3	41.4%	58.6%	62.8%	37.2%
Formaldehyde	[µg/stk]	70.2	6.17	3	7.10	0.607	3	10.1%	89.9%	15.4%	84.6%
Acetaldehyde	[µg/stk]	1713	123	3	197.2	15.6	3	11.5%	88.5%	17.5%	82.5%
Acetone	[µg/stk]	697	47.8	3	31.5	4.92	3	4.5%	95.5%	6.9%	93.1%
Acrolein	[µg/stk]	177	15.5	3	9.20	0.865	3	5.2%	94.8%	7.9%	92.1%
Propionaldehyde	[µg/stk]	125	8.97	3	12.2	1.16	3	9.8%	90.2%	14.9%	85.1%
Crotonaldehyde	[µg/stk]	55.2	4.40	3	<3.29 (LOQ)	*	3	<6.0%	>94.0%	<9.0%	>91.0%
Methyl Ethyl Ketone	[µg/stk]	184	14.0	3	7.08	0.656	3	3.8%	96.2%	5.8%	94.2%
HCN	[µg/stk]	433	5.50	3	2.06	0.040	3	0.5%	99.5%	0.7%	99.3%
Mercury	[ng/stk]	4.36	0.360	3	2.11	0.071	3	48.4%	51.6%	73.5%	26.5%
Cadmium	[ng/stk]	99.4	4.84	3	<0.09 (LOD)	*	3	<0.1%	>99.9%	<0.1%	>99.9%
Lead	[ng/stk]	<25.7 (LOQ)	*	3	<1.62 (LOQ)	*	3	NA	NA	NA	NA
Chromium	[ng/stk]	<11.9 (LOD)	*	3	<11.0 (LOQ)	*	3	NA	NA	NA	NA

HPHCs	Unit	3R4F			THS 2.2 Regular			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Nickel	[ng/stk]	<43.1 (LOQ)	*	3	<15.9 (LOD)	*	3	NA	NA	NA	NA
Arsenic	[ng/stk]	8.23	0.180	3	<1.20 (LOQ)	*	3	<14.6%	>85.4%	<22.1%	>77.9%
Selenium	[ng/stk]	<4.42 (LOD)	*	3	<0.830 (LOQ)	*	3	NA	NA	NA	NA
Cobalt	[ng/stk]	<3.69 (LOD)	*	3	<3.69 (LOD)	*	3	NA	NA	NA	NA
Beryllium	[pg/stk]	<11.9 (LOQ)	*	3	<11.9 (LOQ)	*	3	NA	NA	NA	NA
Quinoline	[µg/stk]	0.409	0.019	3	<0.011 (LOQ)	*	3	<2.7%	>97.3%	<4.1%	>95.9%
Styrene	[µg/stk]	13.0	1.53	3	0.328	0.036	3	2.5%	97.5%	3.8%	96.2%
Nitrobenzene	[µg/stk]	<0.038 (LOD)	*	3	<0.011 (LOD)	*	3	NA	NA	NA	NA
Benzo(b)furan	[µg/stk]	0.592	0.0243	3	0.027	0.003	3	4.6%	95.4%	6.9%	93.1%
Catechol	[µg/stk]	98.1	7.34	3	12.9	0.941	3	13.2%	86.8%	20.0%	80.0%
Phenol	[µg/stk]	14.4	0.777	3	0.941	0.134	3	6.5%	93.5%	9.9%	90.1%
p-cresol	[µg/stk]	6.56	0.679	3	<0.034 (LOQ)	*	3	<0.5%	>99.5%	<0.8%	>99.2%
m-cresol	[µg/stk]	3.34	0.448	3	0.033	0.004	3	1.0%	99.0%	1.5%	98.5%

HPHCs	Unit	3R4F			THS 2.2 Regular			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
o-cresol	[µg/stk]	3.76	0.144	3	0.041	0.007	3	1.1%	98.9%	1.7%	98.3%
CO	[mg/stk]	30.6	1.83	3	<0.067 (LOD)	*	3	<0.2%	>99.8%	<0.3%	>99.7%
Naphthalene	[ng/stk]	1197	83.1	3	7.34	1.18	3	0.6%	99.4%	0.9%	99.1%
1-methylnaphthalene	[ng/stk]	1016	54.4	3	8.36	1.77	3	0.8%	99.2%	1.2%	98.8%
2-methylnaphthalene	[ng/stk]	953	49.5	3	35.3	8.96	3	3.7%	96.3%	5.6%	94.4%
Acenaphthylene	[ng/stk]	196	23.4	2	2.97	0.576	3	1.5%	98.5%	2.3%	97.7%
Acenaphthene	[ng/stk]	129	11.1	3	0.683	0.065	3	0.5%	99.5%	0.8%	99.2%
Fluorene	[ng/stk]	409	27.4	3	10.3	2.32	3	2.5%	97.5%	3.8%	96.2%
Phenanthrene	[ng/stk]	201	19.7	3	6.62	0.573	3	3.3%	96.7%	5.0%	95.0%
Anthracene	[ng/stk]	120	8.56	3	0.942	0.099	3	0.8%	99.2%	1.2%	98.8%
Fluoranthene	[ng/stk]	107	0.568	3	10.5	0.959	3	9.8%	90.2%	14.9%	85.1%
Pyrene	[ng/stk]	88.9	2.12	3	11.4	1.13	3	12.8%	87.2%	19.5%	80.5%
Benzo(a)anthracene	[ng/stk]	31.6	2.27	3	2.75	0.353	3	8.7%	91.3%	13.2%	86.8%
Chrysene	[ng/stk]	40.7	2.78	3	3.86	0.396	3	9.5%	90.5%	14.4%	85.6%
Benzo(b)fluoranthene	[ng/stk]	13.9	0.816	3	1.20	0.133	3	8.6%	91.4%	13.1%	86.9%
Benzo(k)fluoranthene	[ng/stk]	4.86	0.379	3	0.607	0.061	3	12.5%	87.5%	19.0%	81.0%
Benzo(j)fluoranthene	[ng/stk]	7.30	0.479	3	0.849	0.051	3	11.6%	88.4%	17.7%	82.3%
Benzo(e)pyrene	[ng/stk]	6.54	0.454	3	0.680	0.083	3	10.4%	89.6%	15.8%	84.2%

HPHCs	Unit	3R4F			THS 2.2 Regular			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Benzo(a)pyrene	[ng/stk]	15.6	0.946	3	1.12	0.174	3	7.2%	92.8%	10.9%	89.1%
Perylene	[ng/stk]	3.78	0.386	3	<0.379 (LOQ)	*	3	<10.0%	>90.0%	<15.2%	>84.8%
Indeno(1,2,3-cd)pyrene	[ng/stk]	5.36	0.196	3	<0.337 (LOQ)	*	3	<6.3%	>93.7%	<9.6%	>90.4%
Dibenz(a,h)anthracene	[ng/stk]	0.797	0.102	3	<0.124 (LOD)	*	3	<15.6%	>84.4%	<23.6%	>76.4%
Benzo(g,h,i)perylene	[ng/stk]	2.85	0.091	3	<0.337 (LOQ)	*	3	<11.8%	>88.2%	<17.9%	>82.1%
Benzo(c)phenanthrene	[ng/stk]	7.96	2.295	3	1.29	0.132	3	16.2%	83.8%	24.6%	75.4%
Cyclopenta(c,d)pyrene	[ng/stk]	6.00	0.392	3	1.96	0.260	3	32.7%	67.3%	49.7%	50.3%
Benzo(j)aceanthrylene	[ng/stk]	1.15	0.206	3	<0.104 (LOD)	*	3	<9.1%	>90.9%	<13.8%	>86.2%
1,3-butadiene	[µg/stk]	93.0	5.55	3	0.230	0.009	3	0.2%	99.8%	0.4%	99.6%
Isoprene	[µg/stk]	812	11.8	3	1.33	0.077	3	0.2%	99.8%	0.2%	99.8%
Acrylonitrile	[µg/stk]	22.5	1.73	3	<0.107 (LOQ)	*	3	<0.5%	>99.5%	<0.7%	>99.3%
Benzene	[µg/stk]	83.1	3.02	3	0.483	0.023	3	0.6%	99.4%	0.9%	99.1%
Toluene	[µg/stk]	143	6.74	3	1.40	0.054	3	1.0%	99.0%	1.5%	98.5%
Ethylbenzene	[µg/stk]	14.8	0.638	3	0.132	0.001	3	0.9%	99.1%	1.4%	98.6%

HPHCs	Unit	3R4F			THS 2.2 Regular			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Ethylene Oxide	[µg/stk]	21.2	2.11	3	0.198	0.021	3	0.9%	99.1%	1.4%	98.6%
Vinyl Chloride	[ng/stk]	128	8.10	3	<0.657 (LOD)	*	3	<0.5%	>99.5%	<0.8%	>99.2%
Propylene Oxide	[ng/stk]	930	118	3	159	15.5	3	17.1%	82.9%	25.9%	74.1%
Furan	[µg/stk]	58.3	2.93	3	4.43	0.390	3	7.6%	92.4%	11.5%	88.5%
Vinyl Acetate	[ng/stk]	646	44.3	3	60.1	1.09	3	9.3%	90.7%	14.1%	85.9%
Nitromethane	[ng/stk]	809	85.6	3	51.2	3.43	3	6.3%	93.7%	9.6%	90.4%
2-nitropropane	[ng/stk]	36.5	6.69	3	8.40	0.553	3	23.0%	77.0%	35.0%	65.0%
1-aminonaphthalene	[ng/stk]	18.4	0.423	3	<0.027 (LOQ)	*	3	<0.1%	>99.9%	<0.2%	>99.8%
2-aminonaphthalene	[ng/stk]	11.6	0.230	3	<0.012 (LOQ)	*	3	<0.1%	>99.9%	<0.2%	>99.8%
4-aminobiphenyl	[ng/stk]	2.81	0.238	3	0.008	0.0006	3	0.3%	99.7%	0.4%	99.6%
2,6-dimethylaniline	[ng/stk]	8.01	0.417	3	0.316	0.019	3	3.9%	96.1%	6.0%	94.0%
o-anisidine	[ng/stk]	5.20	0.451	3	0.124	0.003	3	2.4%	97.6%	3.6%	96.4%
o-toluidine	[ng/stk]	105	7.39	3	1.08	0.050	3	1.0%	99.0%	1.6%	98.4%
Nitrosonornicotine (NNN)	[ng/stk]	277	39.7	3	15.2	1.55	3	5.5%	94.5%	8.3%	91.7%
4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone (NNK)	[ng/stk]	232	7.31	3	9.00	0.485	3	3.9%	96.1%	5.9%	94.1%

HPHCs	Unit	3R4F			THS 2.2 Regular			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Acetamide	[µg/stk]	12.3	0.354	3	3.28	0.116	3	26.7%	73.3%	40.5%	59.5%
Acrylamide	[µg/stk]	4.33	0.262	3	1.64	0.084	3	37.9%	62.1%	57.5%	42.5%
Caffeic Acid	[µg/stk]	<1.19 (LOD)	*	3	<0.478 (LOD)	*	3	NA	NA	NA	NA
Ethyl Carbamate	[ng/stk]	<6.43 (LOD)	*	3	<1.93 (LOD)	*	3	NA	NA	NA	NA
IQ	[ng/stk]	6.73	0.757	3	<0.64 (LOD)	*	3	<9.5%	>90.5%	<14.4%	>85.6%
Glu-P-2	[ng/cg]	<0.301 (LOD)	*	3	<0.120 (LOD)	*	3	NA	NA	NA	NA
Glu-P-1	[ng/stk]	<0.239 (LOD)	*	3	<0.095 (LOD)	*	3	NA	NA	NA	NA
PhIP	[ng/stk]	<0.365 (LOD)	*	3	<0.486 (LOQ)	*	3	NA	NA	NA	NA
Trp-P-2	[ng/stk]	6.37	0.751	3	<0.113 (LOD)	*	3	<1.8%	>98.2%	<2.7%	>97.3%
AaC	[ng/stk]	206	4.82	3	1.49	0.244	3	0.7%	99.3%	1.1%	98.9%
Trp-P-1	[ng/stk]	5.20	0.872	3	<0.098 (LOD)	*	3	<1.9%	>98.1%	<2.9%	>97.1%
MeAaC	[ng/stk]	26.6	0.872	3	0.385 (LOQ)	*	3	<1.4%	98.6%	<2.2%	97.8%

HPHCs	Unit	3R4F			THS 2.2 Regular			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Hydrazine	[ng/stk]	<6.79 (LOD)	*	3	<2.04 (LOD)	*	3	NA	NA	NA	NA
NDMA	[ng/stk]	6.43	0.219	3	2.79	0.209	3	43.4%	56.6%	65.8%	34.2%
NEMA	[ng/stk]	<0.509 (IOD)	*	3	<0.254 (LOD)	*	3	NA	NA	NA	NA
NDEA	[ng/stk]	<0.617 (LOD)	*	3	<0.308 (LOD)	*	3	NA	NA	NA	NA
NPIP	[ng/stk]	<0.172 (LOD)	*	3	<0.086 (LOD)	*	3	NA	NA	NA	NA
NPYR	[ng/stk]	36.8	6.41	3	<0.198 (LOD)	*	3	<0.5%	>99.5%	<0.8%	>99.2%
NMOR	[ng/stk]	<0.550 (LOD)	*	3	<0.275 (LOD)	*	3	NA	NA	NA	NA
NDELA	[ng/stk]	<0.085 (LOD)	*	3	<0.042 (LOD)	*	3	NA	NA	NA	NA

HPHCs	Unit	3R4F			THS 2.2 Regular			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Polonium-210[1]	[Bq]	0.0062	0.0032	3	<0.005 (LOD)	*	3	NA	NA	NA	NA
2,3,7,8-Tetra CDD	[pg/stk]	<3.9 (LOD)	*	3	<3.7 (LOD)	*	3	NA	NA	NA	NA
1,2,3,7,8-Penta CDD	[pg/stk]	<4.0 (LOD)	*	3	<3.5 (LOD)	*	3	NA	NA	NA	NA
1,2,3,4,7,8-Hexa CDD	[pg/stk]	<3.7 (LOD)	*	3	<3.7 (LOD)	*	3	NA	NA	NA	NA
1,2,3,6,7,8-Hexa CDD	[pg/stk]	<3.7 (LOD)	*	3	<3.8 (LOD)	*	3	NA	NA	NA	NA
1,2,3,7,8,9-Hexa CDD	[pg/stk]	<3.3 (LOD)	*	3	<3.4 (LOD)	*	3	NA	NA	NA	NA
1,2,3,4,6,7,8-Hepta CDD	[pg/stk]	<3.5 (LOD)	*	3	<3.4 (LOD)	*	3	NA	NA	NA	NA

[1] *Polonium 210 was not included in the average reduction as reduction is based on concentration (mass/stick) whereas Polonium is expressed in Bq (Becquerel) radioactivity unit. It is worth noting that the THS 2.2 Regular was found below the limit of detection. The same logic was also applied for the mentholated product*

HPHCs	Unit	3R4F			THS 2.2 Regular			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Octa CDD	[pg/stk]	<200 (LOQ)	*	3	<7.2 (LOD)	*	3	NA	NA	NA	NA
2,3,7,8-Tetra CDF	[pg/stk]	<3.8 (LOD)	*	3	<2.9 (LOD)	*	3	NA	NA	NA	NA
1,2,3,7,8-Penta CDF	[pg/stk]	<3.8 (LOD)	*	3	<3.5 (LOD)	*	3	NA	NA	NA	NA
2,3,4,7,8-Penta CDF	[pg/stk]	<4.0 (LOD)	*	3	<3.5 (LOD)	*	3	NA	NA	NA	NA
1,2,3,4,7,8-Hexa CDF	[pg/stk]	<2.2 (LOD)	*	3	<2.4 (LOD)	*	3	NA	NA	NA	NA
1,2,3,6,7,8-Hexa CDF	[pg/stk]	<2.1 (LOD)	*	3	<2.3 (LOD)	*	3	NA	NA	NA	NA
2,3,4,6,7,8-Hexa CDF	[pg/stk]	<2.4 (LOD)	*	3	<2.6 (LOD)	*	3	NA	NA	NA	NA
1,2,3,7,8,9-Hexa CDF	[pg/stk]	<2.6 (LOD)	*	3	<2.9 (LOD)	*	3	NA	NA	NA	NA
1,2,3,4,6,7,8-Hepta CDF	[pg/stk]	<2.5 (LOD)	*	3	<2.7 (LOD)	*	3	NA	NA	NA	NA
1,2,3,4,7,8,9-Hepta CDF	[pg/stk]	<3.3 (LOD)	*	3	<3.6 (LOD	*	3	NA	NA	NA	NA
Octa CDF	[pg/stk]	<4.4 (LOD)	*	3	<5.4 (LOD)	*	3	NA	NA	NA	NA

HPHCs	Unit	3R4F			THS 2.2 Regular			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Uranium-235	[Bq]	<0.005 (LOD)	*	3	<0.005 (LOD)	*	3	NA	NA	NA	NA
Uranium-238	[Bq]	<0.005 (LOD)	*	3	<0.005 (LOD)	*	3	NA	NA	NA	NA

Average reduction of HPHCs (not including main aerosol deliveries, TPM, nicotine, NFDPM, glycerin and water)

The average reduction is based on HPCHs reported in Table 3 and represent the average of column "% of reduction to 3R4F". The averages were calculated on stick basis and on nicotine basis:

- On stick basis : >91.9%
- On nicotine basis : >87.8%

6.3 Results THS 2.2 Smooth Menthol and 3R4F

Summary statistics and comparisons against the yields of the 3R4F reference combustible cigarette are presented in Table 4 and Table 5. Average reduction on stick basis and on nicotine basis are calculated from Table 4 to exclude the main aerosol deliveries (TPM, nicotine, glycerine and water) from the reduction

Table 4: Main aerosol deliveries

Aerosol deliveries according to ISO 4387; 8454; 1035	Unit	3R4F			THS 2.2 Smooth Menthol		
		mean	SD	n	mean	SD	n
Nicotine	mg/stk	1.87	0.09	3	1.23	0.13	3
Nicotine Free Dry Particulate Matter (NFDPM)	mg/stk	28.6	1.5	3	18.7	1.0	3
Total Particulate Matter (TPM)	mg/stk	44.8	3.33	3	52.8	2.35	3
Water[1]	mg/stk	14.3	1.77	3	32.9	1.40	3

[1] *Due to the high water content of the THS 2.2 aerosol, accurate water measurements cannot be obtained with the ISO standard methods. ISO parameters based on water measurements conducted according to ISO standard cannot be considered and in addition they do not account for aerosol formers such as glycerol which constitute a major part of the THS 2.2 aerosol. For this reason the use of terms NFDPM to describe the aerosol collected mass from THS 2.2 may be misleading given the very different constituent make-up in comparison to conventional products. Alternatively accurate water measurements in the THS 2.2 aerosol require the establishment of new analytical methods. Read more in Ghosh, D. & Jeannet, C. (2014). An Improved Cambridge Filter Pad Extraction Methodology to Obtain More Accurate Water and "Tar" Values: In Situ Cambridge Filter Pad Extraction Methodology. Beiträge zur Tabakforschung / Contributions to Tobacco Research, 26(2), pp. 38-49*

Table 5: HPCHs from the FDA full list (excluding main aerosol deliveries reported in Table 4.When results were either below the LOQ or the LOD, results are shown with " < value of LOQ/LOD", and the % of reduction vs. 3R4F was calculated using the LOQ or LOD value respectively for the THS. When both the THS and the 3R4F were below the LOQ/LOD, no reduction can be calculated.

HPHCs	Unit	3R4F			THS 2.2 Smooth Menthol			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Ammonia	[µg/stk]	31.7	1.13	3	13.38	0.780	3	42.1%	57.9%	63.9%	36.1%
Formaldehyde	[µg/stk]	70.2	6.17	3	7.68	1.234	3	10.9%	89.1%	16.6%	83.4%
Acetaldehyde	[µg/stk]	1713	123	3	199.4	13.5	3	11.6%	88.4%	17.7%	82.3%
Acetone	[µg/stk]	697	47.8	3	32.5	3.02	3	4.7%	95.3%	7.1%	92.9%
Acrolein	[µg/stk]	177	15.5	3	9.36	0.946	3	5.3%	94.7%	8.0%	92.0%
Propionaldehyde	[µg/stk]	125	8.97	3	12.4	0.93	3	10.0%	90.0%	15.1%	84.9%
Crotonaldehyde	[µg/stk]	55.2	4.40	3	<3.29 (LOQ)	*	3	<6.0%	>94.0%	<9.0%	>91.0%
Methyl Ethyl Ketone	[µg/stk]	184	14.0	3	7.10	0.710	3	3.9%	96.1%	5.8%	94.2%
HCN	[µg/stk]	433	5.50	3	2.17	0.200	3	0.5%	99.5%	0.8%	99.2%
Mercury	[ng/stk]	4.36	0.360	3	1.88	0.190	3	43.2%	56.8%	65.4%	34.6%
Cadmium	[ng/stk]	99.4	4.84	3	<0.28 (LOQ)	*	3	<0.3%	>99.7%	<0.4%	>99.6%

HPHCs	Unit	3R4F			THS 2.2 Smooth Menthol			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Lead	[ng/stk]	<25.7 (LOQ)	*	3	<0.490 (LOD)	*	3	NA	NA	NA	NA
Chromium	[ng/stk]	<11.9 (LOD)	*	3	<11.0 (LOQ)	*	3	NA	NA	NA	NA
Nickel	[ng/stk]	<43.1 (LOQ)	*	3	<15.9 (LOD)	*	3	NA	NA	NA	NA
Arsenic	[ng/stk]	8.23	0.180	3	<1.20 (LOQ)	*	3	<14.6%	>85.4%	<22.1%	>77.9%
Selenium	[ng/stk]	<4.42 (LOD)	*	3	<0.830 (LOQ)	*	3	NA	NA	NA	NA
Cobalt	[ng/stk]	<3.69 (LOD)	*	3	<3.69 (LOD)	*	3	NA	NA	NA	NA
Beryllium	[pg/stk]	<11.9 (LOQ)	*	3	<11.9 (LOQ)	*	3	NA	NA	NA	NA
Quinoline	[µg/stk]	0.409	0.019	3	<0.011 (LOQ)	*	3	<2.7%	>97.3%	<4.1%	>95.9%
Styrene	[µg/stk]	13.0	1.53	3	0.336	0.013	3	2.6%	97.4%	3.9%	96.1%
Nitrobenzene	[µg/stk]	<0.038 (LOD)	*	3	<0.011 (LOD)	*	3	NA	NA	NA	NA
Benzo(b)furan	[µg/stk]	0.592	0.0243	3	0.030	0.004	3	5.0%	95.0%	7.6%	92.4%

HPHCs	Unit	3R4F			THS 2.2 Smooth Menthol			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Catechol	[µg/stk]	98.1	7.34	3	12.7	0.949	3	12.9%	87.1%	19.6%	80.4%
Phenol	[µg/stk]	14.4	0.777	3	0.812	0.088	3	5.6%	94.4%	8.5%	91.5%
p-cresol	[µg/stk]	6.56	0.679	3	0.040	0.003	3	0.6%	99.4%	0.9%	99.1%
m-cresol	[µg/stk]	3.34	0.448	3	0.030	0.006	3	0.9%	99.1%	1.4%	98.6%
o-cresol	[µg/stk]	3.76	0.144	3	0.042	0.009	3	1.1%	98.9%	1.7%	98.3%
CO	[mg/stk]	30.6	1.83	3	<0.067 (LOD)	*	3	<0.2%	>99.8%	<0.3%	>99.7%
Naphthalene	[ng/stk]	1197	83.1	3	5.94	0.90	3	0.5%	99.5%	0.8%	99.2%
1-methylnaphthalene	[ng/stk]	1016	54.4	3	6.78	0.80	3	0.7%	99.3%	1.0%	99.0%
2-methylnaphthalene	[ng/stk]	953	49.5	3	29.8	5.24	3	3.1%	96.9%	4.7%	95.3%
Acenaphthylene	[ng/stk]	196	23.4	2	2.44	0.153	3	1.2%	98.8%	1.9%	98.1%
Acenaphthene	[ng/stk]	129	11.1	3	0.702	0.032	3	0.5%	99.5%	0.8%	99.2%
Fluorene	[ng/stk]	409	27.4	3	8.1	0.66	3	2.0%	98.0%	3.0%	97.0%
Phenanthrene	[ng/stk]	201	19.7	3	5.34	0.391	3	2.7%	97.3%	4.0%	96.0%
Anthracene	[ng/stk]	120	8.56	3	0.786	0.018	3	0.7%	99.3%	1.0%	99.0%
Fluoranthene	[ng/stk]	107	0.568	3	7.6	0.590	3	7.0%	93.0%	10.7%	89.3%
Pyrene	[ng/stk]	88.9	2.12	3	8.4	0.31	3	9.5%	90.5%	14.4%	85.6%
Benzo(a)anthracene	[ng/stk]	31.6	2.27	3	2.01	0.242	3	6.4%	93.6%	9.7%	90.3%

HPHCs	Unit	3R4F			THS 2.2 Smooth Menthol			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Chrysene	[ng/stk]	40.7	2.78	3	2.93	0.319	3	7.2%	92.8%	10.9%	89.1%
Benzo(b)fluoranthene	[ng/stk]	13.9	0.816	3	0.84	0.127	3	6.0%	94.0%	9.2%	90.8%
Benzo(k)fluoranthene	[ng/stk]	4.86	0.379	3	<0.395 (LOQ)	*	3	<8.1%	91.9%	<12.3%	87.7%
Benzo(j)fluoranthene	[ng/stk]	7.30	0.479	3	0.574	0.086	3	7.9%	92.1%	11.9%	88.1%
Benzo(e)pyrene	[ng/stk]	6.54	0.454	3	0.496	0.074	3	7.6%	92.4%	11.5%	88.5%
Benzo(a)pyrene	[ng/stk]	15.6	0.946	3	0.74	0.065	3	4.8%	95.2%	7.2%	92.8%
Perylene	[ng/stk]	3.78	0.386	3	<0.379 (LOQ)	*	3	<10.0%	>90.0%	<15.2%	>84.8%
Indeno(1,2,3-cd)pyrene	[ng/stk]	5.36	0.196	3	<0.337 (LOQ)	*	3	<6.3%	>93.7%	<9.5%	>90.5%
Dibenz(a,h)anthracene	[ng/stk]	0.797	0.102	3	<0.124 (LOD)	*	3	<15.6%	>84.4%	<23.6%	>76.4%
Benzo(g,h,i)perylene	[ng/stk]	2.85	0.091	3	<0.337 (LOQ)	*	3	<11.8%	>88.2%	<17.9%	>82.1%
Benzo(c)phenanthrene	[ng/stk]	7.96	2.295	3	0.86	0.051	3	10.8%	89.2%	16.4%	83.6%
Cyclopenta(c,d)pyrene	[ng/stk]	6.00	0.392	3	1.12	0.149	3	18.7%	81.3%	28.3%	71.7%
Benzo(j)aceanthrylene	[ng/stk]	1.15	0.206	3	<0.104 (LOD)	*	3	<9.1%	>90.9%	<13.7%	>86.3%
1,3-butadiene	[µg/stk]	93.0	5.55	3	0.273	0.028	3	0.3%	99.7%	0.4%	99.6%

HPHCs	Unit	3R4F			THS 2.2 Smooth Menthol			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Isoprene	[µg/stk]	812	11.8	3	1.62	0.187	3	0.2%	99.8%	0.3%	99.7%
Acrylonitrile	[µg/stk]	22.5	1.73	3	0.112	0.0390	3	0.5%	99.5%	0.8%	99.2%
Benzene	[µg/stk]	83.1	3.02	3	0.561	0.072	3	0.7%	99.3%	1.0%	99.0%
Toluene	[µg/stk]	143	6.74	3	1.65	0.227	3	1.2%	98.8%	1.8%	98.2%
Ethylbenzene	[µg/stk]	14.8	0.638	3	0.151	0.017	3	1.0%	99.0%	1.6%	98.4%
Ethylene Oxide	[µg/stk]	21.2	2.11	3	0.234	0.068	3	1.1%	98.9%	1.7%	98.3%
Vinyl Chloride	[ng/stk]	128	8.10	3	<0.657 (LOD)	*	3	<0.5%	>99.5%	<0.8%	>99.2%
Propylene Oxide	[ng/stk]	930	118	3	158	25.1	3	17.0%	83.0%	25.8%	74.2%
Furan	[µg/stk]	58.3	2.93	3	4.49	0.437	3	7.7%	92.3%	11.7%	88.3%
Vinyl Acetate	[ng/stk]	646	44.3	3	66.4	5.69	3	10.3%	89.7%	15.6%	84.4%
Nitromethane	[ng/stk]	809	85.6	3	44.3	2.00	3	5.5%	94.5%	8.3%	91.7%
2-nitropropane	[ng/stk]	36.5	6.69	3	6.00	0.261	3	16.4%	83.6%	24.9%	75.1%
1-aminonaphthalene	[ng/stk]	18.4	0.423	3	<0.027 (LOQ)	*	3	<0.1%	>99.9%	<0.2%	>99.8%
2-aminonaphthalene	[ng/stk]	11.6	0.230	3	<0.012 (LOQ)	*	3	<0.1%	>99.9%	<0.2%	>99.8%
4-aminobiphenyl	[ng/stk]	2.81	0.238	3	0.010	0.0011	3	0.4%	99.6%	0.5%	99.5%
2,6-dimethylaniline	[ng/stk]	8.01	0.417	3	0.270	0.024	3	3.4%	96.6%	5.1%	94.9%

HPHCs	Unit	3R4F			THS 2.2 Smooth Menthol			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
o-anisidine	[ng/stk]	5.20	0.451	3	0.131	0.010	3	2.5%	97.5%	3.8%	96.2%
o-toluidine	[ng/stk]	105	7.39	3	1.08	0.089	3	1.0%	99.0%	1.6%	98.4%
Nitrosonornicotine (NNN)	[ng/stk]	277	39.7	3	9.5	1.62	3	3.4%	96.6%	5.2%	94.8%
4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone (NNK)	[ng/stk]	232	7.31	3	6.92	0.902	3	3.0%	97.0%	4.5%	95.5%
Acetamide	[µg/stk]	12.3	0.354	3	3.21	0.067	3	26.1%	73.9%	39.5%	60.5%
Acrylamide	[µg/stk]	4.33	0.262	3	1.80	0.041	3	41.5%	58.5%	63.0%	37.0%
Caffeic Acid	[µg/stk]	<1.19 (LOD)	*	3	<0.478 (LOD)	*	3	NA	NA	NA	NA
Ethyl Carbamate	[ng/stk]	<6.43 (LOD)	*	3	<1.93 (LOD)	*	3	NA	NA	NA	NA
IQ	[ng/stk]	6.73	0.757	3	<0.64 (LOD)	*	3	<9.5%	>90.5%	<14.4%	>85.6%
Glu-P-2	[ng/cg]	<0.301 (LOD)	*	3	<0.120 (LOD)	*	3	NA	NA	NA	NA
Glu-P-1	[ng/stk]	<0.239 (LOD)	*	3	<0.095 (LOD)	*	3	NA	NA	NA	NA
PhIP	[ng/stk]	<0.365 (LOD)	*	3	<0.486 (LOQ)	*	3	NA	NA	NA	NA

HPHCs	Unit	3R4F			THS 2.2 Smooth Menthol			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Trp-P-2	[ng/stk]	6.37	0.751	3	<0.113 (LOD)	*	3	<1.8%	>98.2%	<2.7%	>97.3%
AaC	[ng/stk]	206	4.82	3	1.65	0.361	3	0.8%	99.2%	1.2%	98.8%
Trp-P-1	[ng/stk]	5.20	0.872	3	<0.098 (LOD)	*	3	<1.9%	>98.1%	<2.9%	>97.1%
MeAaC	[ng/stk]	26.6	0.872	3	<0.115 (LOD)	*	3	<0.4%	>99.6%	<0.7%	>99.3%
Hydrazine	[ng/stk]	<6.79 (LOD)	*	3	<2.04 (LOD)	*	3	NA	NA	NA	NA
NDMA	[ng/stk]	6.43	0.219	3	3.38	0.088	3	52.5%	47.5%	79.7%	20.3%
NEMA	[ng/stk]	<0.509 (lOD)	*	3	<0.254 (LOD)	*	3	NA	NA	NA	NA
NDEA	[ng/stk]	<0.617 (LOD)	*	3	<0.308 (LOD)	*	3	NA	NA	NA	NA
NPIP	[ng/stk]	<0.172 (LOD)	*	3	<0.086 (LOD)	*	3	NA	NA	NA	NA
NPYR	[ng/stk]	36.8	6.41	3	<0.198 (LOD)	*	3	<0.5%	>99.5%	<0.8%	>99.2%
NMOR	[ng/stk]	<0.550 (LOD)	*	3	<0.275 (LOD)	*	3	NA	NA	NA	NA

HPHCs	Unit	3R4F			THS 2.2 Smooth Menthol			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
NDELA	[ng/stk]	<0.085 (LOD)	*	3	<0.042 (LOD)	*	3	NA	NA	NA	NA
Polonium-210	[Bq]	0.0062	0.0032	3	<0.005 (LOD)	*	3	NA	NA	NA	NA
2,3,7,8-Tetra CDD	[pg/stk]	<3.9 (LOD)	*	3	<3.8 (LOD)	*	3	NA	NA	NA	NA
1,2,3,7,8-Penta CDD	[pg/stk]	<4.0 (LOD)	*	3	<3.9 (LOD)	*	3	NA	NA	NA	NA
1,2,3,4,7,8-Hexa CDD	[pg/stk]	<3.7 (LOD)	*	3	<3.2 (LOD)	*	3	NA	NA	NA	NA
1,2,3,6,7,8-Hexa CDD	[pg/stk]	<3.7 (LOD)	*	3	<3.1 (LOD)	*	3	NA	NA	NA	NA
1,2,3,7,8,9-Hexa CDD	[pg/stk]	<3.3 (LOD)	*	3	<2.8 (LOD)	*	3	NA	NA	NA	NA
1,2,3,4,6,7,8-Hepta CDD	[pg/stk]	<3.5 (LOD)	*	3	<20 (LOQ)	*	3	NA	NA	NA	NA
Octa CDD	[pg/stk]	<200 (LOQ)	*	3	<200 (LOQ)	*	3	NA	NA	NA	NA
2,3,7,8-Tetra CDF	[pg/stk]	<3.8 (LOD)	*	3	<3.1 (LOD)	*	3	NA	NA	NA	NA

HPHCs	Unit	3R4F			THS 2.2 Smooth Menthol			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
1,2,3,7,8-Penta CDF	[pg/stk]	<3.8 (LOD)	*	3	<3.3 (LOD)	*	3	NA	NA	NA	NA
2,3,4,7,8-Penta CDF	[pg/stk]	<4.0 (LOD)	*	3	<3.2 (LOD)	*	3	NA	NA	NA	NA
1,2,3,4,7,8-Hexa CDF	[pg/stk]	<2.2 (LOD)	*	3	<2.8 (LOD)	*	3	NA	NA	NA	NA
1,2,3,6,7,8-Hexa CDF	[pg/stk]	<2.1 (LOD)	*	3	<2.7 (LOD)	*	3	NA	NA	NA	NA
2,3,4,6,7,8-Hexa CDF	[pg/stk]	<2.4 (LOD)	*	3	<20 (LOQ)	*	3	NA	NA	NA	NA
1,2,3,7,8,9-Hexa CDF	[pg/stk]	<2.6 (LOD)	*	3	<20 (LOQ)	*	3	NA	NA	NA	NA
1,2,3,4,6,7,8-Hepta CDF	[pg/stk]	<2.5 (LOD)	*	3	<20 (LOQ)	*	3	NA	NA	NA	NA
1,2,3,4,7,8,9-Hepta CDF	[pg/stk]	<3.3 (LOD)	*	3	<20 (LOQ)	*	3	NA	NA	NA	NA
Octa CDF	[pg/stk]	<4.4 (LOD)	*	3	<200 (LOQ)	*	3	NA	NA	NA	NA
Uranium-235	[Bq]	<0.005 (LOD)	*	3	<0.005 (LOD)	*	3	NA	NA	NA	NA

HPHCs	Unit	3R4F			THS 2.2 Smooth Menthol			% on stick basis		% on nicotine basis	
		mean	SD	n	mean	SD	n	% of 3R4F	% of reduction to 3R4F	% of 3R4F	% of reduction to 3R4F
Uranium-238	[Bq]	<0.005 (LOD)	*	3	<0.005 (LOD)	*	3	NA	NA	NA	NA

Average reduction of HPHCs (not including main aerosol deliveries, TPM, nicotine, NFDPM, glycerin and water)

The average reduction is based on HPCHs reported in Table 5Table 3 and represent the average of column "% of reduction to 3R4F". The averages were calculated on stick basis and on nicotine basis:

- On stick basis : >92.6%
- On nicotine basis : >88.8%

7 Conclusions Data Evaluation

The total reduction of HPHCs of THS 2.2 Regular and Smooth Menthol vs. combustible reference cigarette 3R4F (not including nicotine, TPM, glycerin and water) was found to be >91.9% to >92.6% on stick basis and >87.8% to >88.8% on nicotine basis respectively. This reduction is fully in alignment with our previous reduction calculated on the 54 HPHCs from the PMI-58 list. This provides additional evidence that the PMI-58 list provides a good approximation to correctly estimate the overall reduction of HPHCs emitted by the THS 2.2 system vs. a combustible cigarette. In addition, the results observed for both THS 2.2 Regular and Smooth Menthol were very similar, providing further evidence that reductions in overall HPHC generation is related to the heat-not burn-principle and not impacted by the nature of the flavor system.

8 References

1. Analytical Test Report, NS367-H revision 1, Peter Joza, Labstat International ULC, March 29 2018

9 Review

This document has been reviewed by:

Name	Justification / Function	Date / Signature
Jeannet Cyril	Singed as Author / Manager Product Characterization	20-Apr-2018
Maeder Serge	Signed as Owner and Approver / Director Product Research	20-Apr-2018

10 Document versions

Version	Description	Change type
1.0	Initial version	NA