

What is combustion and why is the absence of combustion important for heat not burn products

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THS 2.2: Reduced Formation Leads to Reduced Toxicity in vitro



(a) Aerosol collection with Health Canada's Intense Smoking Regime: 55 mL puff volume, 2-second puff duration, 30-second interval puff. Comparison on a per-stick basis. Reduction calculations exclude Nicotine, Glycerin and Total Particulate Matter. (b) The PMI 58 list includes the FDA 18 and (c) the 15 carcinogens of the IARC Group 1. These data alone do not represent a claim of reduced exposure or risk. .THS 2.2 = Tobacco Heating System 2.2 Source: PMI Research & Development



Combustion (Burning) of Biomass



Key attributes of combustion reactions:

- (1) a rapid oxidative process
- (2) occurs at elevated temperatures
- (3) associated with the release of energy in the form of heat (exothermic reaction)
- (4) evolution of emissions



Thermal Process Overview

Temperature (°C)







Cigarette – example of self–sustaining Smoldering Combustion



- The temperature at the burning tip > 600 °C
- When air is drawn through the cigarette (i.e. during a puff) the temperature rises > 850 °C
- The heat released breaks down tobacco components generating smoke and ash
- The cigarette smoke aerosol is a complex mixture of more than 6000 chemicals
- Several of these chemicals are harmful and have been classified by public health authorities as likely causes of smoking related diseases.

Harmful Chemical Formation as a function of Temperature

 Scientific studies have shown that as the temperature of tobacco increases, the levels of harmful chemicals formed increases



McGrath, T. E., Wooten, J. B., Chan W. G. and Hajaligol, M. R. (2007) Formation of Polycyclic Aromatic Hydrocarbons from Tobacco: the "Link" between Low Temperature Residual Solid and PAH Formation, Food and Chemical Toxicology, 45, 6, 1039-1050

Tobacco Heating System (THS 2.2)

• Allows for the controlled heating of tobacco (without burning) to produce a nicotine containing aerosol



Temperature of Tobacco in the Tobacco Heating System (THS 2.2)



Source: PMI R&D. * Radical position of thermocouple relative to the surface of the heater

- Heats tobacco to temperatures below 350 °C
- When air is drawn through the Tobacco Stick (i.e. during a puff) the temperature decreases
- The controlled heating of the tobacco generates an aerosol
- Structural integrity of the Tobacco Stick maintained – no ash formed



Temperature of Tobacco in the Tobacco Heating System (THS 2.2)



- When the heater is turned off
- There is no recovery in the temperature



Source: PMI R&D

Data supports the absence of self-sustaining combustion processes



Operating the Tobacco Heating System (THS 2.2) in Nitrogen

 Operating the THS 2.2 in an atmosphere of nitrogen, where one of the essential elements for combustion (oxygen) is excluded, yields comparable aerosol compositional results compared to experiments run in air.

Source: External Laboratory Analysis Results - Labstat report number NS201. *Total Particulate Matter. Health Canada Intense regime. ISO 4387 method. †Nicotine-free dry particulate matter. BDL: Below the Limit of Detection, NQ: Below the Limit of Quantification (LOQ) - above LOD but below LOQ. Health Canada Intense regime. LOQ for CO, quinoline, resorcinol, crotonaldehyde = 0.53 mg/unit, 0.011 ug/unit, 0.055 ug/unit and 3.29 ug/unit, respectively. Unit = EHTP = Tobacco Stick.

		EHTP in Nitrogen		EHTP in Synthetic Air		Blank	
Constituents	unit	Average	Std. Dev.	Average	Std. Dev.	Average	Std. Dev.
TPM [*]	mg/unit	54.0	1.5	55.2	1.6	0.006	0.015
Water	mg/unit	34.7	4.3	37.3	3.8	BDL	BDL
NFDPM [†]	mg/unit	17.9	3.1	16.5	3.4	BDL	BDL
Glycerin	mg/unit	4.38	0.24	4.39	0.40	BDL	BDL
Nicotine	mg/unit	1.38	0.10	1.37	0.09	BDL	BDL
СО	mg/unit	<0.53 but ≥0.16		0.54	0.16	BDL	BDL
NO	µg/unit	18.8	0.9	19.9	1.3	BDL	BDL
NOx (NO + NO ₂)	µg/unit	19.5	1.0	20.8	1.4	BDL	BDL
Benzo[a]pyrene	ng/unit	0.60	0.09	0.61	0.11	BDL	BDL
1_3_butadiene	µg/unit	0.3	0.03	0.3	0.02	BDL	BDL
Isoprene	µg/unit	2.6	0.4	2.3	0.1	BDL	BDL
Acrylonitrile	µg/unit	0.2	0.02	0.2	0.02	BDL	BDL
Benzene	µg/unit	0.5	0.07	0.6	0.06	BDL	BDL
Toluene	µg/unit	1.9	0.3	2.0	0.2	NQ	NQ
Pyridine	µg/unit	7.4	0.6	7.8	1.4	0.2	0.1
Quinoline	µg/unit	<0.011 but ≥0.003		<0.011 but ≥0.003		BDL	BDL
Styrene	µg/unit	0.8	0.3	0.7	0.2	0.1	0.01
Hydroquinone	µg/unit	7.4	0.7	7.0	0.2	BDL	BDL
Resorcinol	µg/unit	<0.055 but ≥0.016		<0.055 but ≥0.016		BDL	BDL
Catechol	µg/unit	14.7	1.1	14.3	0.5	BDL	BDL
Phenol	µg/unit	1.3	0.1	1.4	0.1	NQ	NQ
p-cresol	µg/unit	0.07	0.01	0.07	0.01	BDL	BDL
m-cresol	µg/unit	0.03	0.01	0.03	0.01	BDL	BDL
o-cresol	µg/unit	0.07	0.01	0.06	0.01	BDL	BDL
Formaldehyde	µg/unit	6.1	1.2	9.1	1.4	1.7	0.2
Acetaldehyde	µg/unit	211	16	230	21	NQ	NQ
Acetone	µg/unit	31.0	2.3	35.9	4.3	NQ	NQ
Acrolein	µg/unit	8.4	1.3	10.7	1.7	BDL	BDL
Propionaldehyde	µg/unit	13.7	1.1	14.9	1.9	BDL	BDL
Crotonaldehyde	µg/unit	<3.29 but ≥0.988		<3.29 but ≥0.988		BDL	BDL
Methyl Ethyl Ketone	µg/unit	7.0	0.6	7.6	0.8	BDL	BDL
Butyraldehyde	µg/unit	22.5	1.9	23.1	1.9	NQ	NQ
1_aminonaphthalene	ng/unit	0.07	0.01	0.07	0.01	NQ	NQ
2_aminonaphthalene	ng/unit	0.04	0.01	0.04	0.01	0.02	0.00
3_aminobiphenyl	ng/unit	0.01	0.00	0.01	0.00	NQ	NQ
4_aminobiphenyl	ng/unit	0.02	0.00	0.02	0.00	0.01	0.01





Suspension of solid and or liquid particles suspended in a gas (usually air)

Source: Hinds, W. C. (1999). Aerosol technology: Properties, behaviour, and measurement of airborne particles. New York: Wiley



Types of Aerosols



Smoke is an aerosol generated when organic matter (such as tobacco) undergoes combustion or pyrolysis processes.^{1,2,3}

Source; (1) D. Gross, J. J. Loftus and A. F. Robertson, Symposium on Fire Test Methods -- Restraint and Smoke, 1966, ASTM STP 422, Am. Soc. Testing and Materials, Washington, D.C., 1967, p. 166. (2) Mulholland, G. W. (2002). Smoke Production and Properties. Chapter 13; Section 2; NFPA HFPE-02. In P. J. DiNenno, D. Drysdale, C. L. Beyler, & W. D. Walton (Eds.), SFPE Handbook of Fire Protection Engineering. (3rd ed., pp. 2/258-268). The National Institute of Standards and Technology (NIST). Retrieved from http://fire.nist.gov/bfrlpubs/fire02/PDF/f02072.pdf (3) 921 National Fire Protection Association, 2016. http://www.nfpa.org/codes-and-standards/resources/glossary-of-terms



Composition of Cigarette Smoke versus THS 2.2 Aerosol

- Due to the controlled operating temperature of the heater in the THS 2.2, there are no self-sustaining combustion processes
- The aerosol generated is formed principally by the evaporation of water, nicotine and glycerin (added as an aerosol former) from the tobacco.



Source: PMI R&D. *Aerosol collection with Health Canada's Intense puffing regime (55 mL puff volume, 2 second puff duration, 30 second interval puff); THS – Tobacco Heating System 2.2



Absence of solid particles in THS 2.2 aerosol



Data supports the absence of combustion derived solid carbonaceous particles in the THS 2.2 aerosol

Source: Pratte et al. 2016. Investigation of solid particles in the mainstream aerosol of the Tobacco Heating System THS2.2 and mainstream smoke of a 3R4F reference cigarette. Human and Experimental Toxicology. 1-6 DOI: 10.1177/0960327116681653



External Scientific verification of the absence of combustion and no smoke formation in the THS 2.2



 The absence of combustion and no smoke formation has been verified by scientific experts in numerous countries including U.S., U.K., Italy, Poland and Japan.



• Executive summaries of reports and related poster presentations available on PMIScience.com

https://www.pmiscience.com/news/absence-combustion-pmi%E2%80%99s-heated-tobacco-product-platform-1



THS 2.2 - Eliminating Combustion Reduces the Formation of Harmful Chemicals

Average reductions in the formation of harmful chemical levels measured in the THS 2.2 aerosol compared to the smoke from the 3R4F reference



*Aerosol collection with Health Canada's Intense puffing regime (55 mL puff volume, 2 second puff duration, 30 second interval puff); Comparison on a per-stick basis. Reduction calculations exclude Nicotine, Glycerin and Total Particulate Matter. 3R4F Reference cigarette. THS 2.2 = Tobacco Heating System 2.2





- Robust scientific experiments confirm that using the Tobacco Heating System (THS 2.2) to heat Tobacco Sticks does not result in the self-sustaining combustion of tobacco nor in the generation of smoke or ash
- Scientific experts in the combustion and thermolysis fields have verified the absence of combustion and no smoke formation in the THS 2.2

Eliminating combustion and reducing the temperature to which tobacco is heated significantly reduces the levels of harmful chemicals formed. In the THS aerosol the levels of harmful chemicals are reduced on average by 90 – 95% compared to cigarette smoke.

*Aerosol collection with Intense Health Canada's puffing regime (55 mL puff volume, 2 second puff duration, 30 second interval puff);Comparison on a per-stick basis to the 3R4F reference cigarette. Reduction calculations exclude Nicotine, Glycerin and Total Particulate Matter. THS = Tobacco Heating System 2.2



Substantiating Reduced Risk: Totality of Scientific Evidence

Post-Market Studies and Surveillance

Consumer Perception and Behavior Assessment

Clinical Trials

Systems Toxicology Assessment

Standard Toxicology Assessment

Aerosol Chemistry and Physics

Product Design and Control Principles **Reduced Population Harm**

Reduced Exposure & Risk

Reduced Risk in Laboratory Models

Reduced Toxicity in Laboratory Models

Reduced Formation of HPHCs

Source: Smith, M.R., *et al.*, Evaluation of the Tobacco Heating System 2.2. Part 1: Description of the system and the scientific assessment program. *Regulatory Toxicology and Pharmacology* (2016). http://dx.doi.org/10.1016/j.yrtph.2016.07.006. HPHCs = Harmful or potentially harmful constituents

