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EXPERIMENTAL REPORT

IQOS_3.0_SYSTEM_4_ADDTIONAL_HARMFUL_OR_POTENTIALLY_HARMFUL_CONSTITUENTS_(HPHCS)

Project Name	Product Characterization of IQOS 3.0 System
WBS number	J-1002MSAT001/0023/0003
Experimental Work Type	☐ Exploratory experimental work ☐ Development experimental work ☒ Regulatory and clinical support experimental work
Business owner	(b) (6)
Author(s)	(b) (6) contracted)

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Document unique ID: RD_PHC_810548_ERP	Status : Approved
Document Title: IQOS_3.0_System_4_additional_Harmful_or_Potentially_Harmful_Constituents_(HPHCs)	Version Number: 2.0, CURRENT

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1 ABSTRACT

Four (4) aerosol constituents identified in the non-targeted differential screening of The Authorized ***IQOS*** System and the ***IQOS*** 3.0 System under two extremes firmware settings (Forced Warm aerosol (WA) and Forced no-Warm aerosol (no-WA)) were tested (glycidol, furfural, 2-furanmethanol, 3-chloro-1,2-propanediol). These four additional HPHCs are neither part of the PMI-58 nor of the FDA-18 list of HPHCs and they were reported at higher levels in the Authorized IQOS System in comparison to the 3R4F reference cigarette.

2 TESTING LABORATORY

Testing of the 4 HPHCs were conducted by Philip Morris Intl. R&D based in Switzerland. Fufural, glycidol and 2-furanemethanol were tested under ISO 17025 accreditation. 3-chloro-1,2-propanediol (3-MCPD) was tested as a part of an exploratory method (no ISO accreditations).

Laboratory address:

Philip Morris Intl. R&D

Quai Jeanrenaud 5

CH-2000 Neuchâtel

3 SAMPLES

Aerosol testing was performed using the following IQOS devices and HeatSticks:

- ***IQOS*** 3.0 System Holder (product no.: DV.000533 (rev. 9) with forced wet[1] profile (FW v1.3.192))
- ***IQOS*** 3.0 System Holder (product no.: DV.000533 (rev. 9) standard C28 profile[2] (FW v1.0.4))
- The Authorized ***IQOS*** System Holder (product no.: DV.000174 (rev. 9))

Reference HeatSticks: P1M2 monitor HeatSticks batch IC-2911171 (product no.: 6AAPR (rev. 9) with manufacturing date of May 18th 2017).

Aerosol testing was also performed with a conventional cigarette 1R6F (product no.: CONS.07464.RD (rev. 1)).

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[1] IQOS 3.0 Forced Warm Aerosol Firmware Setting

[2] IQOS 3.0 Forced no Warm Aerosol Firmware Setting

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Details about the sample numbers in the Table 1 below:

Table 1: Sample description. Method specified in brackets for each LIMS sample number.

Product Description	***LIMS sample number***	***PDIMS sample number***
IQOS 3.0 System Batch of DV.000533(9) HTP Holder - HTH / P1 ***IQOS*** 3 Cortes Holder Graphite / v1.3.192 / C28 with forced wet profile used with P1M2 monitor sticks batch of 6AAPR(9)	2061725 (furan) 2061694 (3-MCPD)	SMP134841
IQOS 3.0 System Batch of DV.000533(9) HTP Holder - HTH / P1 ***IQOS*** 3 Cortes Holder Graphite / 1.0.4 / C28 standard perceived warm aerosol used with P1M2 monitor sticks batch of 6AAPR(9)	2061723 (furan) 2061692 (3-MCPD)	SMP134840
The Authorized IQOS System Batch of DV.000174(9) Platform 1 – ZRH/THD 2.4/ZRH holder firmware - 1.1.2 (v2.4)/C28/P1 THD V2.4 Holder - Dark Slate used with P1M2 monitor sticks batch of 6AAPR(9)	2061644 (furan) 2064634 (3-MCPD)	SMP134667
1R6F Conventional cigarette	2061646 (furan) 2064636 (3-MCPD)	SMP134670

4 RESULTS

4.1 Data availability

Data considered in the present report were obtained and reported by Analytical Chemistry Laboratory (ACL 1) for furfural, glycidol and 2-furanemethanol and by Chemistry Research Laboratory for 3-chloro-1,2-propanediol. Sample(s) were tested in accordance with the working instruction PMI-RRP-WKI-136103 under ISO 17025 accreditation for furfural, glycidol and 2-furanemethanol [1]. 3-chloro-1,2-propanediol is part of an exploratory method [2].

Testing dates:

- Aerosol collection: February 11th and 18th
- Chemical analyses: February 11th and 19th

Raw data files are available in SDMS under projects RLS-THR-2020-1 and RLS-THR-2020-2.

4.2 Sample conditioning and testing environments

Samples were conditioned and tested under the environmental conditions specified in ISO 3402 (1999) “Tobacco and tobacco product – Atmosphere for conditioning and testing”. With respect to conditioning, this document states “The conditioning atmosphere shall be as follows: temperature 22+/-1°C; relative humidity 60+/-3%. Smoking requires an environment in which temperature is 22+/-2°C and relative humidity 60+/-5%.

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Aerosol generation (or puffing) regime

Tobacco sticks are puffed to a fixed puff number: 12 puffs per stick under Health Canada Intense (HCI) smoking regime. This regime is described as follows: puff volume 55.0+/-0.5ml, puff frequency 30+/-0.5s, puff duration 2.00+/-0.02s, bell-shaped puff profile. No vent blocking is needed as tobacco stick has no ventilation.

4.3 Experimental results

The results of analysis of HPHCs levels for the 4 constituents are provided in the Table 2 (furfural, glycidol, 2-furanemethanol) and Table 3 (3-MCPD).

Table 2: Summary of ***IQOS*** 3.0 System furfural, glycidol, 2-furanemethanol deliveries yields with forced wet profile firmware setting, ***IQOS*** 3.0 System yields with standard C28 profile, The Authorized ***IQOS*** System yields, and the yields of 1R6F reference cigarette. SD – standard deviation; n – sample size

Aerosol deliveries	**Unit**	**1R6F**			**IQOS 3.0 System Forced WA**			**IQOS 3.0 System Forced no-WA**			**The Authorized IQOS System**		
		Mean	**SD**	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**	**n**
Furfural	µg/stick	26.09	3.65	4	33.93	2.13	4	31.68	1.74	4	32.09	3.77	4
Glycidol	µg/stick	2.41	0.28	4	6.07	0.31	4	5.44	0.27	4	5.69	0.33	4
2-furanemethanol	µg/stick	4.57	0.35	4	35.73	3.08	4	31.20	2.10	4	31.47	1.66	4

Table 3: Summary of ***IQOS*** 3.0 System 3-chlor-1,2-propanediol deliveries yields with force wet profile firmware setting, ***IQOS*** 3.0 System yields with standard C28 profile, The Authorized ***IQOS*** System yields, and the yields of 1R6F reference cigarette. RSD – residual standard deviation (%); n – sample size

Aerosol deliveries	**Unit**	**1R6F**			**IQOS 3.0 System Forced WA**			**IQOS 3.0 System Forced no-WA**			**The Authorized IQOS System**		
		Mean	**RSD**	**n**	**Mean**	**RSD**	**n**	**Mean**	**RSD**	**n**	**Mean**	**RSD**	**n**
3-MCPD	µg/stick	4.40	4.46	4	10.95	7.24	4	13.67	12.08	4	12.38	10.23	4

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5 REFERENCES AND RELATED DOCUMENTS

[1]: PMI-RRP-WKI-136103, “Quantitation of carbon disulfide, caprolactame, glycidol and furanic compounds by GC-MS (RDNEU)”, version 1.0.0, Celia Sequeira

[2]: https://disco.app.pmi/disco/drl/objectId/0901d4ec809a83db, “Method Summary: Quantification of 3-chloro-1,2-propandiol (3-MCPD) In Aerosol Samples”, version 1.0.0, Arno Knorr

6 REVISION HISTORY

Version N°	Description of change
1.0	Original issue
2.0	Correction of minor bugs observed during transfer from macro-enabled word document to pdf document

7 ABBREVIATIONS

Abbreviations		
3-MCPD	:	3-chloro-1,2-propanediol
FW	:	Firmware
Intl.	:	International
no-WA	:	No Warm Aerosol
WA	:	Warm Aerosol

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Document Information

Document Name	RD_PHC_810548_ERP
Document Title	IQOS_3.0_System_4_additional_Harmful_or_Potentially_Ha
Version	2.0
Lifecycle	Approved Lifecycle
Status	Approved

Signature Table

Approver	Date (UTC time)	Reason for signing	Outcome
(b) (6)	24-Mar-2020 14:29:09	Subject Matter Expert Approval	Approved