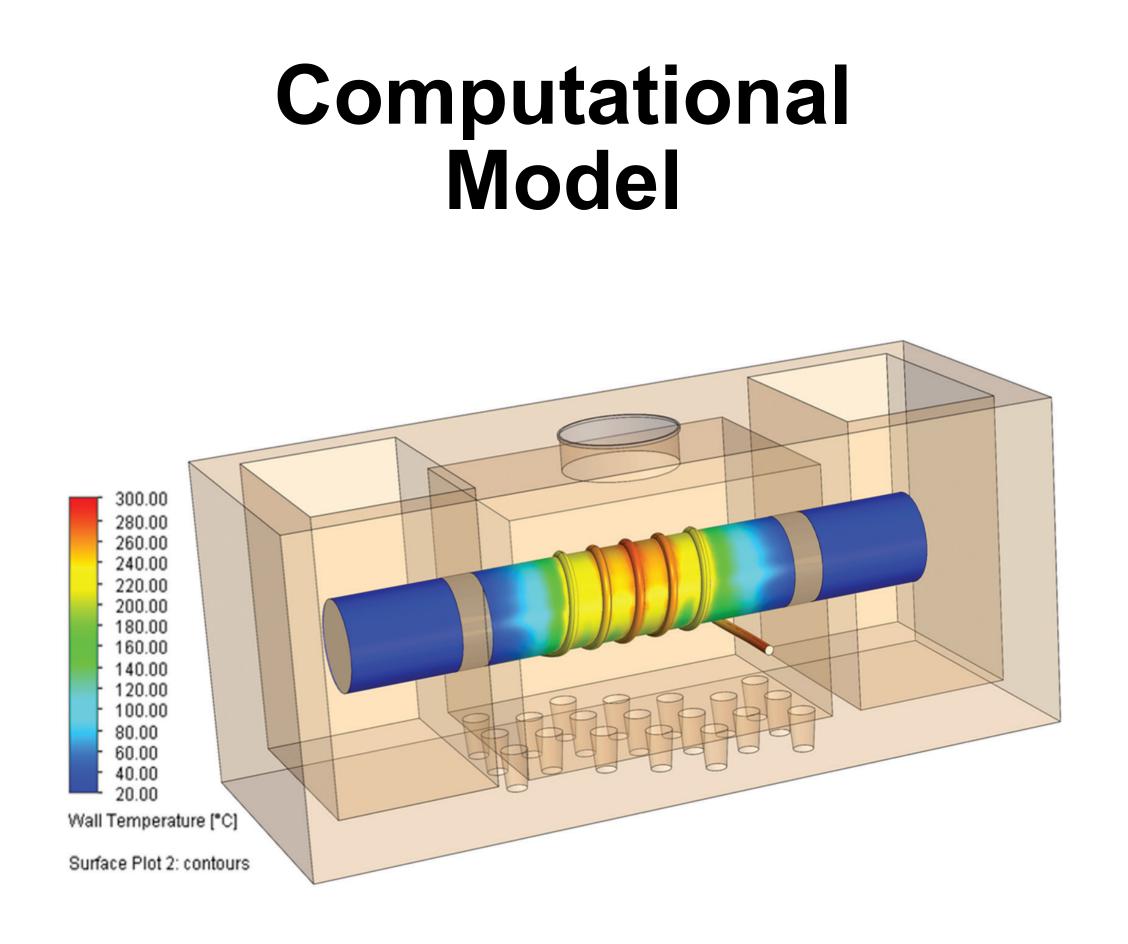
Characterization of Temperature Regulation and HPHC Profile of a Nicotine-Salt Based ENDS Product

Gene Gilman, Ph.D., Melissa Johnson, Alexandra Martin, M.S. Enthalpy Analytical, Inc. USA Dan Myers, Ph.D.*, Bill Alston M.S., Manoj Misra Ph.D., JUUL Labs, USA

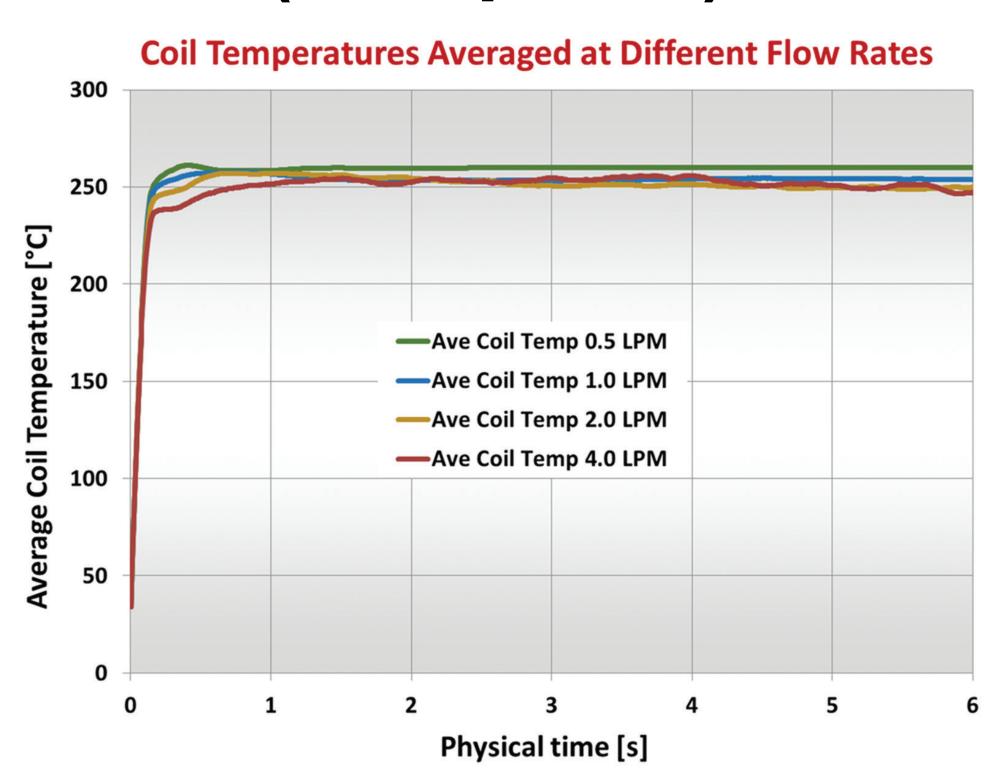
Introduction

When combusted, cigarettes reach temperatures that can exceed 1000°C and consequently generate more than 4000 degradation products and HPHC's (harmful and potentially harmful constituents)¹. JUUL is a nicotine-salt based, pre-filled (closed) ENDS system. With automated temperature regulation and no user-modifiable controls, JUUL ENDS is designed to minimize the generation of degradation products and to maintain consistency of temperature across a range of operating conditions. These studies characterized these features and their effects on the chemical profile of aerosols produced by JUUL ENDS compared to published data for a leading brand of combusted cigarettes.



Calculated temperature profile of the heating coil and wick at one of four airflow rates: 1.0 LPM at 6.0s. Models were consistent with observed temperatures.

Temperature Profile (Computed)



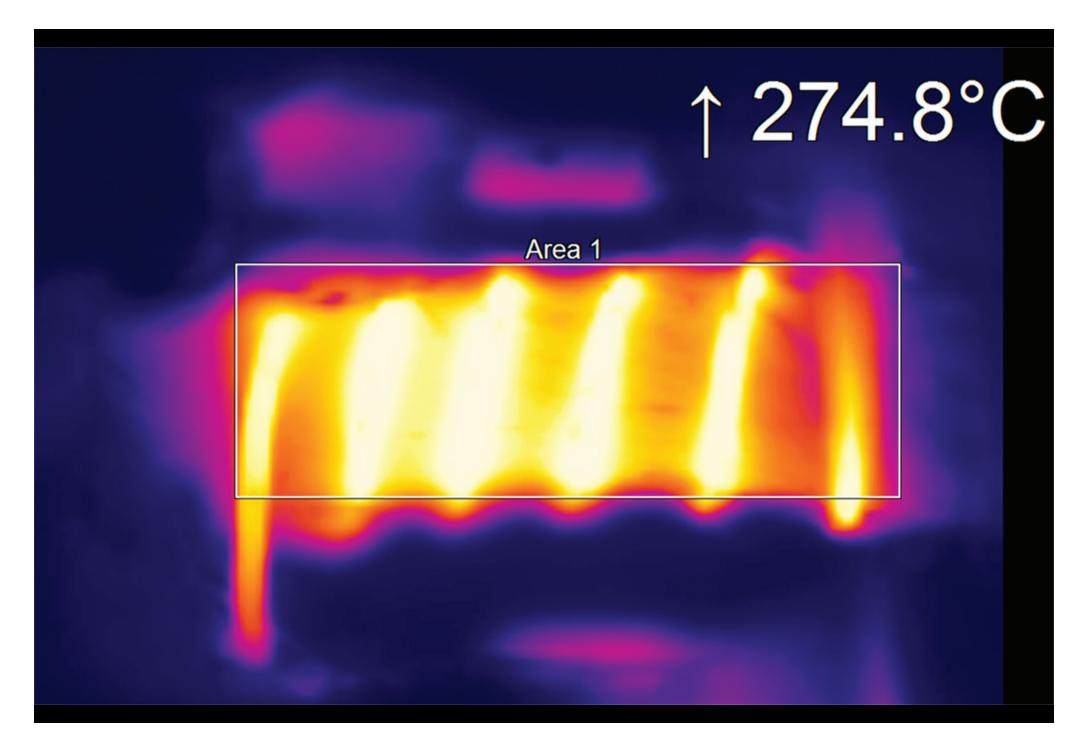
Combined average temperature profiles for a duration of six seconds, using airflow rates of 0.5, 1.0, 2.0, and 4.0 LPM. Coil temperatures were consistently below 300°C.

IR Temperature Measurement ↑ 262.5°C

"Wet Wick"

Representative IR thermography measurement under wet wick conditions, demonstrating a peak temperature (i.e. hottest point of the coil) of 262.5°C at 2.0s and airflow of 1.35LPM.

IR Temperature Measurement



"Dry Wick" / Unfilled Pod Representative IR thermography measurement using unfilled pod (wick is therefore dry), demonstrating a peak temperature of 274.7°C at 2.0s and airflow of 1.35LPM.

Methods

Computational models were generated based on the physicochemical properties of the atomizer wick and both conductive and convective heat transfer mechanisms. Actual atomizer temperatures were measured by infrared thermography (n=4 filled, 3 unfilled pods). The HPHC profile of aerosol generated from JUUL ENDS, Virginia Tobacco flavor, 5% nicotine-filled pods (n=10) was characterized by an independent 3rd party laboratory (Enthalpy Analytical), using smoking machines and validated analytical methods. Puffing profile was 3 seconds, 70 mL, square wave puff with a 30 second puff interval. A reference panel of 31 chemicals including FDA defined HPHC's was measured². Quantified levels were compared against a published reference panel derived from Marlboro Gold cigarettes³.

Results

In this preliminary analysis, atomizer temperatures, measured by infrared thermography, remained below 300°C, during wet wick and dry wick (unfilled pod) conditions, which was consistent with computed modeling. Nicotine, propylene glycol and glycerol, were identified in the aerosol, along with anabasine, a nicotine analogue. Panel analytes in the following classes were present below level of quantification (BQL) or not detected (ND): PAH's (polycyclic aromatic hydrocarbons), VOC's (volatile organic compounds), carbonyls, and PAA's (primary aromatic amines). 4 of 5 metals tested were also BQL or ND, with the exception of chromium which was 2% above LOQ and up to 98% lower than other cigarettes reported in the literature. For TSNA's, NNK was not detected, and NNN was >99% lower than levels found in reference cigarette smoke.

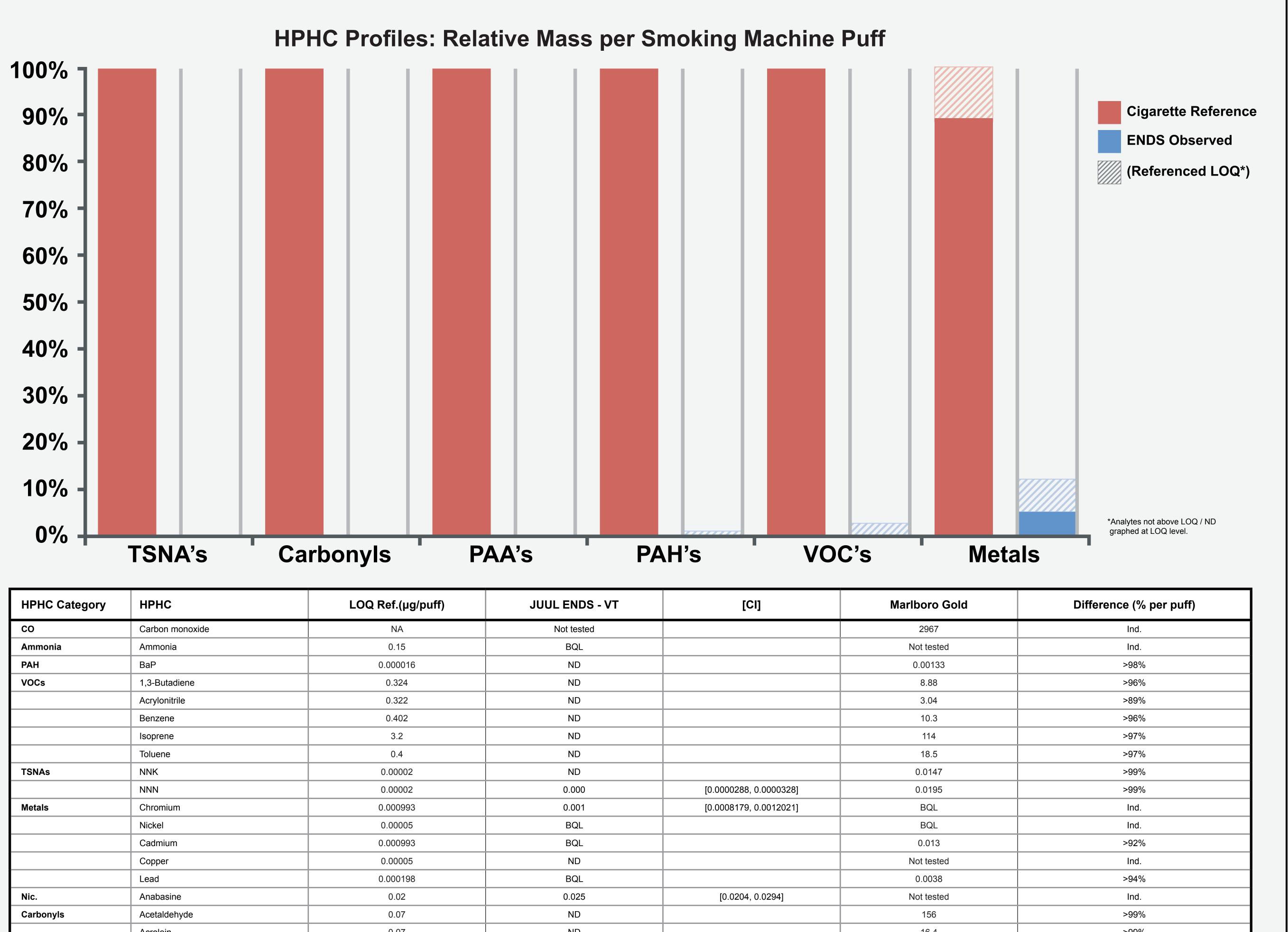
Conclusions

- In a preliminary set of studies, observed coil temperatures in JUUL ENDS corresponded with predicted models of automated temperature regulation and maintained average temperatures below 300°C, under a range of conditions in the laboratory setting, including an unfilled pod with dry wick.
- JUUL ENDS (Virginia-Tobacco, 5%) aerosol was analyzed against a panel of 31 analytes and HPHC's. Beyond 3 intended ingredients (nicotine, propylene glycol, glycerol), 89% (25 of 28) of panel analytes were not detected (ND) or below the level of quantification (BQL). 11% (3 of 28) were observed at quantifiable levels, including NNN at >99% reduction; VT flavor contains tobacco extracts, chromium (previously reported in e-cigarette and cigarette aerosol⁶, at 2% above LOQ), and anabasine (a nicotine isomer, at 1.25x LOQ.)

Preliminary Aerosol / HPHC Analysis (JUUL ENDS Virginia Tobacco 5% vs. Marlboro Gold

Combusted Cigarette)

Aerosol HPHC's were observed to be below LOQ or ND across multiple panel categories (PAH's, VOC's, carbonyls, and PAA's). Nicotine, propylene glycol, and glycerol were observed in the aerosol. Ethylene glycol, diethylene glycol, glycidol, and menthol were not detected (not shown). Anabasine, a nicotine isomer, was observed at 0.0249 ug/puff. NNK was not detected, and NNN was observed at 0.0000308 ug/puff which was >99% lower than reference level from combusted cigarette. Chromium was observed at 2% above analytical LOQ and Ind. relative to reported Marlboro LOQ of 1ng/ puff. Chromium was was up to 98% lower than reported levels for other cigarettes (up to 0.05 ug/ puff.)⁵ Metals have been previously reported in other e-cigarette aerosols⁶. Benzene was not detected, consistent with a previous independent report⁷. For certain analytes, the difference between JUUL ENDS aerosol and combustible cigarette smoke could not be determined because neither were above the prespecified level of quantification or a value was missing ("Ind.") (BQL, below level of quantification; Ind, could not be determined; LOQ, level of quantification; ND, not detected; [CI] = 95% interval.)



HPHC Category	НРНС
СО	Carbon monoxide
Ammonia	Ammonia
РАН	BaP
VOCs	1,3-Butadiene
	Acrylonitrile
	Benzene
	Isoprene
	Toluene
TSNAs	NNK
	NNN
Metals	Chromium
	Nickel
	Cadmium
	Copper
	Lead
Nic.	Anabasine
Carbonyls	Acetaldehyde
	Acrolein
	Crotonaldehyde
	Diacetyl
	Formaldehyde
	Pentanedione
PAAs	1-aminonaphthalene
	2-aminonaphthalene
	4-aminobiphenyl

- ENDS aerosol contained significantly reduced levels of panel HPHC's, per smoking machine puff, in multiple panel categories, compared to published levels from a reference combustible cigarette.
- Limitations: this was a preliminary assessment. IR measurements required modifying pod to view coil. HPHC measurements describe smoking machine testing at a single setting, of a delimited panel of analytes. Ten pods of a single tobacco flavor were tested. Comparisons to an analyte below LOQ assumed a concentration equal to reference LOQ. Comparisons between analytes for which neither were above LOQ were considered indeterminate. Comprehensive characterization of human HPHC exposure will involve topography and human biomarker analyses, which will be addressed in future studies.

16.4 0.0699 4.42 0.0771 Not tested 7 12 0.0747 Not tested 0.00122 0.00072 0.00028

References

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- 3. R. Tayarah, G.A. Long, Regulatory Toxicology and Pharmacology 70, 704–710, 2014.
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Clarifications from rapid abstract: emitted CO was not measured in this panel (exhaled CO is reported in a separate poster.) NNN was above BQL and >99% below reference cigarette on per puff basis. Reduction in emissions per puff was seen for multiple categories of panel analytes. Beyond emissions data, complete characterization of human exposure involves additional studies characterizing topography and human biomarker validation.

Consistent with FDA regulations, JUUL Labs can not and does not promote its products as less harmful or safer than cigarettes.

This document is intended for sharing data with the scientific community.