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# Levels of menthol, nicotine and cooling agents measured in JUUL products purchased across a three-year period

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## ABSTRACT

**Background** In response to the popularity of JUUL and other flavoured ENDS products among youth, the US Food and Drug Administration issued in February 2020 an enforcement policy to remove all flavoured cartridge/pod-based e-cigarettes from the market except for tobacco and menthol. Subsequent studies found that some former users of the now-removed flavoured JUUL pods (especially cool mint) switched to menthol-flavoured JUUL pods with similar satisfaction.

**Methods** We quantified menthol, nicotine, propylene glycol (PG) and vegetable glycerol (VG) in JUUL pod samples (Menthol, Classic Menthol and Cool Mint) that were purchased in 2017, 2018 and 2020 (only Menthol) to evaluate composition differences before and after the enforcement policy. We also analysed the samples to detect other cooling agents using a screening gas chromatography-mass spectrometry headspace method that we developed for this purpose.

**Results** Nicotine and menthol concentrations were significantly higher in 2020 products than in products from prior years. Moreover, other cooling agents varied across pods. The PG/VG volume ratio was 27/63 in all pods examined.

**Conclusion** This study shows that concentrations of nicotine and menthol in JUUL products procured over a three year period decreased over time. The findings highlight the challenges of reconstructing product characteristics at the time of manufacture and time of consumption, and suggests the utility of an ENDS product bank that could preserve samples for retrospective studies. They also underscore that manufacturers should be required to release to the public and the scientific community what they know about time- and temperature-dependent degradation of their products.

## INTRODUCTION

In 2015, JUUL introduced a pod-based electronic cigarette (e-cigarette) system that delivered nicotine efficiently. The liquid in the pod contained nicotine in the salt form, which allowed JUUL to use an unprecedentedly high nicotine concentration without making the aerosol too harsh to inhale.<sup>1</sup> Soon after its release, JUUL sales rose to predominate the electronic cigarette market in the USA,<sup>2</sup> with high prevalence among youth.<sup>3,4</sup>

In response to what it described as an epidemic of youth e-cigarette use, the US Food and Drug Administration (FDA) issued in February 2020 an enforcement policy to remove all flavoured cartridge or/

## WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ In February 2020, an enforcement policy was imposed to remove all flavoured cartridge or/ pod-based e-cigarettes except tobacco and menthol pods from the market.
- ⇒ Some users of the removed flavoured JUUL pods (especially mint) reportedly switched to menthol JUUL pods with similar satisfaction.
- ⇒ This study examined liquid formulations of JUUL menthol and mint products in the USA prior to and after the FDA enforcement policy.

## WHAT THIS STUDY ADDS

- ⇒ Menthol- and Cool Mint JUUL pods contained similar amounts of menthol in a given year.
- ⇒ Cool Mint JUUL pods contained additional cooling agents and other flavorants not found in the Menthol pods
- ⇒ The 2020 Menthol JUUL pods contained significantly greater nicotine and menthol than the 2017 and 2018 pods.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Nicotine and menthol concentrations in a given ENDS product may change with time.

pod-based e-cigarettes except tobacco and menthol-flavoured pods from the market.<sup>5</sup> One report indicated that users of the flavoured JUUL pods (especially mint) switched to menthol, and experienced similar satisfaction.<sup>6</sup> Other studies found that by May 2020, JUUL pod sales were dominated by menthol accounting for >60% of sales.<sup>7,8</sup>

In this study, we analysed the liquid composition, including nicotine content, propylene glycol (PG)/vegetable glycerol (VG) ratio and menthol concentration of Menthol, Classic Menthol and Cool Mint pods purchased in various years. In addition, we developed a gas chromatography-mass spectrometry (GC-MS) headspace method to detect other cooling agents in the tested pods.

## METHODS

### Tested items

Cool Mint (2017, 2018), Classic Menthol (2017, 2018) and Menthol (2018) pods were purchased in 2017 and 2018 and Menthol (2020) pods were purchased in May 2020. All products were purchased at convenience markets in the USA. Three different pods from each purchase year and



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**Table 1** Liquid composition of JUUL pods before and after the Food and Drug Administration flavour enforcement policy

	Cool Mint 2017	Classic Menthol 2017	Cool Mint 2018	Classic Menthol 2018	Menthol 2018	Menthol 2020
JUUL liquid composition						
Nicotine concentration (mg/mL)	58.13* (0.96)	58.14* (0.38)	57.69* (0.65)	60.14 (0.96)	60.14 (1.34)	64.09 (2.00)
Free base nicotine (%)	2.26 (0.26)	2.05 (0.31)	3.60 (0.41)	2.33 (0.20)	3.18 (0.29)	2.88 (0.06)
PG/VG (%v/v)	27/63	27/63	27/63	27/63	27/63	26/64
Menthol concentration (mg/mL)	7.44† (0.28)	7.54† (0.12)	8.05† (0.23)	7.39* (0.34)	9.71† (0.20)	11.96 (0.19)
% other compounds (semi-quantitative)						
3-Octanol	0.23 (0.02)	ND	0.41 (0.02)	ND	ND	ND
p-Mentha-1.4 (8) diene	0.03 (0.01)	ND	0.02 (0.01)	ND	ND	ND
Eucalyptol	0.40 (0.03)	ND	0.47 (0.01)	ND	ND	ND
β-Terpeneole	0.03 (0.01)	ND	0.06	ND	ND	ND
β-Linalool	0.12	ND	0.15 (0.01)	ND	ND	ND
Neomenthol‡	0.51 (0.02)	ND	0.46 (0.02)	ND	ND	ND
Neoisomenthol‡	0.17 (0.01)	ND	0.16 (0.02)	ND	ND	ND
Pulegone	0.19 (0.01)	ND	0.21 (0.01)	ND	ND	ND
Carvone	0.05 (0.01)	ND	0.05	ND	ND	ND
Piperitone	0.06	ND	0.08	ND	ND	ND
Menthyl acetate	0.56 (0.04)	ND	0.54 (0.04)	ND	ND	ND
p-Menth-3-one	5.90 (0.44)	0.11 (0.02)	5.76 (0.01)	0.08 (0.01)	0.10 (0.01)	0.06 (0.01)
Isomenthol‡	20.31 (1.03)	0.9 (0.03)	21.51 (0.32)	0.78 (0.24)	0.90 (0.08)	0.70 (0.08)
Menthol‡	71.44 (0.70)	98.98 (0.01)	70.12 (0.35)	99.13 (0.25)	99.00 (0.07)	99.24 (0.09)

Results are shown as mean (SD) for n=3 samples.

Mean (SD).

\*p<0.05 relative to Menthol 2020.

†p<0.01 relative to Menthol 2020.

‡Cooling agent.

ND, not detected.

flavour were analysed. Liquids were removed from the previously unopened pods using a Pasteur pipette then transferred to a vial which was stored in a darkened refrigerator at 4°C.

### Determination of nicotine and PG/VG ratio

Nicotine concentration and PG/VG ratio were determined using previously described methods.<sup>9 10</sup>

### Quantification of menthol

Menthol concentration was determined by injecting the diluted liquid solution onto a GC-MS. In brief, 5 µL of JUUL liquid was dissolved in 1 mL of methanol, 5 µL of an internal standard: Carvacrol (1000 µg/mL in methanol), was added and the mixture was shaken for 5 min. The prepared samples were then injected on GC-MS and quantified versus a direct calibration curve (0–50 µg/mL) prepared from standard menthol solutions. The limit of detection and the limit of quantification were determined at 0.210 and 0.637 µg/mL, respectively. The tested

validation parameters were found to be within acceptable limits (%RSD: 5.38–8.97). Each sample was analysed in triplicate.

For GC-MS analysis, a Trace GC Ultra system coupled with a DSQ II Quadrupole spectrometer was used, equipped with a Triplus autosampler and X-Calibur software. Compounds were separated using a DB-5MS with helium as a carrier gas in a constant flow rate of 1 mL/min. The temperature programme was set at 60°C (hold for 2 min), ramp to 150°C with 5°C/min then another ramp to 250°C with 15°C/min (hold for 2 min). The total run time was 28.67 min. The injection volume was 1 µL. The injector temperature and the transfer line temperature were set at 230°C and 280°C, respectively. The MS operated in positive electron impact mode. The ion source temperature was set at 250°C.

### Screening for other cooling agents

A new method was developed to screen for other cooling agents in the tested pods. In brief, 30 µL of the e-liquid was added

to 3 mL of water and shaken for 3 min in a well-sealed headspace vial. Then the samples were allowed to equilibrate in a heated compartment at 80°C for 5 min. Samples were analysed in triplicate.

Detection of cooling agents was performed in full scan mode covering 40–400 m/z. It was based on the mass fragmentation of the detected compounds. The temperature programme on the GC was set at 50°C for 3 min, then ramped at 10°C/min to 220°C (hold for 3 min) for a total run time of 23 min. All the other details of the GC-MS system are like the menthol analysis described in the previous paragraph.

A semi-quantitative analysis of the detected flavour agents was done using a previously described method.<sup>11</sup> In brief, areas of all the detected compounds were summed, and the percentage of each compound in the sample was computed as  $\frac{\text{Area compound}}{\text{Sum of all the areas}} \times 100$ .

### Statistical methods

A two-tailed distribution and heteroscedastic t-test were used to investigate any significant difference in nicotine and menthol concentrations between the pods purchased before the enforcement policy (2017, 2018) vs those purchased after the enforcement policy (2020).

### RESULTS

We found that the tested JUUL pods contained approximately the same PG/VG ratio (table 1). The nicotine content, which was predominantly in the protonated form, ranged between 57.7 and 64.1 mg/mL. The nicotine concentration was found to be significantly higher in Menthol (2020) pods than in Classic Menthol (2017):  $p < 0.05$ , Cool Mint (2017):  $p < 0.05$  and Cool Mint (2018):  $p < 0.05$ . Menthol concentration was found to be the highest in Menthol (2020) pods compared with Menthol (2018):  $p < 0.001$ , Classic Menthol (2018):  $p < 0.05$ , Cool Mint (2018):  $p < 0.001$ , Classic Menthol (2017):  $p < 0.0001$  and Cool Mint (2017):  $p < 0.0001$ . No significant difference was found in menthol concentration between the different batches of Menthol (2020):  $p = 0.5948$ . The non-targeted analysis using GC-MS headspace showed various levels of isomenthol and p-menth-3-one in all the tested pods. Two additional cooling agents and many other non-cooling compounds were identified in Cool Mint (2017, 2018). All identified compounds were present at levels lower than menthol.

### Discussion

Menthol has been widely used as a cooling agent in tobacco products.<sup>12</sup> It induces a perception of a cool sensation by activating the transient receptor potential cation channel subfamily M member 8 found in the oral cavity.<sup>13</sup> Studies have found that menthol in cigarettes such as Newport (menthol range: 4.21–5.30 mg/cigarette)<sup>14</sup> contributed to the appeal, initiation and addiction potential among youth.<sup>15 16</sup> Recent evidence extended this observation to e-cigarettes.<sup>17 18</sup> Furthermore, menthol reduces the bitterness and increases the smoothness of inhaled nicotine, impacting e-cigarette appeal.<sup>19</sup>

In this work, we quantified menthol and nicotine levels in JUUL pods purchased across a three-year period. Our data show that JUUL Menthol pods, procured in May 2020, exhibited higher menthol concentrations than the tested products purchased in 2017 and 2018. Also, nicotine concentration for the 2020 products was greater than that of the 2017 products and the Cool Mint 2018 products. We also found that Cool Mint

contained at least ten constituents not found in the Menthol product, including several flavorants and cooling agents.

One limitation of this study is that product differences across year of purchase may reflect product degradation during storage rather than a different formulation. Another limitation is that a limited pool of products was available for analysis, and that observed differences across products may reflect variations by production batch.

Importantly, Krishnan-Sarin *et al*<sup>17</sup> evaluated the independent and interactive effects of menthol and nicotine and found that higher concentrations of menthol may increase the reward of high nicotine concentration.<sup>17</sup> In addition, other natural and synthetic cooling agents can be added to tobacco products to impart or enhance cooling sensation.<sup>20–23</sup> For example, WS-3 is a synthetic cooling agent that has replaced menthol in JUUL Mint pods sold in the European Union but not in the USA.<sup>24</sup> Our non-targeted analysis showed that Menthol (2018, 2020) and Classic Menthol (2017, 2018) pods have similar profiles and levels of cooling agents such as isomenthol. In contrast, Cool Mint (2017, 2018) exhibited higher levels of isomenthol and trace levels of two other cooling agents.

This study shows that concentrations of nicotine and menthol in JUUL products procured over a three-year period decreased over time, possibly due to product degradation during storage. The findings highlight challenges of reconstructing product characteristics at the time of manufacture and time of consumption, and suggests the utility of an ENDS product bank that could preserve samples for retrospective studies.

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**Contributors** AY, REH, AEH, AS, TE and NS: conception and design of research. AY, REH, RS: performed experiments. AY and AEH: drafted the manuscript. All the authors edited, revised and approved the final version of the manuscript.

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**Competing interests** TE and AS are paid consultants in litigation against the tobacco and e-cigarette industry and are named on one patent for a device that measures the puffing behaviour of e-cigarette users and another patent application for a smoking cessation intervention. TE is also named on a patent application for a smartphone app that determines e-cigarette device and liquid characteristics.

**Patient consent for publication** Not applicable.

**Ethics approval** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** The data supporting the findings are available within the article.

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# Correction: *Did JUUL alter the content of menthol pods in response to US FDA flavour enforcement policy?*

Yassine A, El Hage R, El-Hellani A, *et al.* Did JUUL alter the content of menthol pods in response to US FDA flavour enforcement policy? *Tob Control* 2022;31:s234–s237.

1. The title of the paper has been updated to *Levels of menthol, nicotine and cooling agents measured in JUUL products purchased across a three-year period.*
2. The abstract and body of the paper have been re-worded to remove any reference to alteration of pod ingredients by JUUL as shown below in detail.

## ABSTRACT

### Replaced text

**Original:** This study highlights how regulations intended to reduce e-cigarette prevalence among youth may influence changes in tobacco product characteristics in ways that regulations may not have foreseen.

**Revised:** This study shows that concentrations of nicotine and menthol in JUUL products procured over a 3 year period decreased over time. The findings highlight the challenges of reconstructing product characteristics at the time of manufacture and time of consumption, and suggests the utility of an ENDS product bank that could preserve samples for retrospective studies. They also underscore that manufacturers should be required to release to the public and the scientific community what they know about time- and temperature-dependent degradation of their products.

## WHAT IS ALREADY KNOWN

### Replaced text

**Original:** This study sought to examine whether JUUL's liquid formulations changed in the years surrounding the flavour restriction.

**Revised:** This study examined liquid formulations of JUUL menthol and mint products in the USA prior to and after the FDA enforcement policy.

## WHAT THIS STUDY ADDS

### Added text

- ▶ Menthol- and Cool Mint JUUL pods contained similar amounts of menthol in a given year.
- ▶ Cool Mint JUUL pods contained additional cooling agents and other flavorants not found in the Menthol pods.

### Replaced text

**Original:** Following the enforcement policy, tested samples of JUUL menthol pods had significantly greater menthol content than the pre-restriction products.

**Revised:** The 2020 Menthol JUUL pods contained significantly greater nicotine and menthol than the 2017 and 2018 pods.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

### Removed text

Menthol and other coolants in e-cigarettes should be target for regulation.

### Added text

Nicotine and menthol concentrations in a given ENDS product may change with time.

## INTRODUCTION

### Removed text

In this study, we sought to examine whether JUUL's liquid formulations changed in the years surrounding the flavour enforcement policy.

## DISCUSSION

### Replaced text

**Original:** In this work, we quantified menthol and nicotine levels in JUUL pods purchased in the year surrounding the FDA flavour enforcement policy of February 2020.

**Revised:** In this work, we quantified menthol and nicotine levels in JUUL pods purchased across a 3 year period.

**Original:** Our data show that JUUL Menthol pods, procured in May 2020, exhibited higher menthol concentrations than all the test products purchased before the enforcement policy.

**Revised:** Our data show that JUUL Menthol pods, procured in May 2020, exhibited higher menthol concentrations than the tested products purchased in 2017 and 2018.

#### Removed text

These findings therefore suggest that JUUL's menthol content increased following the FDA flavour enforcement policy, and that nicotine content may vary by product even when the label indicates the same 5% concentration. That the Cool Mint pods contained as much menthol as the Menthol pods highlights that manufacturer market flavours under different labels and may explain why previous users of Cool Mint found Menthol pods similarly satisfying.

#### Added text

We also found that Cool Mint contained at least ten constituents not found in the Menthol product, including several flavorants and cooling agents.

#### Replaced text

**Original:** One limitation of this study is that we did not have information on the production dates of the products; what we procured from store shelves in May 2020 might have been from stocks shipped before the enforcement policy. Nonetheless, the difference in menthol content across products is clear, and manufacturers may adjust liquid composition in anticipation of enforcement policies.

**Revised:** One limitation of this study is that product differences across year of purchase may reflect product degradation during storage rather than a different formulation.

#### Removed text

The array of compounds that impart a cooling sensation found in JUUL pods suggests that industry may readily circumvent regulations if the later focus narrowly on menthol.

#### Replaced text

**Original:** In conclusion, our findings suggest the possibility that the menthol content of JUUL pods changed in a manner that may have increased the appeal of these products when other flavoured pod- based products were no longer available. This work highlights the need to consider menthol and other natural and synthetic coolants in e- cigarettes as a possible target for regulation, as well as the need for regular independent testing to assure that products remain compliant with regulation.

**Revised:** This study shows that concentrations of nicotine and menthol in JUUL products procured over a 3 year period decreased over time, possibly due to product degradation during storage. The findings highlight challenges of reconstructing product characteristics at the time of manufacture and time of consumption, and suggests the utility of an ENDS product bank that could preserve samples for retrospective studies.



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