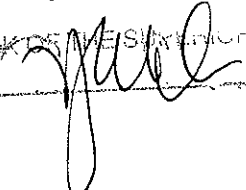


1 LEXINGTON LAW GROUP
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6 Attorneys for Plaintiff
7 CENTER FOR ENVIRONMENTAL HEALTH

FILED
ALAMEDA COUNTY

SEP - 6 2017

CLERK OF THE SUPERIOR COURT
By  Deputy

9 SUPERIOR COURT FOR THE STATE OF CALIFORNIA
10 FOR THE COUNTY OF ALAMEDA

12 CENTER FOR ENVIRONMENTAL HEALTH,) Case No. RG 15-794036
13)
14 Plaintiff,) **[PROPOSED] CONSENT**
15) **JUDGMENT AS TO SPARK**
16 v.) **INDUSTRIES, LLC**
17)
18 TOTALLY WICKED-E LIQUID (USA))
19 INCORPORATED, et al.,)
20)
21 Defendants.)

21 **1. INTRODUCTION**

22 **1.1.** This Consent Judgment is entered into by Plaintiff Center for Environmental
23 Health, a non-profit corporation (“CEH”), and Defendant Spark Industries, LLC (“Settling
24 Defendant”) to settle claims asserted by CEH against Settling Defendant as set forth in the
25 operative Complaint (the “Complaint”) in the matter *Center for Environmental Health v. Totally*
26 *Wicked-E Liquid (USA) Incorporated, et al.*, Alameda County Superior Court Case No. RG 15-
27 794036 (the “Action”). CEH and Settling Defendant are referred to collectively as the “Parties.”

1 **1.2.** On November 19, 2015, CEH served 60-Day Notices of Violation (the “Notices”)
2 relating to the California Safe Drinking Water and Toxic Enforcement Act of 1986, California
3 Health & Safety Code § 25249.5, *et seq.* (“Proposition 65”) on Settling Defendant, the California
4 Attorney General, the District Attorneys of every County in the State of California, and the City
5 Attorneys for every City in State of California with a population greater than 750,000. The
6 Notices allege violations of Proposition 65 with regard to exposures to formaldehyde and
7 acetaldehyde resulting from use of Settling Defendant’s e-cigarette devices and the e-liquids used
8 in such devices (the “Products”).

9 **1.3.** On November 19, 2015, CEH filed the Action. On February 17, 2016, CEH
10 named Settling Defendant as a defendant in the Action.

11 **1.4.** Settling Defendant is a corporation that employs ten (10) or more persons and that
12 manufactures, distributes, and/or sells Covered Products (as defined herein) in the State of
13 California or has done so in the past.

14 **1.5.** For purposes of this Consent Judgment only, the Parties stipulate that: (i) this
15 Court has jurisdiction over the allegations of violations contained in the Notices and Complaint
16 and personal jurisdiction over Settling Defendant as to the acts alleged in the Complaint; (ii)
17 venue is proper in the County of Alameda; and (iii) this Court has jurisdiction to enter this
18 Consent Judgment as a full and final resolution of all claims which were or could have been
19 raised in the Complaint based on the facts alleged in the Notices and Complaint with respect to
20 Covered Products manufactured, distributed, and/or sold by Settling Defendant.

21 **1.6.** The Parties enter into this Consent Judgment as a full and final settlement of all
22 claims which were or could have been raised in the Notices and Complaint arising out of the facts
23 or conduct related to Settling Defendant alleged therein. By execution of this Consent Judgment
24 and agreeing to comply with its terms, the Parties do not admit any fact, conclusion of law, or
25 violation of law, nor shall compliance with this Consent Judgment constitute or be construed as
26 an admission by the Parties of any fact, conclusion of law, or violation of law. Settling Defendant
27 denies the material, factual, and legal allegations in the Notices and Complaint, expressly denies
28

1 any wrongdoing whatsoever, and maintains that all of its products comply with all laws and meet
2 all legal requirements for their intended use. Except as specifically provided herein, nothing in
3 this Consent Judgment shall prejudice, waive, or impair any right, remedy, argument, or defense
4 any of the Parties may have in this or any other pending or future legal proceedings. This
5 Consent Judgment is the product of negotiation and compromise and is accepted by the Parties
6 solely for purposes of settling, compromising, and resolving issues disputed in this Action.

7 **2. DEFINITIONS**

8 **2.1.** “Covered Products” means “Covered Liquid Products” and “Covered Device
9 Products.”

10 **2.2.** “Covered Liquid Products” means liquids that are designed for use with electronic
11 cigarette devices, also known as tanks and vape pens, that are manufactured, distributed, and/or
12 sold by Settling Defendant in California.

13 **2.3.** “Covered Device Products” means electronic cigarette devices, also known as
14 tanks and vape pens, which contain nicotine or are designed and intended for use with Covered
15 Liquid Products, that are manufactured, distributed, and/or sold by Settling Defendant in
16 California.

17 **2.4.** “Effective Date” means the date on which the Court enters this Consent Judgment.

18 **3. INJUNCTIVE RELIEF**

19 **3.1. Clear and Reasonable Warnings for Covered Liquid Products.** Except as
20 provided in Section 3.1.1 below, as of the Effective Date, no Covered Liquid Product may be
21 manufactured for sale, distributed or sold by Settling Defendant in California unless such
22 Covered Liquid Product has a clear and reasonable warning on the product, its labeling, or its
23 outer packaging. The warning shall state the following:

24 **WARNING:** Use of this product can expose you to chemicals, including
25 formaldehyde and acetaldehyde, known to the State of California to cause
26 cancer, and chemicals, including nicotine, known to the State of California
27 to cause birth defects or other reproductive harm.

1 The warning shall not be preceded by, surrounded by, or include any additional words or phrases
2 that contradict, obfuscate, or otherwise undermine the warning. The warning statement shall be
3 prominently displayed on the Covered Liquid Product, its labeling, or its packaging with such
4 conspicuousness, as compared with other words, statements, or designs, as to render it likely to be
5 read and understood by an ordinary individual prior to sale. To the extent that other warning
6 statements are included on the outer label or packaging of a Covered Liquid Product, the warning
7 required herein shall be the same size or larger than other warnings and separated from the other
8 warnings by a space that is at least the same height as a line of text on the label. For internet,
9 catalog, or any other sale by Settling Defendant where the consumer is not physically present and
10 cannot see a warning displayed on the Covered Liquid Product or its packaging prior to purchase
11 or payment, the warning statement shall be displayed in such a manner that it is likely to be read
12 and understood as being applicable to the Covered Liquid Product being purchased prior to the
13 authorization of or actual payment. Placement of the warning statement at the bottom of an
14 internet webpage that offers multiple products for sale does not satisfy the requirements of this
15 Section.

16 **3.1.1. Warnings for Covered Liquid Products in the Stream of Commerce.**

17 In an effort to ensure that consumers receive clear and reasonable warnings in compliance with
18 Proposition 65 for Covered Products that have not been labeled in accordance with Section 3.1,
19 within thirty (30) days following the Effective Date, Settling Defendant shall provide warning
20 materials by certified mail to each of its California retailers or distributors whom Settling
21 Defendant reasonably believes still have inventory of Covered Liquid Products that are being
22 offered for sale in California without a Proposition 65 warning. Such warning materials shall
23 include a reasonably sufficient number of stickers in order to permit the retailer or distributor to
24 affix the warning on each Covered Liquid Product such customer has purchased from Settling
25 Defendant and that Settling Defendant reasonably believes remains in inventory for sale in
26 California. The warning stickers shall contain the warning language set forth in Section 3.1
27 above. The warning materials shall also include a letter of instruction for the placement of the
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1 warning stickers. To the extent that Settling Defendant has any of its own inventory that does not
2 contain warnings as of the Effective Date, Settling Defendant shall provide warning materials as
3 described above to any of its customers that it reasonably understands may offer such products for
4 sale in California.

5 **3.2. Clear and Reasonable Warnings for Covered Device Products.** Except as
6 provided in Section 3.2.1 below, as of the Effective Date, no Covered Device Product may be
7 manufactured for sale, distributed or sold in California unless such Covered Device Product has a
8 clear and reasonable warning on the product, its labeling, or its outer packaging. For Covered
9 Device Products, the warning shall state the following:

10 **WARNING:** Use of this product can expose you to chemicals, including
11 formaldehyde and acetaldehyde, known to the State of California to cause
12 cancer, and chemicals, including nicotine, known to the State of California
13 to cause birth defects or other reproductive harm.

14 The warning shall not be preceded by, surrounded by, or include any additional words or phrases
15 that contradict, obfuscate, or otherwise undermine the warning. The warning statement shall be
16 prominently displayed on the Covered Device Product, its labeling, or its outer packaging with
17 such conspicuousness, as compared with other words, statements, or designs, as to render it likely
18 to be read and understood by an ordinary individual prior to sale. To the extent that other
19 warning statements are included on the Covered Device Product or its outer packaging, the
20 warning required herein shall be the same size or larger than such warning and separated from the
21 other warnings by a space that is at least the same height as a line of text on the label. For
22 internet, catalog, or any other sale by Settling Defendant to California where the consumer is not
23 physically present and cannot see a warning displayed on the Covered Device Product prior to
24 purchase or payment, the warning statement shall be displayed in such a manner that it is likely to
25 be read and understood as being applicable to the Covered Device Product being purchased prior
26 to the authorization of or actual payment. Placement of the warning statement at the bottom of an
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1 internet webpage that offers multiple products for sale does not satisfy the requirements of this
2 Section.

3 **3.2.1. Warnings for Covered Device Products in the Stream of Commerce.**

4 In an effort to ensure that consumers receive clear and reasonable warnings in compliance with
5 Proposition 65 for Covered Products that have not been labeled in accordance with Section 3.2,
6 within thirty (30) days following the Effective Date, Settling Defendant shall provide warning
7 materials by certified mail to each of its California retailers or distributors whom Settling
8 Defendant reasonably believes still have inventory of Covered Device Products that are being
9 offered for sale in California without a Proposition 65 warning. Such warning materials shall
10 include a reasonably sufficient number of stickers in order to permit the retailer or distributor to
11 affix the warning on each Covered Device Product such customer has purchased from Settling
12 Defendant and that Settling Defendant reasonably believes remains in inventory for sale in
13 California.. The warning stickers shall contain the warning language set forth in Section 3.2
14 above. The warning materials shall also include a letter of instruction for the placement of the
15 stickers. To the extent that Settling Defendant has any of its own inventory that does not contain
16 warnings as of the Effective Date, Settling Defendant shall provide warning materials as
17 described above to any of its customers that it reasonably understands may offer such products for
18 sale in California.

19 **3.3. Optional Additional Injunctive Provisions.** In order for Settling Defendant to be

20 eligible for any waiver of the additional civil penalty payments/additional settlement payments set
21 forth in Section 4.1.5 below, Settling Defendant shall undertake one or more of the additional
22 actions below. If Settling Defendant opts to be bound by this Section, Settling Defendant must
23 provide CEH with a written election stating which optional provision(s) it is agreeing to
24 implement within 90 days of the Effective Date.

25 **3.3.1. Product Reformulation.** Within ninety (90) days following the Effective

26 Date, all Covered Products manufactured for sale in California shall be manufactured such that
27 use of the Covered Products will not produce detectable levels of formaldehyde and acetaldehyde

1 when tested in accordance with the testing protocol described in the published research paper
2 titled Effect of Variable Power Levels on the Yield of Total Aerosol Mass and Formation of
3 Aldehydes in E-Cigarette Aerosols, a copy of which is attached hereto as Exhibit 1. In the event
4 that Settling Defendant certifies its compliance with this Section, Settling Defendant will no
5 longer have any obligation to provide warnings pursuant to Sections 3.1-3.2 of this Consent
6 Judgment. In the event that Settling Defendant provides this certification as to any Covered
7 Product after 90 days after the Effective Date, Settling Defendant shall still be liable for the
8 additional payment specified in Section 4.1.5 below related to this section.

9 **3.3.2. Product Safety Requirements.** If Settling Defendant opts to participate in
10 Section 3.3, Settling Defendant shall make the following changes to the Covered Products to
11 increase the safety of such products:

12 **3.3.2.1.** Within ninety (90) days following the Effective Date, all
13 Covered Liquid Products manufactured for sale in California shall be manufactured with child
14 proof caps in accordance with the standards set forth in 16 C.F.R. § 1700.15(b) and flow
15 restrictions in accordance with the standard set forth in 16 C.F.R. § 1700.15(d).

16 **3.3.2.2.** Within ninety (90) days following the Effective Date, all
17 Covered Products manufactured for sale in California shall be manufactured without diacetyl in
18 the Covered Products.

19 **3.3.3. Prohibition on Sales and Advertising to Minors.** Within ninety (90)
20 days following the Effective Date, if Settling Defendant opts to participate in Section 3.3, Settling
21 Defendant shall not sell Covered Products to persons younger than eighteen (18) years of age in
22 California and shall take reasonable steps to prevent the sale of Covered Products to such persons,
23 including, but not limited to the following measures:

24 **3.3.3.1.** Settling Defendant shall implement one or more systems for
25 checking the age of persons who purchase Covered Products on the Internet in California. The
26 system shall include age verification by requiring and checking an official government
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1 identification card or verifying through a reputable credit agency the age of anyone who
2 purchases Covered Products on the Internet.

3 **3.3.3.2.** Settling Defendant shall not use advertisements that target
4 minors younger than 18 years of age. Specifically, Settling Defendant will not use models or
5 images of people that appear to be minors, cartoons, art, fashion, or music that is intended and
6 designed to appeal to people under the legal smoking age in advertisements or promotional
7 materials that appear in California, including on the Internet. Additionally, Settling Defendant
8 will not: (a) advertise in any media that Settling Defendant understands is directed primarily to
9 readership aged under 18 years; (b) utilize any form of outdoor advertising within 1,000 feet of
10 any California school or playground; (c) advertise using Instagram in a manner intended to appeal
11 to persons under age 18 or that permits purchase by persons under age 18; and (d) sponsor any
12 athletic, musical or other cultural events directed primarily at persons under the age of eighteen
13 (18).

14 **3.3.4. Prohibition on Health and Safety Claims.** Within ninety (90) days
15 following the Effective Date, if Settling Defendant opts to participate in Section 3.3, Settling
16 Defendant shall not make health and/or safety claims unless such claims have been reviewed and
17 approved by the Federal Food and Drug Administration. Examples of prohibited claims without
18 FDA approval include the following:

19 **3.3.4.1.** Settling Defendant shall not advertise Covered Products as
20 smoking-cessation devices. This prohibition includes any claims or testimonials about quitting
21 smoking, or using e-cigarettes as a treatment for tobacco dependence or addiction.

22 **3.3.4.2.** Settling Defendant shall not make any claim that the
23 Covered Products do not expose users to carcinogens or are better or safer than tobacco.

24 **3.3.4.3.** Settling Defendant shall not make any claim that the
25 Covered Products produce no second hand smoke.

1 **4. PAYMENTS**

2 **4.1.** Settling Defendant shall initially pay to CEH the total sum of \$10,000 in resolution
3 of all claims that were or could have been raised in the Notices and Complaint, which shall be
4 allocated as follows:

5 **4.1.1.** \$1,315 as a civil penalty pursuant to California Health & Safety Code §
6 25249.7(b), such money to be apportioned by CEH in accordance with California Health &
7 Safety Code § 25249.12 (25% to CEH and 75% to the State of California’s Office of
8 Environmental Health Hazard Assessment). This civil penalty shall be paid in one (1) check on
9 the date set forth in Exhibit A and shall be made payable to the Center for Environmental Health.

10 **4.1.2.** \$985 as an additional settlement payment (“ASP”) in lieu of civil penalty
11 to CEH pursuant to Health & Safety Code § 25249.7(b), and California Code of Regulations,
12 Title 11, § 3204. CEH intends to place these funds in CEH’s Toxics and Youth Fund and use
13 them to: (1) support CEH programs and activities that seek to educate the public about nicotine,
14 formaldehyde, and acetaldehyde in electronic cigarettes and other toxic chemicals in consumer
15 products that are marketed to youth; (2) expand its use of social media to communicate with
16 Californians about the risks of exposures to nicotine, formaldehyde, and acetaldehyde and other
17 toxic chemicals in the products they and their children use and about ways to reduce those
18 exposures; and (3) work with industries that market products to youth to reduce exposures to
19 nicotine, formaldehyde, and acetaldehyde and other toxic chemicals, and thereby reduce the
20 public health impacts and risks of exposures to nicotine, formaldehyde, and acetaldehyde and
21 other toxic chemicals in consumer products that are marketed to youth in California. CEH shall
22 obtain and maintain adequate records to document that ASPs are spent on these activities and
23 CEH agrees to provide such documentation to the Attorney General within thirty (30) days of any
24 request from the Attorney General. This ASP shall be paid in one (1) check on the date set forth
in Exhibit A and shall be made payable to the Center for Environmental Health.

25 **4.1.3.** \$7,700 as a reimbursement of a portion of CEH’s reasonable attorneys’
26 fees and costs.

1 **4.1.4.** The payments required under Sections 4.1.1-4.1.3 shall be delivered on or
2 before the dates set forth in Exhibit A. All checks shall be delivered to Mark Todzo at Lexington
3 Law Group at the address set forth in Section 8.1.2.

4 **4.1.5.** In the event that Settling Defendant elects not to certify its compliance with
5 one or more of the optional provisions in Section 3.3 in accordance with that Section, on the date
6 specified in Exhibit A, Settling Defendant must make an additional payment for each provision
7 not certified, as follows: (i) \$2,000 if Settling Defendant elects to not participate in Section 3.3.1;
8 (ii) \$9,600 if Settling Defendant elects to not participate in Section 3.3.2; (iii) \$9,700 if Settling
9 Defendant elects to not participate in Section 3.3.3; and (iv) \$8,700 if Settling Defendant elects to
10 not participate in Section 3.3.4. Each of these payments shall be paid in two (2) separate checks,
11 each payable to the Center for Environmental Health, to be allocated as follows:

12 **4.1.5.1.** Forty percent (40%) shall constitute a civil penalty pursuant to
13 California Health & Safety Code § 25249.7(b), such money to be apportioned by CEH in
14 accordance with California Health & Safety Code § 25249.12 (25% to CEH and 75% to the State
15 of California’s Office of Environmental Health Hazard Assessment).

16 **4.1.5.2.** Sixty percent (60%) shall constitute an ASP in lieu of civil
17 penalty to CEH pursuant to Health & Safety Code § 25249.7(b), and California Code of
18 Regulations, Title 11, § 3204. CEH intends to place these funds in CEH’s Toxics and Youth
19 Fund and use them to: (1) support CEH programs and activities that seek to educate the public
20 about nicotine, formaldehyde, and acetaldehyde in electronic cigarettes and other toxic chemicals
21 in consumer products that are marketed to youth; (2) expand its use of social media to
22 communicate with Californians about the risks of exposures to nicotine, formaldehyde, and
23 acetaldehyde and other toxic chemicals in the products they and their children use and about ways
24 to reduce those exposures; and (3) work with industries that market products to youth to reduce
25 exposures to nicotine, formaldehyde, and acetaldehyde and other toxic chemicals, and thereby
26 reduce the public health impacts and risks of exposures to nicotine, formaldehyde, and
27 acetaldehyde and other toxic chemicals in consumer products that are marketed to youth in
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1 California. CEH shall obtain and maintain adequate records to document that ASPs are spent on
2 these activities and CEH agrees to provide such documentation to the Attorney General within
3 thirty (30) days of any request from the Attorney General.

4 **5. ENFORCEMENT OF CONSENT JUDGMENT**

5 **5.1.** CEH or Settling Defendant may, by motion or application for an order to show
6 cause before the Superior Court of Alameda County, enforce the terms and conditions contained
7 in this Consent Judgment. Prior to bringing any motion or application to enforce the
8 requirements of Section 3 above, the moving party shall provide the other party with a Notice of
9 Violation and a copy of all test results and/or any other evidence which purportedly supports the
10 Notice of Violation of this Consent Judgment. The Parties shall then meet and confer regarding
11 the basis for the Notice of Violation in an attempt to resolve it informally, including providing the
12 responding party with a reasonable opportunity of at least thirty (30) days to cure any alleged
13 violation and/or present evidence to the moving party as to why there is no violation. Should
14 such attempts at informal resolution fail, the moving party may file its enforcement motion or
15 application. The prevailing party on any motion to enforce this Consent Judgment shall be
16 entitled to its reasonable attorney's fees and costs incurred as a result of such motion or
17 application. This Consent Judgment may only be enforced by the Parties.

18 **6. MODIFICATION OF CONSENT JUDGMENT**

19 **6.1.** This Consent Judgment may only be modified by written agreement of CEH and
20 Settling Defendant, or upon motion of CEH or Settling Defendant as provided by law.

21 **7. CLAIMS COVERED AND RELEASE**

22 **7.1.** This Consent Judgment is a full, final, and binding resolution between CEH,
23 acting in the public interest, and Settling Defendant and Settling Defendant's parents, officers,
24 directors, shareholders, divisions, subdivisions, subsidiaries, affiliates, agents, and their respective
25 successors and assigns ("Defendant Releasees"), and all entities to whom they distribute or sell or
26 have distributed or sold Covered Products including, but not limited to, distributors, wholesalers,
27 customers, retailers, franchisees, cooperative members, and licensees ("Downstream Defendant
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1 Releasees”), of all claims alleged in the Notices and Complaint in this Action arising from any
2 alleged or actual violation of Proposition 65 that has been or could have been asserted in the
3 public interest against Settling Defendant, Defendant Releasees, and Downstream Defendant
4 Releasees, regarding the failure to warn about actual or alleged exposure to formaldehyde and/or
5 acetaldehyde in or from use of the Covered Products manufactured, distributed, or sold by
6 Settling Defendant prior to the Effective Date.

7 **7.2.** CEH, on behalf of itself, and its past and current agents, representatives, attorneys,
8 successors, and/or assignees only, hereby releases, waives, and forever discharges any and all
9 claims against Settling Defendant, Defendant Releasees, and Downstream Defendant Releasees
10 arising from any violation of Proposition 65 that has been or could have been asserted in
11 connection with Covered Products manufactured, distributed, or sold by Settling Defendant prior
12 to the Effective Date.

13 **7.3.** Compliance with the terms of this Consent Judgment by Settling Defendant and
14 the Downstream Defendant Releasees shall constitute compliance with Proposition 65 by Settling
15 Defendant and Downstream Defendant Releasees with respect to any alleged failure to warn
16 about formaldehyde and/or acetaldehyde exposures from the Covered Products manufactured,
17 distributed, or sold by Settling Defendant after the Effective Date.

18 **8. PROVISION OF NOTICE**

19 **8.1.** When any Party is entitled to receive any notice under this Consent Judgment, the
20 notice shall be sent by first class and electronic mail as follows:

21 **8.1.1. Notices to Settling Defendant.** The persons for Settling Defendant to
22 receive notices pursuant to this Consent Judgment shall be:

23 Spencer Thompson
24 Spark Industries, LLC
25 750 Calle Plano
26 Camarillo, CA 93012

26 With Copy to:

27 J. Robert Maxwell
28 Rogers Joseph O’Donnell

1 311 California Street, 10th Floor
2 San Francisco, CA 94104
3 jmaxwell@rjo.com

4 **8.1.2. Notices to Plaintiff.** The persons for CEH to receive notices pursuant to
5 this Consent Judgment shall be:

6 Mark Todzo
7 Lexington Law Group
8 503 Divisadero Street
9 San Francisco, CA 94117
10 mtodzo@lexlawgroup.com

11 **8.2.** Any Party may modify the person and address to whom the notice is to be sent by
12 sending the other Parties notice by first class and electronic mail.

13 **9. COURT APPROVAL**

14 **9.1.** This Consent Judgment shall become effective on the Effective Date, provided
15 however, that CEH shall prepare and file a Motion for Approval of this Consent Judgment and
16 Settling Defendant shall reasonably cooperate in supporting approval of such Motion.

17 **9.2.** If this Consent Judgment is not entered by the Court, it shall be of no force or
18 effect and shall not be introduced into evidence or otherwise used in any proceeding for any
19 purpose.

20 **10. GOVERNING LAW AND CONSTRUCTION**

21 **10.1.** The terms and obligations arising from this Consent Judgment shall be construed
22 and enforced in accordance with the laws of the State of California. In the event that Proposition
23 65 is repealed or is otherwise rendered inapplicable by reason of law generally, or if any of the
24 provisions of this Consent Judgment are rendered inapplicable or no longer required as a result of
25 any such repeal or preemption or rendered inapplicable by reason of law generally as to the
26 Covered Products, then Settling Defendant shall provide written notice to CEH of any asserted
27 change in the law and the parties will meet and confer in good faith about a proposed
28 modification to this Consent Judgment to account for such change in law.

1 **11. ENTIRE AGREEMENT**

2 **11.1.** This Consent Judgment contains the sole and entire agreement and understanding
3 of CEH and Settling Defendant with respect to the entire subject matter hereof, and any and all
4 prior discussions, negotiations, commitments, or understandings related thereto, if any, are hereby
5 merged herein and therein.

6 **11.2.** There are no warranties, representations, or other agreements between CEH and
7 Settling Defendant except as expressly set forth herein with respect to the subject matter hereof.
8 No representations, oral or otherwise, express or implied, other than those specifically referred to
9 in this Consent Judgment have been made by any Party hereto with respect to the subject matter
10 hereof.

11 **11.3.** No other agreements not specifically contained or referenced herein, oral or
12 otherwise, shall be deemed to exist or to bind any of the Parties hereto.

13 **11.4.** No supplementation, modification, waiver, or termination of this Consent
14 Judgment shall be binding unless executed in writing by the Party to be bound thereby, or unless
15 ordered by the Court.

16 **11.5.** No waiver of any of the provisions of this Consent Judgment shall be deemed or
17 shall constitute a waiver of any of the other provisions hereof whether or not similar, nor shall
18 such waiver constitute a continuing waiver.

19 **12. RETENTION OF JURISDICTION**

20 **12.1.** This Court shall retain jurisdiction of this matter to implement or modify the
21 Consent Judgment.

22 **13. AUTHORITY TO STIPULATE TO CONSENT JUDGMENT**

23 **13.1.** Each signatory to this Consent Judgment certifies that he or she is fully authorized
24 by the Party he or she represents to stipulate to this Consent Judgment and to enter into and
25 execute the Consent Judgment on behalf of the Party represented and to legally bind that Party.
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14. NO EFFECT ON OTHER SETTLEMENTS

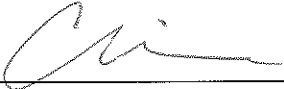
14.1. Nothing in this Consent Judgment shall preclude CEH from resolving any claim against another entity on terms that are different from those contained in this Consent Judgment.

15. EXECUTION IN COUNTERPARTS

15.1. The stipulations to this Consent Judgment may be executed in counterparts and by means of facsimile or pdf, which taken together shall be deemed to constitute one document.

IT IS SO STIPULATED:

CENTER FOR ENVIRONMENTAL HEALTH



Charlie Pizarro
Associate Director

SPARK INDUSTRIES, LLC

Signature

Printed Name

Title

IT IS SO ORDERED:

Dated: _____, 2017

Judge of the Superior Court

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14. NO EFFECT ON OTHER SETTLEMENTS

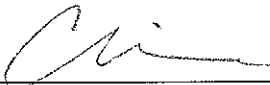
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IT IS SO STIPULATED:

CENTER FOR ENVIRONMENTAL HEALTH



Charlie Pizarro
Associate Director

SPARK INDUSTRIES, LLC

Signature

Printed Name

Title

IT IS SO ORDERED:

Dated: 9/6, 2017



Judge of the Superior Court
GEORGE C. HERNANDEZ, JR.

Exhibit 1



Effect of variable power levels on the yield of total aerosol mass and formation of aldehydes in e-cigarette aerosols



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ABSTRACT

The study objective was to determine the effect of variable power applied to the atomizer of refillable tank based e-cigarette (EC) devices. Five different devices were evaluated, each at four power levels. Aerosol yield results are reported for each set of 25 EC puffs, as mass/puff, and normalized for the power applied to the coil, in mass/watt. The range of aerosol produced on a per puff basis ranged from 1.5 to 28 mg, and, normalized for power applied to the coil, ranged from 0.27 to 1.1 mg/watt. Aerosol samples were also analyzed for the production of formaldehyde, acetaldehyde, and acrolein, as DNPH derivatives, at each power level. When reported on mass basis, three of the devices showed an increase in total aldehyde yield with increasing power applied to the coil, while two of the devices showed the opposite trend. The mass of formaldehyde, acetaldehyde, and acrolein produced per gram of total aerosol produced ranged from 0.01 to 7.3 mg/g, 0.006 to 5.8 mg/g, and <0.003 to 0.78 mg/g, respectively. These results were used to estimate daily exposure to formaldehyde, acetaldehyde, and acrolein from EC aerosols from specific devices, and were compared to estimated exposure from consumption of cigarettes, to occupational and workplace limits, and to previously reported results from other researchers.

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1. Introduction

Electronic cigarettes (ECs) are becoming increasingly popular, with millions of users both in the US and in Europe (Pearson et al., 2012; Regan et al., 2013; Vardavas et al., 2014) and are often used as a replacement for combustible cigarette usage (Barbeau et al., 2013). Aldehydes including formaldehyde, acetaldehyde, and acrolein are known to form during heating of mixtures of glycerol (GLY) and propylene glycol (PG) (Flora et al., 2015; Lauterbach and Spencer, 2015; Ohta et al., 2011; Paschke et al., 2014; Uchiyama et al., 2013), the most common solvent formulation for EC liquids. These aldehydes are of concern since formaldehyde is classified by the International Agency for Research of Cancer (IARC) as a human carcinogen (Group 1) and acetaldehyde is classified as possibly carcinogenic to humans (Group 2B) (IARC, 2012). Acrolein causes irritation of the nasal cavity and damages the lining of the lung (USEPA, 2003). Glycerol has been shown to produce these three

aldehydes due to thermal decomposition (pyrolysis) in temperature-dependent amounts (Paine et al., 2007), with small amounts of acrolein being formed in some ionic environments at 350 °C, and all three aldehydes being formed at 600 °C. The pathway for this pyrolysis is shown in Fig. 1, and it involves a free-radical dehydration of glycerol to form 3-hydroxyl-1-propen-1-ol, which tautomerizes to 3-hydroxypropionaldehyde. This then loses another water in a free-radical mechanism to form acrolein. At higher temperatures 3-hydroxypropionaldehyde can convert to formaldehyde and acetaldehyde, by way of a retro-aldol reaction, which easily cleaves the C2–C3 bond at >400 °C.

Because of these known decomposition products, one of the main concerns related to EC use is the inhalation of aldehydes contained in EC aerosol. Studies on relatively lower power, prefilled disposable devices have found that formaldehyde, acetaldehyde, and acrolein are produced at levels far lower in comparison to tobacco cigarette smoke (Bekki et al., 2014; Cheng, 2014; Goniewicz et al., 2014; Lauterbach and Spencer, 2015). However, recent studies on higher powered, refillable tank systems have found that these devices may produce levels of aldehydes exceeding the levels found in mainstream cigarette smoke (Jensen et al., 2015; Kosmider et al., 2014). To date, however, there has not been a systematic

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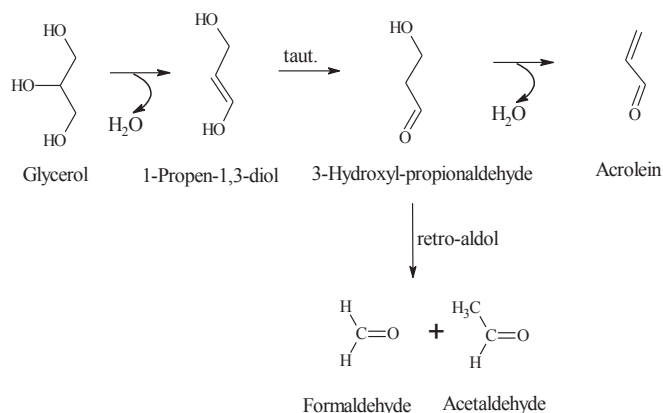


Fig. 1. The pyrolytic reactions of glycerol to produce formaldehyde, acetaldehyde and acrolein. Radical intermediates for steps involving loss of water are omitted for simplicity.

study on the formation of aldehydes in EC aerosol using a variety of devices and power levels.

It should be noted that PG can also decompose thermally, to propionaldehyde (Dai et al., 2004), however, in order to better compare to the previous studies mentioned above, which only reported formaldehyde, acetaldehyde and acrolein production, and to focus more on device dependence of their formation, we did not analyze for propionaldehyde in this study. Such analysis, as well as dependence on EC liquid solvent composition, is planned for future studies.

2. Methods

2.1. EC devices

In this study, five refillable “tank” based EC were studied:

- Device 1: Single top coil, 2.8 Ω ,
- Device 2: Single bottom coil, 2.7 Ω ,
- Device 3: Dual bottom coil, 2.8 Ω ,
- Device 4: Single bottom coil, 2.2 Ω , and
- Device 5: Single bottom coil, 0.72 Ω .

All samples were commercial “tank” products (Hare, 2015) and were used according to the manufacturer's instructions. They all have similar functional parts: a tank which holds the liquid, a resistive heating wire (“coil”) to which voltage is applied to generate heat and aerosolize the liquid, a “wick” which can be silica string (Devices 1–3), poly-fill (Device 4) or cotton (Device 5), that transports the liquid in the tank to the coil, a mouth piece for inhalation, and a threaded connector to attach to and receive current from the power source. Device 1 was a CE4 “top-coil” tank-style (Vision, Shenzhen, China). Three separate devices were used in this study, and from the same manufacturer, all virtually identical save for some variations in coil resistance. The three devices used in this study were determined to have coil resistance of 2.2, 2.8 and 3.4 Ω (average was 2.8 Ω , with standard deviation of 0.5 Ω). In this device, the liquid is held inside a tank, and silica strings acting as wicks descend from a ceramic cup containing the coil into the liquid, which is fed to the coil through the wicks. “CE4” refers to the general design, using a ceramic coil cup, fourth version of this type of tank system. Air flow travels up through a center tube to under the coil, and then to the mouth. Adequate wetting of any EC coil depends on the ability of the wick to feed the liquid as fast as the coil vaporizes it. It should be noted that this style of atomizer is

largely out of favor now in the vaping community, due to the difficulty of wicking with some liquids, and the propensity for dry-puff to occur. It should also be noted that this was the atomizer style chosen recently by previous researchers who reported high aldehyde and acrolein content of EC aerosol using 5 V or more (Jensen et al., 2015). Device 2 was a Protank 1 (KangerTech, Shenzhen, China) with a replaceable 2.7 Ω bottom single-coil-head. A single tank and three separate coils were used in this study. In this device the liquid is held in a tank and gravity fed to the coil, which is positioned at the bottom of the tank, through short silica wicking threads which the coil is wrapped around and oriented horizontally if the tank is held tip-up. It was expected that this design would allow more consistent wetting of the coil compared to Device 1. Device 3 was a Gladius (Innokin, Shenzhen, China) bottom coil tank system with a replaceable dual-coil-head and a total resistance of 2.8 Ω . A single tank and three unique coil-heads were used in this study. The overall design with respect to liquid feed is very similar to the Protank, but here there are two coils in parallel, at 5.6 Ω each, each wrapped horizontally around short silica wicks, stacked vertically on top of each other and across the central air-flow, which travels through a center tube to the mouth. The two coils in parallel have the effect of spreading the heat out evenly over the coils, compared to one coil when the same wattage is applied, assuming total resistance and all other factors are identical. Device 4 was bottom single coil Nautilus (Aspire USA, Kent, WA) with 2.2 Ω resistance. The overall design is visually similar to the Protank, but the replaceable coil-head is larger and the coil is vertically oriented, longer and of thicker gauge, and in contact with more wicking material (poly-fill). A single tank and three unique coil-heads were used in this study. Device 5 was a SubTank (KangerTech) with a 0.72 Ω bottom-coil-head. Since wattage is inversely proportional to coil resistance, reducing coil resistance will increase the wattage for a given battery voltage proportionally, allowing very high wattage from typical 3.7 V Li-ion batteries. The coil is vertically oriented, similar to the Nautilus coil-head, but the wicking material is cotton. A single atomizer was used with each device. In all cases, samples were collected from lowest power to highest power levels. All tanks were maintained at a minimum of 50% of the maximum liquid level. Where adjustment was possible for a device, airflow was set to maximum. Detailed images for the devices used in this study are available online (Google, 2015) and schematics of example top coil and bottom coil devices are given in supplemental materials Appendix A.

2.2. Sample collection

Puffing of devices was carried out using either a Cerulean SM450 (Milton Keynes, UK) or a KC Automation KC-5 (Richmond, VA) analytical smoking machine. The smoking regime was a puff every 30 s with 4-s duration and a volume of 55 mL collected using a “square” wave profile (Farsalinos et al., 2013). All devices were automatically activated at the start of each puff using an air power linear actuator attached to the battery. The button on each device was depressed during each puff. All devices were puffed with the tank held in a horizontal orientation. Between each puff block, devices were removed from the smoking machine to record the weight change. During the weighing process the devices were transported in a vertical orientation to allow for liquid equilibration. A puff block consisting of 25 puffs was performed and collected for each device and condition in duplicate, and this was repeated twice more with different units of the same device, three times total. Thus, each device and condition was averaged over 6 trials ($N = 6$). Batteries were fully charged before use, and the weight of each device was measured before and after each puff block. Devices were allowed to rest for least ten minutes between

puff blocks.

Samples generated for Devices 1–4 were collected using an Innokin iTaste VV4 battery (Shenzhen, China) as the power source, with samples collected at 3.8, 4.2, 4.6, and 5.0 V. Samples for Device 5 were collected using a DNA 40 power supply (Evolv, Ashtabula, OH) with samples collected at 10, 15, 20, and 25 W. Total resistance for all devices was measured using an Extech milliohm meter, P/N 380560 (Nashua, NH) prior to analysis and, for Devices 1–4, with power supply voltage, was used to calculate wattage. Voltages delivered were assumed to be the same as displayed by the power supply.

The liquid used for all samples was 48% (wt/wt) propylene glycol (PG), CAS # 57-55-6, USP grade, The Flavor Apprentice (Circle Scotts Valley, CA); and glycerin (GLY), CAS # 56-81-5, USP grade, Essential Depot (Sebring, FL); with 2% nicotine, CAS# 54-11-5, Sigma Aldrich (St. Louis, MO).

2.3. Chemical analysis

All methods used for this study were validated for linearity, recovery, precision, and limits of detection in the EC sample matrix prior to analyses. Method validation details are given in Appendix B.

2.4. Determination of formaldehyde, acetaldehyde, and acrolein as dinitrophenylhydrazine derivatives

The procedure followed was based on the HPLC carbonyl compound analysis method for mainstream cigarette smoke by CORESTA (Paris, France) (CORESTA, 2014), with the following modifications. Aerosol samples were collected in 35 mL of 2,4-dinitrophenylhydrazine (DNPH) trapping solution using a single glass impinger and coarse fritted impinger inserts (Prism Research Glass, Raleigh, NC). The samples were collected directly in a DNPH trapping solution; a 5 mL aliquot was then quenched with 0.250 mL of pyridine. An Agilent Model 1100 High Performance Liquid Chromatograph (Santa Clara, CA, USA) was equipped with an Agilent Model 1100 Ultraviolet (UV) Detector operating at 365 nm and a Waters Xterra C18 3.0 × 250 mm column (Billerica, MA) for the analyses. The limit of detection was 0.015 µg/mL for all aldehyde compounds. The materials used for the HPLC analysis were: deionized water, Millipore (Billerica, MA); phosphoric acid (H₃PO₄), CAS # 7664-38-285, 85%, Sigma–Aldrich; DNPH, CAS# 119-26-6, 50% in water, TCI America (Portland, OR); acetonitrile, CAS #75-05-8, Fisher (Waltham, MA); tetrahydrofuran, CAS #109-99-9, Fisher; isopropanol, CAS #67-63-0, distilled-in-glass, Fisher; pyridine, CAS #110-86-1, Aldehyde-Ketone-DNPH TO-11A Calibration Mix, P/N 270407, Sigma–Aldrich.

DNPH trapping solution was prepared by adding 2.0 g of DNPH (50%) to 500 mL of acetonitrile and 40 mL of 10% H₃PO₄. This was brought to a final volume of 1 L with deionized water. It should be noted that while it is possible for aldehydes to form hydrates, acetals and hemiacetals in EC liquid or in the heating process, through various dynamic and rapid solution equilibria with water, PG or GLY (Funderburk et al., 1978), because addition of DNPH leads to very stable dinitro-phenylhydrazone carbonyl derivatives, this effectively drives all of these equilibria in the direction of the carbonyl form of the aldehydes, resulting in eventual trapping of all forms of these aldehydes as the hydrazone derivative, and thus rendering this derivative method unable to distinguish between the carbonyl form of these aldehydes and their hydrate, acetal or hemiacetal forms (García-Alonso et al., 2006). It should, however, be noted that collection of air samples using DNPH media is a well-established method to determine occupational and ambient exposure to aldehydes (USEPA, 1999) without speciation of hydrates, acetals and

hemiacetals forms.

3. Results

The mass of aerosol produced from each device varied depending on the amount of power that was applied to the atomizer. The five devices tested in the study produced between 38 mg to over 692 mg of aerosol in 25 puffs, in the range of 5.2–25 W, as shown in Table 1. Data for all replicates are given in supplemental materials Appendix C. Since yield depends on the total number of puffs, results are also presented in mg of aerosol per puff, which ranged from 1.5 to 28 mg/puff over the same range of power. It was also found that devices 2–5 produced more aerosol mass as increasing power was applied to the atomizer. In contrast, the highest power level for Device 1, 9.2 W, produced less aerosol mass than produced at 7.8 W. Since the aerosol yield varied by device and power level, the calculation of total aerosol mass per puff divided by power applied to the coil ((mg per puff)/(watt)) is also given in Table 1. Reporting the results in these units allows for a direct comparison of aerosol yield independent of coil resistance. The mass of aerosol produced per puff/watt ranged from 0.27 to 1.1

Table 1
Aerosol yield by device and power level. Average values are boldfaced. Standard deviation (SD) for each average is given below the average value.

	Volts	Ohms	Watts	mg (25 puffs)	mg/puff	(mg/puff)/watt
Device 1: Single top coil						
Average	3.8	2.8	5.3	103	4.1	0.78
SD	NA	0.5	1.0	28	1.1	0.26
Average	4.2	2.8	6.5	155	6.2	0.95
SD	NA	0.5	1.3	36	1.4	0.29
Average	4.6	2.8	7.8	185	7.4	0.95
SD	NA	0.5	1.5	51	2.0	0.32
Average	5.0	2.8	9.2	176	7.1	0.77
SD	NA	0.5	1.8	38	1.5	0.22
Device 2: Single bottom coil						
Average	3.8	2.6	5.2	95	3.8	0.72
SD	NA	0.3	0.1	24	1.0	0.18
Average	4.2	2.6	6.4	134	5.4	0.84
SD	NA	0.3	0.1	27	1.1	0.17
Average	4.6	2.6	7.7	162	6.5	0.85
SD	NA	0.3	0.1	39	1.6	0.20
Average	5.0	2.6	9.0	193	7.7	0.85
SD	NA	0.3	0.2	45	1.8	0.20
Device 3: Dual bottom coil						
Average	3.8	2.8	5.6	38	1.5	0.27
SD	NA	0.1	0.7	16	0.6	0.12
Average	4.2	2.8	6.9	98	3.9	0.57
SD	NA	0.1	0.9	8	0.3	0.05
Average	4.6	2.8	8.2	137	5.5	0.66
SD	NA	0.1	1.1	6	0.2	0.03
Average	5.0	2.8	9.7	173	6.9	0.71
SD	NA	0.1	1.3	8	0.3	0.03
Device 4: Single bottom coil						
Average	3.8	2.8	7.3	57	2.3	0.31
SD	NA	0.1	0.5	12	0.5	0.07
Average	4.2	2.8	8.9	108	4.3	0.49
SD	NA	0.1	0.7	26	1.0	0.12
Average	4.6	2.8	10.6	167	6.7	0.63
SD	NA	0.1	0.8	36	1.5	0.14
Average	5.0	2.8	12.6	234	9.4	0.75
SD	NA	0.1	0.9	26	1.0	0.08
Device 5: Single bottom coil						
Average	2.6	0.7	10.0	187	7.5	0.75
SD	NA	NA	NA	14	0.5	0.05
Average	3.2	0.7	15.0	385	15	1.0
SD	NA	NA	NA	33	1.3	0.1
Average	3.7	0.7	20.0	543	22	1.1
SD	NA	NA	NA	34	1.4	0.1
Average	4.2	0.7	25.0	692	28	1.1
SD	NA	NA	NA	149	5.9	0.24

(mg/puff)/(watt).

The amount of each aldehyde compound, as the DNPH adduct, was determined by passing the aerosol through an impinger containing DNPH trapping solution. The summary results for each device at each of four power levels are given in Table 2 on a per puff basis ($\mu\text{g}/\text{puff}$). Data for all replicates are given in Appendix C. The amount of formaldehyde, acetaldehyde, and acrolein produced per puff ranged from 0.05 to 51 μg , 0.03–40.7 μg and <0.02–5.5 μg respectively. To account for the large differences in total aerosol yield between devices and power levels, the amount of each compound was divided by aerosol mass in a puff block of 25 puffs, to yield mg/g values for each compound. These results are presented in Table 3. The mass of formaldehyde, acetaldehyde, and acrolein produced per gram of total aerosol produced ranged from 0.01 to 7.3 mg/g, 0.006–5.8 mg/g, and <0.002–0.78 mg/g, respectively.

To estimate daily exposure to aldehydes, as the DNPH derivatives, from the devices in this study, we based our calculations on an average daily consumption of 3 mL of EC liquid, which is the reported average usage amount for experienced users of EC devices (Farsalinos et al., 2014), assuming a density close to 1 g/mL, this corresponds to an average daily consumption of approximately 3 g.

For this calculation, amounts in $\mu\text{g}/\text{mg}$ were converted to mg/g and multiplied by 3. The values are given in Table 4. The amount of formaldehyde, acetaldehyde, and acrolein that would be produced per 3 g of e-liquid consumed ranged from 0.04 to 22 mg, 0.02–17 mg, and <0.003–2.4 mg, respectively. The sum of all compounds was also calculated and ranged from 0.06 to 41 mg.

4. Discussion

The results show the amount of aerosol produced from heating the e-liquid varies depending on the device and power. Every device, with the exception of Device 1 at 9.2 W, produced more aerosol with an increasing amount of power applied to the coil. To normalize for the range of power used, yield results are also presented as the mg/puff of aerosol produced per watt of power applied to the coil (mg/watt) in Table 1. Results are presented as the mg/watt production, which enables a direct comparison of the efficiency of each atomizer to convert power into aerosol formation.

Surprisingly, the devices had unique aerosol yield profiles under the test conditions in this study. Device 1 gave a decrease in mg/watt output at the highest power level applied to the atomizer, while Device 2 gave a relatively constant mg/watt output over the

Table 2

Aldehydes produced by device and power level on a per puff basis. Average values are boldfaced. Standard deviation (SD) for each average is given below the average value.

	Power Watts	Aerosol mass mg/puff	Formaldehyde $\mu\text{g}/\text{puff}$	Acetaldehyde $\mu\text{g}/\text{puff}$	Acrolein $\mu\text{g}/\text{puff}$
Device 1: Single top coil					
Average	5.3	4.1	8.5	6.9	0.23
SD	1.0	1.1	8.9	7.4	0.23
Average	6.5	6.2	21	17	0.47
SD	1.3	1.4	16	14	0.53
Average	7.8	7.4	32	25	1.0
SD	1.5	2.0	12	11	0.45
Average	9.2	7.1	51	41	5.5
SD	1.8	1.5	31	25	9.0
Device 2: Single bottom coil					
Average	5.2	3.8	0.25	0.06	<0.02
SD	0.1	1.0	0.22	0.03	NA
Average	6.4	5.4	1.5	0.33	0.11
SD	0.1	1.1	0.83	0.14	0.05
Average	7.7	6.5	8.0	2.6	0.70
SD	0.1	1.6	5.0	2.0	0.52
Average	9.0	7.7	17	8.3	2.0
SD	0.2	1.8	19	10	2.3
Device 3: Dual bottom coil					
Average	5.6	1.5	0.07	0.04	<0.02
SD	0.7	0.6	0.04	0.02	NA
Average	6.9	3.9	0.07	0.06	<0.02
SD	0.9	0.3	0.04	0.02	NA
Average	8.2	5.5	0.05	0.03	0.08
SD	1.1	0.2	0.01	0.02	0.03
Average	9.7	6.9	0.59	0.53	0.23
SD	1.3	0.3	0.52	0.33	0.08
Device 4: Single bottom coil					
Average	7.3	2.3	0.13	0.05	<0.02
SD	0.5	0.5	0.08	0.02	NA
Average	8.9	4.3	0.28	0.06	<0.02
SD	0.7	1.0	0.33	0.01	NA
Average	11	6.7	0.14	0.05	<0.02
SD	0.8	1.5	0.14	0.02	NA
Average	13	9.4	0.21	0.06	<0.02
SD	0.9	1.0	0.11	0.03	NA
Device 5: Single bottom coil					
Average	10	7.5	0.13	0.08	<0.02
SD	NA	0.5	0.08	0.06	NA
Average	15	15	0.21	0.16	<0.02
SD	NA	1.3	0.06	0.07	NA
Average	20	22	0.31	0.15	<0.02
SD	NA	1.4	0.07	0.04	NA
Average	25	28	0.34	0.16	<0.02
SD	NA	5.9	0.08	0.08	NA

Table 3
Aldehydes produced by device and power level on a per gram of aerosol basis. Average values are boldfaced. Standard deviation (SD) for each average is given below the average value.

	Power Watts	Formaldehyde mg/gram	Acetaldehyde mg/gram	Acrolein mg/gram
Device 1: Single top coil				
Average	5.3	2.1	1.7	0.05
SD	1.0	2.2	1.9	0.06
Average	6.5	3.3	2.7	0.08
SD	1.3	2.7	2.4	0.09
Average	7.8	4.3	3.4	0.14
SD	1.5	2.0	1.7	0.07
Average	9.2	7.3	5.8	0.78
SD	1.8	4.7	3.8	1.28
Device 2: Single bottom coil				
Average	5.2	0.07	0.02	<0.01
SD	0.1	0.06	0.01	NA
Average	6.4	0.28	0.06	0.02
SD	0.1	0.16	0.03	0.01
Average	7.7	1.2	0.40	0.11
SD	0.1	0.82	0.33	0.09
Average	9.0	2.2	1.1	0.26
SD	0.2	2.5	1.3	0.30
Device 3: Dual bottom coil				
Average	5.6	0.04	0.03	<0.02
SD	0.7	0.03	0.02	NA
Average	6.9	0.02	0.01	<0.02
SD	0.9	0.01	0.01	NA
Average	8.2	0.03	0.02	0.05
SD	1.1	0.04	0.02	0.06
Average	9.7	0.08	0.08	0.03
SD	1.3	0.08	0.05	0.01
Device 4: Single bottom coil				
Average	7.3	0.06	0.02	<0.01
SD	0.5	0.04	0.01	NA
Average	8.9	0.06	0.01	<0.006
SD	0.7	0.08	0.005	NA
Average	11	0.02	0.008	<0.004
SD	0.8	0.02	0.004	NA
Average	13	0.02	0.006	<0.003
SD	0.9	0.01	0.003	NA
Device 5: Single bottom coil				
Average	10	0.017	0.011	<0.003
SD	NA	0.011	0.009	NA
Average	15	0.014	0.010	<0.002
SD	NA	0.004	0.005	NA
Average	20	0.014	0.007	<0.002
SD	NA	0.003	0.002	NA
Average	25	0.012	0.006	<0.002
SD	NA	0.004	0.003	NA

three highest power levels. In contrast, Devices 3, 4 and 5 had an increasing mg/watt output as more power was applied to the atomizer. These results indicate that differences in the atomizer design impact their ability to efficiently produce aerosol at a given power level. The decrease in mg/watt output seen in Device 1 at higher power levels, may be due to insufficient liquid flow to the atomizer resulting in less efficient aerosol production and therefore overheating of the atomizer coil, commonly called a “dry puff” (Farsalinos et al., 2013). The efficient production of aerosol depends on an adequate supply of liquid to the coil, and maximum liquid supply would be limited by the wicking rate of wick material. Power levels that produce aerosol beyond the ability of the wick to resupply the liquid to the coil could result in overheating of the atomizer coil.

The production of aldehydes from overheating PG and GLY in EC aerosols has been previously shown by Uchiyama et al (Uchiyama et al., 2013). The devices with the lowest aerosol production in mg/watt output might be anticipated to produce more aldehydes as less efficient formation of aerosol might imply that the power supplied to the coil is converted into excess heat instead of aerosol formation. Aldehyde yields adjusted for total aerosol production

are given in Table 3. Device 1 gave the lowest average mg/watt production of all devices and also produced the highest total aldehydes per gram of aerosol produced. However, no clear trends in the mg/watt production versus aldehyde formation per gram of aerosol produced were found for Devices 2–5. Interestingly, it was found that the devices that produced the lowest aldehyde yields also had the largest increase in aerosol production in terms of mg/watt output with increasing power. For Device 4, the mg/puff per watt production increased from 0.31 mg/puff/(watt) to 0.75 mg/puff/(watt), a 142% increase in efficiency from the lowest to highest power level used in this study. The % increase, from lowest to highest power level, in mg/puff/(watt) production for Devices 1, 2, 3 and 5 was –1.3%, 18%, 163%, and 47%, respectively. Device 1 showed an actual decrease in production and also yielded the highest amount of aldehyde formation per gram of aerosol produced, and Devices 2–5 showed increases in efficiency, with Device 2 showing the least increase, but the highest aldehyde production of those four devices. These results indicate that decreased efficiency of aerosol production, in terms of mg/watt, at higher power levels might indicate overheating of the atomizer leading to elevated levels of aldehydes in the aerosol. This effect may be due to

Table 4

Daily exposure with consumption of 3 g of EC liquid per day. Average values are boldfaced. Standard deviation (SD) for each average is given below the average value.

	Power Watts	Formaldehyde mg per day	Acetaldehyde mg per day	Acrolein mg per day	Total aldehydes mg per day
Device 1: Single top coil					
Average	5.3	6.2	5.0	0.16	11
SD	1.0	6.7	5.6	0.17	8.7
Average	6.5	10	8.0	0.23	18
SD	1.3	8.1	7.1	0.26	11
Average	7.8	13	10	0.41	23
SD	1.5	6.0	5.1	0.22	7.9
Average	9.2	22	17	2.3	41
SD	1.8	14	11	3.8	18
Device 2: Single bottom coil					
Average	5.2	0.20	0.05	<0.03	0.25
SD	0.1	0.18	0.03	NA	0.19
Average	6.4	0.85	0.18	0.06	1.1
SD	0.1	0.49	0.09	0.03	0.5
Average	7.7	3.7	1.2	0.32	5.2
SD	0.1	2.5	0.98	0.26	2.7
Average	9.0	6.7	3.2	0.78	11
SD	0.2	7.5	4.0	0.90	8.5
Device 3: Dual bottom coil					
Average	5.6	0.13	0.08	<0.06	0.22
SD	0.7	0.10	0.05	NA	0.11
Average	6.9	0.05	0.04	<0.06	0.09
SD	0.9	0.03	0.02	NA	0.03
Average	8.2	0.10	0.06	0.16	0.32
SD	1.1	0.11	0.07	0.17	0.21
Average	9.7	0.25	0.23	0.10	0.58
SD	1.3	0.23	0.14	0.04	0.27
Device 4: Single bottom coil					
Average	7.3	0.17	0.07	<0.03	0.27
SD	0.5	0.11	0.03	NA	0.12
Average	8.9	0.19	0.04	<0.01	0.25
SD	0.7	0.23	0.01	NA	0.23
Average	11	0.06	0.02	<0.01	0.08
SD	0.8	0.07	0.01	NA	0.07
Average	13	0.07	0.02	<0.009	0.09
SD	0.9	0.03	0.01	NA	0.04
Device 5: Single bottom coil					
Average	10	0.05	0.03	<0.009	0.09
SD	NA	0.03	0.03	NA	0.04
Average	15	0.04	0.03	<0.003	0.08
SD	NA	0.01	0.01	NA	0.02
Average	20	0.04	0.02	<0.003	0.07
SD	NA	0.01	0.01	NA	0.01
Average	25	0.04	0.02	<0.003	0.06
SD	NA	0.01	0.01	NA	0.01

insufficient liquid supply to coil, leading to production of excess heat instead of conversion of the liquid into aerosol. From a thermodynamic stand point, formation of the aerosol and liquid decomposition can be viewed as competing pathways, and decomposition, involving bond breaking, would be in thermal competition with formation of the aerosol since both pathways would absorb available heat from the atomizer coil.

In order to put the aldehyde results in context, it might be valuable to compare our results with both occupational exposure limits and exposure results due to use of combustible tobacco cigarettes. This comparison is intended only to compare our results with other known sources of aldehyde exposure and not to assay health effect. E-cigarettes are recreational usage products, and any toxins delivered to the users would be additive to other exposure sources.

For occupational exposure, the time weighted average (TWA) limits (8-h) as defined by OSHA is 0.92 mg/m³ for formaldehyde (USOSHA, 2015c), 0.25 mg/m³ for acrolein (USOSHA, 2015b), and 360 mg/m³ for acetaldehyde (USOSHA, 2015a). These TWA limits (8-h exposure) were compared to the levels of each aldehyde compound in EC aerosols. To approximate the workplace environment, the recommended short-term, light activity, respiratory rate

for a 21 to <31 year old adult of 0.012 m³/min was used to estimate total breath volume (USEPA, 2011). Using this value, within 8 h (480 min), the total volume of air inhaled is 5.8 m³ (0.012 m³/min × 480 min). Using this volume, the total amount of formaldehyde, acetaldehyde, and acrolein inhaled daily at the maximum OSHA limits would be approximately 5.3 mg, 2088 mg, and 1.5 mg, respectively.

The yield of formaldehyde, acetaldehyde, and acrolein delivered by combustible cigarettes has been estimated from the Counts et al. study on smoke yields from 44 commercial cigarettes under intense smoking conditions (Counts et al., 2005). Using these data, the exposure to formaldehyde, acetaldehyde, and acrolein from consuming a pack of combustible cigarettes is approximately 1.5–2.5 mg for formaldehyde, 10–30 mg for acetaldehyde, and 1.5–3 mg for acrolein.

As shown in Table 4, formaldehyde yields from Device 1 exceeded both the yield from combustible cigarettes (20 per day) and the OSHA limit even at the lowest power level and, at the maximum power level, produced formaldehyde almost 10 times the OSHA workplace exposure limit. This device also exceeded the acrolein yield from 20 combustible cigarettes per day and the OSHA workplace exposure limit, but only at the highest power level tested.

Device 2 also exceeded the formaldehyde yield from combustible cigarettes but again only at the highest power level tested. In contrast, the other three devices all produced aldehydes below both combustible cigarettes and the OSHA workplace exposure limit. One device, Device 5, produced less than 1% of the aldehydes delivered from 20 combustible cigarettes per day and the OSHA workplace exposure limit. Also, there was over a 750-fold difference in total aldehyde yield between Devices 1 and 5. The extreme levels of aldehydes produced by Device 1 indicate that the coil may have overheated due to lack of liquid in the wick. In this case, the excess energy would be transformed into heat and the coil temperature would exceed the evaporation point of the e-liquid (22), with heat-induced decomposition processes competing with aerosolization. At the conclusion of this study, the coil for Device 1 was examined and found to be charred, an indication of thermal decomposition. The charred coil, the observed decrease in yield in mg/watt production at the highest power level, and the elevated levels of aldehydes and acrolein, all indicate that the results for Device 1 may not represent typical usage of this device, we hypothesize, and a typical user might experience noxious dry-puff effects and discontinue use at that power setting. However, determination of dry-puffs is outside of the scope of this study since dry-puffs can only be confirmed by sensory evaluation of the aerosol by a user (Farsalinos et al., 2015).

5. Conclusion

The range of aerosol produced on a per puff basis ranged from 1.5 to 28 mg or approximately a 17-fold increase. The range of aerosol produced normalized for power applied to the coil ranged from 0.27 to 1.1 mg/watt or a 3.1-fold increase. From these results, it is clear that it is impossible to accurately estimate EC aerosol yield based on the coil resistance alone and that calculations based on power applied to the coil can only estimate the EC aerosol yield.

The trapped aerosol was also analyzed for aldehydes, as DNPH derivatives, produced during EC aerosol formation. The amount of formaldehyde, acetaldehyde, and acrolein produced per puff ranged from 0.05 to 17 μg , 0.03–8.3 μg and <0.02–2.0 μg respectively. The amount of formaldehyde, acetaldehyde, and acrolein produced per gram of total aerosol produced ranged from 0.01 to 7.3 mg/g, 0.006–5.8 mg/g, and <0.003–0.78 mg/g, respectively. Our results demonstrate that the amount of aldehydes in EC aerosols varies by device and the power applied to the atomizer coil. An increase in the efficiency of aerosol production with increasing power supplied to the atomizer was correlated with lower levels of aldehydes in the EC aerosol.

Formaldehyde and acrolein yields for one device exceeded both the yield from combustible cigarettes (20 per day) and the OSHA limit at the maximum power level tested, produced formaldehyde almost 10 times the OSHA workplace exposure limit. However, three of the five devices studied yielded less formaldehyde, acetaldehyde, and acrolein than delivered by combustible cigarettes and also less than an 8-h occupation exposure limit. Our results demonstrate that large differences exist in the EC devices available in the market place, and that, depending on the device, changes in power applied to the atomizer can have dramatic, but different, impacts on both total aerosol yield and the formation of aldehyde compounds in the EC aerosol, with some devices far more capable than others of maximizing liquid aerosolization while minimizing thermal decomposition at higher power levels.

The high levels of aldehyde formation seen in Device 1 could be due, in part, to the formulation or viscosity of the test liquid used in this study. The composition of the liquid may have an impact on the rate at which liquid is transferred to the coil and also the formation of aldehydes. The purpose of this study was to compare different

devices and power levels using a simple PG and GLY liquid formulation. Similar e-liquids are widely used both by consumers and by previous researchers. Repeating the analysis using different liquids formulations was beyond the scope of this study. However, it would be of interest for future studies to compare the results of the formulation used here with nicotine solutions using only PG, or various PG, GLY and water mixtures, including liquids that contain popular flavor compounds. There are some caveats to studying this: mixtures with a different composition or components may change the boiling point of the e-liquid and may impact the yield of EC devices, and flavor compounds themselves may have wide variance in propensity for thermal decomposition. Another interesting and important consideration for future studies would be direct measurement of the temperature of the coil during activation to better understand what coil temperatures lead to decomposition, but this was technologically beyond the scope of this study. Finally, we only measured the levels of three aldehydes, and there could be other toxic substances produced, including propionaldehyde (Dai et al., 2004) and free-radicals, which have been detected previously at low levels in EC emissions (Goel et al., 2015; Sussan et al., 2015). Since these thermal decomposition processes (pyrolysis) have been shown to involve formation of free-radical species during dehydration steps of PG and GLY on the pathway to aldehydes (Dai et al., 2004; Paine et al., 2007), it is possible that these free-radicals would be detected at levels commensurate with the amounts of aldehydes being produced. However, this also was technologically beyond the scope of this study. One also needs to consider that, in terms of actual risks from aldehyde toxicity to the user, it is very possible that when significant thermal decomposition of an EC liquid is occurring, commonly called the dry-puff phenomenon (Farsalinos et al., 2015), the aerosol produced may be quite noxious, and cause the user to discontinue use until the dry-puff issue is resolved. More quantitative analysis of actual aldehyde production under human usage conditions should be done in the future, since it is possible that a user would avoid inhalation of EC aerosols under significant thermal decomposition conditions. Also, the aldehydes present in EC aerosol have been shown by others to be a mixture of the free aldehydes along with hydrate, acetal and hemiacetal forms. The health effect due to the inhalation of this mixture of complexed aldehydes relative to free aldehydes is currently unknown and warrants further study. It is also possible that these hydrates, acetals and hemiacetals convert back to free aldehydes *in vivo* through hydrolysis, which is in principle possible under the aqueous and slightly basic conditions of the lungs (Funderburk et al., 1978), however to our knowledge this has not been studied under physiological conditions.

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Appendix A-C. Supplementary data

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Transparency document

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