Washington State
Liquor and Cannabis Board

Date: February 17, 2021

To: Jane Rushford, Board Chair
Ollie Garrett, Board Member
Russ Hauge, Board Member

From: Casey Schaufler, Policy and Rules Coordinator

Copy: Rick Garza, Agency Director
Megan Duffy, Deputy Director
Justin Nordhorn, Chief of Enforcement
Becky Smith, Licensing Director
Kathy Hoffman, Policy and Rules Manager

Subject: Request for approval of final rules (CR 103) regarding amendment to WAC 314-55-010 – Definitions; adoption of new sections WAC 314-55-550 – Marijuana vapor products and WAC 314-55-1055 – Ingredient disclosure.

The Policy and Rules Coordinator requests that the Board adopt the final rules and approve the CR 103 to implement the law as established by House Bill (HB) 2826 (Chapter 133, Laws of 2020), now codified in RCW 69.50.101, RCW 69,50.327, and RCW 69.50.342, to amend language in WAC 314-55-010 and to adopt new sections WAC 314-55-550 and WAC 314-55-1055.

The Board has been briefed on the rule development background and public comment received for this rule making project. A CR 103 memorandum, CR 103 form, and rule text are attached.

If approved, the Policy and Rules Coordinator will send the concise explanatory statement concerning this rulemaking to all persons who provided comments. The Policy and Rules Coordinator will file the rules with the Office of the Code Reviser. The effective date of the rules will be 31 days after filing, or March 20, 2021.

_____ Approve	_____ Disapprove	_____ Jane Rushford, Chair	_____ Date
_____ Approve	_____ Disapprove	_____ Ollie Garrett, Board Member	_____ Date
_____ Approve	_____ Disapprove	_____ Russ Hauge, Board Member	_____ Date

Washington State
Liquor and Cannabis Board

CR 103 Memorandum

Regarding WAC 314-55-010 – Definitions; New Section WAC 314-55-550 – Marijuana vapor products; New Section WAC 314-55-1055 – Ingredient disclosure

Date: February 17, 2021
Presented by: Casey Schaufler, Policy and Rules Coordinator

Background

On September 27, 2019, Governor Inslee issued Executive Order 19-03 to address an outbreak of lung injuries emerging in previously healthy individuals who had vaped THC or nicotine vapor products.

Under direction of Executive Order 19-03, on October 10, 2019, the Washington State Board of Health (SBOH) issued emergency rules prohibiting the sale of flavored vapor products by persons licensed under chapter 69.50 RCW or chapter 70.345 RCW.

On October 16, 2019, the Washington State Liquor and Cannabis Board (Board) adopted an emergency rule as WSR 19-21-100 creating new WAC 314-55-1055 requiring manufacturers of THC vapor products to disclose all compounds, including ingredients, solvents, additives, etc. used in the production and processing as well as the source of all vapor products as directed by Executive Order 19-03.

On November 20, 2019, the SBOH adopted an emergency rule as WSR 19-24-001 on November 20, 2019, prohibiting the sale of vapor products containing vitamin E acetate. The SBOH found that the outbreak of lung disease continued to grow, and that the adoption of an emergency rule prohibiting the sale of vapor products containing vitamin E acetate was necessary for the preservation of the public health, safety, and general welfare. The SBOH relied on the following to support its finding:

- In July 2019, the United States Centers for Disease Control and Prevention (CDC), United States Food and Drug Administration (FDA), state and local health departments, and other clinical and public health partners began investigating outbreaks of lung injury associated with e-cigarette product use, or vaping.

- In September 2019, the CDC activated its Emergency Operations Center to aid in the investigation of the multistate outbreak.

- As of November 13, 2019, there have been two thousand one hundred seventy-two confirmed cases reported across forty-nine states, the District of Columbia, Puerto Rico and the United States Virgin Islands, including forty-two deaths confirmed in twenty-four states. Fourteen cases of lung injury have been reported in Washington State.

- As part of the investigation into the multistate outbreak of lung disease associated with the use of vapor products, the CDC conducted laboratory tests of twenty-nine samples of fluid collected from the lungs of patients with vaping-associated lung disease from ten states. An article released on November 8, 2019, showed that all of the samples contained vitamin E acetate, providing direct evidence of vitamin E acetate at the primary site of injury in the lungs. Vitamin E acetate is a chemical that is used as an additive or thickening ingredient in vapor products. The CDC has not determined that vitamin E acetate is present in only THC vapor products or only non-THC vapor products. THC was identified in eighty-two percent of the samples, and nicotine was identified in sixty-two percent of the samples. None of a range of other potential chemicals of concern was detected in the samples, but evidence is not yet sufficient to rule out the contribution of other chemicals, substances, or product sources to the disease. The CDC has identified vitamin E acetate as a chemical of concern and stated that, until the relationship of vitamin E acetate and lung health is better characterized, it is important that vitamin E acetate not be added to vapor products.

On February 5, 2020, the Board extended its emergency rule originally filed as WSR 19-21-100 that created new WAC 314-55-1055 requiring manufacturers of THC vapor products to disclose all compounds, including ingredients, solvents, additives, etc. used in the production and processing as well as the source of all vapor products as directed by Executive Order 19-03 as WSR 20-05-004.

The SBOH emergency flavor ban expired on or about February 7, 2020.

On March 19, 2020, the SBOH extended its emergency rule concerning the prohibition of the sale of vapor products containing vitamin E acetate as WSR 20-08-007.

On March 25, 2020, House Bill (HB) 2826 (Chapter 133, Laws of 2020), now codified in RCW 69.50.101, RCW 69,50.327, RCW 69.50.342, was enacted in

response to concerns related to marijuana vapor product and vapor related lung illnesses. The legislation contained an emergency clause, and in its intent section, found that “recent reports of lung illnesses associated with vapor products” demanded “serious attention by the state in the interest of protecting public health and preventing youth access. While state law grants the liquor and cannabis board broad authority to regulate vapor products containing marijuana, the legislature finds that risks to public health and youth access can be mitigated by clarifying that the board is granted specific authority to prohibit the use of any additive, solvent, ingredient, or compound in marijuana vapor product production and processing and to prohibit any device used in conjunction with a marijuana vapor product.”

On May 27, 2020, the Board issued its own emergency rule as WSR 20-12-035 as new WAC 314-55-1065 prohibiting the sale of vapor products containing vitamin E acetate consistent with the authority granted by HB 2826, now codified in RCW 69.50.101, RCW 69.50.327, RCW 69.50.342.

Also on May 27, 2020, the Board rescinded WSR 20-05-004, and replaced it with WSR 20-12-039, extending the requirements for disclosure of all ingredients used in the production of marijuana concentrates for inhalation and marijuana extracts for inhalation as described in WAC 314-55-105, and consistent with the authority granted by HB 2826, now codified in RCW 69.50.101, RCW 69.50.327, RCW 69.50.342.

On July 17, 2020, the SBOH extended its emergency rule concerning the prohibition of the sale of vapor products containing vitamin E acetate as WSR 20-15-117.

On September 16, 2020, the Board extended emergency rule WAC 314-55-1055 as WSR 20-19-083, and emergency rule WAC 314-55-1065 as WSR 20-19-080. Each of these rules will expire on January 14, 2021.

On November 15, 2020, the SBOH adopted WAC 246-80-012 as WSR 20-23-006, permanently prohibiting the sale of vapor products containing vitamin E acetate. The prohibition applies to any person licensed under chapter 69.50 or 70.345 RCW. The rule went into effect immediately upon filing.

On January 6, 2021, the Board again extended emergency rule WAC 314-55-1055 as WSR 21-02-095, and emergency rule WAC 314-55-1065 as WSR 21-02-092. Each of these rules will expire on May 6, 2021.

Rule Necessity

Consistent with HB 2826, new rule sections and amendment to existing rule is necessary to allow the Board to accomplish the following:

- Prohibit any type of device used in conjunction with a marijuana vapor product, and prohibit the use of any type of additive, solvent, ingredient, or compound in the production and processing of marijuana products, including marijuana vapor products one the Board has determined, following consultation with the Department of Health (DOH) or other authority the WSLCB deems appropriate, that the device, additive, solvent, ingredient or compound may pose a risk to public health or youth access;
- Establish definitions for terms including, but not limited to "characterizing flavor," botanical terpenes," and others; and
- Require marijuana processors to submit, under oath, to the DOH, a complete list of all constituent substances and the amount and sources of all constituent substances in each marijuana vapor product, including all additives, thickening agents, preservatives, compounds, and any other substance used in the production and processing of each marijuana vapor product.

Description of Rule Changes

Amended section. WAC 314-55-010 – Definitions. Adds definitions for "characterizing flavor" and "terpenes." Additionally, existing subsections were renumbered to accommodate this amendment.

New section. WAC 314-55-550 – Marijuana products. Establishes a procedure for the Board to monitor, evaluate and prohibit devices or additives used in conjunction with marijuana vapor products.

New section. WAC 314-55-1055 – Ingredient disclosure. Requires marijuana processors and producers to disclose all compounds, including but not limited to ingredients, solvents, additives, preservatives, thickening agents, terpenes, and other substances used to produce or added to marijuana concentrates for inhalation or marijuana-infused extracts for inhalation at any point during production and processing, regardless of source or origin. Disclosure must be made to the board on forms provided by the board

Variance between proposed rule (CR 102) and final rule:

There is no variance between the proposed rule and the final rule.

Rule Implementation

Informing and Educating Persons Impacted by the Rule

To help inform and educate persons impacted by the rule, the WSLCB will:

- Email notice with the adoption materials to persons who commented on the rules, the rule making and licensee distribution lists, and the general WSLCB GovDelivery list;
- Post rule adoption materials, including final rule language, response to comments, final analysis (Concise Explanatory Statement), and any other relevant documents on the rulemaking webpage for public access.
- Provide information and training on request.

Promoting and Assisting Voluntary Compliance

WSLCB will promote and assist voluntary compliance through technical assistance.

- WSLCB staff are available to respond to phone and email inquiries about the rules.
- Licensing and Enforcement/Education leadership and staff have participated in rule revisions, and are familiar with the final product. Internal and external education efforts to share knowledge and assure consistent application of rule will be supported.
- Rule and guidance documents will be available on the WSLCB website.
- WSLCB will use available and customary resources to disseminate materials and information to all persons impacted by the rules.

These actions are designed to inform and educate all persons impacted by the rules to support and promote voluntary compliance.

Training and Informing WSLCB Staff

Several WSLCB staff responsible for implementing these adopted rules work directly with impacted parties and are already familiar with the nuances of the rule changes. Additional internal guidance documents may be prepared as necessary. The WSLCB will also consider:

- Provision of internal and external training and education, as needed, potentially including webinars, training, and videos if appropriate;
- Coordinating and centrally locating decisions to assure consistency between agency, staff, and industry.

Rule Effectiveness Evaluation

The WSLCB will evaluate the effectiveness of these rules in the following ways, including but not limited to:

- Monitoring questions received after the effective date of these rules, and adjusting training and guidance accordingly;
- Monitoring the number of enforcement actions, including type, resolution, and final outcome;
- Monitoring the number of requests for rule language revisions or changes;

- Monitoring the number of requests for rule interpretation;
- Monitoring licensee feedback including, but not limited to, the number of requests for assistance.

CODE REVISER USE ONLY

RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

Agency: Washington State Liquor and Cannabis Board

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: The Washington State Liquor and Cannabis Board (Board) has adopted amendments to WAC 314-55-010 and new sections WAC 314-55-550 and WAC 314-55-1055 to implement the directives and requirements of House Bill (HB) 2826 (Chapter 133, Laws of 2020) concerning marijuana vapor products, now codified in RCW 69.50.101, RCW 69,50.327, RCW 69.50.342.

Citation of rules affected by this order:

New: WAC 314-55-550, WAC 314-55-1055

Repealed: _____

Amended: WAC 314-55-010

Suspended: _____

Statutory authority for adoption: RCW 69.50.342; RCW 69.50.345.

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 21-01-058 on December 9, 2020 (date).

Describe any changes other than editing from proposed to adopted version: There were no changes from the proposed rules to the adopted rules.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: Casey Schaufler

Address: 1025 Union Avenue SE, Olympia WA 98501

Phone: 360-664-1760

Fax: 360-664-3208

TTY:

Email: rules@lcb.wa.gov

Web site: www.lcb.wa.gov

Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New		Amended		Repealed	
Federal rules or standards:	New		Amended		Repealed	
Recently enacted state statutes:	New	2	Amended	1	Repealed	

The number of sections adopted at the request of a nongovernmental entity:

	New		Amended		Repealed	

The number of sections adopted on the agency's own initiative:

	New		Amended		Repealed	

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New		Amended		Repealed	

The number of sections adopted using:

Negotiated rule making:	New		Amended		Repealed	
Pilot rule making:	New		Amended		Repealed	
Other alternative rule making:	New	2	Amended	1	Repealed	

Date Adopted: February 17, 2021	**Signature:**
Name: Jane Rushford	
Title: Chair	

NEW SECTION

WAC 314-55-1055 Ingredient disclosure. (1) All licensed marijuana processors and producers must disclose all ingredients used in the production of marijuana concentrates for inhalation and marijuana-infused extracts for inhalation.

(2) All chemicals, compounds, additives, preservatives, thickening agents, terpenes, and other substances used at any point in the production or processing of marijuana concentrates for inhalation or marijuana-infused extracts for inhalation, regardless of source or origin, must be disclosed to the board as follows:

(a) On a form provided by the board and stored by the licensee, either electronically or in hard copy, and made available for inspection if requested by an employee of the board; and

(b) In a manner directed by the board including, but not limited to, submission to an email address or other online platform provided and maintained by the board.

(3) The complete list of all chemicals, compounds, additives, preservatives, thickening agents, terpenes, and other substances used at any point in the production or processing of marijuana concentrates for inhalation or marijuana-infused extracts for inhalation, regardless of source or origin, that is required under subsection (2) of this section must be kept and maintained, consistent with recordkeeping requirements described in WAC 314-55-087, at the facility in which the products are processed. The list must be updated whenever there is any change in product composition.

AMENDATORY SECTION (Amending WSR 18-22-055, filed 10/31/18, effective 12/1/18)

WAC 314-55-010 Definitions. The following definitions apply for the purpose of this chapter in addition to the definitions provided in RCW 69.50.101.

(1) "Applicant" or "marijuana license applicant" means any person or business entity who is considered by the WSLCB as a true party of interest in a marijuana license, as outlined in WAC 314-55-035. However, for purposes of determining an application's priority under RCW 69.50.331 (1)(a), only the person or business entity that is applying for the license will be considered the applicant.

(2) "Batch" means a quantity of marijuana-infused product containing material from one or more lots of marijuana.

(3) "Business name" or "trade name" means the name of a licensed business as used by the licensee on signs and advertising.

(4) "Characterizing flavor" means a noticeable taste, other than one of cannabis, resulting from an additive or combination of additives including, but not limited to, fruit, spice, herbs, alcohol, candy, or menthol, or that is noticeable before or during consumption of the cannabis product.

(5) "Child care center" means an entity that regularly provides child day care and early learning services for a group of children for periods of less than twenty-four hours licensed by the Washington state department of early learning under chapter 170-295 WAC.

((~~(5)~~)) (6) "Consultant" means an expert who provides advice or services in a particular field, whether a fee is charged or not. A consultant who is in receipt of, or has the right to receive, a percentage of the gross or net profit from the licensed business during any full or partial calendar or fiscal year is a true party of interest and subject to the requirements of WAC 314-55-035. A consultant who exercises any control over an applicant's or licensee's business operations is also subject to the requirements of WAC 314-55-035(4).

((~~(6)~~)) (7) "Cooperative" means a group of more than one, but no more than four qualified medical marijuana patients and/or designated providers who share responsibility for growing and processing marijuana only for the medical use of the members of the cooperative.

((~~(7)~~)) (8) "Domicile" means a person's true, fixed, primary permanent home and place of habitation and the tax parcel on which it is located. It is the place where the person intends to remain and to which the person expects to return when the person leaves without intending to establish a new domicile elsewhere.

((~~(8)~~)) (9) "Elementary school" means a school with a physical location for early education that provides the first four to eight years of basic education and recognized by the Washington state superintendent of public instruction.

((~~(9)~~)) (10) "Employee" means any person performing services on a licensed premises for the benefit of the licensee whether or not such person is compensated by the licensee.

((~~(10)~~)) (11) "End product" means a marijuana product that requires no further processing prior to retail sale.

((~~(11)~~)) (12) "Financier" means any person or entity, other than a banking institution, that provides money as a gift or loans money to the applicant/business and expects to be paid back the amount of the loan with or without reasonable interest.

((~~(12)~~)) (13) "Game arcade" means an entertainment venue featuring primarily video games, simulators, and/or other amusement devices where persons under twenty-one years of age are not restricted.

((~~(13)~~)) (14) "Harvest" means the marijuana plant material derived from plants of the same strain that were cultivated at the same licensed location and gathered at the same time.

((~~(14)~~)) (15) "Immature plant or clone" means a marijuana plant or clone that has no flowers, is less than twelve inches in height, and is less than twelve inches in diameter.

((~~(15)~~)) (16) "Intermediate product" means marijuana flower lots or other material lots that have been converted by a marijuana processor to a marijuana mix lot, marijuana concentrate or marijuana-infused product that must be or are intended to be converted further to an end product.

((~~(16)~~)) (17) "Library" means an organized collection of resources made accessible to the public for reference or borrowing supported with money derived from taxation.

((~~(17)~~)) (18) "Licensed premises" means all areas of a premises where the licensee has leasehold rights as listed in the property lease submitted to the board. Any vehicle assigned for the purposes of transporting marijuana, useable marijuana, marijuana concentrates, or marijuana-infused products shall be considered an extension of the licensed premises.

((~~(18)~~)) (19) "Licensee" or "marijuana licensee" means any person or entity that holds a marijuana license, or any person or entity who is a true party of interest in a marijuana license, as outlined in WAC 314-55-035.

((~~(19)~~)) (20) "Lot" means either of the following:

(a) The flowers from one or more marijuana plants of the same strain. A single lot of flowers cannot weigh more than five pounds; or

(b) The trim, leaves, or other plant matter from one or more marijuana plants. A single lot of trim, leaves, or other plant matter cannot weigh more than fifteen pounds.

((~~(20)~~)) (21) "Lozenge" means a marijuana-infused product such as a hard candy, mint, pastille, tablet, or similar type of edible product that is generally swallowed whole, chewed and swallowed, or dissolved in the mouth.

((~~(21)~~)) (22) "Marijuana strain" means a pure breed or hybrid variety of Cannabis reflecting similar or identical combinations of properties such as appearance, taste, color, smell, cannabinoid profile, and potency.

((~~(22)~~)) (23) "Marijuana mix" means an intermediate lot that contains multiple strains of useable marijuana and is chopped or ground so no particles are greater than 3 mm.

((~~(23)~~)) (24) "Marijuana mix infused" or "mix infused" means an end product that contains marijuana mix and may contain other intermediate products or useable marijuana.

((~~(24)~~)) (25) "Marijuana mix packaged" or "mix packaged" means an end product containing only marijuana mix and no other product types.

((~~(25)~~)) (26) "Member," except as that term is used in relation to registered cooperatives, means a principal or governing person of a given entity, including but not limited to: LLC member/manager, president, vice president, secretary, treasurer, CEO, director, stockholder, partner, general partner, limited partner. This includes all spouses of all principals or governing persons named in this definition and referenced in WAC 314-55-035.

((~~(26)~~)) (27) "Paraphernalia" means items used for the storage or use of useable marijuana, marijuana concentrates, or marijuana-infused products, such as, but not limited to, lighters, roach clips, pipes, rolling papers, bongs, and storage containers. Items for growing, cultivating, and processing marijuana, such as, but not limited to, butane, lights, and chemicals are not considered "paraphernalia."

((~~(27)~~)) (28) "Pesticide" means, but is not limited to: (a) Any substance or mixture of substances intended to prevent, destroy, control, repel, or mitigate any insect, rodent, snail, slug, fungus, weed, and any other form of plant or animal life or virus, except virus on or in a living person or other animal which is normally considered to be a pest; (b) any substance or mixture of substances intended to be used as a plant regulator, defoliant, or desiccant; and (c) any spray adjuvant. Pesticides include substances commonly referred to as herbicides, fungicides, insecticides, and cloning agents.

((~~(28)~~)) (29) "Perimeter" means a property line that encloses an area.

((~~(29)~~)) (30) "Plant" means a marijuana plant.

((~~(30)~~)) (31) "Plant canopy" means the square footage dedicated to live plant production, such as maintaining mother plants, propagating plants from seed to plant tissue, clones, vegetative or flowering area. Plant canopy does not include areas such as space used for the storage of fertilizers, pesticides, or other products, quarantine, office space, etc.

((~~(31)~~)) (32) "Playground" means a public outdoor recreation area for children, usually equipped with swings, slides, and other playground equipment, owned and/or managed by a city, county, state, federal government, or metropolitan park district.

((~~(32)~~)) (33) "Product(s) otherwise taken into the body" means a marijuana-infused product for human consumption or ingestion intended for uses other than inhalation, oral ingestion, or external application to the skin.

((~~(33)~~)) (34) "Public park" means an area of land for the enjoyment of the public, having facilities for rest and/or recreation, such as a baseball diamond or basketball court, owned and/or managed by a city, county, state, federal government, or metropolitan park district. Public park does not include trails.

((~~(34)~~)) (35) "Public transit center" means a facility located outside of the public right of way that is owned and managed by a transit agency or city, county, state, or federal government for the express purpose of staging people and vehicles where several bus or other transit routes converge. They serve as efficient hubs to allow bus riders from various locations to assemble at a central point to take advantage of express trips or other route to route transfers.

((~~(35)~~)) (36) "Recreation center or facility" means a supervised center that provides a broad range of activities and events intended primarily for use by persons under twenty-one years of age, owned and/or managed by a charitable nonprofit organization, city, county, state, federal government, or metropolitan park district.

((~~(36)~~)) (37) "Residence" means a person's address where he or she physically resides and maintains his or her abode.

((~~(37)~~)) (38) "Secondary school" means a high and/or middle school with a physical location: A school for students who have completed their primary education, usually attended by children in grades seven to twelve and recognized by the Washington state superintendent of public instruction.

((~~(38)~~)) (39) "Selling price" means the same meaning as in RCW 82.08.010, except that when the product is sold under circumstances where the total amount of consideration paid for the product is not indicative of its true value. Selling price means the true value of the product sold as determined or agreed to by the WSLCB. For purposes of this subsection:

(a) "Product" means marijuana, marijuana concentrates, useable marijuana, or marijuana-infused products; and

(b) "True value" means market value based on sales at comparable locations in the state of the same or similar product of like quality and character sold under comparable conditions of sale to comparable purchasers. In the absence of such sales of the same or similar product, true value means the value of the product sold as determined by all of the seller's direct and indirect costs attributed to the product.

((~~(39)~~)) (40) "Terpenes" means a class of compounds that impart smell, taste, or both occurring in the cannabis plant which consist of a carbon skeleton derived from isoprene units. The word "terpene" may include, but is not limited to, the following:

(a) "Botanical terpenes" means constituents derived from a spice, fruit, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, or leaf or similar plant material. Their significant function in cannabis products is flavoring. This includes:

(i) Essential oil, which is natural oil typically obtained by distillation and possessing the characteristic fragrance of the plant or other source from which it is extracted;

(ii) Oleoresin, which is a natural or artificial mixture of essential oils and a resin;

(iii) Distillate; or

(iv) Any product of roasting, heating, or enzymolysis which contains terpenes.

(b) "Synthetic terpenes" means any terpene that does not occur in the cannabis plant, or in other botanical sources, and is produced through chemical manipulation in a laboratory or similar facility.

(c) "Terpenoids" means the natural products and related compounds formally derived from isoprene units, or "isoprenoids," that have the same meaning as that found in the current version of the International Union of Pure and Applied Chemistry (IUPAC) and as hereafter amended.

(41) "Unit" means an individually packaged marijuana-infused solid or liquid product meant to be eaten or swallowed, not to exceed ten servings or one hundred milligrams of active tetrahydrocannabinol (THC), or Delta 9.

((~~(40)~~)) (42) "WSLCB" means the Washington state liquor and cannabis board.

NEW SECTION

WAC 314-55-550 Marijuana vapor products. (1) The purpose of this section is to:

(a) Support and further the protection of public health and prevention of youth access consistent with RCW 69.50.101(xx).

(b) Mitigate the risks to public health and youth access by prohibiting the use of any additive, solvent, ingredient, or compound in

marijuana vapor product production and processing when appropriate, consistent with RCW 69.50.342 (1)(m).

(c) Mitigate the risks to public health and youth access by prohibiting any device used in conjunction with a marijuana vapor product when appropriate, consistent with RCW 69.50.342 (1)(n).

(2) Procedure for prohibited substances.

(a) The board may prohibit any type of device used in conjunction with a marijuana vapor product, and may prohibit the use of any type of additive, solvent, ingredient, or compound in the production of marijuana vapor products that may pose a risk to public health or youth access.

(b) The board may consider, following consultation with the department of health or other authority the board deems appropriate, any relevant data when determining whether a device, additive, solvent, ingredient or compound may pose a risk to public health or youth access including, but not limited to:

(i) Case report data;

(ii) Other local, state and federal agency findings, reports, etc.;

(iii) A product or substance that is the subject of a recall under WAC 314-55-225;

(iv) Any other information sourced and confirmed from reliable entities.

(c) The board may prohibit the use of a product or substance by adoption of emergency or permanent rules. The board will provide notices of rule making consistent with the requirements of chapter 34.05 RCW.

(d) The board will maintain a list of prohibited substances prohibited by permanent or emergency rules on its website.

(e) The list of prohibited substances will be reviewed on an annual basis.

(f) Prohibited substances may be removed from the list of prohibited substances if the board determines, after a review consistent with (b)(i) through (iv) of this subsection, that it no longer poses a risk to public health or youth access.

Washington State
Liquor and Cannabis Board

Notice of Permanent Rules

Regarding Amendment WAC 314-55-010 – Definitions; New Section WAC 314-55-550 – Marijuana vapor products; New Section WAC 314-55-1055 – Ingredient disclosure.

This concise explanatory statement concerns the Washington State Liquor and Cannabis Board's (Board) adoption of amendment to section WAC 314-55-010 and adoption of new sections WAC 314-55-550 and WAC 314-55-1055 allowing the Board oversight and regulation of marijuana vapor products.

The Administrative Procedure Act (RCW 34.05.325(6)) requires agencies to complete a concise explanatory statement before filing adopted rules with the Office of the Code Reviser. The concise explanatory statement must be provided to any person upon request, or from whom the Board received comment.

The Board appreciates and encourages your involvement in the rule making process. If you have questions, please contact Casey Schaufler, Policy and Rules Coordinator, at (360) 664-1760 or e-mail at rules@lcb.wa.gov.

Background and reasons for adopting these rules

The adopted rules amend WAC 314-55-010 and add new sections WAC 314-55-550 and WAC 314-55-1055 to implement the directives and requirements of House Bill (HB) 2826 (Chapter 133, Laws of 2020) concerning marijuana vapor products, now codified in RCW 69.50.101, RCW 69,50.327, RCW 69.50.342. HB 2826 provides that the Board may adopt rules prohibiting any type of marijuana vapor product device, or prohibit the use of any type of additive, solvent, ingredient, or compound in the production and processing of marijuana products, including marijuana vapor products.

The adopted rules are necessary to allow the Board to implement marijuana vapor product regulation consistent with HB 2826, and to establish definitions for terms including, but not limited to "characterizing flavor," botanical terpenes," and others.

Rulemaking history for this adopted rule:

CR 101 – filed July 8, 2020 as WSR #20-15-041;
CR 102 – filed December 9, 2020 as WSR #21-01-058.
Public hearing held February 3, 2021.

The effective date of these rules is March 20, 2021.

Public comment received on the rule proposal:

The following comments were received as indicated below, and are presented in their native form, including formatting, text and spelling. A response to each comment is provided, along with an indication regarding whether the comment was reflected in the adopted rule.

1. Email received December 18, 2020:
David Heldreth wrote:
"https://mjbizdaily.com/wp-content/uploads/2020/12/10-11-20-Report-VP-and-ERSA.pdf

I'd like this pdf entered into the record and shared with the WSLCB board."

WSLCB response: The WSLCB appreciates these comments, and the demonstration of meaningful, collaborative participation in the rulemaking process. The WSLCB looks forward to your continued partnership on future policy and rule development projects.

No changes to the rules were requested. Article is presented in full per request and guidelines of original publishers.

2. Email received February 3, 2021:
Ezra Eickmeyer wrote:
Dear Mr. Schaufler,

Attached, please find comments from Producers NW on the draft rules for marijuana vapor products. Thank you. (attachment contents below)

Dear LCB Rules Coordinator,

Producers NW would like to thank LCB for a good overall set of draft rules regarding Marijuana Vapor Products and propose the edits listed below.

We appreciate the need to protect the public from harmful additives and believe these rules will do more than enough to ensure vape product safety. It is also our goal to ensure that the process is streamlined and minimizes costs to the industry. Please contact us anytime with questions. Thank you.

Proposed Changes

- Add definition of marijuana vapor products –

"Marijuana vapor products" means any marijuana concentrate that is intended to be heated into a vapor state and inhaled into the lungs by the consumer. "Marijuana vapor

products" does not include marijuana concentrates or extracts intended to be used as topicals, suppositories, pills, tinctures or any other concentrate-based product that is not intended for inhalation.

- The vapor disclosure form needs to be amended to be less redundant and it is not made clear that all marijuana concentrates for inhalation need to have a form disclosed.
    - We do not support having the WSLCB collecting these forms because of the potential for public records requests making proprietary information public. Instead, we suggest having disclosures kept on site and available for WSLCB audit upon request.

- Characterizing flavor in the definitions section (314-55-010 (4)) needs to be amended in the following way –

  (4) "Characterizing flavor" means a noticeable taste, other than one of cannabis, resulting from an additive or combination of additives including, but not limited to, fruit, spice, herbs, alcohol, candy, or menthol~~, or that is noticeable before or during consumption of the cannabis product~~.

  NOTE - Since WSLCB enforcement is not allowed to consume cannabis this could allow enforcement to write AVN's based upon subjective smell of the product. The smell of a botanical mix can be more fragrant than the actual flavor. This industry should not be in a position where the smell of a cartridge is a determining factor.

- Terpenes (314-55-010 (40)) -

We need to be careful with this section as this definition would apply to the upcoming QA rules that, in their current draft, require the addition of terpenes to require a terpene analysis. If the WSLCB does go through with those rules as drafted, any compound that meets the definition above when added to a cannabis product would then require another test, adding redundant expenses to the cost of the product.

WSLCB Response: The WSLCB appreciates these comments, and the demonstration of meaningful, collaborative participation in the rulemaking process. The WSLCB looks forward to your continued partnership on future policy and rule development projects.

With respect to the definition of marijuana vapor products: The adopted rules do not reflect this suggested revision. WAC 314-55-1055 as adopted distinguishes "ingredients used in the production of marijuana concentrates for inhalation and marijuana-infused extracts for inhalation" as products subject to disclosure and to new section WAC 314-55-550 – Marijuana vapor products.

With respect to marijuana vapor product disclosure forms: The adopted rules do not reflect this suggested revision. There is no proprietary protection afforded to information

required under RCW 69.50.342(1)(n). Additionally, the format and contents of the ingredient disclosure form are outside of the scope of rulemaking.

With respect to the definition for characterizing flavor: The adopted rules do not reflect this suggested revision. It is important to note that the definition includes, "or that is noticeable before or during consumption of the cannabis product." The inclusion of the singular "or" implies that an individual may reasonably determine that a characterizing flavor is present through means other than taste alone, including but not limited to smell or packaging design.

With respect to the definition for terpenes: The adopted rules do not reflect this suggested revision. A definition in concept or proposed language, was not offered.

Public Hearing, February 3, 2021:

There was no oral testimony offered at the public hearing held on February 3, 2021.

Changes from Proposed Rules (CR-102) to the Rules as Adopted:

There were no changes to the proposed rules.

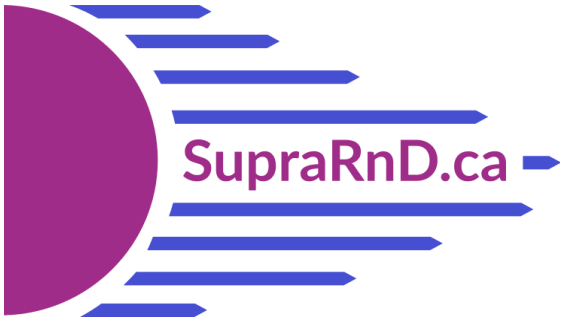
Vaporization Potential and

Effective Residual Solvent Analysis Report

Vitamin E Acetate, Squalane and Squalene

November 10, 2020

Prepared by



Supra Research and Development

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1.0 Introduction

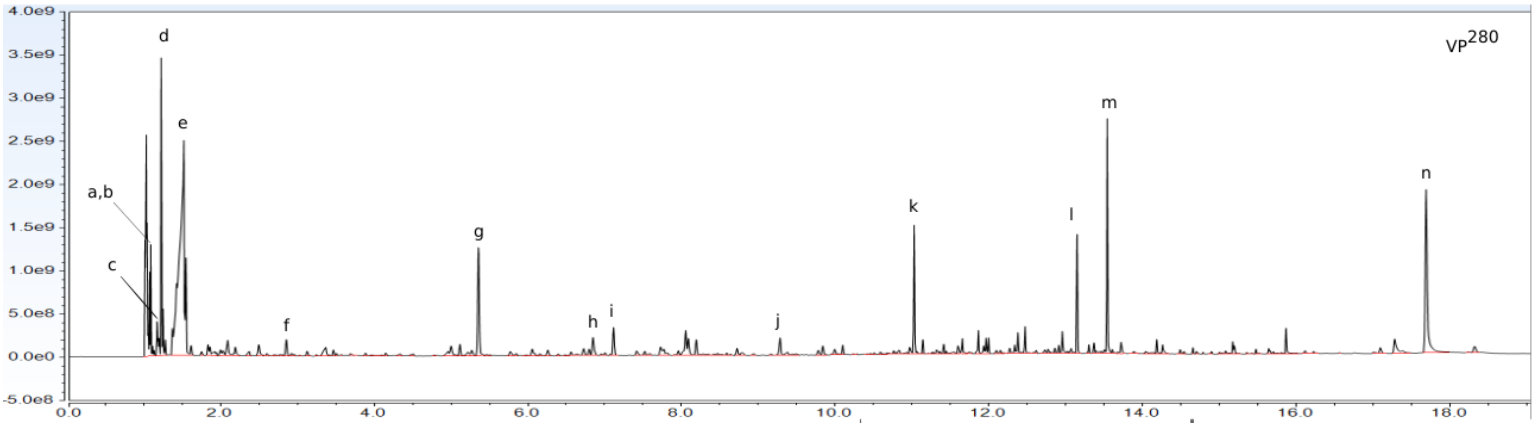
Consumer products that are intended to be consumed by inhalation after high temperature vaporization are a relatively new category of products that require a unique approach to determine the relative risks associated with consumer use. The most significant variable is that at elevated temperatures ingredients can rearrange, react and/or thermally degrade to create new chemical structures that can have fundamentally different chemical properties with different pharmacological consequences of use. This chemical change is dependent not only on the vaporization temperature but also on the composition of the material being vaporized. In some cases, compounds such as Vitamin E acetate which are Generally Regarded as Safe (“**GRAS”**) when introduced to a consumer at room temperature by ingestion may decompose to produce a complex mixture of chemical agents with significant toxicities at high temperatures. Furthermore, the lack of standardization for devices used to generate vapors after high temperature vaporization means that the temperature used is often unknown. Some of the compounds generated at elevated temperatures are themselves reactive and can further react, rearrange or decompose to alternate structures. This type of possible chemical behavior greatly complicated traditional chemical analysis as quantitation standards would also decompose at the temperatures in question. The sampling of vapors produced by devices is a potential approach to determine exposure risk for consumers of devices, however, the diversity of devices used makes determination of the correct devices to use for such studies a significant challenge. Regardless of the challenges, it is critically important to develop approaches to evaluate ingredients that could be used in products that are intended to be consumed by Inhalation after high temperature vaporization so that those materials that have a high likelihood of exposing the consumer to dangerous chemical agents are not used as ingredients. This work will highlight such an approach and apply it to the examination of 3 different potential ingredients, Vitamin E Acetate, Squalane and Squalene.

2.0 Vaporization Potential

Supra Research and Development (“**SUPRA**”) has developed an approach to determine the profile of the diverse range of thermally generated compounds generated by ingredients that are intended to be used in vaporizers. Rather than try and develop a standardized device for producing vapors, we use an analytical instrument that can heat a sample in a controlled manner and then collect and analyse the byproducts. The instrumentation we are using is called Headspace - Gas Chromatography Mass Spectrometry. In this approach a small quantity of sample is accurately heated in hermetically sealed glass vials to a series of well defined temperatures. At each temperature, a sample of the gas phase vapour, also called the “HeadSpace”, is collected and analysed. This analysis involves separation of individual chemical components in a Gas Chromatograph followed by detection in a Mass Spectrometer. The Mass Spectrometer allows for both identification of individual components as well as relative quantitation. The

information can be graphically displayed as a chromatogram where individual compounds are displayed as 'peaks'. A sample chromatogram is presented in Figure 1 below;

Figure 1: Vaporization Potential Chromatogram of Vitamin E Acetate collected at 280ºC



The Chromatograph shows the range of thermal degradation vaporization byproducts that are generated at a given temperature. We have defined this profile of products that can be produced at a given temperature as the Vaporization Potential ("**VP**"). This profile is temperature dependent and so to further define the profile we use the nomenclature **VP^{xyz}** where the number "xyz" is the temperature that the profile was gathered, for example **VP^{280}** is the Vaporization Potential profile collected at 280ºC.

The **VP** profiles are representative of the gas phase above a vaporized sample and thus the profile of chemical agents that would be delivered to the consumer when the user draws in this vapor when using a heated device. This information is critical to understanding the potential pharmacological consequences of inhaling the chemical profile generated at a specific temperature from a specific composition from a vaporized sample. However, at the current time there are no established regulatory limits to the quantity of chemical agents a user can safely be exposed to when using a vaporized product. The development of these types of regulatory standards and the universal acceptance of such standards would require a lengthy and potential contentious legal and scientific based process. Although, we fundamentally agree that this type of process has significant merit, there is also merit in finding an alternate approach that could identify additives, such as Vitamin E Acetate, that have been clearly linked to adverse health events, specifically the **EVALI** hospitalizations and deaths observed in late 2019 and 2020. **EVALI** is the name given by the US Centers for Disease Control and Prevention ("**CDC**") to the dangerous, newly identified lung disease linked to vaping. The name **EVALI** is an acronym that stands for e-cigarette or vaping product use-associated lung injury.

In order to develop an approach for screening ingredients and mixtures intended to be used in vaporization devices for their potential to produce dangerous chemical agents, we have developed an alternate approach we refer to as Equivalent Residual Solvent Analysis ("**ERSA**").

3.0 Equivalent Residual Solvent Analysis

Most finished consumer products intended for human consumption which could include exposure to solvents as extraction agents or chemical cleaning agents are required to be tested for Residual Solvents. This Residual Solvent Analysis is a well established approach and section 467 of the US Pharmacopeia ("**USP<467>**") outlines limits for a variety of potential residual solvents. These limits are universally accepted as levels that consumer products should not exceed in order to be safe. We have observed that many of the chemical agents observed when collecting VP data are in fact included on the residual solvent list. Given this we developed a testing protocol where we place a test sample in an hermetically sealed glass headspace vial, then heat this to a defined test temperature, say 240ºC, hold it for 5 minutes, then cool it to room temperature and then analysed this material using a validated Residual Solvent Analysis method. The validated Residual Solvent Analysis method we employ is also a Headspace-GCMS method, however, in this case the vial is only heated to 95ºC and an external calibration curve is used to quantify the observed residual solvents generated from the heated incubation step. We refer to this approach as Equivalent Residual Solvent Analysis ("**ERSA**"). If the residual solvent analysis indicates that a sample would fail, then we conclude that the material should not be used in any product intended for inhalation that heats the material at a temperature above the temperature at which it failed.

Even though the stated approach will work at any temperature, we have found that as the temperature approaches 300ºC almost all materials we have examined fail and for practical considerations we have selected a temperature of 280ºC as the highest test point in this study. Furthermore, we also consider 240ºC to be the highest temperature that any vaporization device should be set as, as above this the concentrations of problematic thermal degradation products increase drastically. Given that, we typically recommend that a **VP^{240}** be the test temperature for routine screening and the **ERSA** analysis at 240ºC be used as the definitive pass fail test criteria. We have also observed that 180ºC is a temperature where Cannabinoids, typical Terpenes and Nicotine and related chemical compounds are effectively vaporized with little or no thermal degradation. Although we have observed a few problematic compounds begin to thermally degrade at temperatures as low as 210ºC, most do not begin to degrade until the temperature exceeds 220ºC. With this in mind we can imagine a public health message that strongly discourages any vaporization above 420ºF or 215.6ºC.

4.0 Summary of results for Vitamin E Acetate, Squalane and Squalene

In this report 3 ingredients have been examined: Vitamin E Acetate, Squalane and Squalene. Each of these have "failed" the **ERSA** assessment at 240ºC.

4.1 Vitamin E Acetate

The chemical structure of Vitamin E Acetate is presented below. This compound was a known additive in e-juice and Cannabis concentrates associated with many of the **EVALI** hospitalizations and deaths observed in late 2019 and 2020. It has been suggested that this compound is responsible for many of the adverse health effects in the **EVALI** event.

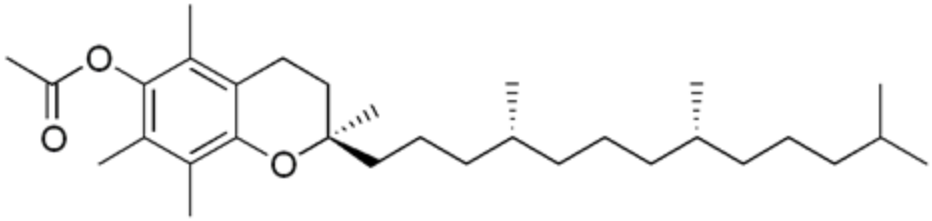


Figure 2: Chemical structure of Vitamin E Acetate

The VP profiles at a series of temperatures for Vitamin E Acetate is presented in Figure A.1 of Appendix A. The most dominant Oxidation products are Acetic acid and Formic acid and these are observed at sufficient quantities to have the compound fail the **ERSA** screening approach at 240ºC. This data is presented in Table A.2 presented in Appendix A.

4.2 Squalane

The chemical structure of squalene is presented in Figure 3 below. This is a possible ingredient that could be used in vaporization devices.

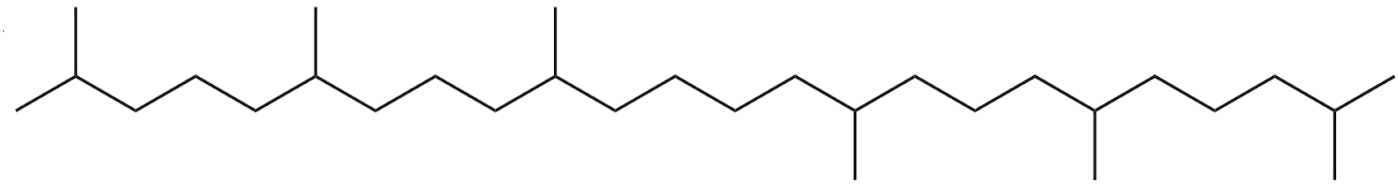


Figure 3: Chemical structure of squalane

The VP profiles at a series of temperatures for this compound is presented in Figure B.1 of Appendix B. The most dominant Oxidation products are Acetone, Methanol and Acetic acid and these are produced at sufficient quantities to have the compound fail the **ERSA** analysis at 240ºC. This **ERSA** data is presented in

Table B.2 presented in Appendix B. There are a diverse number of thermal degradation and oxidation products produced by squalane and based on this and the very high concentration of Acetone, Methanol and Acetic Acid we speculate that this additive would produce more diverse and adverse health effects as Vitamin E Acetate does.

4.3 Squalene

The chemical structure of squalene is presented in Figure 4 below. This is also a possible ingredient that could be used in vaporization devices.

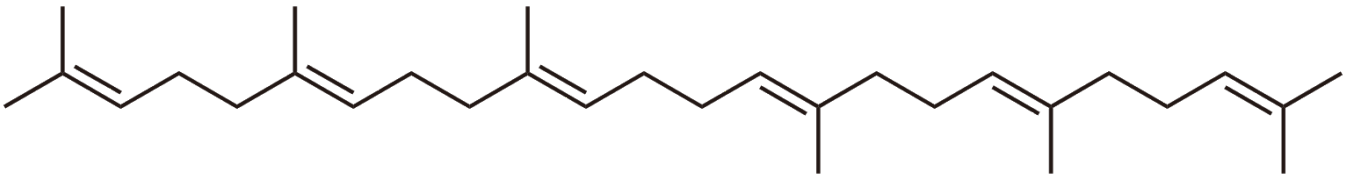


Figure 4: Chemical structure of squalene

The VP profiles at a series of temperatures for this compound is presented in Figure C.1 of Appendix C. There are a large number of Oxidation products generated including Acetone, Methanol, Acetic acid and Formic Acid that are produced at sufficient quantities to have the compound fail the **ERSA** analysis at 240ºC. This **ERSA** data is presented in Table C.2 presented in Appendix C. The diverse number of thermal degradation and oxidation products produced by squalene is of significant concern, especially, because this degradation begins at much lower temperature, 180ºC, than observed for other ingredients that we have studied previously. It is speculated that Squalene would produce more adverse health effects as Vitamin E Acetate does and that these adverse effects could begin at much lower vaporization temperatures.

5.0 Conclusion

The three compounds that we have examined in this report, Vitamin E Acetate, Squalane and Squalene each have failed the **ERSA** assessment protocol we have defined at 240ºC. Vitamin E Acetate has been identified as a problematic ingredient associated with **EVALI** hospitalizations and deaths. The data presented here suggests that Squalane and Squalene thermally degrade in a manner that produces higher levels of chemical agents than we observed for Vitamin E Acetate. From this, we speculate that these compounds could be more problematic than Vitamin E Acetate. However, it should be noted that these are speculations based on assumptions and this opinion is provided for discussion purposes only and is not intended to be a definitive statement on the safety of a given product or ingredient.

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Appendix A: Sample Results for Vitamin E Acetate

Client ID: n.a.

Supra Details: α-Tocopheryl acetate (Vitamin E acetate) (Sigma-Aldrich PN#R1030 Lot#LRAC1696)

Batch ID: 201022_VP-RS-quant-Oregon

Submission Date: 2020 October 15

Reporting Date: 2020 November 12

Analysis Date: 2020 October 22

Analyst: RJH / SRS

Authorized By: Ryan Hayward

Job Function: Laboratory Manager

Date Authorized: 2020 November 10

Signature: 

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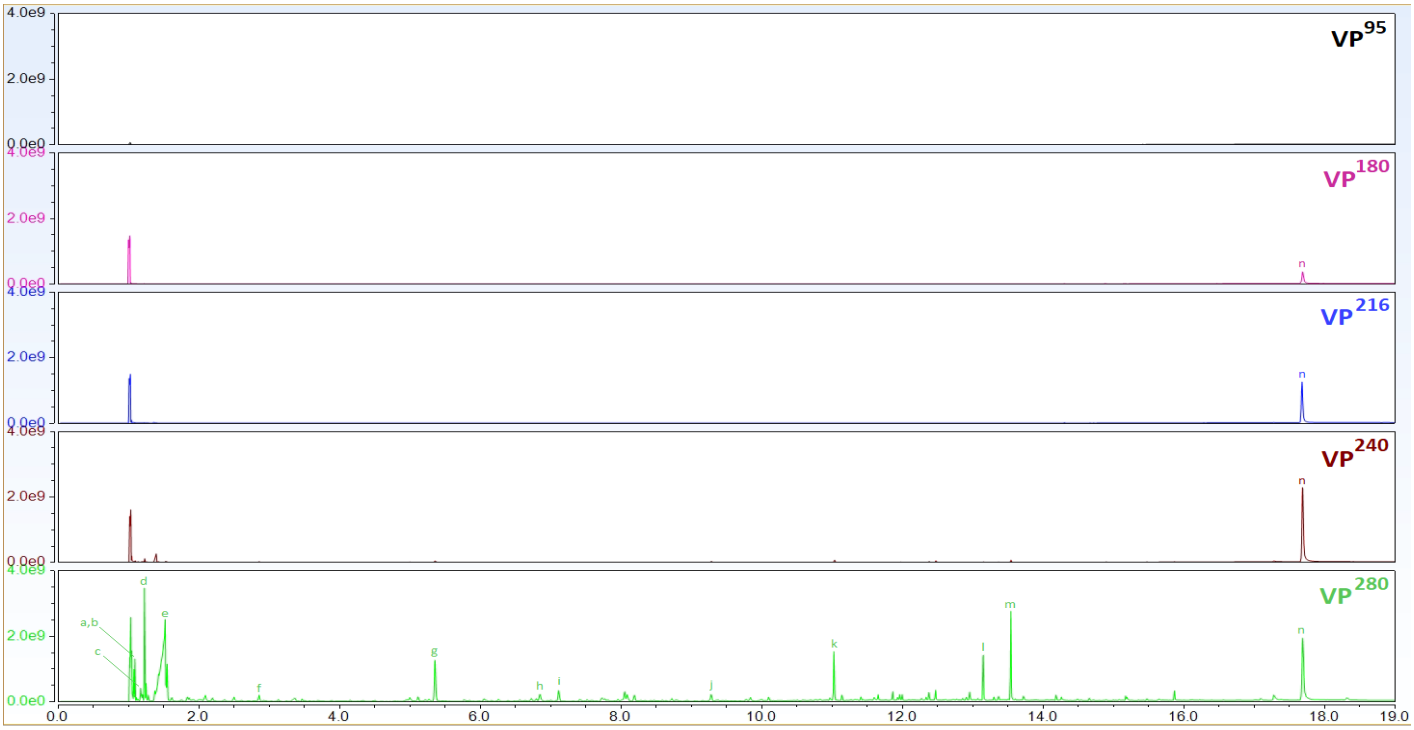
Figure A.1: Vaporization Potential Chromatograms For Vitamin E Acetate



Total Ion Chromatograms (TICs) of VP^{95}, VP^{180}, VP^{216}, VP^{240} and VP^{280} of vitamin E acetate. The chromatograms are scaled to the same *y*-axes.

Table A.1: Identified peaks for Vitamin E Acetate (qualitative profile)

Compound	Retention time (min)	Chromatogram label
methanol	1.07	a
acetaldehyde*	1.09	b
oxalic acid*	1.17	c
acetone	1.23	d
formic acid	1.50	e
hexanal*	2.86	f
6-methyl-2-heptanone*	5.36	g
2-nonanone*	6.85	h
4-methyl-3-pentenoic acid*	7.13	i
4,8-dimethylnonanol*	9.28	j
6,10-dimethyl-2-undecanone*	11.04	k
6,10,14-trimethyl-2-pentadecanone*	13.15	l
3-formyl-4-hydroxy-2,5,6-trimethylphenyl acetate*	13.54	m
vitamin E acetate	17.69	n

List of identified compounds in thermally-treated samples (see Figure 1 for labelled chromatograms). Compounds marked with an asterisk (*) were identified using NIST library matching (>800 SI and RSI). All other compounds were identified using analytical standards

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Table A.2: Equivalent Residual Solvent Analysis at 240ºC Vitamin E Acetate

	USP limit	VP^{240}
2-Butanone	5000	< 1000
2-Propanol	5000	nd
Acetone	5000	< 1000
Acetonitrile	410	nd
Benzene	2	nd
Cyclohexane	3880	nd
Ethanol	5000	< 1000
Ethyl formate	5000	nd
Hexane	290	nd
Isobutanol	5000	< 1000
Isopropyl acetate	5000	< 1000
Methanol	3000	< 600
Methylcyclohexane	1180	nd
n-Pentane	5000	< 1000
Acetic acid*	5000	> 10000
Formic acid*	5000	> 10000

Table 2 Description: Quantitated concentrations (parts-per-million [ppm] relative to original sample mass [Table 3]) of degradation products identified for each sample treatment at 240 ºC. Values were calculated using a full evaporation technique (FET) headspace method calibrated with residual solvent standards. Calibration ranges were 0.2x to 2x each analyte's USP limit. Results outside the calibration range are reported as greater than (>) or less than (<) the respective upper or lower limits of calibration. A semi-quantitative calibration was performed for formic acid and acetic acid. These compounds have been marked with an asterisk (*) and their results should be treated as estimates. Shaded values indicate failures.

Table A.3: Experimental details Vitamin E Acetate

After accurate weighing (Table 3), all samples were incubated in gas-tight headspace vials fitted with PTFE-lined silicone septa for temperatures ranging from 95 - 280 °C (*n* = 1/temperature). All incubations were performed for five minutes and included a blank vial alongside client formulations.

	Vaporization Potential ($VP^{°C}$)				
	VP^{95}	VP^{180}	VP^{216}	VP^{240}	VP^{280}
Vitamin E acetate (g)	0.0104	0.0098	0.0111	0.0111	0.0105

Masses of materials used for each temperature treatment. Samples were incubated at their designated temperature for five minutes to achieve an equilibrated headspace, from which 1 mL was sampled for analysis. Sampling was performed directly from the incubated vial to reflect delivery of volatiles into the headspace at respective temperatures.

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Appendix B: Sample Results for Squalane

Client ID: n.a.

Sample Details: Squalane (Sigma-Aldrich PN#PMR1417 Lot#LRAC4099)

Batch ID: 201022_VP-RS-quant-Oregon

Submission Date: 2020 October 15

Reporting Date: 2020 November 12

Analysis Date: 2020 October 22

Analyst: RJH / SRS

Authorized By: Ryan Hayward

Job Function: Laboratory Manager

Date Authorized: 2020 November 10

Signature: 

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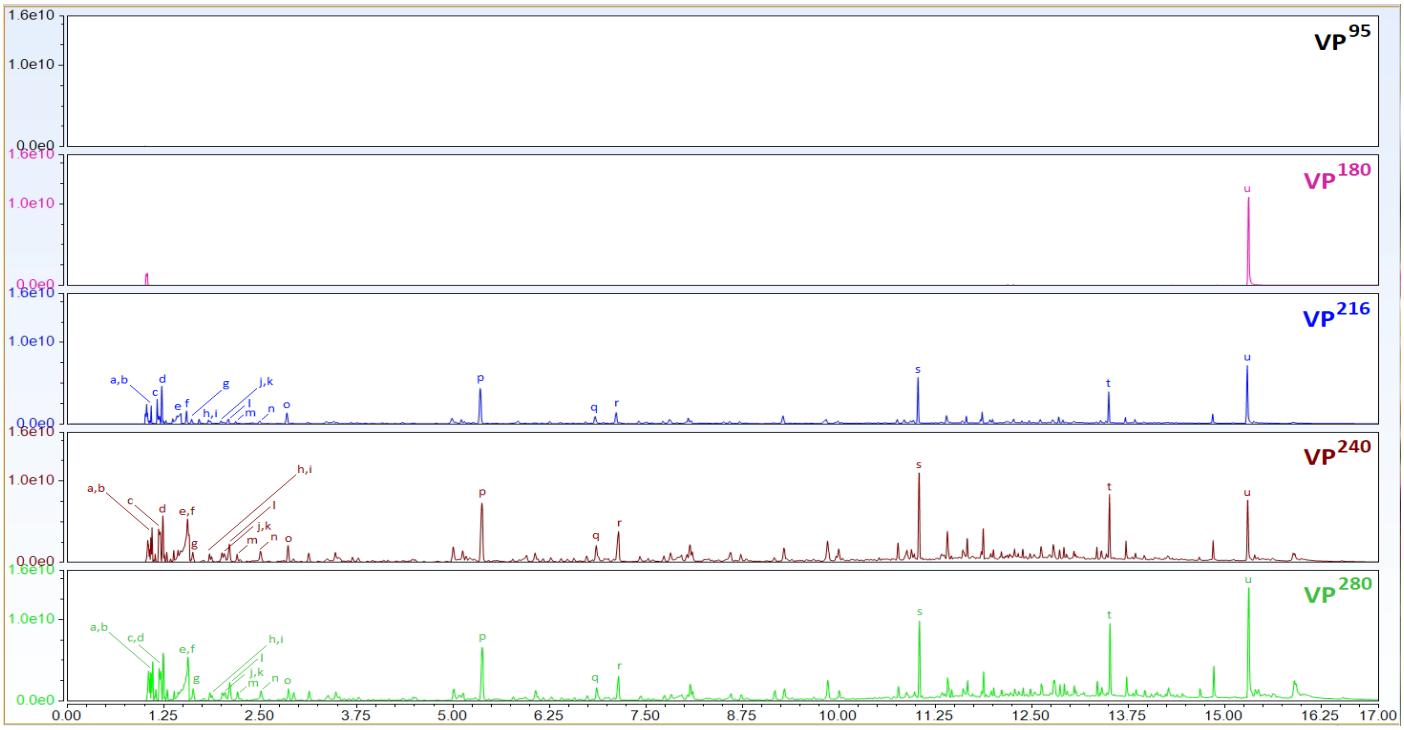
Figure B.1: Vaporization Potential Chromatograms For Squalane



Total Ion Chromatograms (TICs) of VP^{95}, VP^{180}, VP^{216}, VP^{240} and VP^{280} of squalane. See Table 1 for peak labels. The chromatograms are scaled to the same *y*-axes.

Table B.1: Identified peaks for Squalane (qualitative profile)

Compound	Retention time (min)	Chromatogram label
methanol	1.07	a
acetaldehyde*	1.09	b
oxalic acid*	1.17	c
acetone	1.23	d
acetic acid	1.50	e
2-butanone	1.55	f
4-methyl-3-pentenal*	1.62	g
3-methylbutanal*	1.85	h
3-methyl-2-butanone*	1.87	i
2-methylheptane*	2.00	j
2,2-dimethyltethrahydrofuran	2.04	k
2-pentanone*	2.10	l
acetol*	2.19	m
2-hexanone*	2.50	n
hexanal*	2.86	o
6-methyl-2-heptanone*	5.36	p
2-nonanone*	6.85	q
4-methyl-3-pentenoic acid*	7.14	r
6,10-dimethyl-2-undecanone*	11.04	s
2-nonadecanone*	13.52	t
squalane	15.31	u

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List of identified compounds in thermally-treated samples (see Figure B.1 for labelled chromatograms). Compounds marked with an asterisk (*) were putatively identified using NIST library matching (>800 SI and RSI). All other compounds were identified using analytical standards.

Table B.2: Equivalent Residual Solvent Analysis at 240ºC Squalane

	USP limit	VP^{240}
2-Propanol	5000	nd
Acetone	5000	> 10000
Acetonitrile	410	< 82
Benzene	2	nd
Cyclohexane	3880	< 776
Ethanol	5000	< 1000
Ethyl formate	5000	nd
Hexane	290	nd
Isobutanol	5000	nd
Isopropyl acetate	5000	nd
Methanol	3000	> 6000
Methylcyclohexane	1180	< 236
n-Pentane	5000	< 1000
Acetic acid*	5000	> 10000
Formic acid*	5000	< 1000

Quantitated concentrations (parts-per-million [ppm] relative to original sample mass [Table B.3]) of degradation products identified for each sample treatment at 240 ºC. Values were calculated using a full evaporation technique (FET) headspace method calibrated with residual solvent standards. Calibration ranges were 0.2x to 2x each analyte's USP limit. Results outside the calibration range are reported as greater than (>) or less than (<) the respective upper or lower limits of calibration. A semi-quantitative calibration was performed for formic acid and acetic acid. These compounds have been marked with an asterisk (*) and their results should be treated as estimates. Shaded values indicate failures.

Table B.3: Experimental details Squalane

After accurate weighing (Table B.3), all samples were incubated in gas-tight headspace vials fitted with PTFE-lined silicone septa for temperatures ranging from 180 - 300 °C (*n* = 1/temperature). All incubations were performed for five minutes and included a blank vial alongside client formulations.

	Vaporization Potential ($VP^{°C}$)				
	VP^{95}	VP^{180}	VP^{216}	VP^{240}	VP^{280}
Squalane (g)	0.0100	0.0094	0.0094	0.0103	0.0099

Masses of materials used for each temperature treatment. Samples were incubated at their designated temperature for five minutes to achieve an equilibrated headspace, from which 1 mL was sampled for analysis. Sampling was performed directly from the incubated vial to reflect delivery of volatiles into the headspace at respective temperatures.

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Appendix C: Sample Results for Squalene

Client ID: n.a.

Supra Details: Squalene (Sigma-Aldrich PN#S3626 Lot#MKCJ2769)

Batch ID: 201022_VP-RS-quant-Oregon

Submission Date: 2020 October 15

Reporting Date: 2020 November 12

Analysis Date: 2020 October 22

Analyst: RJH / SRS

Authorized By: Ryan Hayward

Job Function: Laboratory Manager

Date Authorized: 2020 November 10

Signature: 

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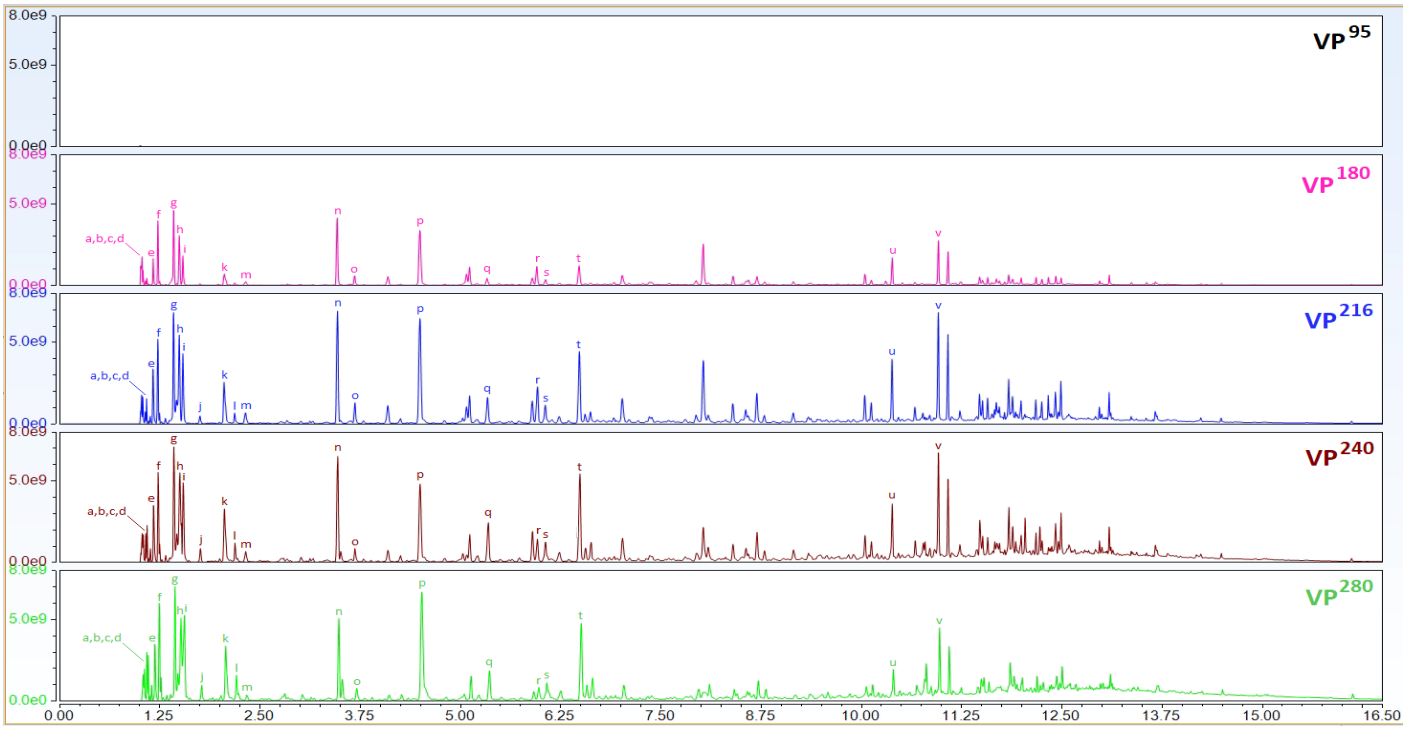
Figure C.1: Vaporization Potential Chromatograms For Squalene



Total Ion Chromatograms (TICs) of VP^{95}, VP^{180}, VP^{216}, VP^{240} and VP^{280} of squalene. See Table 1 for peak labels. The chromatograms are scaled to the same *y*-axes.

Table C.1: Identified peaks for Squalene (qualitative profile)

Compound	Retention time (min)	Chromatogram label
methanol	1.07	a
acetaldehyde*	1.09	b
glyoxal*	1.10	c
ethanol	1.13	d
oxalic acid*	1.17	e
acetone	1.23	f
methacrolein*	1.42	g
2-methyl-3-buten-2-ol*	1.50	h
3-buten-2-one*	1.54	i
3-hydroxy-3-methyl-2-butanone*	1.76	j
3-ethyl-2,2-dimethyloxirane*	2.06	k
1-hydroxy-2-propanone*	2.18	l
1-ethyl-5-methylcyclopentene*	2.32	m
3-methyl-2-butenal*	3.46	n
4-hydroxy-2-butanone*	3.69	o
3-methylcyclopentyl acetate*	4.50	p
4,4,5-trimethyl-1,3-dioxan-5-ol*	5.36	q
2,3-dimethyl-3-buten-2-ol*	5.95	r
6-methyl-5-hepten-2-one*	6.06	s
1-(1-butenyloxy)pentane*	6.49	t
citral*	10.04	u
3,6-dimethyloctan-2-one*	10.96	v

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List of identified compounds in thermally-treated samples (see Figure C.1 for labelled chromatograms). Compounds marked with an asterisk (*) were putatively identified using NIST library matching (>800 SI and RSI). All other compounds were identified using analytical standards.

Table C.2: Equivalent Residual Solvent Analysis at 240ºC Squalene

	USP limit	VP^{240}
2-Propanol	5000	< 1000
Acetone	5000	> 10000
Acetonitrile	410	nd
Benzene	2	0.4
Cyclohexane	3880	nd
Ethanol	5000	1382
Ethyl formate	5000	< 1000
Hexane	290	136
Isobutanol	5000	< 1000
Isopropyl acetate	5000	< 1000
Methanol	3000	> 6000
Methylcyclohexane	1180	< 236
n-Pentane	5000	< 1000
Acetic acid*	5000	> 10000
Formic acid*	5000	> 10000

Quantitated concentrations (parts-per-million [ppm] relative to original sample mass [Table 3]) of degradation products identified for each sample treatment at 240 ºC. Values were calculated using a full evaporation technique (FET) headspace method calibrated with residual solvent standards. Calibration ranges were 0.2x to 2x each analyte's USP limit. Results outside the calibration range are reported as greater than (>) or less than (<) the respective upper or lower limits of calibration. A semi-quantitative calibration was performed for formic acid and acetic acid. These compounds have been marked with an asterisk (*) and their results should be treated as estimates. Shaded values indicate failures.

Table C.3: Experimental details Squalene

After accurate weighing (Table 3), all samples were incubated in gas-tight headspace vials fitted with PTFE-lined silicone septa for temperatures ranging from 95 - 280 °C (*n* = 1/temperature). All incubations were performed for five minutes and included a blank vial alongside client formulations.

	Vaporization Potential ($VP^{°C}$)				
	VP^{95}	VP^{180}	VP^{216}	VP^{240}	VP^{280}
Squalene (g)	0.0096	0.0095	0.0102	0.0103	0.0111

Masses of materials used for each temperature treatment. Samples were incubated at their designated temperature for five minutes to achieve an equilibrated headspace, from which 1 mL was sampled for analysis. Sampling was performed directly from the incubated vial to reflect delivery of volatiles into the headspace at respective temperatures.

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END OF REPORT

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