Recreational Marijuana Program Compliance Education Bulletin

Bulletin CE2020-07 December 29, 2020



The Oregon Liquor Control Commission is providing the following information to recreational marijuana licensees and applicants.

The bulletin is part of OLCC's compliance education. It is important that you read it, and understand it. If you don't understand it please contact the OLCC for help.

Failure to understand and follow the information contained in this bulletin *could result in an OLCC administrative* violation affecting your ability to work or operate your business.

Bulletin CE2020-07 covers the following issues:

- New Definitions;
- Important Dates Implementation and Sell-down;
- CTS Changes for Inhalable Cannabinoid Products;
- Processor Requirements for Inhalable Cannabinoid Products with Non-cannabis Additives; and
- Labeling for Inhalable Cannabinoid Products with Non-cannabis Additives.

Questions regarding the contents of this bulletin may be sent to: marijuana.packaging@oregon.gov and if you have questions related to Metrc or CTS contact marijuana.cts@oregon.gov.

New Definitions

The new definitions are summarized below, the exact definitions are found on OAR 845-025-1015(44) and (64).

- "Inhalable Cannabinoid Product": a cannabinoid product or hemp cannabinoid product that is intended for human inhalation. Examples of inhalable cannabinoid products: vape cartridges, infused pre-rolls, bulk extract or concentrate, and extract or concentrate containing syringes or "drippers" combined with flavorings or non-cannabis terpenes.
- "Non-cannabis Additive": a substance or group of substances that are derived from a source other than marijuana or industrial hemp. Examples include: isolates of non-cannabis derived terpenes (e.g. myrcene, limonene, or linalool), blends of terpenes and other substances (e.g. ketones, aldehydes, esters) meant to mimic certain cultivars of cannabis (e.g. Banana Kush or Blue Dream), and flavorings (e.g. apple, grape, watermelon). This definition does not include plant material that is in the whole, broken, or ground form.

Important Dates – Implementation and Sell-down:

On **December 22, 2020,** the OLCC adopted rules to regulate non-cannabis additives in inhalable cannabinoid products. These rules create additional requirements for processors, but many of the provisions are <u>applicable to all licensees</u>.

For Processors

- On or after <u>April 1, 2021</u>, a processor may not manufacture or process an inhalable cannabinoid product that does not meet the requirements of OAR 845-025-3265.
- Processors may transfer or sell an inhalable cannabinoid product that does not meet the requirements
 of <u>OAR 845-025-3265</u> until <u>July 1, 2021</u>, if the non-compliant inhalable cannabinoid product was
 processed *prior* to April 1, 2021 (see <u>OAR 845-025-3220(d)</u>).
- On or after <u>July 1, 2021</u>, a processor may not possess, sell, deliver, transfer, transport, purchase, or receive an inhalable cannabinoid product that does not meet the requirements of OAR 845-025-3265.

For all Licensees

- On or after July 1, 2021, no licensee or permittee may possess, sell, deliver, transfer, transport, purchase, or receive a "prohibited cannabinoid product" (a product that does not meet the requirements of OAR 845-025-3265), if the product was processed or manufactured prior to April 1, 2021.
- On or after <u>July 1, 2021</u>, inhalable cannabinoid products with non-cannabis additives with labels approved by the OLCC prior to <u>April 1, 2021</u> that do not meet requirements of <u>OAR 845-025-3265</u> or <u>845-025-7120</u> may not be possessed, sold, delivered, transferred, transported, purchased, or received.
- On or after <u>July 1, 2021</u>, all inhalable cannabinoid products with non-cannabis additives will require a label pre-approved by the OLCC to be possessed, sold, delivered, transferred, transported, purchased, or received. In other words, as of July 1, 2021, inhalable cannabinoid products with non-cannabis additives may no longer use generic labels.

| | Uses Generic Label | Uses Pre-approved Label |
|--|---|--|
| Manufactured before April 1, 2021 | May be possessed and sold with generic label until June 30, 2021; as of July 1, 2021, must meet new requirements (including pre-approved label), or be destroyed. | May be possessed and sold with existing label until June 30, 2021; as of July 1, 2021, must meet new requirements (including OLCC approval of revised labels) or be destroyed. |
| Manufactured <u>on</u> <u>or after</u> April 1, 2021 | Cannot be sold; must have pre-approved label and item must meet new requirements. | Cannot be sold; must meet new requirements, including OLCC approval of revised labels. |

Industrial Hemp Certificate Holders

On or after <u>July 1, 2021</u>, industrial hemp certificate holders may not transfer any inhalable cannabinoid product that a licensee is prohibited from receiving under <u>OAR 845-025-8520</u> (see <u>OAR 845-025-2755(3)(F)</u>).

CTS Changes for Inhalable Cannabinoid Products:

Item Category

On and after <u>April 1, 2021</u>, <u>OAR 845-025-3270</u> requires all inhalable cannabinoid products with non-cannabis additives to be explicitly categorized in Metrc under one of two categories:

- 1) "Inhalable Cannabinoid Product with Non-Cannabis Additives" if the item is a marijuana item; and
- 2) "Inhalable Hemp Cannabinoid Product with Non-Cannabis Additives" if the item is a hemp item

<u>Reminder:</u> an item that co-mingles hemp-derived extract or concentrate with marijuana-derived extract or concentrate, the resulting item would be a *marijuana item*.

"Non-cannabis additive" does <u>not</u> mean hemp-derived terpenes. An item that combines marijuana extract with hemp-derived terpenes (or combines marijuana extract with marijuana-derived terpenes that meet the definition of a marijuana concentrate), the resulting item would be an "other cannabinoid product" under rule — this item would be tracked in Metrc as a "Combined Category" item.

As with other cannabinoid product item types, Metrc will have a weight-based option or a count ("each")-based option for these product categories.

Any licensee with a Metrc package in inventory that meets this definition of "inhalable cannabinoid product with non-cannabis additives" will have to have the items re-created under the new product category by **April 1, 2021**. In most circumstances a package's item and item type cannot be edited or changed under a pre-existing package tag; as such, licensees with affected inventory will have one of two choices:

- 1) Use the license's own tag(s) to "repackage" the full amount of the existing package into a new Metrc package with the appropriate category. This will require that the license create a new "item" in Metrc (see below for more information).
- 2) <u>Physically</u> transfer (within license privileges) the package(s) to another license to do the package recategorization for you.

Item Creation and Ingredients Tracking

In addition to the requirement discussed above that all relevant items be tracked under a new category in Metrc, , <u>OAR 845-025-3270(2)</u> requires that <u>processor</u> licenses record the manufacturer and mix name of any non-cannabis additive(s) used in the inhalable cannabinoid product. This information will be recorded at the item level in Metrc (the point at which a name and category is created in the administrative section of Metrc).

This requirement is limited to processors only in order to avoid other businesses from accessing the processor's proprietary information – the ingredient information in Metrc will be accessible only to the OLCC and employees at the processor given access to the license's administrative area of Metrc.

<u>Important</u>: in order to ensure protection of the information entered by processors, new functionality is being built in Metrc to accommodate "ingredient" tracking in Metrc that will <u>not</u> be accessible via the API. This functionality will <u>not</u> be available until early 2021, but licensees can still create items and packages under the new categories immediately. Once the functionality for recording ingredients goes live in Metrc, processors will be able to <u>edit</u> the already created items in Metrc to add the required non-cannabis additive information without using any new tags. This information will "flow down" to packages created under this item, and as long as the information is entered prior to April 1, 2021, and packages are tracked under the appropriate category, processors will be compliant with the new requirements.

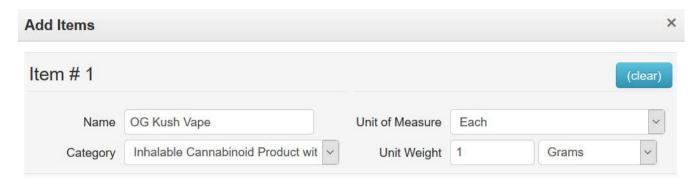


Figure 1: Creation of "Inhalable Cannabinoid Product with Non-Cannabis Additives (no ingredients)" or "Inhalable Cannabinoid Product with Non-Cannabis Additives (each; no ingredients)" will be available for licensees who may need to repack items previously sent by processors. The only difference between these two categories is that the "each" category is tracked by number of units (with a weight per unit), whereas the other is tracked by weight.

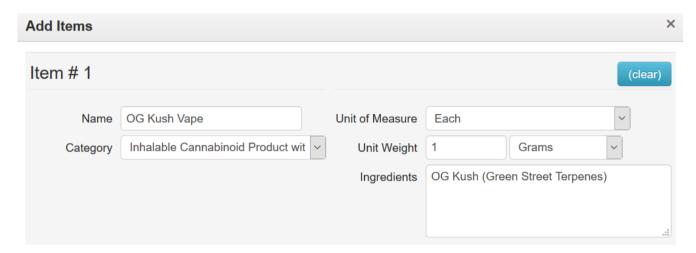


Figure 2: Processors will have the ability to create "Inhalable Cannabinoid Product with Non-Cannabis Additives (each)" or "Inhalable Cannabinoid Product with Non-Cannabis Additives." The only difference between these two categories is that the "each" category is tracked by number of units (with a weight per unit), whereas the other is tracked by weight. The ingredient entry will change as Metrc puts into place the ability to hide the ingredient list from the API. A future bulletin will be released once this change has been completed.

Processor Requirements for Inhalable Cannabinoid Products with Non-cannabis Additives:

This is only a <u>summary</u> of the new requirements applicable to processors who wish to manufacture inhalable cannabinoid products with non-cannabis additives. Review OAR 845-025-3220 and 845-025-3265.

Inhalable Cannabinoid Product Processor Requirements

Processors may only use a non-cannabis additive in an inhalable cannabinoid product if it is accompanied by a list of ingredients from the <u>manufacturer</u> of the non-cannabis additive that:

- In a header section, displays the name of the non-cannabis additive and the business name of the manufacturer of the non-cannabis additive;
- Includes a statement that the non-cannabis additive is for use in a product intended for human inhalation;
- Identifies all ingredients in the non-cannabis additive, including the Chemical Abstracts Service Reference Number that specifies the ingredient's isomer, and if applicable, enantiomer; and

• The ingredient's concentration range within 20 percentage points.

This documentation must be supplied by the manufacturer of the non-cannabis additive (i.e. the person or entity responsible for the final blending and formulation of the product). It cannot be supplied by a third-party, such as a distributor. This documentation must be supplied as part of a label application and an example of this documentation can be found at the end of the bulletin.

Prohibited Substances in Non-Cannabis Additives

<u>OAR 845-025-3265(2)</u> prohibits processors from using a non-cannabis additive in an inhalable cannabinoid product that contains any amount of the following:

- Squalene;
- Squalane;
- Vitamin E Acetate;
- Triglycerides, including but not limited to Medium-Chain Triglycerides (MCT) Oil; or
- Propylene Glycol.

Note these prohibitions *only* apply to inhalable cannabinoid products with non-cannabis additives. These compounds are not prohibited in other products such as topicals or edibles.

Labeling for Inhalable Cannabinoid Products with Non-cannabis Additives:

Generic Labels

Licensees may no longer utilize generic labels for inhalable cannabinoid products with a non-cannabis additive that are processed or manufactured on or after <u>April 1, 2021</u>. This means that any of these products manufactured on and after <u>April 1, 2021</u>, must have labels pre-approved by the OLCC before they can be offered for ultimate sale to a consumer, patient, or designated primary caregiver. Licensees that are unfamiliar with this process should consult the <u>Packaging and Labeling Guide</u>.

Inhalable cannabinoid products with non-cannabis additives manufactured prior to April 1, 2021 with generic labels may only be used until June 30, 2021 and as of July 1, 2020 they must have pre-approved labels or be destroyed.

New Labeling Requirements

Licensees must adhere to several new changes for labeling these products. <u>OAR 845-025-7120</u> controls how these products must be labeled. This is only a <u>summary</u> and licensees must read the rule to understand all the requirements.

- Product Identity: the product identity <u>must</u> contain the words "non-cannabis additive."
 These examples are compliant with this new requirement and other labeling requirements:
 - o "Marijuana Extract with Non-cannabis Additives";
 - "[Flavoring Name] Flavored Marijuana Extract with Non-cannabis Additives," e.g. "Lime Flavored Marijuana Extract with Non-cannabis Additives";
 - o "Hemp Extract with Non-cannabis Additives"; and
 - o "[Strain Specific Blend Name] Flavored Marijuana extract with Non-cannabis Additives," e.g. "Blue Dream Flavored Marijuana Extract with Non-cannabis Additives."

- **Ingredient Listing:** The ingredients listed on the label must match what is required by <u>OAR 845-025-3265(1)</u>.
 - In addition to the other ingredients in the product, the ingredient listing must use the term "non-cannabis additive" and the ingredients of the additive must be listed as sub-ingredients of this term.
 - OAR 845-025-7120(16)(b) requires clearly indicating the usage of multiple additives.
 - A "non-cannabis additive" can be considered a singular terpene isolate, such as myrcene or a premade mixture such as a strain specific blend or a flavoring blend. Examples below including the additive blend name (e.g. "OG Kush") are optional.
 - Examples with one additive used:
 - Ingredients: marijuana extract, non-cannabis additive (myrcene).
 - Ingredients: marijuana extract, OG Kush non-cannabis additive (alpha pinene, beta pinene, linalool, beta caryophyllene, geranyl acetate, camphene).
 - Ingredients: hemp extract, non-cannabis additive (terpinolene, limonene, beta pinene, ocimeme, humulene, nerol, frenchol, geraniol, valencene, cedrene, isoborneol, cintronellol, camphor, alpha terpinene).
 - Examples with multiple additives used:
 - Ingredients: marijuana extract, non-cannabis additive (mycene), non-cannabis additive (linalool).
 - Ingredients: marijuana extract, OG Kush non-cannabis additive (myrcene, linalool, limonene), Blueberry Kush non-cannabis additive (terpinolene, ocimene, linalool, humulene, myrcene), Banana Kush non-cannabis additive (myrcene, alpha terpinene, pinene, ocimeme, limonene, linalool).
 - Ingredients: hemp extract, watermelon non-cannabis additive (alpha pinene, beta caryophyllene, myrcene, cis-3-hexenol, ethyl isovalerate, ethyl caproate, linalool), mint non-cannabis additive (menthol, myrcene, linalool, limonene).
 - Ingredients: marijuana extract, non-cannabis additive (pinene, caryophyllene, terpinolene, ocimene, linalool), non-cannabis additive (myrcene, limonene)
 - The ingredients can either be listed in descending order of predominance by weight or volume, or alphabetically.
 - o The ingredients can either be listed on the exterior of the label or on an insert so long as the insert makes it clear that the ingredients listed are contained in the product. A visual example of an insert ingredient listing can be found at the end of this bulletin.
 - Labels may utilize peel-back or accordion style labels to list the ingredients, but must comply with the requirements of OAR 845-025-7030(11)(c).

• Submission Materials:

- o In addition to the requirements of <u>OAR 845-025-7160</u>, label applications must be accompanied by the additive's list of ingredients as required by <u>OAR 845-025-3265(1)</u>. Note the list of ingredients must be supplied for *each* non-cannabis additive being used in the product.
- Label applications <u>must</u> be accompanied by the "<u>Non-Cannabis Additive Documentation</u>" form.
 It must be signed by the licensee or an authorized representative of the licensee.
- Note that a change in ingredients, including a new non-cannabis additive being used or an existing non-cannabis additive being reformulated by the manufacturer, requires resubmission and pre-approval of the label. For example, if the "Blue Dream" mix you submitted changes ingredients or you added a new flavor or blend, both would require resubmission and pre-approval. See OAR 845-025-7160(7) for what you can change on a label without resubmission and pre-approval.

- Existing Label Applications for Inhalable Cannabinoid Products: Licensees with a label approved by the OLCC prior to April 1, 2021 that contain a non-cannabis additive and do not meet the requirements of these new rules will have their label applications automatically reverted to "resubmission required" status on July 1, 2021 because they are no longer compliant with OLCC rules.
 - o Licensees may use these existing applications for labels that are compliant with these new rules or repurpose them for another use.

Questions?

If you have any questions about these changes or this Bulletin please send them to marijuana.packaging@oregon.gov and if you have questions related to Metrc or CTS contact marijuana.cts@oregon.gov.

Green Street Terpenes

123 Green St., Portland, OR 97210 | 503-555-5555 | greenstreet@notarealemailaddress.com

Oregon Liquor Control Commission,

Green Street Terpenes supplies Processing Green, LLC with the following non-cannabis additives. Below you will find a list each of additive supplied to this business, including every ingredient in the additive, its CAS number, and maximum concentration range. All non-cannabis additives listed below are intended for human inhalation.

OG Kush Blend

| Name | CAS Number | Maximum Concentration Range (%) |
|-------------|------------|---------------------------------|
| Myrcene | 123-35-3 | 30-50 |
| Linalool | 78-70-6 | 10-20 |
| β-Pinene | 127-91-3 | 10-20 |
| Nerolidol | 7212-44-4 | 10-20 |
| α-Pinene | 80-56-8 | 10-20 |
| α-Terpineol | 98-55-5 | 1-5 |
| Fenchol | 1632-73-1 | 0.1-1 |
| Camphene | 79-92-5 | 0.1-1 |
| L-Fenchone | 7787-20-4 | 0.1-1 |

Banana Kush Blend

| Name | CAS Number | Maximum Concentration Range (%) |
|-------------------|------------|---------------------------------|
| Trans-β-Ocimene | 13877-91-3 | 30-50 |
| | | |
| D-Limonene | 5989-27-5 | 10-20 |
| Terpinolene | 586-62-9 | 10-20 |
| Geranyl Acetate | 105-87-3 | 1-5 |
| 1,8-Cineole | 470-82-6 | 1-5 |
| Trans-α-Farnesene | 502-61-4 | 1-5 |
| Cedrol | 77-53-2 | 0.1-1 |
| (-) – Isopulegol | 89-79-2 | 0.1-1 |
| Thymol | 89-83-8 | 0.1-1 |
| L-Piperitone | 6091-50-5 | 0.1-1 |
| Nerol | 106-25-2 | 0.1-1 |

Sincerely,

John Doe

Blue Dream Flavored Marijuana Extract with Non-cannabis Additives

Suggested serving size is one 5-second draw. Each cartridge provides about 150 servings with a 5 second draw.

Ingredients: marijuana extract, Blue Dream non-cannabis additive.

DO NOT EAT. For use only by adults 21 and older. Keep out of reach of children. Do not drive a motor vehicle while under the influence of marijuana. This product is not approved by the FDA to treat, cure, or prevent any disease.

THC: 6 mg/serving; 900 mg/container CBD: 10 mg/serving; 1500 mg/container

Immediate Activation

UID 1A4018297310677118742955 Made: 6/11/16, Lab Name, Tested:

6/20/16

Processing Green, LLC, 1000026J04D, 123

Green St., Portland, OR 97210

1 gram (0.035 ounces)



Ingredient Insert Example

*Note the non-cannabis additives are listed alphabetically in this example.

This product contains a Blue Dream noncannabis additive, which contains the following non-cannabis ingredients:

Alpha-pinene

Beta-pinene

Bisabolol

Camphene

Citronellol

d-Limonene

Linalool

Myrcene

Nerolidol

Terpinolene

Thymol

Valence