TECHNICAL BULLETIN

Supersedes November 27, 2019
February 4, 2020

Requirements for Marihuana Products Intended for Inhalation

The intent of this technical bulletin is to publish information in accordance with the Emergency Rules for Manufacturing of Marihuana Products Intended for Inhalation filed on November 22, 2019.

Rule 3. Ingredients.

> (1) All inactive ingredients shall be clearly listed on the product label for any marihuana product intended for inhalation produced after the effective date of these rules.
> (2) A licensee is prohibited from adding an inactive ingredient to a marihuana product intended for inhalation unless it has been approved by the FDA for inhalation. The concentration of any inactive ingredient in a marihuana product intended for inhalation shall not exceed the maximum concentration listed in the FDA Inactive Ingredient database.
> (3) Processors and marihuana processors shall keep records of formulation for a minimum of two years after the use of the formulation is discontinued for all marihuana products intended for inhalation.
> (4) All records of formulation and changes to formulations must be submitted to the agency for all marihuana products intended for inhalation.

Any product created after November 22, 2019, must be accompanied by the Record of Formulation for Marijuana Products Intended for Inhalation.

Please see the proceeding pages for additional information on how to compliantly submit documentation to the agency.

Acceptable Ingredients:

Formulations for marijuana vape cartridges may include distillate and terpenes processed within the regulated market by licensed processors or distillate and terpenes (**including botanically derived terpenes**) brought in from the external market. The process and procedures for which those products move through the Record of Formulation process are outlined in the flow charts below.

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Source Oil (Regulated Market), Terpenes (Regulated Market)

Begin

- **Source Oil**: Plants obtained by a licensed processor from *either* a caregiver or the regulated market, processed in regulated market.
- **Terpenes**: Created through distillation/separation process from the marijuana plants used to create the source oil by a licensed processor.

Obtain

- **Source Oil**: Include information about the extraction process on the Record of Formulation (ROF).
- **Terpenes**: Include information about the distillation process on the ROF.

Submit

- **Source Oil**: Submit the process for extraction, include attestation (signed and dated) stating that oil is processed within the regulated market by the submitting licensed processor*.
- **Terpenes**: Submit the process for extraction. Include all information for the processing of marijuana flower into oil and terpenes, including any separation and recombination of products.
- Vitamin E Acetate testing in final state is **not required.**

*If the processor continues to process flower within the regulated market, a new ROF is not necessary for each strain type or strain mix that is processed.

More information on the MRA can be found at the agency's website

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Source Oil (Regulated Market), Terpenes (External Market)

Begin

- **Source Oil**:Plants obtained by a licensed processor from *either* a caregiver or the regulated market, processed in regulated market.
- **Terpenes**: Obtained from either caregiver or external vendor.

Obtain

- **Source Oil**: Include information about the extraction process on the Record of Formulation (ROF).
- **Terpenes**: All terpenes sourced from the external market (***Cannabis* derived, botanical, or caregiver**) must be submitted with the Vendor name and all associated Certificates of Analysis / Safety Data Sheets provided by the vendor.

Submit

- **Source Oil**: Include a statement on the ROF stating that all oil is processed within the regulated market by the submitting licensed processor*.
- **Terpenes**: Include attestation and a summary of the extraction process with submission of the completed ROF. Include all strain/flavors sourced from vendor. Any time a vendor changes a new ROF must be submitted. If the licensee wishes to add strains/flavors from the same vendor, please submit this form.
- Vape cartridges **must be tested for Vitamin E Acetate** and full compliance in final state.

*If the processor continues to process flower within the regulated market, a new ROF is not necessary for each strain type or strain mix that is processed.

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Source Oil (External Market), Terpenes (External Market)

Begin

- **Source Oil**: Obtained from a valid Michigan caregiver and brought in to the regulated market via external transfer.
- **Terpenes**: Obtained from either caregiver or vendor.

Obtain

- **Source Oil:** Attestation (signed and dated) stating that the distillate contains no additives or materials other than *Cannabis* concentrate.
- **Terpenes:** All terpenes sourced from the external market (***Cannabis* derived, botanical, or caregiver**) must be submitted with the Vendor name and all associated Certificates of Analysis / Safety Data Sheets provided by the vendor.

Submit

- **Source Oil:** Include attestation and a summary of the extraction process with submission of the completed ROF. If the licensee wishes to add a new batch of distillate, please submit this form.
- **Terpenes**: Include attestation and a summary of the extraction process with submission of the completed ROF. Include all strain/flavors sourced from vendor. Any time a vendor changes a new ROF must be submitted. If the licensee wishes to add strains/flavors from the same vendor, please submit this form.
- Vape Cartridges **must be tested** for Vitamin E Acetate and full compliance in final state.

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FREQUENTLY ASKED QUESTIONS

Where is the Record of Formulation (ROF) form?

You can find the form here. Please fill it out in its entirety before submission or the request is subject to denial.

Where do we submit our Record of Formulation request?

Please send an email to: **MRA-compliance@michigan.gov**

When submitting, please make sure that all sections are completed. In the submission email, please include the facility name and license number in the subject line of the email along with the phrase "Submission of Record Formulation".

When submitting an update to an approved ROF, in the subject line of the email please include the following:

"Update- AXXXX – Name of Licensee and License number"

What documents are required for approval?

All relevant documents listed in the ROF form must be submitted with the ROF request. Please refer to the previous pages and the information below to ensure that the ROF request is complete before submission.

Can we use terpenes and what kind of terpenes may we use?

Licensees may use terpenes that are botanically derived from *Cannabis* or other plants.

Terpenes from a vendor:

All terpenes and terpene blends submitted as part of a record of formulation must be submitted along with the associated Certificate of Analysis and Safety Data Sheets from the vendor as an attachment. If you use multiple vendors for the procurement of terpenes/blends, you will need to submit ROF for each vendor with their respective terpene products.

My formulation process didn't change, but I want to add additional terpenes or distillate to my record, how do I do this?

Please submit an ROF Update Form which can be found here. On the form, you will need to include the name, date of request, and the full Metrc number. When submitting an update to an approved ROF, in the subject line of the email please include the following:

"Update- AXXXX – Name of Licensee and License number."