

Guidance on Tinctures

Approved by Commission: November 20, 2018

This guidance is not legal advice. It was created with the intent to assist licensed product manufacturers engaged in the production of tinctures in the adult-use marijuana market. Please consult an attorney if you have any questions regarding the legal requirements that apply to tinctures and the production of tinctures.

1. Are tinctures considered an edible?

No, tinctures are not considered an edible product under 935 CMR 500.

Therefore, tinctures are not subject to the dosing limitations applicable to edible marijuana products included in 935 CMR 500.150(4).

2. Because tinctures are administered orally, how do I determine if my product is a tincture or an edible?

Tinctures are generally cannabis-infused alcohol or oils administered orally in small amounts using a dropper or measuring spoon. The smaller volume of product typically administered and mode of consumption differentiates tinctures from marijuana products that are consumed by eating or drinking.

In contrast, “edible cannabis products” or “edibles” is defined under the Adult Use of Marijuana regulations as “a cannabis or marijuana product that is to be consumed by humans by eating or drinking.” *See* 935 CMR 500.002. Edibles appear and taste like commonly prepared foods consumed by eating or drinking, such as cookies, brownies, candies or sodas.

3. Are tinctures considered a beverage?

No, tinctures are not considered a beverage under the Commission’s regulations.

4. Are tinctures considered a concentrate?

Yes, tinctures are considered a concentrate under the Commission’s regulations. However, please note that there are separate labeling requirements for tinctures and for concentrates. *See* Question 5, below.

5. What are the labeling requirements for tinctures?

Tinctures must be labeled according to 935 CMR 500.105(5)(d). These labeling requirements also apply to tinctures being transported by a product manufacturer to a marijuana retailer in compliance with 935 CMR 500.105(13).

The labeling requirements include the following, but you should refer to the regulations for the full set of requirements:

- There should be a legible, firmly affixed label with words no less than $\frac{1}{16}$ inch in size on each container of marijuana-infused tincture.
- The label should contain, at a minimum, the following information:
 - The name and registration number of the product manufacturer that produced the tincture;
 - The product manufacturer's business telephone number, e-mail address, and website information, if any;
 - The marijuana-infused tincture's identity (product name);
 - The type of marijuana used to produce the tincture, including what, if any, processing technique or solvents were used – the “type of marijuana” refers to what material is being used, for example whether it was created using the flower, trim, rosin, kief, or some sort of solvent-assisted concentrate, or if it was made from the root of the plant; listing the strain of cannabis is optional;
 - A list of ingredients, including the full Cannabinoid profile of the marijuana contained within the tincture, including the amount of delta-nine-tetrahydrocannabinol (Δ 9-THC) and other cannabinoids in the package and in each serving of a container of tincture as expressed in absolute terms and as a percentage of volume;
 - Net weight or volume as expressed in US customary units or metric units;
 - The date the tincture was created;
 - A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and processing;
 - Directions for use of the tincture;
 - A statement and a seal that the tincture has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
 - A warning if nuts or other known allergens are contained in the product;
 - This statement (with the capitalization):

This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.;
 - The following symbol or easily recognizable mark issued by the Commission that indicates the package contains marijuana product:



- The following symbol or other easily recognizable mark issued by the Commission that indicates not that the product is harmful to children:



6. What are the packaging requirements for tinctures?

Tinctures must be packaged according to the requirements in 935 CMR 500.105(6).

Tinctures may be packaged to contain multiple servings; and each single serving of a tincture does not need to be marked, stamped or otherwise imprinted with a Commission-issued symbol. If tinctures are packaged to contain multiple servings, they must include the following statement on the exterior of the package in a printed font that is no smaller than ten-point Times New Roman, Helvetica or Arial, including capitalization: “INCLUDES MULTIPLE SERVINGS.” *See* 935 CMR 500.105(6)(c)1.

An individual serving size in a package of tincture can be determined by the product manufacturer but can never contain more than 5 milligrams (mg) of delta-nine-tetrahydrocannabinol (Δ 9-THC). *See* CMR 500.105(6)(e). The Commission recommends packaging tinctures with a dropper that provides a measured dose of up to the 5 mg, to comply with this requirement.

One bottle or container of tincture cannot contain more than 1000 milligrams (mg) of delta-nine-tetrahydrocannabinol (Δ 9-THC).

7. What is the limitation on sales of tinctures?

A tincture is considered a concentrate. Under the regulations, a marijuana retailer may not sell more than 1 ounce of marijuana (flower) or 5 grams of marijuana concentrate to an adult-use consumer per transaction. *See* 935 CMR 500.140(4) and 500.140(5)(c). Therefore, a marijuana retailer may not sell more than 5 grams of tincture to an adult-use consumer per transactions.

Only a duly licensed marijuana retailer may sell an adult-use marijuana-infused tincture to a consumer.

Questions? If you have additional questions, please contact the Commission at (617) 701-8400 or CannabisCommission@Mass.Gov