



## Trade requirement and guidance policy for labeling undiluted essential oils used topically and offered for retail sale

(Trade requirement adopted July 2009, revised July 2011; Guidance policy adopted July 2012)

Undiluted plant essential oils offered for retail sale and intended for topical use:

1. Do include all of the information and statements, or significantly similar statements, identified in the table below as a “trade requirement,” directly on package labels;
2. May include any of the information identified in the table below under “Guidance Policy,” either directly on package labels or on labeling. \* (see page 2)

Subject	Trade requirement	Guidance policy
<b>Identity of the source plant:</b>	<ul style="list-style-type: none"> <li>♣ Latin name</li> <li>♣ Plant part</li> </ul>	<ul style="list-style-type: none"> <li>♣ Common or usual name</li> </ul>
<b>Product identity:</b>		<ul style="list-style-type: none"> <li>♣ An expiration date or date of manufacture.</li> <li>♣ A lot number or other batch identifier.</li> <li>♣ The extraction process, (i.e., distilled; expressed; solvent extraction; etc.), with any additional specific accurate information.</li> </ul>
<b>Storage cautions:</b>	<ul style="list-style-type: none"> <li>♣ “Keep out of reach of children.”</li> </ul>	<ul style="list-style-type: none"> <li>♣ “Keep away from flame.” Usage instructions: Instructions for use with, at minimum, the recommended amount for each application method described.</li> </ul>
<b>Usage cautions:</b>	<ul style="list-style-type: none"> <li>♣ “External Use Only” or “Not for Internal Use” or “Not for Ingestion”</li> <li>♣ “Keep away from eyes and mucous membranes.”</li> <li>♣ “Do not apply undiluted directly on skin,” except that information may be included on direct application in an undiluted state if the marketer has expert support that such use is appropriate and safe for the intended use.</li> </ul>	<ul style="list-style-type: none"> <li>♣ “If swallowed, seek medical attention or contact a Poison Control Center.”</li> <li>♣ “If skin irritation or sensitivity develops or increases, stop use and, if condition persists, seek medical attention.”</li> <li>♣ Risk and safety information regarding photosensitizing effects, if applicable to the specific essential oil.</li> <li>♣ Risk and safety phrases for specific oils as identified by the Research Institute for Fragrance Materials (RIFM) and the International Fragrance Association (IFRA), if applicable to the specific essential oil.</li> </ul>



*\*For purposes of this guidance, the following definitions apply:*

- “Label” has the meaning ascribed in 21 U.S.C. 321(k) and means a display of written, printed, or graphic matter upon the immediate container of any article.
- “Labeling” has the meaning ascribed in 21 U.S.C. 321(m) and means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

*In addition, for purposes of these policies, the following notes apply:*

- These policies do not address the safety of specific essential oils. Contraindications exist for the use of some essential oils in special populations, such as infants and children; pregnant and lactating women; and those with certain health conditions (e.g., hypertension). Such individuals should use essential oils under the supervision of a professional or qualified person.
- All of the required storage and usage cautions can be stated succinctly, for example, as: “Keep away from children. No use orally, in eyes or mucus membranes, or undiluted on skin.”

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## **\*\*Specific Types of Extraction**

### *Types of Distillation*

- **Steam distillation:** Natural raw material is placed in or above water in a retort and exposed to steam, which carries the volatile oils into a condenser where the mixture is cooled.[\[1\]](#) The oils separate from the water and can be collected.
- **Hydro distillation:** Steam distillation in which the natural raw material is exposed to steam from above, rather than from below, the raw material.
- **Water distillation:** Natural raw material is submerged in water. The water is then slowly heated and brought to a boil.
- **Dry distillation:** Used primarily to obtain essential oils from wood. Natural raw material is heated in a retort in the absence of liquid to release vapors or liquids. The heat applied to the retort is commonly direct flame. This process may or may not involve pyrolysis.

### *Types of Expression*

- **Cold-pressing:** Used primarily to obtain citrus essential oils. Fruit is punctured and then mechanically pressed. No external heat is applied during the extraction process.
- **Sponge expression:** Pulp is removed from the fruit and the remaining rind and pith are soaked in water. The softened peel is pressed against a sponge, which absorbs the exuded oil.
- **Scarification (aka: Écuelle à piquer):** Outer peel of a fruit is scarified. The liquid exuding from the ruptured oil glands collects in stem.
- **Machine abrasion:** Outer peel of a fruit is scarified and then removed by machine and dropped into a flow of water, which carries the result to a large centrifugal separator machine.

### *Types of Solvent*

**Enfleurage:** Flower petals are placed on solid sheets of warm fat that absorbs the essential oil from the flowers. A solvent, usually alcohol, is then added to the saturated fat, which separates the essential oil from the fat.

**Supercritical CO<sub>2</sub>:** Carbon dioxide is liquefied and used as extraction solvent.

**Solvent:** Use of a solvent other than those mentioned thus far, such as hexane. Solvent should be identified.

**Extrait:** Extraction of flower oils (generally organic) without the use of harmful solvents, such as benzene and hexane, etc.

<sup>1</sup> When the natural raw material is placed in water during steam distillation it is sometimes called “water and steam distillation.”