



THE AMERICAN HERBAL PRODUCTS ASSOCIATION'S

GUIDANCE

PULEGONE: DOES NATURALLY OCCURRING PULEGONE REPRESENT “EXPOSURE” UNDER CA PROPOSITION 65?

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Regulatory background.

On April 18, 2014, the California Office of Environmental Health Hazard Assessment (OEHHA), the agency responsible for the administration of Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986, hereinafter Prop 65) listed pulegone as a chemical “known to cause cancer.”¹ Under Prop 65 regulations, a person who causes an exposure to a listed carcinogen must provide a “clear and reasonable warning” within 12 months from the date of OEHHA’s listing unless otherwise exempted. Under the current rules this warning, when required, would be deemed to be “clear and reasonable” if it states: “WARNING: This product contains a chemical known to the State of California to cause cancer.”

What is pulegone and where is it found?

Pulegone is a ketonic monoterpene that is a naturally present constituent in numerous plant species, especially mints (e.g., peppermint and spearmint) and particularly concentrated in the essential oils derived from these plants. Use of these plants and their essential oils as ingredients in foods, supplements, cosmetics and other consumer products may therefore result in the presence of small amounts of pulegone in these products.

It is important to acknowledge that the studies that resulted in OEHHA’s listing of pulegone as a carcinogen were tests of the toxicity of 96% pure pulegone on laboratory animals that were force-fed over virtually their entire lifetime doses that far exceed any human exposure related to common uses of mints and other plants and their essential oils.

While appropriate as a hazard identification exercise, this research does not constitute an appropriate risk assessment applicable to human exposure through normal dietary pulegone exposure.

What exemptions apply to Prop 65 warnings for pulegone?

There are several means to be exempted from Prop 65’s warning rule for chemicals listed by California as known to cause cancer. For example, warnings are not required to be provided by companies with less than 10 employees or for exposures below the level at which there is no significant risk of cancer (defined in the law as the level of

¹ OEHHA Notice of Chemical Listed Effective April 18, 2014, http://www.oehha.org/prop65/prop65_list/files/041814ListingNoticeLCSet%2020Pulegone.pdf.

PROPOSITION 65/PULEGONE

exposure at which not more than one excess case of cancer would occur in an exposed population of 100,000, assuming 70-year lifetime exposure at the level in question²).

But the most relevant exemption in the case of pulegone is for chemicals that are “naturally occurring” food constituents. Notably, in its 2014 Notice of Intent to List Pulegone, OEHHA identified pulegone as a “natural constituent of various plants, including mint and other herbs, and of their essential oils.”³ OEHHA’s regulations clarify that an exposure to a Prop 65 listed chemical does not occur, such that no warning is required, in the following situations:

1. For a food, when the chemical is naturally occurring in the food and is a natural constituent of the food;^{4, 5}
2. For a consumer product other than food, when the chemical is a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, “exposure” can only occur as to that portion of the chemical from other sources.⁶

In a 2002 letter OEHHA commented on the applicability of these naturally occurring regulatory exemptions to methyleugenol, a constituent of basil and other plants in commerce and listed in 2001 as a chemical known to the State of California to cause cancer. OEHHA agreed in this letter that methyleugenol was found to be a natural constituent of basil and thereby the “naturally occurring” exemption was applicable. OEHHA additionally concluded that by adding the naturally occurring methyleugenol to a food or a consumer product would not create an “exposure” within the meaning of Prop 65, and thereby such food or consumer product would also qualify for the “naturally occurring” exemption.

² OEHHA itself may establish an NSRL (no significant risk level) for chemicals listed as known to the state to cause cancer; it has not done so for pulegone. Independent persons and companies may also make an NSRL determination but this would be a complex undertaking and could be subject to challenge by the State of California or by a private plaintiff purportedly acting in the public interest.

³ OEHHA Notice of Intent to List Pulegone by the Labor Code Mechanism [02/07/14].

⁴ Title 27 California Code of Regulations §25501(a)(1).

⁵ Note that other rules apply to a Prop 65 listed chemical that is a “contaminant” (see CA HSC §25501(a)(4)), though this is not relevant to pulegone or other naturally-occurring constituents.

⁶ Title 27 California Code of Regulations §25501(b).

Should Prop 65 warnings be provided on products that contain herbs and essential oils in which pulegone is a naturally occurring constituent?

OEHHA's regulations for providing warnings for exposures to Prop 65 listed chemicals can be read to mean:

- A food that contains pulegone due to the presence of a mint, another herb or spice, or an essential oil in which pulegone is known to be a natural constituent does not constitute an exposure to pulegone for purposes of Prop 65, as clearly established by 27 CCR § 25501(a)(1); no Prop 65 warning should be required for such foods.
- A dietary supplement is a food for purposes of the naturally occurring provisions of OEHHA's regulation on Prop 65 warnings⁷ such that 27 CCR § 25501(a)(1) also established that a dietary supplement that contains pulegone due to the presence of a mint, another herb or spice, or an essential oil in which pulegone is known to be a natural constituent does not constitute an exposure to pulegone for purposes of Prop 65; no Prop 65 warning should be required for such dietary supplements.
- A cosmetic or other consumer product that contains pulegone due to the presence of a food ingredient consisting of a mint, another herb or spice, or an essential oil in which pulegone is known to be a natural constituent does not constitute an exposure to pulegone for purposes of Prop 65, as clearly established by 27 CCR § 25501(b); no Prop 65 warning should be required for such cosmetics or other consumer products.
- On April 20, 2015 several marketers of essential oil of pennyroyal intended to be applied topically to the skin were given notice alleging violations of Proposition 65 for failure to provide warnings for these products. The plaintiff who issued this notice apparently takes the position that pennyroyal (or pennyroyal oil) is not a food or food ingredient so that while pulegone is known to be naturally occurring in pennyroyal the above discussed exemption should not apply. Note however that both European pennyroyal (*Mentha pulegium*) and American pennyroyal (*Hedeoma pulegioides*) are listed in federal regulation as "natural flavoring substances ... [that] may be safely used in food" under certain conditions. 21 CFR 172.510. This issue has not been resolved as of the date of issuance of this document and readers are advised to consult with qualified Proposition 65 counsel.

NOTE: AHPA anticipates the listing by OEHHA in the near future of beta-myrcene⁸, another naturally occurring constituent in several plant species, as a chemical known to the state to cause cancer. The information provided in this document for pulegone is likely to also apply to beta-myrcene, and AHPA will provide updates upon receipt of additional information.

⁷ *Gillett v. Garden Of Life, Inc. et al.* (San Francisco Superior Court, Case No. CGC-08-479027).

⁸ OEHHA Notice of Intent to List: Beta-myrcene [02/07/14].