

## Substance Information Document

**Spearmint oil****1. Substance identity**

Name	Spearmint oil
Synonyms	Mint oil Curled mint oil Aceites Hierbabuena Curled mint oil FEMA 3032
IUPAC Name	N/A*
CAS	8008-79-5

\*Non answered, IUPAC Name was not found.

**2. Toxicological information**

Spearmint oil is constituted for the majority by carvone (67%) and limonene (11.5%), which are determining the characteristic flavor (IOFI/IFRA Labeling Manual 2020, FEMA). The estimated daily intake according to FEMA is 490 µg/person/day (with 14 µg of unidentified constituents).

Spearmint oil is considered a category 2 skin irritant and skin sensitizer, classified in accordance with the criteria outlined in Annex I of the CLP Regulation (1272/2008/EC). Data on spearmint extract (OECD 405; CAS 84696-51-5) showed fully reversible eye irritation (ECHA Reach dossier).

Oral acute toxicity and dermal acute toxicity were determined in an OECD 401 and OECD 402 studies with a LD<sub>50</sub> of ≥5000 mg/kg bw (ECHA Reach dossier). No substance-specific acute inhalation data are available.

No substance-specific data are available for repeated dose toxicity studies. A subchronic 13-week oral gavage study (non-OECD) with d-carvone (CAS 2244-16-8) in rats determined a NOAEL of <93 mg/kg bw/day based on the decreased male body weights and increased liver and kidney weights in males as well as females (ECHA Reach dossier).

Spearmint oil was negative (non-mutagenic) when assessed in the Ames and chromosomal aberration assay in vitro and micronucleus assay in vivo. Negative results were also shown when carvone was tested in the same assays (FEMA, ECHA Reach dossier).

Read-across data with d-carvone (OECD 416, Two-Generation Reproduction Toxicity Study, CAS 2244-16-8) showed no adverse effects on fertility (NOAEL ≥ 90 mg/kg bw/day, maximum dose tested). Another read-across OECD 414 study with d-carvone showed a NOAEL ≥ 200 mg/kg bw/day for developmental toxicity (maximum dose tested) (ECHA Reach dossier). An OECD 414 prenatal developmental toxicity study in rats showed a LOAEL = 125 mg/kg/day for l-carvone (CAS 6485-40-1), based on decrease in mean body weights of fetuses, transitional findings of supraoccipital bone, sternbrae, vertebrae, and malformations of the ribs (RIFM). NOAEL (maternal toxicity) was established as 250 mg/kg bw/day (OECD 414) (maximum dose tested).

Based on their 14-step approach, FEMA considered spearmint oil as GRAS.

JECFA	-
FEMA	<a href="#">FEMA GRAS assessment of natural flavor complexes: Mint, buchu, dill and caraway derived flavoring ingredients - ScienceDirect</a>  <a href="#">SPEARMINT OIL (MENTHA SPICATA L.)   FEMA (femaflavor.org)</a>
EFSA	<a href="#">Conclusion on the peer review of the pesticide risk assessment of the active substance plant oils/spearmint oil - - 2012 - EFSA Journal - Wiley Online Library</a>
ECHA – REACH dossier	<a href="#">Registration Dossier - ECHA (europa.eu)</a> <a href="#">Registration Dossier - ECHA (europa.eu)</a> (l-carvone)
PUBCHEM	<a href="#">SID 363905449 - PubChem (nih.gov)</a>
CIR	-
OSHA	-

### 3. Addictiveness and attractiveness

No substance specific data were identified.

SCENIHR	<a href="#">Final Opinion on Additives used in tobacco products (Opinion 1) (europa.eu)</a>
EMA	-
PUBMED	-