

## Substance Information Document

### Peppermint oil

#### 1. Substance identity

Name	Peppermint oil
Synonyms	Mentha piperita oil; peppermint extract
IUPAC Name	3,7-dimethyl-1-oxaspiro[3.5]nonane;3,6-dimethyl-4,5,6,7-tetrahydro-1-benzofuran;5-methyl-2-propan-2-ylcyclohexan-1-ol;5-methyl-2-propan-2-ylcyclohexan-1-one;(5-methyl-2-propan-2-ylcyclohexyl) acetate;5-methyl-2-propan-2-ylidenecyclohexan-1-one
CAS	8006-90-4

#### 2. Toxicological information

Peppermint oil is a natural extract with major constituents' menthol (30-55%), menthone (14-32%), and as minor constituent pulegone (up to 3%).

FEMA scientists considered that peppermint oil "is not of genotoxic concern". In the past, some concerns have been raised over the possible genotoxicity and carcinogenicity of the minor constituent pulegone, which has induced bladder and liver tumours in rodents. The recent opinions of the EMA and FEMA is that neither pulegone nor peppermint oil are genotoxic, furthermore the rodent tumours were considered either not relevant to humans or were induced by a threshold mechanism that would not operate in the absence of other toxicity.

Adverse effects on fertility were not observed in a reproductive toxicity study. A NOAEL of 150 mg/kg bw/day for reproductive and developmental toxicity was identified. No expert group-derived HBGVs were identified.

No conclusive data on respiratory tract irritation of peppermint oil. There is conflicting information in the literature with regards to the dermal and ocular irritation potential of peppermint oil. A "splash" of peppermint oil was reported to cause serious, reversible, eye damage in humans.

Numerous allergic contact dermatitis reactions to peppermint oil have been described in the literature. One case report was identified that indicated that exposure to the vapour of peppermint oil could cause allergic asthma in a sensitive individual.

No conclusive inhalation toxicity data were identified on peppermint oil. LD50 values exceeding 2000 mg/kg bw was noted for acute oral systemic toxicity in rodents. No mortality was seen in rabbits following a 24-hour skin application at a dose of 5000 mg/kg bw, indicating a very low order of acute dermal systemic toxicity.

There are several oral repeated-dose toxicity studies available for peppermint oil. FEMA scientists identified the study NOAEL to be the mid dose of 200 mg/kg bw/day.

JECFA	<a href="#">THE SAFETY EVALUATION OF NATURAL FLAVOURING COMPLEXES (JECFA 52, 2004) (inchem.org)</a>
FEMA	<a href="#">3. GRAS Substances(2001-3124) 0.pdf (femaflavor.org)</a>
EFSA	<a href="#">Scientific Opinion on Flavouring Group Evaluation 57, Revision 1 (FGE.57Rev1): consideration of isopulegone and three flavouring substances evaluated by JECFA (55th meeting) - - 2017 - EFSA Journal - Wiley Online Library</a>
ECHA – REACH dossier	<a href="#">Registration Dossier - ECHA (europa.eu)</a> (peppermint extract CAS 84082-70-2)
PUBCHEM	<a href="#">Peppermint oil   C62H108O7 - PubChem (nih.gov)</a>
CIR	<a href="#">Final Report on the Safety Assessment of Mentha Piperita (Peppermint) Oil, Mentha Piperita (Peppermint) Leaf Extract, Mentha Piperita (Peppermint) Leaf, and Mentha Piperita (Peppermint) Leaf Water, 2001 (sagepub.com)</a>
OSHA	-

### 3. Addictiveness and attractiveness

Peppermint oil is the most prominent oil using in pharmaceutical formulations with its significant therapeutic value.

It is also a common flavouring ingredient added to e-liquids, reportedly providing a peppermint flavour. Investigation done on the Dutch marked, showed that such flavouring increase e-cigarette attractiveness and use and thereby exposure to potentially toxic ingredients.

SCENIHR	<a href="#">Final Opinion on Additives used in tobacco products (Opinion 1) (europa.eu)</a>
EMA	<a href="#">Peppermint oil - Herbal summary for the public (europa.eu)</a>
PUBMED	<a href="#">Comprehensive overview of common e-liquid ingredients and how they can be used to predict an e-liquid's flavour category - PubMed (nih.gov)</a>