

## Substance Information Document

### Geraniol

#### 1. Substance identity

Name	Geraniol
Synonyms	<i>trans</i> -3,7-Dimethyl-2,6-octadien-1-ol (E)-Geraniol Lemonol (E)-Nerol
IUPAC Name	(2E)-3,7-dimethylocta-2,6-dien-1-ol
CAS	106-24-1

#### 2. Toxicological information

No geraniol-specific data for acute or repeated-dose toxicity were identified in humans and acute or repeated-dose toxicity is very low in laboratory animals. An oral LD50 of 4800 mg/kg bw was reported in rats administered geraniol by gavage. Dermal LD50 values of >5000 mg/kg bw and 2650-5000 mg/kg bw were reported in rabbits in two separate studies.

SCHEER (2016) cited “relevant” no-observed-adverse-effect levels (NOAELs) of 558 mg/kg bw/day for rats and 279 mg/kg bw/day for mice. While no specific study was cited, the NOAELs appear to have been adapted from long-term oral studies in rodents given a mixture containing 71% geranyl acetate. “Systemic general toxicity” was “not considered relevant” by SCHEER for the (unspecified) doses of geraniol used as tobacco additives. Effects following inhalation “are not expected to be different” as “oral absorption has been demonstrated to be >80%”. For oral EFSA (2016) used a NOAEL of 345 mg/kg bw/day. The NOAEL was based on a 14-week study with citral in rats conducted under the auspices of the National Toxicology, the critical effects being in the kidneys of males.

In its scientific opinion on aliphatic, branched-chain saturated and unsaturated alcohols, aldehydes, acids and related esters (including geraniol), the EFSA FAF29 Panel concluded that genotoxicity is not a concern for all 31 substances in the flavouring group. The Joint FAO/WHO Expert Committee on Food Additives also evaluated geraniol as a (non-genotoxic) threshold toxin. SCHEER (2016) agreed that the genotoxic data on geraniol are sufficient to rule out concerns for this endpoint, acknowledging equivocal clastogenicity test data *in vitro*. In its assessment of cyclic and non-cyclic terpene alcohols used as fragrance ingredients (including geraniol), the RIFM Expert Panel concluded that this group of substances would not be expected to exhibit genotoxicity *in vivo* at the intended use levels. SCHEER (2016) and a RIFM Expert Panel concluded that the available data rule out concerns for carcinogenicity.

With regards to local effects, SCHEER (2016) considered geraniol a “known” skin and eye irritant and that there is a high potential for [geraniol] inducing irritation of the airway mucosa, given its potential to irritate the skin and eyes. SCHEER (2016) also considered that geraniol would be a respiratory sensitiser.

JECFA	<a href="#">WHO food additives series: 52</a>
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	<a href="#">ALIPHATIC BRANCHED-CHAIN SATURATED AND UNSATURATED ALCOHOLS, ALDEHYDES, ACIDS, AND RELATED ESTERS (JECFA 52, 2004) (incchem.org)</a>
FEMA	<a href="#">3. GRAS Substances(2001-3124)_0.pdf (femaflavor.org)</a>
EFSA	<a href="http://www.efsa.europa.eu/en/efsajournal/doc/3392.pdf">http://www.efsa.europa.eu/en/efsajournal/doc/3392.pdf</a> <a href="http://www.efsa.europa.eu/en/efsajournal/doc/3091.pdf">http://www.efsa.europa.eu/en/efsajournal/doc/3091.pdf</a> <a href="https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2016.4512">https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2016.4512</a> <a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6029">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6029</a>
ECHA – REACH dossier	<a href="#">Registration Dossier - ECHA (europa.eu)</a>
PUBCHEM	<a href="#">Geraniol   C10H18O - PubChem (nih.gov)</a>
CIR	-
OSHA	-

### 3. Addictiveness and attractiveness

Expert-group opinion The European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR, 2016) reported that there was “no information available” on the addictiveness of geraniol.

In an investigation into the most common flavouring ingredients added to e-liquids on the Dutch market, geraniol was identified in 4.06% of e-liquid samples. The investigators noted that such flavourings 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	-
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>