Substance Information Document

Orange oil sweet

1. Substance identity

Name	Orange oil sweet
Synonyms	Citrus sinensis Oil; Citrus sinensis peel oil; Oil sweet orange *(non-exhaustive list)*
IUPAC Name	N/A*
CAS	8008-57-9

*Non answered, IUPAC Name was not found.

2. Toxicological information

No relevant published toxicokinetic studies, on respiratory tract irritation were identified. Orange sweet oil was slightly to moderately irritating in rabbits and not irritating when applied undiluted in mice and pig. In human subjects, it was not skin irritating (up to 8%). Orange sweet oil was found to be slightly irritating to the eyes of rabbits. Orange sweet oil was non-phototoxic. As furocoumarins have both phototoxic and photomutagenic properties following exposure to UV light, there is a potential risk associated with the presence of furocoumarins in such Citrus essential oil.

In a guinea pig maximization test, cold pressed orange oil was not sensitizing. From a Local Lymph Node Assay (LLNA) performed in mice with orange peel oil, an EC3 (calculated estimated concentration) of 50.98% was determined. In a maximization test conducted on 21 volunteers, orange oil applied at 8% did not produce any sensitizing reactions.

The oral and dermal LD_{50} of oil orange were respectively reported as greater than 5 g/kg in rabbits. Orange sweet oil was administered by oral gavage to rats in a 28-day subchronic toxicity study. Renal changes were observed at all tested doses but the overall severity of these changes was considered of minimal significance. In addition, toxicological data were available for representatives of the congeneric group of hydrocarbons, such as d-limonene (reported level up to 97.5%), β-myrcene, β-caryophyllene and p-mentha-1,3-diene which can be relevant depending on the actual composition of the oil.

Orange sweet oil was not mutagenic in *in vitro* assays. No genotoxicity was neither observed in a chromosomal aberration test and in an unscheduled DNA synthesis assay. Weak evidence of mutagenicity was detected in the mouse lymphoma forward mutation assay but outcomes were not considered biologically relevant.

There was no convincing evidence of local carcinogenicity on repeated topical application of orange sweet oil on mouse skin. However, orange sweet oil has been reported to promote tumor formation on mouse skin treated with a primary carcinogen. Otherwise, the major component of orange sweet oil, d-limonene, is reported to have anticarcinogenic activity.

Overall, orange sweet oil was not considered to be hazardous to female rat reproductive performance or on development and pup growth. The NOAEL values for maternal and fetal toxicity were 375 and 750 mg/kg respectively. Orange sweet oil is considered GRAS in foods for human consumption and in animal drugs, feed, and related products.

JECFA	-
FEMA	ORANGE PEEL SWEET OIL (CITRUS SINENSIS (L.) OSBECK) | FEMA (femaflavor.org) Cohen, et al., 2019
EFSA	-
ECHA – REACH dossier	-
PUBCHEM	SID 363898633 - PubChem (nih.gov)
CIR	International Journal of Toxicology 2019, Vol. 38(Supplement 2) 33S-59S, Safety Assessment of Citrus-Derived Peel Oils as Used in Cosmetics
OSHA	-
RIFM	RIFM Database

3. Addictiveness and attractiveness

No specific-ingredient data were identified.

SCENIHR	-
EMA	-
PUBMED	-