Substance Information Document

Clary oil

1. Substance identity

Name	Clary oil
Synonyms	Clary (Salvia sclarea L.); Clary oil (Salvia sclarea L.); Clary sage absolute (Salvia sclarea L.); Clary sage concrete; Clary sage oil; Clary sage oil (Salvia sclarea L.); Muscatel oil; Oil of clary sage; Oil of muscatel; Oils, clary sage; Sage (clary) oil. (not exhaustive list)
IUPAC Name	N/A*
CAS	8016-63-5

*Non answered, IUPAC Name was not found.

2. Toxicological information

Oxygenated monoterpenes were the most abundant compounds of Clary oil (Salvia sclarea L.), among which linalyl acetate reached the higher percentages in both liquid and vapor phases followed by linalool.

From an acute oral toxicity study performed in rats, an oral LD_{50} of 5600 mg/kg bw of clary sage oil was obtained. The dermal LD_{50} of clary sage oil in New Zealand rabbits exceeded 2000 mg/kg. The animals were treated on the clipped and abraded abdominal skin with 2000 mg/kg of neat clary sage oil for 24 hours under occlusion. Slight to moderate erythema and edema were observed up to day 4 and were absent on day 5.

An *in vitro* skin irritation study was performed according to the OECD TG 439 and in compliance with GLP, using the EPISKIN™ reconstructed human epidermis model. Under the experimental conditions of this study, clary sage oil was considered to be non-irritant to skin.

An in vitro eye irritation test on the EpiOcular™ cornea epithelial model was performed according to the OECD TG 492 and in compliance with GLP. Under the experimental conditions of this study, clary sage oil was considered to be non-irritating to Reconstructed Human Cornea-like Epithelium.

From a Maguire hypersensitivity test conducted on guinea pigs, clary sage oil (Russian) was considered to be a questionable or weak sensitizer. From a Local Lymph Node Assay (LLNA) performed according to OECD TG 429 and in compliance with GLP, clary oil was considered as a moderate skin sensitizer (i.e. EC3 > 2%). According to an Open Epicutaneous Test (OET) conducted on a panel of 22 subjects with a previous history of allergic reactions to Peru balsam and/or fragrance materials, the effect of clary oil was classified as weak to moderate. A maximization study was conducted on 25 male subjects with clary sage oil (Russian) at 8% in petrolatum. No sensitization reactions were observed.

An Open Epicutaneous Test (OET) intended to evaluate photoallergic potential was conducted on a panel of 25 subjects with a previous history of allergic reactions to Peru balsam and/or fragrance materials. No photoallergy reactionsre were observed.

In an OECD-compliant study, clary oil was negative for mutagenicity when incubated with *S. typhimurium* TA98, TA100, TA1535 and TA1537 and *E. coli* WP2 uvrA/pKM101 both in the presence and absence of metabolic activation. Clary oil was also negative in an OECD-compliant *in vitro* micronucleus test in human lymphocytes in both the presence and absence of metabolic activation. Genotoxicity of clary oil was not observed in an unscheduled DNA synthesis assay in rat hepatocytes up to 101 µg/mL or in a rec assay at 10 and 30 µg/disk.

JECFA	-
FEMA	CLARY OIL (SALVIA SCLAREA L.) | FEMA (femaflavor.org)
EFSA	-
ECHA – REACH dossier	ECHA. (2022, 02 16). ECHA Dossier: Sage, Salvia sclarea, ext.
PUBCHEM	SID 135311392 - PubChem (nih.gov)
CIR	-
OSHA	-

3. Addictiveness and attractiveness

5% clary oil have been demonstrated to have the strongest anti-stressor effect among essential oils tested in a forced swim test. The antidepressant-like effect of clary oil was likely mediated via a DAnergic pathway.

In a study conducted in mice with prominent dominant and submissive features in behavioral assays, mood stabilizing and anxiolytic-like effects of chronic food administration of S. sclarea oil extract on behavioral and physiological parameters were examined. Findings of this study enforced the hypothesis that S. sclarea oil possesses anxiolytic properties.

SCENIHR	-
EMA	-
PUBMED	Gross, M., Nesher, E., Tikhonov, T., Raz, O., & Pinhasov, A. (2013). Chronic food administration of Salvia sclarea oil reduces animals' anxious and dominant behavior. *Journal of medicinal food*, *16*(3), 216–222. https://doi.org/10.1089/jmf.2012.0137 Seol, G. H., Shim, H. S., Kim, P. J., Moon, H. K., Lee, K. H., Shim, I., Suh, S. H., & Min, S. S. (2010). Antidepressant-like effect of Salvia sclarea is explained by modulation of dopamine activities in rats. *Journal of ethnopharmacology*, *130*(1), 187–190. https://doi.org/10.1016/j.jep.2010.04.035