Substance Information Document

Ethyl laurate

1. Substance identity

Name	Ethyl laurate
Synonyms	Ethyl dodecanoate Dodecanoic acid, ethyl ester Lauric acid ethyl ester Ethyl laurinate; Ethyl dodecylate Lauric acid, ethyl ester; Ethyl n-dodecanoate
IUPAC Name	ethyl dodecanoate
CAS	106-33-2

2. Toxicological information

According to Api et al's fragrance ingredient safety assessment of ethyl laurate, genotoxicity, repeated dose toxicity, reproductive toxicity, phototoxicity/photoallergenicity and skin sensitization endpoints were evaluated (Food and Chemical Toxicology 2022 164: 113099). The mutagenic activity of ethyl laurate was evaluated in a bacterial reverse mutation assay conducted in compliance with GLP regulations and in accordance with OECD TG 471 using the standard plate incorporation method. Salmonella typhimurium strains TA98, TA100, TA1535, TA1537, and Escherichia coli strain WP2uvrA were treated with concentrations up to 5000 µg/plate. No increases in the mean number of revertant colonies were observed at any tested concentration in the presence or absence of S9. Under the conditions of the study, ethyl laurate was not mutagenic in the Ames test. The clastogenic activity of ethyl laurate was evaluated in an in vitro micronucleus test conducted in compliance with GLP regulations and in accordance with OECD TG 487. Human peripheral blood lymphocytes were treated with concentrations up to 2280 µg/mL in the dose range study; micronuclei analysis was conducted at concentrations up to 100 µg/mL in the presence and absence of S9 for 4 h and in the absence of metabolic activation for 24 h. Ethyl laurate did not induce binucleated cells with micronuclei when tested up to cytotoxic levels in either the presence or absence of an S9 activation system. Under the conditions of the study, ethyl laurate was considered as non-clastogenic in the in vitro micronucleus test. Based on the data available, ethyl laurate does not present a concern for genotoxic potential. Read-across material methyl laurate (CAS # 111-82-0) has sufficient data to support the repeated dose toxicity evaluation of ethyl laurate; its NOAEL was 1000 mg/kg/day. The same read-across analogue methyl laurate was used to assess fertility and developmental toxic potential; again the NOAEL was 1000 mg/kg/day. Based on the existing data and read-across material methyl hexadecanoate (CAS # 112-39-0), ethyl laurate is considered a skin sensitizer with a defined NESIL of 2400 µg/cm^2. Ethyl laurate's UV/Vis spectra indicate it would not be expected to present a concern for phototoxicity or photoallergenicity.

JECFA	No safety concern at then-current levels of intake when used as a flavoring agent: https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/2284
FEMA	GRAS substance: https://www.femaflavor.org/flavor-library/ethyl-laurate
EFSA	ADI for the consumer of 1 mg/kg bw: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2013.3169
ECHA – REACH dossier	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/26612
PUBCHEM	https://pubchem.ncbi.nlm.nih.gov/compound/Ethyl-dodecanoate
CIR	-
OSHA	-

3. Addictiveness and attractiveness

No substance-specific information was identified.

SCENIHR	-
EMA	-
PUBMED	-