# Substance Information Document

# Ethyl lactate

## 1. Substance identity

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| Name | Ethyl lactate |
| Synonyms | 2-Hydroxypropanoic acid ethyl ester<br>Ethyl 2-hydroxypropanoate<br>Lactic acid, ethyl ester<br>Propanoic acid, 2-hydroxy-, ethyl ester |
| IUPAC Name | ethyl 2-hydroxypropanoate |
| CAS | 97-64-3 |

## 2. Toxicological information

Ethyl lactate (CAS 97-64-3) is a racemic mixture of two enantiomers: ethyl-L-lactate (CAS RN 687-47-8) and ethyl-D-lactate (CAS 7699-00-5). Data on ethyl lactate and its L-isomer indicate a similar toxicological profile; no toxicity data were identified on the D-isomer.

Ethyl lactate and the L-isomer have EU harmonised classifications for eye damage and potential respiratory irritation. In addition, the REACH registrants have classified ethyl lactate as a Category 2 skin irritant on the basis of an in vitro assay. Ethyl lactate lacks skin sensitising potential in tests including a guideline LLNA.

Ethyl lactate and its L-isomer are of low acute systemic toxicity in laboratory animals by the inhalation, oral and dermal routes of exposure. Neurotoxic and narcotic effects are a concern at high exposures. In rats inhaling ethyl-L-lactate vapour at concentrations of 2500 mg/m$^3$ for 6 hours/day, 5 days/week for 28 days, body weight gain, food consumption and absolute liver weight were decreased, and blood glucose level was increased, resulting in a systemic inhalation NOAEC of 600 mg/m$^3$. A local NOAEC of 200 mg/m$^3$ was determined by the same investigators.

No adverse systemic effects were seen a guideline combined repeated-dose toxicity and reproduction and developmental screening assay in which groups of rats were orally administered ethyl lactate at 75-600 mg/kg bw/day for up to about 60 days. However, reproductive and developmental effects were seen in the study at 75 mg/kg bw/day and above. No systemic or developmental effects were seen when pregnant rats were treated dermally for 6 hours/day with ethyl lactate at up to about 3600 mg/kg bw/day.

No evidence of genotoxic activity was seen in bacteria (Ames assays) or cultured mammalian cells. No in vivo genotoxicity or carcinogenicity data were identified.

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| JECFA | ALIPHATIC ACYCLIC DIOLS, TRIOLS, AND RELATED SUBSTANCES (JECFA Food Additives Series 48) (inchem.org) |
| FEMA | GRAS Substances (2001-3124)_0.pdf (femaflavor.org) |

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| EFSA | Flavouring Group Evaluation 64 (FGE.64): Consideration of aliphatic acyclic diols, triols, and related substances evaluated by JECFA (57th meeting) structurally related to aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids and esters containing an additional oxygenated functional group and lactones from chemical groups 9, 13 and 30 evaluated by EFSA in FGE.10Rev1 (EFSA, 2008ab) \| EFSA (europa.eu) |
| ECHA – REACH dossier | Registration Dossier - ECHA (europa.eu) |
| PUBCHEM | Ethyl lactate \| C5H10O3 - PubChem (nih.gov) |
| CIR | ahas.pdf (cir-safety.org) |
| OSHA | - |

## 3. Addictiveness and attractiveness

RIFM describes ethyl lactate and ethyl-L-lactate as fragrance ingredients. Scientists from the Dutch National Institute for Public Health and the Environment (RIVM) identified ethyl lactate as an ingredient added to at least 100 e-liquids of the European Common Entry Gate (EU-CEG) dataset and it was reported to be present in 3.6% of all e-liquids and within the flavour categories, nuts and dessert, it was present at average concentrations of 46.28 and 0.67 mg/10 mL, respectively, and, as such, might be assumed to increase the attractiveness of an ENDS product containing it.

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| SCENIHR | - |
| EMA | - |
| PUBMED | RIFM fragrance ingredient safety assessment, cinnamaldehyde, CAS Registry Number 104-55-2 - PubMed (nih.gov)<br><br>Comprehensive overview of common e-liquid ingredients and how they can be used to predict an e-liquid's flavour category - PubMed (nih.gov) |