Substance Information Document

Lactic acid

1. Substance identity

Name	Lactic acid
Synonyms	2-Hydroxypropionic Acid Ammonium Lactate Propanoic Acid, 2-Hydroxy-, (2S)- Sarcolactic Acid
IUPAC Name	2-hydroxypropanoic acid
CAS	50-21-5

2. Toxicological information

According to the ECHA registered dossier, there are no studies available for the assessment of the acute oral, inhalation and dermal toxicity for lactic acid. Therefore, data available from the suitable read-across substance L(+)-lactic acid was used to assess the acute toxicity via the standard routes of administration (oral, inhalation, dermal). In an acute oral toxicity study according to EPA OPP81-1, groups of young Albino rats (5/sex/dose) were given single oral doses of L(+)-lactic acid in water of 3162, 3548, 3981, 4467, 5012, 5623, 6310 mg/kg bw and were observed for 14 days. Mortality occurred after dosing mainly on day 0 or in the morning of day 1 in a dose-dependent manner. At the highest dose, no animal survived. The LD_{50} was determined to be 3543 mg/kg bw for females and 4936 mg/kg bw for males. In an acute inhalation toxicity study conducted according to OECD 403, groups of young adult F344 rats (5/sex/dose) were exposed by inhalation to L(+)-lactic acid at a concentration of approximately 7.94 mg/L for 4 hours. One female rat from the treated group died on day 9. All other animals survived until the end of the study. Based on these results, the LC_{50} of L(+)-lactic acid is greater than 7.94 mg/L. In an acute dermal toxicity study conducted according to EPA OPP 81-2, young adult New Zealand White rabbits (5/sex) were dermally exposed to L(+)-lactic acid for 24 hours via 10% of the body surface area at a dose of 2000 mg/kg bw. Animals were then observed for 14 days. All animals survived the 14-day duration of the study and gained body weight. No abnormal clinical signs were observed during the study. Severe erythema and oedema were observed at the test sites of all animals after removal on day 1. The dermal LD_{50} is >2000 mg/kg bw. Data from L(+)-lactic acid was also used to assess the skin and eye irritation potential of lactic acid. In accordance with the harmonized classification of the source substance L(+)-lactic acid, classification as Skin Corr. 1C, H314; Eye. Dam 1, H318 and supplementary labelling as EUH071 is also warranted for lactic acid. A similar read-across approach using L(+)-lactic acid indicates lactic acid is not a skin sensitizer. Based on the available data from the read-across analogue calcium lactate, lactic acid does not warrant classification for specific target organ toxicity in accordance with CLP Regulation 1272/2008. In addition, L(+)-lactic acid was tested negative in a bacterial reverse gene mutation test conducted according to OECD 471, in an in vitro chromosome aberration assay conducted according to OECD 473 and in a mammalian cell gene mutation assay conducted according to OECD 476 (nowadays OECD 490). In these studies, lactic acid showed no potential to induce any mutagenic or clastogenic effect.

JECFA	No safety concern: https://inchem.org/documents/jecfa/jecmono/v48je16.htm
FEMA	GRAS substance: https://www.femaflavor.org/flavor-library/lactic-acid
EFSA	No safety concern would arise for the consumer from the use of compounds belonging to Chemical Group 9 up to the highest safe level in feeding stuffs for all animal species. The FEEDAP Panel considers it prudent to treat all compounds under assessment as irritants to skin, eyes and respiratory tract, and as skin sensitizers: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2012.2928
ECHA – REACH dossier	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/5165
PUBCHEM	https://pubchem.ncbi.nlm.nih.gov/compound/Lactic-acid
CIR	https://www.cir-safety.org/sites/default/files/ahas.pdf
OSHA	-

3. Addictiveness and attractiveness

SCENIHR	Information has been found stating that lactic acid can offset the nicotine, however, no further details were given: https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_051.pdf
EMA	-
PUBMED	-