

Substance Information Document

Delta-dodecalactone

1. Substance identity

Name	Delta-dodecalactone
Synonyms	6-Heptyltetrahydro-2H-pyran-2-one 2H-Pyran-2-one delta-Dodecanolactone 5-Dodecanolide Dodecan-5-olide
IUPAC Name	6-heptyloxan-2-one
CAS	713-95-1

2. Toxicological information

Daily pro-capita intake of delta-dodecalactone in US and Europe are 1.14 and 6.8 mg/person, respectively (JECFA).

Data from an OECD 404 study on rabbits showed that delta-dodecalactone was not irritant to the skin. An OECD 405 study in rabbits showed no eye irritation. Skin sensitization was tested on 30 volunteers treated with delta-dodecalactone in 12% petrolatum, showing no adverse effects (ECHA Reach dossier).

The acute oral toxicity dose (LD₅₀) was considered based on different studies conducted on rats. The studies concluded that the LD₅₀ value is >2000 mg/kg bw, for acute oral toxicity. Acute dermal toxicity studies in rabbits showed an LD₅₀ value is >2000 mg/kg bw. Thus, delta-dodecalactone is not classified for acute oral and dermal toxicity (ECHA Reach dossier).

There are no repeated-dose substance-specific toxicity data on delta-dodecalactone. Read-across material delta-decalactone (CAS # 705-86-2) has sufficient data to support the repeated dose toxicity endpoint. The oral NOAEL was established from a rat study administering delta-decalactone for 28 days; it corresponded to 1000 mg/kg bw/day (highest dose tested). Safety factor 3 was applied (used when deriving a NOAEL from an OECD 407 study), giving a final NOAEL of 333 mg/kg bw/day. Another study with delta-decalactone was used to infer reproductive and developmental toxicity, giving a NOAEL of 1000 mg/kg bw/day (highest dose). No repeated-dose inhalation studies are available (ECHA Reach dossier, RIFM).

The local respiratory toxicity endpoint was evaluated using the Threshold of Toxicological Concern (TTC) for a Cramer Class I material; exposure is below the TTC (1.4 mg/day) (RIFM).

No substance-specific data were identified for genotoxicity, however, data from read-across analog hydroxynonanoic acid, delta-lactone (CAS # 3301-94-8) show that delta-dodecalactone is not expected to be genotoxic from the Ames test (ECHA Reach Dossier). No carcinogenicity data are available.

JECFA	908. Aliphatic lactones (WHO Food Additives Series 40) (inchem.org)
FEMA	DELTA-DODECALACTONE FEMA (femaflavor.org)
EFSA	Scientific Opinion on the safety and efficacy of primary aliphatic saturated or unsaturated alcohols/aldehydes/acids/acetals/esters with a second primary, secondary or tertiary oxygenated functional group including aliphatic lactones (chemical group 9) when used as flavourings for all animal species (wiley.com)
ECHA – REACH dossier	Registration Dossier - ECHA (europa.eu)
PUBCHEM	delta-Dodecalactone C12H22O2 - PubChem (nih.gov)
CIR	-
OSHA	-

3. Addictiveness and attractiveness

No substance-specific data were identified.

SCENIHR	-
EMA	-
PUBMED	-