Substance Information Document

Gamma-nonalactone

1. Substance identity

Name	Gamma-nonalactone
Synonyms	1,4-Nonalolide; 1,4-Nonyl lactone; 2(3H)-Furanone, dihydro-5-pentyl-; 4-Amyl-4-hydroxybutyric acid lactone
IUPAC Name	5-pentyloxolan-2-one
CAS	104-61-0

2. Toxicological information

Gamma-nonalactone is considered of low acute dermal (in rabbits) and oral (in rats) toxicity with LD_{50} values estimated at greater than 5000 mg/kg bw and 6600 mg/kg bw, respectively. Gamma-nonalactone is considered as not skin (OECD 439) nor eye (OECD 405) irritant.

No substance specific data for sensitization was identified. However, based on read-across data obtained with gamma-caprolactone and gamma-undecalactone, gamma-nonalactone is not considered to be a skin sensitizer. This absence of sensitising potential is also confirmed by two human maximisation tests, in which gamma-nonalactone (unknown %) was applied to a panel of 25 male and female human healthy volunteers.

Based on *in vitro* mutagenicity tests conducted in bacterial strains and mammalian cells and *in vivo* study (micronucleus), gamma-nonalactone is considered as non-mutagenic, non-clastogenic and non-aneugenic.

No substance specific data for repeated-dose toxicity was identified. However, based on read-across data obtained with gamma-caprolactone, under the test conditions, the NOEL was considered to be 300 mg/kg bw/day and the NOAEL to be 1000 mg/kg bw/day.

In a carcinogenic study, gamma-nonalactone was administered via subcutaneous injections to mice. Under the test conditions, there was no evidence of carcinogenic activity of gamma-nonalactone was observed.

No developmental toxicity study was located on gamma-nonalactone while a reliable study is available on gamma-caprolactone, considered adequate for read-across purpose. Hence, in a developmental toxicity study conducted according to the OECD guideline No. 414 and in compliance with GLP, the dose level of 1000 mg/kg bw/day was considered to be the NOAEL for both maternal toxicity and developmental toxicity.

JECFA	908. Aliphatic lactones (WHO Food Additives Series 40) (inchem.org) No safety concern at current levels of intake when used as a flavouring agent.

	The 1967 ADI of 0-1.25 mg/kg bw was maintained at the forty-ninth meeting (1997).
FEMA	Adams et al, 1998_cleaned.pdf (femaflavor.org)
EFSA	-
ECHA – REACH dossier	Registration Dossier - ECHA (europa.eu)
PUBCHEM	Gamma-nonalactone | C9H16O2 - PubChem (nih.gov)
CIR	-
OSHA	-

3. Addictiveness and attractiveness

No substance specific data were identified.

SCENIHR	-
EMA	-
PUBMED	RIFM fragrance ingredient safety assessment, γ-nonalactone, CAS Registry Number 104-61-0 (elsevier.com)