

Substance Information Document

Ethyl butyrate**1. Substance identity**

Name	Ethyl butyrate
Synonyms	Ethyl butanoate Butyric acid ethyl ester Butanoic acid, ethyl ester
IUPAC Name	ethyl butanoate
CAS	105-54-4

2. Toxicological information

Local effects – Ethyl butyrate is considered a mucous membrane irritant in humans. Other local effects including cytotoxicity is not observed.

Sensitization and Intolerance – Substance-specific data are not identified regarding respiratory tract sensitization and oral allergy/intolerance. For skin sensitization, in humans, sensitization reactions were not produced when ethyl butyrate was administered at 5% in petrolatum; in Guinea pigs, sensitization reaction were not produced when tested at a concentration of up to 5%.

Acute toxicity – Substance-specific data are not identified regarding acute inhalation toxicity. For oral acute toxicity, substance specific data are not identified in human; however, an oral LD₅₀ of 13,050 mg/kg BW (rats) and 5200 mg/kg BW (rabbits) were reported. Moreover, an ND₅₀ of 3020 mg/kg BW (rabbits) was reported, causing disappearance of corneal reflexes, nystagmus, shortness of breath and decreased heart rate. Dermal acute toxicity was not reported in humans, but a dermal LD₅₀ in rabbits was detected at more than 2000 mg/kg BW.

Repeat-dose toxicity – Substance-specific data are not identified for inhalation, dermal, and oral. However, an acceptable daily intake was derived from a rat study provided with ethyl butyrate containing diet (14.4 mg/kg BW/day) for 12 weeks, in which adverse effects were not detected.

Genotoxicity – Ethyl butyrate is considered non mutagenic.

Carcinogenicity – Substance-specific data are not identified.

Reproductive and Developmental Toxicity – Substance-specific data are not identified.

JECFA	WHO JECFA
FEMA	3. GRAS Substances(2001-3124)_0.pdf (femaflavor.org)
EFSA	Scientific Opinion on the safety and efficacy of straight-chain primary aliphatic alcohols/aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing

	saturated aldehydes (chemical group 1) when used as flavourings for all animal species - - 2013 - EFSA Journal - Wiley Online Library
ECHA – REACH dossier	Substance Information - ECHA (europa.eu)
PUBCHEM	Ethyl butyrate C6H12O2 - PubChem (nih.gov)
CIR	-
OSHA	-

3. Addictiveness and attractiveness

No substance-specific data were identified.

SCENIHR	-
EMA	-
PUBMED	-