Substance Information Document

Butan-1-ol

1. Substance identity

Name	Butan-1-ol
Synonyms	1-Butanol Butyl alcohol Butanol
IUPAC Name	butan-1-ol
CAS	71-36-3

2. Toxicological information

Butan-1-ol is a flavoring agent, which belongs to the saturated aliphatic acyclic linear primary alcohols, aldehydes and acids of chain length C1-18 that has been evaluated by JECFA. Linear alcohols like butan-1-ol can be absorbed through the gastrointestinal tract and is metabolized via fatty acid and tricarboxylic acid pathways.

Butan-1-ol has low acute toxicity. Several studies are available for the oral acute toxicity end point. Based on one study that was conducted similarly to OECD TG 401, the oral LD50 has been set at 2290 mg/kg bw in rats. Butan-1-ol has a harmonized GHS classification of H302, which is the category 4 of acute oral toxicity. Acute inhalation studies are available as well. Based on one study that is similar to OECD TG 403, the LC50 value is higher than 17.76 mg/L air in rat. One acute dermal study is available in rabbits. The study is similar to OECD TG 402. LD50 is 3430 mg/kg bw after correction.

Several irritation studies are available for butan-1-ol on skin and eye. Based on those studies, butan-1-ol is irritating to both skin and eye. Harmonized GHS classifications were granted for this chemical as H315, skin irritation category 2, and H318, eye irritation category 1. Those classifications are further supported by observations in human studies that butan-1-ol causes irritation to both eye and skin. There are also human data indicating that inhalation of butan-1-ol can cause local irritation of the respiratory tract. The skin sensitizing potential of butan-1-ol has been evaluated in a LLNA study. The results indicated that butan-1-ol does not have a sensitizing effect on the skin under the test conditions. In addition, in vitro data also showed that butan-1-ol is not peptide reactive and shows no activation of keratinocytes or dendritic cells.

Repeated dose toxicity studies exist for oral, inhalation, and dermal exposure routes. In a 90-day repeated dose oral toxicity study conducted in rats by US EPA, 125 mg/kg bw/day was identified as the NOEL value. At the dose of 500 mg/kg bw/day, transient clinical signs of CNS depression (ataxia and hypoactivity) were observed as typically observed for alcohols. For inhalation, two 90-day studies are available in rats. Both studies indicated a NOEL of 500 ppm (correspond to 1.5 mg/L). At 1500 ppm, decreased body weight and feed consumption were noted, but there was no systemic or organ-specific toxicity. Degeneration of the olfactory epithelium was observed in areas of the nasal cavity that have demonstrated carboxylesterase activity, but there was no evidence of pulmonary toxicity. One dermal repeated dose toxicity is available in rabbits. No systemic toxicity was observed, only drying of the skin.

For genotoxicity, several in vitro gene mutation studies in bacteria (Ames) and in mammalian cells are available. There are also in vitro studies on cytogenicity in mammalian cells. All results were negative. No carcinogenicity study is available for butan-1-ol, but there is no evidence for a carcinogenic potential either.

Reproductive and developmental effects of butan-1-ol have been extensively studied via both the oral and inhalation routes in rats. The oral NOAEL maternal toxicity including fertility has been demonstrated as 5000 mg/kg bw/day. The inhalation NOAEC parental including fertility is 18.5 mg/L. Therefore, based on those results, together with read across data from n-butyl acetate (CAS no. 123-86-4), butan-1-ol is not considered as a reproductive toxicant.

JECFA	906. Saturated aliphatic acyclic linear primary alcohols, aldehydes and acids (WHO Food Additives Series 40) (inchem.org)
FEMA	BUTYL ALCOHOL | FEMA (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	Registration Dossier - ECHA (europa.eu)
PUBCHEM	1-Butanol | C4H9OH - PubChem (nih.gov)
CIR	Final Report of the Addendum to the Safety Assessment of n-Butyl Alcohol as Used in Cosmetics (personalcarecouncil.org) Unknown (personalcarecouncil.org)
OSHA	N-BUTYL ALCOHOL (N-BUTANOL) | Occupational Safety and Health Administration (osha.gov)

3. Addictiveness and attractiveness

No substance specific data were identified.

SCENIHR	-
EMA	-
PUBMED	-