

## Isobutyl alcohol; CASRN 78-83-1

Human health assessment information on a chemical substance is included in the IRIS database only after a comprehensive review of toxicity data, as outlined in the [IRIS assessment development process](#). Sections I (Health Hazard Assessments for Noncarcinogenic Effects) and II (Carcinogenicity Assessment for Lifetime Exposure) present the conclusions that were reached during the assessment development process. Supporting information and explanations of the methods used to derive the values given in IRIS are provided in the [guidance documents located on the IRIS website](#).

### STATUS OF DATA FOR Isobutyl alcohol

**File First On-Line 03/31/1987**

Category (section)	Assessment Available?	Last Revised
<b>Oral RfD (I.A.)</b>	yes	03/31/1987
<b>Inhalation RfC (I.B.)</b>	not evaluated	
<b>Carcinogenicity Assessment (II.)</b>	not evaluated	

## I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

### I.A. Reference Dose for Chronic Oral Exposure (RfD)

Substance Name — Isobutyl alcohol

CASRN — 78-83-1

Last Revised — 03/31/1987

The oral Reference Dose (RfD) is based on the assumption that thresholds exist for certain toxic effects such as cellular necrosis. It is expressed in units of mg/kg-day. In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Please refer to the Background Document for an elaboration of these concepts. RfDs can also be derived for the noncarcinogenic health effects of substances that are also carcinogens. Therefore, it is essential to refer to other sources of

information concerning the carcinogenicity of this substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

### I.A.1. Oral RfD Summary

Critical Effect	Experimental Doses*	UF	MF	RfD
<b>Hypoactivity and ataxia</b>	NOEL: 316 mg/kg/day LOAEL: 1000 mg/kg/day	1000	1	3E-1 mg/kg/day
<b>Rat Oral Subchronic Study</b>				
<b>U.S. EPA, 1986</b>				

\*Conversion Factors: none

### I.A.2. Principal and Supporting Studies (Oral RfD)

U.S. EPA. 1986. Rat oral subchronic toxicity study with isobutyl alcohol. Office of Solid Waste, Washington, DC.

Animal toxicity studies indicate that butyl alcohol may produce liver/ kidney effects and decreased red blood cell numbers. Using pathways similar to buty alcohol, isobutyl alcohol is metabolized to its aldehydes and further catabolized to carbon dioxide and water (Cornish, 1980).

To evaluate the toxicity of isobutyl alcohol, U.S. EPA (1986) conducted a subchronic study in rats (30/sex/group). Animals were given oral doses of 0, 100, 316, and 1000 mg/kg/day of isobutyl alcohol for 13 weeks. This study contained data on body weight changes, food consumption, ophthalmologic examinations, clinical and biochemical parameters, and gross and microscopic examinations. An evaluation of the data revealed no effect on body weight or clinical and histopathologic parameters at doses less than or equal to 316 mg/kg/day. Treatment at the high dose (1000 mg/kg/day) resulted in a minor decrease in body weight gain during week 2 and decreased serum potassium levels and hypoactivity. Hypoactivity was the most frequently observed clinical sign. It occurred in every rat in the 1000-mg/kg/day dose group during week 1; hypoactivity was markedly decreased by week 4 and occurred only sporadically thereafter.

Ataxia was also seen at low incidence in the 1000- mg/kg/day dose group throughout the study. The NOEL for this study is 316 mg/kg/day.

### **I.A.3. Uncertainty and Modifying Factors (Oral RfD)**

UF — An uncertainty factor of 1000 was applied: 10 for interspecies extrapolation, 10 for intraspecies variability and 10 for extrapolating subchronic exposure to chronic exposure.

MF — None

### **I.A.4. Additional Studies/Comments (Oral RfD)**

No adequate chronic toxicity studies have been conducted on isobutyl alcohol. Of the two other published subchronic (2- or 4-month) oral studies (Hillbom et al., 1974a,b), one was available only as an abstract (1974a) and contained insufficient information upon which to evaluate the adequacy of experimental design, etc. The second Hillbom et al. (1974b) study examined the effects of isobutanol only at a single concentration (1M), which could be considered a LOAEL for gastrointestinal damage for isobutanol. However, this study is not of appropriate design for risk assessment purposes, and histopathological examination of stomach, small and large intestine in the much more detailed and experimentally sound 1986 EPA study failed to reproduce the gastrointestinal effects reported by Hillbom et al. (1974b) at dosages five to six orders of magnitude greater than those used by Hillbom et al. (1974b). Isobutyl alcohol has not been scheduled for NTP testing for chronic toxicity, carcinogenicity, or other reproductive effects.

### **I.A.5. Confidence in the Oral RfD**

Study — Medium

Database — Low

RfD — Low

The oral subchronic study is a well-designed study which employed several dose levels and measured adequate toxicologic endpoints; thus, a medium to high confidence is recommended. The database lacks adequate supporting or chronic toxicity and reproduction studies; thus, low confidence is recommended. Low confidence in the RfD follows.

### **I.A.6. EPA Documentation and Review of the Oral RfD**

Source Document — This assessment is not presented in any existing U.S. EPA document.

Other EPA Documentation — U.S. EPA, 1986

Agency Work Group Review — 05/14/1986

Verification Date — 05/14/1986

Screening-Level Literature Review Findings — A screening-level review conducted by an EPA contractor of the more recent toxicology literature pertinent to the RfD for Isobutyl alcohol conducted in September 2002 identified one or more significant new studies. IRIS users may request the references for those studies from the IRIS Hotline at [hotline.iris@epa.gov](mailto:hotline.iris@epa.gov) or (202)566-1676.

### **I.A.7. EPA Contacts (Oral RfD)**

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in general, at (202)566-1676 (phone), (202)566-1749 (FAX) or [hotline.iris@epa.gov](mailto:hotline.iris@epa.gov) (internet address).

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### **I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)**

Substance Name — Isobutyl alcohol

CASRN — 78-83-1

Not available at this time.

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## **II. Carcinogenicity Assessment for Lifetime Exposure**

Substance Name — Isobutyl alcohol

CASRN — 78-83-1

This substance/agent has not undergone a complete evaluation and determination under US EPA's IRIS program for evidence of human carcinogenic potential.

**III. [reserved]**

**IV. [reserved]**

**V. [reserved]**

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## **VI. Bibliography**

Substance Name — Isobutyl alcohol

CASRN — 78-83-1

### **VI.A. Oral RfD References**

Cornish, H.H. 1980. Solvents and vapors. In: Casarett and Doull's Toxicology, The Basic Science of Poisons, 2nd. ed., J. Doull, C.D. Klaassen and M.O. Amdur, Ed. MacMillan Publishing Co., Inc., New York. p. 480-481.

Hillbom, M.E., K. Franssila and O.A. Forsander. 1974a. Effects of chronic ingestion of some lower aliphatic alcohols in rats. *Arukow Kenkyu*. 9(2): 101-108. (Abstract)

Hillbom, M.E., K. Franssila and O.A. Forsander. 1974b. Effects of chronic ingestion of some lower aliphatic alcohols in rats. *Res. Commun. Chem. Pathol. Pharmacol*. 9(1): 177-180.

U.S. EPA. 1986. Rat oral subchronic toxicity study with isobutyl alcohol. Office of Solid Waste, Washington, DC.

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### **VI.B. Inhalation RfC References**

None

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### **VI.C. Carcinogenicity Assessment References**

None

## VII. Revision History

Substance Name — Isobutyl alcohol

CASRN — 78-83-1

Date	Section	Description
12/03/2002	I.A.6.	Screening-Level Literature Review Findings message has been added.

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## VIII. Synonyms

Substance Name — Isobutyl alcohol

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Last Revised — 03/31/1987

- 78-83-1
- ALCOOL ISOBUTYLIQUE
- FERMENTATION BUTYL ALCOHOL
- 1-HYDROXYMETHYLPROPANE
- ISOBUTANOL
- Isobutyl Alcohol
- ISOBUTYLALKOHOL
- ISOPROPYLCARBINOL
- 2-METHYL PROPANOL
- 2-METHYL-1-PROPANOL
- 2-METHYLPROPYL ALCOHOL
- 1-PROPANOL, 2-METHYL-
- RCRA WASTE NUMBER U140
- UN 1212