1-Propanol, 2-methyl-: Human health tier II assessment

22 November 2013

CAS Number: 78-83-1

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

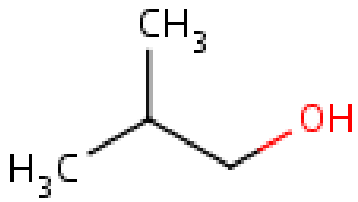
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:www.nicnas.gov.au

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	Isobutanol Isobutyl alcohol 2-Methyl propanol Isopropylcarbinol 1-Hydroxymethylpropane
Structural Formula	
Molecular Formula	C4H10O
Molecular Weight (g/mol)	74.12
Appearance and Odour (where available)	Colourless oily liquid with a sweet musty odour
SMILES	C(C)(C)CO

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information.

The chemical has reported domestic use including as:

- an additive; and
- cleaning/washing agent.

The chemical has reported commercial use as a solvent.

The total volume introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was between 100 and 1000 tonnes.

International

The following international uses have been identified through European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR); Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and eChemPortal: OECD High Production Volume chemical program (OECD HPV); US Household Products Database; and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical is included in CosIng database and US Personal Care Products Council INCI directory with the identified functions of perfuming. However, there is currently no documented use of the chemical in cosmetic products in the United States (Personal Care Products Council 2011).

The chemical has reported domestic use including in:

- adhesives (binding agents);
- aerosol propellants;
- colouring agents;
- cleaning/washing agents;
- fillers;
- corrosion inhibitors;
- paints, lacquers and varnishes;
- odour agents; and
- surface-active agents, and also in surface treatment.

The chemical has reported domestic use in the SPIN database. However, it should be noted that SPIN does not distinguish between direct use of the chemical or using the materials that are produced from its chemical reactions. The US Household Products Database states a concentration of >1 % (liquid & aerosol) for use in arts and crafts, a concentration of up to 4 % for home maintenance use (aerosol), and a concentration of up to 2 % (liquid) for use as auto products.

The chemical has reported commercial use including:

- as a solvent (major use) for surface coatings and adhesives, and for lacquers, paint strippers, perfumes, cleaners and hydraulic fluid;
- in anti-freezing and anti-adhesive agents;
- in construction materials;
- in dust binding and fixing agents;
- in fuels & fuel additives;
- in lubricants and additives;
- in impregnation materials;
- in process regulators, softeners and viscosity adjustors;
- in reprographic and flotation agents;
- in photo chemicals;
- in tanning agents; and
- as anti-static agents.

The chemical has reported site-limited use including;

- as a chemical intermediate (major use) to produce zinc dialkyldithiophosphates, which are antiwear and corrosion inhibitor additives for lube oils, greases and hydraulic fluids;
- also as a chemical intermediate (major use) for conversion to isobutyl acetate, isobutylamines, acrylate and methacrylate esters, plasticisers, diisobutyl phthalate, textile chemicals and foundry resin binders;
- as laboratory chemicals; and
- as a stabiliser.

The chemical has reported non-industrial use including:

- in non-agricultural pesticides and preservatives;
- as a processing solvent (major use) for agricultural pesticides, food/foodstuff flavourings, and nutrients; and
- as a processing solvent for pharmaceutical products.

Restrictions

Australian

No known restrictions have been identified.

International

No known restrictions have been identified.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is classified as hazardous, with the following risk phrases, for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

Xi; R37/38-41 (Irritation)

R67 (Vapours may cause drowsiness and dizziness)

Exposure Standards

Australian

The chemical has an exposure standard of 152 mg/m³ (50 ppm) time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit (TWA) of 150–154 mg/m³ (50 ppm) in countries such as Canada, Denmark, Spain, Switzerland, United Kingdom, and the USA.

An exposure limit (STEL) of 225–250 mg/m³ (75 ppm) in countries such as Canada, Ireland, Sweden, United Kingdom and the USA.

Health Hazard Information

Toxicokinetics

The chemical is absorbed through the skin, lungs and gastrointestinal tract. The chemical is first metabolised to isobutyraldehyde, primarily through alcohol dehydrogenase, then to isobutyric acid primarily via aldehyde dehydrogenase, and ultimately to carbon dioxide and water in rodents and humans. Isobutyric acid has been shown to be the major metabolite of the chemical in rats and humans (OECD, 2005; US EPA, 2005; REACH).

Acute Toxicity

Oral

The chemical is of low acute toxicity in animal tests following oral exposure. The median lethal dose (LD50) in rats is greater than 2000 mg/kg bw. Observed sub-lethal effects included sluggishness, unsteady gait, lacrimation, piloerection, slow breathing, and prostration. Traces to large amounts of blood were also found in the urine (OECD, 2005; HSDB; REACH).

Dermal

The chemical is of low acute toxicity in animal tests following dermal exposure. The median lethal dose (LD50) in rabbits is greater than 2000 mg/kg bw. Observed sub-lethal effects included sluggishness, prostration, laboured breathing and red eyes, and erythema and necrosis at the site of application. Skin lesions were still apparent 14 days after application (OECD, 2005; HSDB; REACH).

Inhalation

Although the chemical is of low acute toxicity in animal tests following inhalation exposure (median lethal concentration—LC50 >24 mg/L/4 hr in rats), the chemical is classified with the risk phrase ‘Vapours may cause drowsiness and dizziness (R67)’ in Australia (Safe Work Australia—HSIS). The available data in animals support this classification (OECD, 2005; US EPA, 2005; HSDB; REACH).

In a poorly described acute inhalation toxicity study, an LC50 value of >8000 ppm (24 mg/L/4 hr) was determined in Sherman rats. Two out of six animals died at this dose during the 14 day post exposure period (OECD, 2005; US EPA, 2005; HSDB). An LC50 value of 19.2 mg/L/4 hr has also been reported in rats (strain not specified). Decreased activity in the central nervous system was noted (OECD, 2005; REACH).

In another acute inhalation toxicity study, male and female Sprague Dawley (SD) rats (10 animals/sex/dose) were exposed (whole body) to vapours of the chemical at 0, 1500, 3000, or 6000 ppm (0, 4.54, 9.09, 18.18 mg/L) for six hours with a 14 day observation period. There was a clear evidence of a dose-dependent depression of the central nervous system—the most affected animals were in the 6000 ppm group. Animals in 3000 and 6000 ppm groups were non-responsive to tapping on the side of the inhalation chambers and also showed laboured respiration during the six hours of exposure. No mortalities or gross pathological lesions were observed. An LC50 value of >6000 ppm (>18.18 mg/L/6 hr) was reported (OECD, 2005; REACH).

In another acute inhalation toxicity study, five male and female SD rats were exposed to a statically-generated, substantially saturated vapour of the chemical for six hours. There were no deaths during the study. Clinical signs during exposure were hypoactivity, lacrimation, prostration, narcosis, negative reflexes (surface righting, toe and tail pinch), and abnormal breathing (short, shallow breaths). All signs of toxicity disappeared by 24 hours following expsoure (OECD, 2005; REACH). Even though the analytical concentration of the chemical was not provided in the original report, based on other acute neurotoxicity studies, it was concluded that a concentration of 6000 ppm (18 mg/L) was attainable in this situation (REACH).

Corrosion / Irritation

Respiratory Irritation

The chemical is classified in Australia as hazardous with the risk phrase ‘Irritating to respiratory system’ (Xi; R37) in HSIS (Safe Work Australia). The available data from observations in animals support this classification. Irritation of the airways has been observed during acute inhalation toxicity studies in rats and rabbit (OECD, 2005; WHO, 1987).

Skin Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in HSIS (Safe Work Australia). The available data support this classification (OECD, 2005; US EPA, 2005; REACH).

In a skin irritation study conducted in accordance with OECD Test Guideline (TG) 404, the chemical (0.5 mL) was applied to rabbit skin (occluded) for four hours. Minor to moderate erythema and oedema was noted in all six rabbits within 24 hours following exposure. While erythema and oedema subsided in five out of six rabbits by day 14 following exposure, minor erythema and oedema still persisted in one rabbit. Superficial necrosis was noted in one animal at day one and in the second animal at day seven following exposure. Fissuring and desquamation were noted in one and four out of six animals, respectively, by day seven. Alopecia was observed in two out of six rabbits by day 14. Only two rabbits had a normal appearance at day 14 following exposure; minor irritation still persisted in the remaining four rabbits at this time interval. The chemical was considered to be a minor to moderate skin irritant in this study (OECD, 2005; REACH).

Eye Irritation

The chemical is classified as hazardous with the risk phrase 'Risk of serious damage to eyes' (Xi; R41) in HSIS (Safe Work Australia). The available data support this classification (OECD, 2005; REACH).

In an eye irritation study (OECD TG 405), 0.1 mL of the chemical was applied to the conjunctival sac of one eye of one male and one female New Zealand White rabbit. Minor to moderate corneal injury and iritis, and severe conjunctival irritation were observed in both rabbits. Both rabbits had also had haemorrhages of the nictitating membrane (third eyelid) at 24 hours following exposure. Purulent ocular discharge was evident in one rabbit. Corneal vascularisation was noted in one rabbit by day seven following exposure. Minor conjunctival redness still persisted at day 21 following exposure in both rabbits. As a result of severe ocular irritancy observed from a dose of 0.1 mL of the chemical, an additional four rabbits (two males, two females) were dosed with 0.01 mL and observed up to 14 days following exposure. Iritis and moderate to severe conjunctival irritation were noted in all rabbits. Minor corneal injury was apparent in only two rabbits. Haemorrhages of the nictitating membrane and/or sclera (white of the eye) developed in two rabbits at 48 and 72 hours following exposure. In all four rabbits, the eyes had returned to a normal appearance by day 14. Therefore the chemical was considered to be a severe eye irritant (OECD, 2005; REACH).

Other eye irritation studies (OECD TG 405) have also been reported where 0.1 mL of the chemical was applied to eyes of New Zealand White rabbits. The chemical produced irreversible effects on the eye and was classified as a Category 1 irritant (REACH).

Sensitisation

Skin Sensitisation

No data are available. The chemical does not contain a structural alert for skin sensitisation (OECD Toolbox).

Repeated Dose Toxicity

Oral

Based on the available information, the chemical is not considered to cause serious damage to human health from repeated oral exposure. Hypoactivity and ataxia were the most common clinical signs observed following high oral doses of the chemical (OECD, 2005; US EPA, 2005; REACH).

In a repeated dose toxicity study, groups of CD rats were dosed (gavage) with the chemical at 0, 100, 316, or 1000 mg/kg bw/day for 90 days. Although there were no treatment-related clinical signs in the 100 or 316 mg/kg bw/day dose groups, clinical signs were noted in the 1000 mg/kg bw/day dose group. These included hypoactivity, ataxia, salivation, laboured respiration, rales, prostration, hypothermia, and emaciation. Hypoactivity and ataxia were the most common clinical signs and these were resolved primarily after week four of the study. A no observed adverse effect level (NOAEL) of 316 mg/kg bw/day was determined for this study, based on observed clinical signs at the highest tested dose of 1000 mg/kg bw/day (OECD, 2005; US EPA, 2005; REACH).

In another repeated dose toxicity study (OECD TG 408), Wistar rats were administered the chemical in drinking water at doses of 0, 1000, 4000, or 16000 ppm (approx. 80, 340, or 1450 mg/kg bw/day) for 90 days. The mean daily intake of the chemical was determined to be 0, 75, 300, 1251 mg/kg for the male rats and 0, 91, 385, 1657 mg/kg for the female rats consuming 0, 1000, 4000, or 16,000 ppm of the chemical in the drinking water. A NOAEL of 16000 ppm (highest tested dose) was established for this study, based on no treatment-related effects observed at this dose (OECD, 2005; US EPA, 2005; REACH).

Dermal

No data are available.

Inhalation

In a 13-week repeated dose inhalation toxicity study in male and female SD rats, the no observed adverse effect concentration (NOAEC) for the chemical was reported to be 3030 mg/m³.

In a repeated dose toxicity study, SD rats were administered the chemical by inhalation, six hours/day for five days/week, for 13 weeks, at doses of 0, 250, 1000, and 2500 ppm (approx. 0.75, 3.0, 7.5 mg/L). Although a slight reduction in responsiveness to external stimuli was observed in all treated groups during exposure, there was no difference from the control group animals with respect to responsiveness during non-exposure periods. Therefore, transient effects from acute exposure to the chemical have probably resulted in slightly decreased responsiveness. A systemic NOAEC of 1000 ppm was established in this study, based on slight (but statistically significant) increased red blood cell counts, haematocrit, and haemoglobin parameters in the 2500 ppm female rats when compared with the control female rats (OECD, 2005; US EPA, 2005; REACH).

Genotoxicity

The chemical is not expected to be genotoxic.

The chemical tested negative in several in vitro tests (Ames assays; an *Escherichia coli* WP2 uvrA bacterial gene mutation assay; mouse lymphoma assay using L5178Y cells; gene mutation assay in *Saccharomyces cerevisiae*; a Comet assay, a micronucleus assay, and a HPRT-gene mutation assay-all using V79 Chinese hamster fibroblasts; and also a Comet assay with human lung carcinoma epithelial A549 cells and human peripheral blood cells). The in vivo test was also negative (mouse micronucleus test in NMRI mice at doses up to 2000 mg/kg bw) for gene mutation and clastogenicity (OECD, 2005; REACH).

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

Results of reproductive and developmental toxicity studies conducted in animals indicate that the chemical does not show specific reproductive or developmental toxicity.

In a two-generation reproductive toxicity study (US EPA Guideline OPPTS 870.3800), SD male and female rats were exposed to the chemical daily by inhalation for six hours/day at doses of 0, 500, 1000, or 2500 ppm (0, 1520, 3030, or 7580 mg/m³) for two generations. As there was no evidence of parental systemic, reproductive, or neonatal toxicity at the highest tested dose (2500 ppm), a NOAEL of 2500 ppm was chosen for parental and offspring toxicity. It was also concluded that the chemical did not affect testicular function in these animals up to the highest tested dose (OECD, 2005; REACH).

In a developmental toxicity study, pregnant Wistar rats were exposed to the chemical by inhalation for six hours/day on gestation days 6–15 at doses of 0, 0.5, 2.5, or 10 mg/L (164, 820, and 3300 ppm). As no treatment related effects were observed either on the dams or the offspring, a maternal and developmental NOAEL of 10 mg/L was determined.

In a similar developmental toxicity study, pregnant Himalayan rabbits were exposed to the chemical by inhalation for six hours/day on gestation days 7–19 at doses of 0, 0.5, 2.5, or 10 mg/L. The NOAEL for maternal toxicity was determined to be 2.5 mg/L, based on slight decreases in body weight gain in rabbits at the highest dose group. As there was no evidence of developmental toxicity during the study, the NOAEL for developmental toxicity was established as 10 mg/L, the highest tested dose (OECD, 2005; REACH).

Other Health Effects

Neurotoxicity

In a repeated dose neurotoxicity toxicity study, groups of CD rats were dosed (gavage) with the chemical at 0, 100, 316, or 1000 mg/kg bw/day for 90 days (see **Repeat dose toxicity**: **oral**). Clinical signs were noted in the 1000 mg/kg bw/day dose group including hypoactivity, ataxia, salivation, laboured respiration, rales, prostration, hypothermia, and emaciation. A NOAEL of 316 mg/kg bw/day was determined for neurotoxicity in this study, based on hypoactivity and ataxia observed at the highest tested dose of 1000 mg/kg bw/day (OECD, 2005; US EPA, 2005; REACH).

In a repeated dose neurotoxicity study, SD rats were administered the chemical by inhalation, six hours/day for five days/week, for 13 weeks, at doses of 0, 250, 1000, and 2500 ppm (approx. 0.75, 3.0, 7.5 mg/L) (see **Repeat dose toxicity: inhalation**). No treatment-related effects were noted during the functional observational battery (FOB) examinations. Although a slight reduction in responsiveness to external stimuli was observed in all treated groups during exposure, there was no difference from the control group animals with respect to responsiveness during non-exposure periods. Therefore, transient effects from acute exposure to the chemical have probably resulted in slightly decreased responsiveness. A NOAEC of 2500 ppm (highest tested dose) has been determined for neurotoxicity in this study (OECD, 2005; US EPA, 2005; REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local effects (serious damage to the eyes and respiratory irritation). The chemical also possesses hazardous properties such as skin irritation and intoxication symptoms following inhalation of high concentrations of vapour.

Public Risk Characterisation

The chemical has reported domestic use in Australia. The general public may be exposed to the chemical through dermal, ocular and inhalation routes when using domestic products containing the chemical.

Based on the available use information (see **Import, manufacture and use)**, the concentration in these products is not considered to be sufficiently high to cause any significant human health effects.

Based on information on use of the chemical in cosmetics internationally (see **International uses**) significant use of the chemical in cosmetics is not anticipated in Australia and therefore the risk to public health is not considered to be unreasonable.

Overall, the risk to public health is not considered to be unreasonable and further risk management is not considered necessary for public safety.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. Worker exposure to the chemical at lower concentrations may also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical health effects, the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemical are implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine appropriate controls.

Based on the available data, the hazard classification in HSIS is considered appropriate.

NICNAS Recommendation

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory. No further assessment is required.

Regulatory Control

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical hazards and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Vapours may cause drowsiness and dizziness (R67)*	May cause drowsiness or dizziness - Specific target organ tox, single exp Cat. 3 (H336)
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41)* Irritating to skin (Xi; R38)* Irritating to respiratory system (Xi; R37)*	Causes serious eye damage - Cat. 1 (H318) Causes skin irritation - Cat. 2 (H315) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)

[a] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

[*] Existing Hazard Classification. No change recommended to this classification

Advice for consumers

Products containing the chemical should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular, and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- air monitoring to ensure control measures in place are working effectively and continue to do so;

- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals— Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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