1-Butanol, 2-amino-: Human health tier II assessment

21 April 2016

CAS Number: 96-20-8

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	2-aminobutanol 2-amino-1-butanol 1-(hydroxymethyl)propylamine 1-hydroxy-2-butylamine
Structural Formula	 Structural formula of 1-Butanol, 2-amino-
Molecular Formula	C4H11NO
Molecular Weight (g/mol)	89.14
Appearance and Odour (where available)	Colourless to yellow liquid with an ammonia odour.
SMILES	C(N)(CC)CO

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified for the chemical.

International

The following international uses have been identified through:

- the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers;
- Galleria Chemica;

- the Substances and Preparations in Nordic countries (SPIN) database;
- the European Commission Cosmetic Ingredients and Substances (CosIng) database;
- the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary;
- the OECD High Production Volume chemical program (OECD HPV);
- the US Environmental Protection Agency Chemical and Product Categories (CPCat) database; and
- the US Environmental Protection Agency Aggregated Computer Toxicology Resource (ACToR).

The chemical has reported cosmetic use in personal care products as a buffering agent (pH adjuster).

The chemical has reported domestic use, including:

- in adhesives and binding agents; and
- in paints, lacquers and varnishes.

The chemical has reported commercial use, including:

- in cutting fluids (lubricants);
- in corrosion inhibitors;
- in surfactants;
- in the manufacture of metallic products (metal-working fluids);
- in photochemicals; and
- in fillers and other construction materials.

The chemical has reported site-limited use, including:

- in process regulators;
- in vulcanising accelerators;
- as an intermediate; and
- in the manufacture of mineral oils, waxes and polishes.

The chemical has reported non-industrial use in the manufacture of:

- pharmaceuticals; and
- non-agricultural pesticides and preservatives.

Restrictions

Australian

No known restrictions have been identified for the chemical.

International

The chemical is listed on the following (Galleria Chemica):

European Union (EU): Using the chemical in cosmetics in the European Union is subject to the restrictions described in EU Regulation Annex III (Ref. 61), which concerns monoalkylamines, monoalkanolamines and their salts: the chemical may be used in cosmetics and personal care products provided that the maximum secondary amine content does not exceed 0.5 % (CosIng).

In addition, the following restrictions apply to limit the formation of nitrosamines in cosmetic products:

- do not use with nitrosating systems;
- minimum purity 99 %;
- maximum nitrosamine content 50 µg/kg; and
- keep in nitrite-free containers.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Substances Information System (HSIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available for the chemical.

International

The following exposure standards are identified (Galleria Chemica).

An exposure limit of 3.7–15 mg/m^3 (1–5 ppm) time weighted average (TWA) and 7.4–15 mg/m^3 (2–5 ppm) short-term exposure limit (STEL)/MAK/occupational exposure limit (OEL) in different countries such as Denmark, Eygpt, Germany, Spain and Switzerland.

Health Hazard Information

The chemical, 2-amino-1-butanol (CAS No. 96-20-8), exists as a racemic (50:50) mixture of stereoisomers (enantiomers). The purified enantiomers, (S)-2-amino-1-butanol (CAS No. 5856-62-2) and (R)-2-amino-1-butanol (CAS No. 5856-63-3) are not listed individually on the Australian Inventory of Chemical Substances (AICS); however, they are expected to have similar toxicological profiles to that of the racemic mixture.

There are limited toxicological data available for 2-amino-1-butanol. The main concerns regarding effects on human health are expected to be driven by the corrosive nature of the chemical due to its high alkalinity (pK_a = 9.6), with local effects expected to predominate upon exposure to the chemical in its pure form. The hydrochloride salt of the chemical, 2-amino-1-butanol hydrochloride (1:1) (CAS No. 59173-62-5, not listed on the AICS) is used in several studies instead of the parent base. The structural isomer, 2-amino-2-methyl-1-propanol (AMP) (CAS No. 124-68-5), has similar end use as a buffering agent in

cosmetics (pK_a = 9.88), and has previously been assessed by NICNAS in an IMAP Tier I human health assessment (NICNAS). The assessed chemical and its analogue have the same active functional groups, but different metabolic profiles. Where appropriate, the structural isomer AMP has been used as read across for endpoint data gaps for 2-amino-1-butanol due to their identical molecular weights, similar physical properties and end uses.

Toxicokinetics

There are no toxicokinetic data for the chemical. The toxicokinetic profile of the chemical is expected to be similar to that of the structural isomer, AMP.

The structural isomer AMP is extensively absorbed following oral administration. Almost 100 % of the dose was excreted via the urine and faeces within 168 hours, with the vast majority of the dose excreted within the first 24 hours. The chemical AMP is not metabolised prior to excretion and does not appear to accumulate in the tissues. Dermal dosing of AMP led to an absorption of ~40 % of the dose, the majority of which was excreted in the urine. Of the absorbed dose, approximately 25 % remained in the skin at the dose site (REACHb).

Acute Toxicity

Oral

The chemical has low to moderate acute toxicity based on limited results from animal tests following oral exposure. The median lethal dose (LD50) in mice is 1800–2300 mg/kg bw. The available data warrant hazard classification of the chemical with the risk phrase ‘Harmful if swallowed’ (Xn; R22) in the HSIS (Safe Work Australia).

In a study carried out according to OECD TG 401, a single dose of the undiluted chemical (800, 1800 and 2800 mg/kg bw) was administered to male and female Sprague Dawley (SD) rats via gavage, followed by a two-week observation period. The LD50 was estimated to be approximately 1800 mg/kg bw. Clinical signs of toxicity included prostration and lethargy (REACHa). In another (non-guideline) study, the LD50 of the chemical was found to be 2300 mg/kg bw in mice, with observed sub-lethal effects including tetany. However, no further study details were reported (ChemIDplus; RTECS).

Dermal

No data are available for the chemical.

Inhalation

No data are available. The low vapour pressure of the chemical and the results of repeated inhalation studies have indicated that acute systemic toxicity via inhalation is not expected (see **Repeat Dose Toxicity - Inhalation** section).

Corrosion / Irritation

Corrosivity

The chemical is reported to have a pH of 11.1 in a 0.1 M aqueous solution (REACHa), and is therefore expected to produce significant corrosive effects on the skin and mucous membranes when applied in undiluted or concentrated form. In addition, the limited data available for the chemical indicate that the chemical is corrosive, warranting hazard classification with the risk phrase 'Causes burns' (C; R34) (see **Recommendation** section). The local effects observed during acute dermal studies of the structural isomer, AMP, support this classification.

In a non-guideline study, the chemical (0.5 mL) was administered undiluted under occlusive conditions to the shaved skin of 6 albino rabbits for 4 hours. No description or information was provided on individual animal scores for erythema and oedema, or the time taken to produce these effects. The chemical was classified as corrosive (REACHa).

Corrosive effects were observed for the structural isomer, AMP, for 24-hour exposure. In an acute dermal toxicity study in rabbits (strain unknown), animals were administered single doses of 1000, 1500 or 2000 mg/kg bw of undiluted AMP under occlusive conditions to shaved abdomens. After a 24-hour exposure period, all intact and abraded skin sites were severely irritated and black in colour. The sites became necrotic in 2–3 days, and remained necrotic for the rest of the 2-week observation period, resulting in severe eschar formation (Burnett et al., 2009).

Sensitisation

Skin Sensitisation

Based on the limited human data available for the chemical (see **Observation in Humans** section), and the lack of sensitisation activity observed for the structural isomer AMP, which has the same active functional groups, the chemical is not expected to be a skin sensitiser.

In a skin sensitisation study carried out according to OECD TG 406, guinea pigs were topically administered a 10 % (v/v) aqueous solution of AMP under occlusive conditions for 24 hours. After 48 hours, the application process was repeated until a total of 10 applications of AMP were completed. After the first two induction doses, the concentration was reduced to 5 % (v/v) due to the formation of necrotic lesions and other irritant effects observed in all animals in the test group. After a recovery period of two weeks following the final induction dose, the guinea pigs were challenged with 2.5 % and 5 % aqueous solutions of AMP on previously unexposed skin. Dinitrochlorobenzene (0.3 %) was used as a positive control. There was no evidence of inflammation indicative of a sensitising response in the test animals (REACHb).

Observation in humans

In a study carried out on 229 dermatitis patients with present or past occupational exposure to metal-working fluids, a 1 % solution of the chemical in petroleum was included in a patch test with other substances that are present in metal-working processes. None of the patients patch tested positive to the chemical (Geier et al., 2003).

Repeated Dose Toxicity

Oral

Based on the limited data available, the chemical is not expected to cause serious adverse effects following repeated oral exposure.

In a combined repeated dose, reproductive and developmental toxicity study (OECD TG 422), the hydrochloride salt of the chemical (CAS No. 59173-62-5) was administered in the diet of SD rats (12 animals/sex/dose) at doses of 0, 10, 50 and 300 mg/kg bw/day (equivalent to 0, 7.1, 35.5, 212.9 mg/kg bw/day of the chemical) for 33 days (males) and 64 days (females). There were no clinical signs or systemic toxicity observed in the animals given 10 mg/kg bw/day. In the 50 mg/kg bw/day group, increases in relative liver and adrenal weights were observed in males and females respectively; however, no histopathological changes were reported at this dose. In the high dose group (300 mg/kg bw/day), decreased body weight and feed consumption, and an increased incidence of centrilobular/midzonal hepatocyte hypertrophy associated with increased liver weights in males was observed. No changes in adrenal gland weights were reported in females. Dermal irritation (acanthosis, inflammation, erosions and/or ulcers) was also observed in the high dose group, possibly induced by feed contact during grooming. The no observed adverse effect level (NOAEL) for the hydrochloride salt was determined to be 50 mg/kg bw/day based on the liver effects at the higher dose in male rats, as well as a decrease in body weight and food consumption in both sexes (REACHa).

Dermal

No data are available for the chemical. Given the alkalinity of the chemical, concentration-dependent local effects are expected to predominate upon repeated dermal exposure.

Inhalation

Based on the limited information available, the chemical is not considered to cause serious damage to health from repeated inhalation exposure at the concentrations reported.

In a 2-week inhalation toxicity study, rats (2 animals/sex) were exposed to a nearly saturated atmosphere of the chemical (85 ppm, 0.55 mg/L) for six hours per day, five days per week. Increased white blood cell count and high blood urea were observed upon haematology analysis. Upon autopsy after 15 days, organs were found to be normal in all test animals. In a similar 2-week study, rats (4 animals/sex) were exposed to an atmosphere of the chemical (50 ppm) for six hours per day, five days per week. No effects were observed during blood, urine and organ analysis (Gage, 1970).

Genotoxicity

Based on the limited evidence available, the chemical is not considered to be genotoxic.

The chemical was tested in the bacterial reverse mutation assay according to OECD TG 471, where concentrations of 0, 75, 200, 600, 1800 and 5000 µg/plate of 2-aminobutanol in water were tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* strain WPF uvrA via the plate incorporation method, with and without metabolic activation. No positive responses were observed in any bacterial strain (REACHa).

Carcinogenicity

No carcinogenicity data are available for the chemical. Based on the lack of genotoxic activity for the chemical, the chemical is unlikely to be carcinogenic.

Concerns have been raised about the potential for cosmetic formulations containing amines (including alkanolamines) and their salts to form carcinogenic nitrosamines (SCCNFP, 2001; SCCS, 2012). Primary, secondary and tertiary amines can all be nitrosated in the presence of nitrosating agents such as nitrites to generate nitrosamines, which are of concern for carcinogenicity. Secondary amines are considered the most reactive of the amines, and as the chemical 2-amino-1-butanol is a primary amine, it is an unlikely substrate for N-nitrosation reactions. Current international restrictions for the chemical are based on the presence of possible secondary amine impurities in cosmetic formulations containing the chemical (see **Restrictions - International** section) (CosIng).

Reproductive and Developmental Toxicity

There is evidence of a dose-dependent increase in litter resorptions following oral administration, with complete litter loss observed at the highest dose, not accompanied by maternal effects. It is recommended that the chemical be classified as a Category 3 reproductive toxin, with the risk phrase "Possible risk of impaired fertility" (Xn; R62) (see **Recommendation** section).

In a combined repeated dose, reproductive and developmental toxicity study (OECD TG 422), the hydrochloride salt of the chemical was administered in the diet of SD rats (12 animals/sex/dose) at doses of 0, 10, 50 and 300 mg/kg bw/day (equivalent to 0, 7.1, 35.5, 212.9 mg/kg bw/day of the chemical). Males were fed for a total of 33 days including 2 weeks before breeding, while the females were fed for a total of 64 days, including before mating, during breeding, gestation and the first 4 days of lactation. The effects in parental animals are discussed in the **Repeat Dose Toxicity - Oral** section. No adverse effects were identified in females, while males showed liver changes and decreased body weight at the highest dose. A dose-related increase in post-implantation losses (embryo resorptions) was found for the 50 mg/kg bw/day group (24 % vs 3.9 % in controls) and 300 mg/kg bw/day group (100 % litter resorption). Offspring from the 10 mg/kg bw/day and 50 mg/kg bw/day groups were

found to be normal at birth and did not show treatment-related effects. The NOAEL for maternal toxicity was determined to be 300 mg/kg bw/day. The NOAEL for reproductive toxicity was determined to be 10 mg/kg bw/day based on a dose-related increase in litter resorptions (REACHa).

A similar toxicological response has been observed for the structural isomer AMP (REACHb). There is some evidence that both the chemical and AMP inhibit uptake of choline (REACHa; REACHb), which is an essential nutrient for many biological processes including foetal development during pregnancy. It has been suggested that the observed reproductive toxicity for AMP is secondary to an increase in choline deficiency in the treated dams compared to control animals, resulting in increased liver vacuolisation (Ball et al, 2014; REACHa); however, this hepatotoxicity was not observed in the dams in the study for the chemical, 2-amino-1-butanol. There is also some evidence from a recent study indicating that AMP initiates a maternally-mediated mode of action for reproductive toxicity, involving down-regulation of tight junction regulatory genes that are necessary to support postimplantation embryo development (Ball et al., 2014). However, in this particular study, it was reported that the effects were observed at maternally toxic doses.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include potential systemic long-term effects (reproductive toxicity), systemic acute effects from oral exposure and concentration-dependent local effects (corrosivity) due to the alkalinity of the chemical.

Public Risk Characterisation

Currently, there are no restrictions in Australia on using this chemical in cosmetics or domestic products. Products containing the chemical may come into contact with the skin, eyes and mucous membranes. The chemical may also be inhaled when aerosol hair products are used. Since the chemical is used as a buffering agent in cosmetics (CosIng), cosmetic use is not expected to expose the public to high concentrations. In addition, the chemical is unlikely to exist as the free base in cosmetic products, but rather as a salt due to the neutralisation of acidic components of the cosmetic formulation.

Considering the low concentrations of the chemical in cosmetic and domestic products, and the low dermal absorption expected for the cationic form of the chemical which will dominate in the product, the chemical is not expected to be locally or systemically available in sufficiently high concentrations to cause any significant human health concerns. Therefore, 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 may occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemical at lower concentrations could 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. Oral exposure is also possible but can be prevented by good hygiene practices.

Given the critical effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure 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 the appropriate controls.

The data available support an amendment to the hazard classification in the HSIS (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

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 and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful if swallowed (Xn; R22)	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Causes burns (C; R34)	Causes severe skin burns and eye damage - Cat. 1 (H314)
Reproductive and Developmental Toxicity	Repro. Cat 3 - Possible risk of impaired fertility (Xn; R62)	Suspected of damaging fertility - Cat. 2 (H361f)

[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 industry

Control measures

Control measures to minimise the risk from oral, 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 that could 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;
- health monitoring for any worker who is at risk of exposure to the chemical, if valid techniques are available to monitor the effect on the worker’s health;
- 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 help meet 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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