Ethanol, 2,2'-(butylimino)bis-: Human health tier II assessment

30 June 2017

CAS Number: 102-79-4

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.

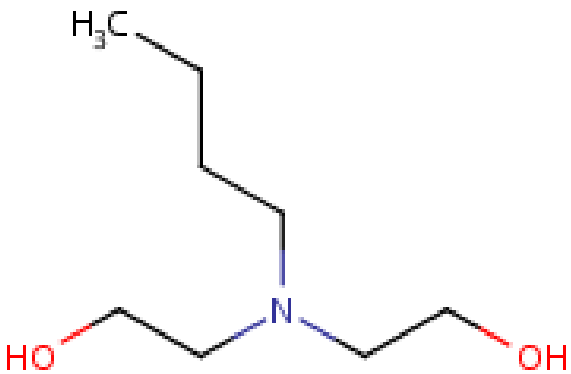
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	(2,2-butylimino)diethanol N-butyldiethanolamine 2,2'-(butylimino)bisethanol 2,2'-butyliminodiethanol Vantex T (trade name)
Structural Formula	
Molecular Formula	C8H19NO2
Molecular Weight (g/mol)	161.243
Appearance and Odour (where available)	Light yellow liquid with slight odour.
SMILES	C(CCC)N(CCO)CCO

Import, Manufacture and Use

Australian

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

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 and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported cosmetic use as a buffering agent.

The chemical has reported commercial use as an additive in:

- hydraulic fluids;
- lubricants;
- paints;
- coatings; and
- resins.

Restrictions

Australian

No known restrictions have been identified.

International

Using the chemical in cosmetics in the European Union is subject to the restrictions described in EU Regulation Annex III (Reference number 62). This chemical may be used in cosmetics and personal care products at a maximum concentration of 2.5 % (CosIng).

Existing Work Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit of 15 mg/m^3 (5 ppm) time weighted average, and 15 mg/m^3 (5 ppm) short-term exposure limit, in Denmark, Egypt and Spain.

Health Hazard Information

Toxicokinetics

Ethanol, 2,2'-(butylimino)bis-, also referred to as N-butyldiethanolamine, is expected to be well absorbed orally, based on its low molecular weight (161.24 g/mol), high water solubility and its systemic effects observed in acute oral toxicity studies in rats. Given its lipophilicity (LogKow 0.58), absorption is expected to occur directly across the respiratory tract. The chemical is thought to be metabolised in alveolar and bronchial tissue. Metabolism is expected to occur via Phase I reactions, leading to hydroxylated derivatives and/or derivatives of oxidative deamination (REACH).

The chemical and its metabolites are expected to be eliminated primarily via the urine (REACH).

Acute Toxicity

Oral

The chemical has low acute toxicity based on results from animal tests following oral exposure. The median lethal dose (LD50) in rats is >2000 mg/kg body weight (bw).

Ethanol, 2,2'-(butylimino)bis- was assessed for acute oral toxicity, in a study conducted similar to the Organisation for Economic Cooperation and Development (OECD) Test Guideline (TG) 401 (acute oral toxicity). Rats (strain unspecified) of both sexes (five animals/sex/dose) were administered the chemical at 190, 1900, 3100 (this dose was repeated), 3900, 4850 or 6200 mg/kg bw, by oral gavage. Following dosing, animals were observed for a period of seven days for mortalities and clinical signs. The main signs reported at the highest doses (3900, 4800 and 6200 mg/kg bw), were irregular breathing, slight dyspnoea, agitation, slight salivation, abnormal gait and slight tremor when touched. At 190 and 1900 mg/kg bw, no animals died. At 3100 mg/kg bw, in the first test, mortality was 30 % (3/5 females died), while in the second test at the same dose level, none of the treated animals died. At 3900 mg/kg bw, mortality was 10 % (1/5 females died), while at 4800 mg/kg bw, none of the treated animals died. At 6200 mg/kg bw, mortality was 80 % (4/5 males and 4/5 females died). Almost all cases of death occurred within 48 hours of treatment. Slight dyspnoea, prostration, piloerection, irregular breathing, unclean fur in the anal region and red incrusted noses were observed at 190, 1900 and 3100 mg/kg bw. Surviving animals recovered from day three post-treatment. Necropsy of sacrificed animals revealed some respiratory signs including bronchitis and bronchiectasis. On the basis of these results, an oral LD50 of 4800 mg/kg bw, for both male and female rats was determined (REACH).

Dermal

The chemical has low acute toxicity based on results from animal tests following dermal exposure. The dermal LD50 in Wistar rats is >2000 mg/kg bw.

The test chemical was assessed for acute dermal toxicity in a study conducted according to OECD TG 402 (acute dermal toxicity). Wistar rats of both sexes (five/sex) were topically administered the chemical at a dose level of 2000 mg/kg bw to intact skin under semi-occlusive conditions. There were no deaths or signs of systemic toxicity in any animals. Very slight erythema was noted at the test sites of one male and four females. Small scattered superficial scabs and glossy skin were also noted at the test sites of four females. There were no signs of dermal irritation noted at the test sites of four males and one female. On the basis of these results, the dermal LD50 was determined to be >2000 mg/kg bw. Therefore, the chemical has low acute toxicity via the dermal route (REACH).

Inhalation

The chemical has low acute toxicity based on results from animal tests following inhalation exposure. The median lethal concentration (LC50) in rats could not be determined given no mortality occurred in the studies described below.

To assess acute inhalation toxicity, rats of an unspecified strain (three/sex) were exposed to a saturated vapour atmosphere of ethanol, 2,2'-(butylimino)bis- (calculated to be 24.69 mg/L) for eight hours in a study conducted similar to OECD TG 403 (acute inhalation toxicity). No mortalities occurred during the study, and clinical observations were limited to mucous membrane irritation. No LC50 could be established, and the test chemical was determined to have little to no acute toxicity via inhalation (REACH).

Similar acute inhalation toxicity studies have been conducted on the chemical assessing the effect of exposure of the chemical to rats at lower concentrations (0.15 mg/L and 0.54 mg/L). No mortality occurred in either of these studies and no LC50 values could be established. In both studies, ethanol, 2,2'-(butylimino)bis- was determined to be practically non-toxic via inhalation (REACH).

Corrosion / Irritation

Skin Irritation

The chemical was slightly irritating to skin in a study performed in accordance with OECD TG 404 (acute dermal irritation/corrosion).

Ethanol, 2,2'-(butylimino)bis-, (as Vantex T (trade name)) was assessed for skin irritation in an OECD TG 404 study. Three male New Zealand White rabbits were topically administered the test chemical undiluted, at a single dose of 0.5 mL. The material was administered under semiocclusive patches and remained on the skin for four hours. Assessments of skin irritation were performed at one, 24, 48 and 72 hours after patch removal. There were no mortalities or systemic clinical changes related to the test chemical. At one hour after patch removal, well-defined erythema (score of 2) was observed in one animal, very slight erythema (score of 1) was observed in one animal and very slight oedema (score of 1) was observed in two animals. At 24 hours, very slight erythema (score of 1) was observed in one animal and very slight oedema (score of 1) was observed in two animals. At 48 and 72 hours, there were no observed signs on the skin of the treated animals. The animals' individual mean scores (at 24, 48 and 72 hours after patch removal) for erythema were 0, 0 and 0.3, respectively. The animals' individual mean scores (at 24, 48 and 72 hours after patch removal) for oedema were 0.3, 0.3 and 0, respectively. On the basis of these findings, the chemical was not considered to be a dermal irritant (REACH).

In a dermal irritation study, the test chemical was applied undiluted to the clipped dorsal skin of two Vienna White rabbits by means of a test patch for either one, five, 15 minutes or 20 hours, under occlusive conditions. Following removal of the patches and skin washing (washing was only done for animals exposed for one, five and 15 minutes), animals were observed for a period of eight days with skin assessments made at 24, 48 and 72 hours and at days six, seven, eight. After eight days, the 20-hour treatment animals exhibited severe skin necrosis and scaling. Animals exhibited reversible redness following exposure for one to five minutes. Treatment for 15 minutes resulted in questionable to well-defined redness, with accompanying crusting, which was present through to day seven of the observation period (REACH).

Eye Irritation

Severe, irreversible damage to corneal tissue and the conjunctivae and eyelids were observed when 50 µL of the undiluted chemical was applied to the eye. These findings were not reversible after eight days. The chemical is a severe eye irritant.

The chemical was tested for eye irritation in a study conducted similarly to OECD TG 405 (acute eye irritation/corrosion). Approximately 50 µL of the unchanged test material was instilled into the conjunctival sac of one eye of each of two Vienna White rabbits. The eyes were not rinsed. The animals were assessed at 10 minutes, one, three, 24, 48 and 72 hours, and at day six, seven and eight. The findings were evaluated according to the Draize scoring system. The animals developed signs of severe ocular irritation, including bloody discharge, skin detachment, grey-brown signs of corrosion, corneal opacity, chemosis, conjunctival and iridial inflammation. These effects were not reversible within the eight day observation period of the study. On the basis of these findings, the test chemical was determined to be corrosive to the eyes (REACH).

Sensitisation

Skin Sensitisation

The chemical did not induce dermal sensitisation when tested according to OECD TG 406 (skin sensitisation).

The test chemical was assessed for skin sensitisation in a Beuhler test conducted according to OECD TG 406. Following a range-finding experiment to determine optimal test concentrations, 20 Hartley guinea pigs of both sexes received three topical induction exposures (approximately six hours each) at a concentration of 100 %, over a period of 14 days. Animals received a single topical challenge exposure 14 days after the last induction exposure, at a concentration of 50 %. Minimal evidence of skin sensitisation was observed and it was concluded that the test chemical did not possess potential for skin sensitisation under these test conditions (REACH).

Repeated Dose Toxicity

Oral

Considering the no observed adverse effect levels (NOAELs) available from 28-day rat studies (100–430 mg/kg bw/day), and based on the treatment-related effects reported in various repeated dose toxicity studies, repeated oral exposure to the chemical is not considered to cause serious damage to health.

A repeat dose toxicity study was conducted according to OECD TG 407 (repeated dose 28-day oral toxicity in rodents). Sprague Dawley (SD) rats were administered the chemical daily via oral gavage at 0, 25, 100 or 400 mg/kg bw/day, for 28 days. Ten animals of each sex were included in the 0 and 400 mg/kg bw/day groups, and five animals of each sex were included in the 25 and 100 mg/kg bw/day groups. Males and females in the highest dose group had significant increases in relative liver weights. Males had increased kidney weights and females had increased adrenal weights in the same group. Animals in the highest dose group exhibited histopathological changes consistent with hepatic and renal toxicity. The other organs affected by treatment in this group were the adrenals, lungs, spleen and thymus. Three male and five female mortalities occurred in the highest dose group during the study. There were no other mortalities during the study. Three females in the highest dose group developed convulsions during the study. On the basis of these findings, the investigators reported an NOAEL of 100 mg/kg bw/day for both males and females (REACH).

The test chemical was assessed for repeated dose toxicity in a study conducted similarly to OECD TG 407. For 30 days, SD rats of both sexes were administered the test chemical in their drinking water at 0, 1, 2 or 4 g/L (equivalent to 0, 130, 200 and 430 mg/kg bw/day and 0, 140, 240 and 330 mg/kg bw/day, for males and females, respectively). No treatment-related mortalities occurred and no clinical signs were reported in any of the animals. There were no treatment-related changes in blood chemistry, haematology or organ weights in any of the treated animals. There was a modest reduction in body weight gain in animals from the two highest dose groups; however, weight gain returned to a level comparable to that of control animals after ten days. On

the basis of these findings, investigators reported NOAELs of 430 mg/kg bw/day for males and 330 mg/kg bw/day for females (the highest dose tested) (REACH).

Dermal

No data are available.

Inhalation

In 28-day and six month repeated dose inhalation toxicity studies in male and female SD rats, the no observed adverse effect concentrations (NOAECs) for the chemical were reported to be 20.6 and 156 mg/m^3. No hazard classification is warranted.

A combined inhalational repeat dose toxicity study and reproductive/developmental toxicity screening test was conducted on the test chemical, according to OECD TG 422 (combined repeated dose toxicity study with the reproduction/developmental toxicity screening test). Wistar rats of both sexes were exposed to the aerosolised chemical. Males were exposed for 28 days, including for 14 days during premating, and up to 14 days during mating. Females were exposed for 50 days, including for 14 days during premating, up to 14 days during mating, during pregnancy up to and including gestation day 19 and after necropsy of the pups (four exposures on four consecutive days including the day before scheduled sacrifice). Animals (ten/sex/dose) were exposed for six hours a day, for five days per week at 0, 20.6, 72.1 or 236.3 mg/m^3. There were transient effects on body weight gain and food consumption. No adverse parental or pup findings were evident at any concentration. There was some evidence of adverse effects (nasal epithelial lesions) of treatment in animals exposed at 20.6 mg/m^3. On the basis of these results the NOAEC for repeated dose toxicity was determined to be 20.6 mg/m^3 (REACH).

A non-guideline study was conducted to assess the effect of repeated inhalational exposure to ethanol, 2,2'-(butylimino)bis- in SD rats. Animals (50 males) were exposed to the chemical at 156 mg/m^3 for six hours daily, for six months and were sacrificed periodically after one, four, 15, 27 and 29 weeks. No mortalities occurred during the study and no animals exhibited any signs consistent with toxicity. Body weight gain was comparable to the control group. Serum bilirubin levels were higher than controls in three of five rats in the animals that were sacrificed after four weeks of exposure. Kidney-to-body weight ratios were slightly elevated at the end of the first week of exposures. Histological sections were not significantly different to those harvested from control animals. It was not reported whether histopathological assessment of nasal tissue was performed. On the basis of these findings, an NOAEC of 156 mg/m^3 was reported for this study (REACH).

In a limited non-guideline repeated dose inhalational toxicity study, five male SD rats were exposed to the chemical at 0, 234 or 495 mg/m^3, for six hours a day for a period of five days. The chemical at the highest dose produced tremors and convulsive seizures. Evidence of eye and nasal irritation was also observed and one mortality occurred in this group. Exposure to 234 mg/m^3 resulted in reduced body weight gain and no other significant clinical findings. Exposure at the high dose also resulted in slightly elevated bilirubin levels in the blood of some animals. The same was not observed in the lower dose group. Given these findings, investigators reported an NOAEC of 234 mg/m^3 in male SD rats under these test conditions (REACH).

Genotoxicity

Based on the weight of evidence from the available in vitro studies, the chemical is not considered to be genotoxic.

In vitro

The chemical was assessed for genetic toxicity in an Ames test according to OECD TG 471 (bacterial reverse mutation assay). The chemical was tested with the following bacterial strains: *Salmonella typhimurium* TA 98, TA 100, TA 1535 and TA 1537 and *Escherichia coli* WP2 uvrA, at 0, 20, 100, 500, 2500 or 5000 µg/plate both in presence or absence of metabolic activation with S9 mix. No mutagenic effects were observed in any of the strains tested, at any of the concentrations assessed. Therefore, the chemical was found to be non-mutagenic under these conditions (REACH).

An in vitro mammalian cell gene mutation test was conducted according to OECD TG 476. Mouse lymphoma L5178Y cells were incubated with the test chemical at 0, 100.6, 201.2, 402.5, 805.0, 1207.3 or 1610.0 µg/mL for four hours, and at 0, 50, 100, 200, 300, 400, and 500 µg/mL for 24 hours. The chemical did not induce any toxicologically significant dose-related increases in the frequency of mutants at any concentration tested, at any time point, either in the presence or absence of metabolic activation (REACH).

A mammalian cell chromosome aberration study was conducted with the chemical according to OECD TG (473 in vitro mammalian chromosome aberration test). Human lymphocytes were incubated with the chemical at 0, 50.3, 100.6, 201.3, 402.5, 805.0, 1610.0 (with S9 mix (at 2 %) and without S9 mix), at 0, 100.6, 201.3, 402.5, 805.0, 1207.5, 1610.0 (with S9 mix (at 1 %)) or at 0, 100.63, 201.3, 402.5, 603.8, 805.0, 1207.5, 1610.0 (without S9). The test item did not produce a statistically significant increase in the frequency of cells with chromosome aberrations at any of the doses tested, either in the absence or presence of metabolic activation. The test chemical was therefore considered to be non-clastogenic under these conditions (REACH).

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

A combined inhalational repeat dose toxicity study and reproductive/developmental toxicity screening test was conducted on the test chemical according to OECD TG 422 (combined repeated dose toxicity study with the reproduction/developmental toxicity screening test) (see **Repeated dose toxicity**: **Inhalation** section). Wistar rats of both sexes were exposed to the aerosolised chemical. Males were exposed for 28 days, including for 14 days during premating, and up to 14 days during mating. Females were exposed for 50 days, including for 14 days during premating, up to 14 days during mating, during pregnancy up to and including gestation day 19 and after necropsy of the pups (four exposures on four consecutive days including the day before scheduled killing). Animals (ten/sex/dose) were exposed for six hours a day, for five days per week at 0, 20.6, 72.1 or 236.3 mg/m^3. Inhalational exposure to the chemical, to a maximum of 236.3 mg/m^3 (saturated atmosphere), did not result in any adverse effects to any of the developmental or reproductive parameters assessed in the study. No adverse parental or pup findings were evident at any concentration. There were transient effects on body weight gain and food consumption. The NOAEC for reproductive and developmental toxicity was determined to be 236.3 mg/m^3 (the highest dose tested) (REACH).

Risk Characterisation

Critical Health Effects

The critical health effect for risk characterisation is severe eye irritation.

Public Risk Characterisation

Although use in cosmetic or domestic products in Australia is not known, the chemical is reported to be used in cosmetics and domestic products overseas. Use concentrations in these products are also not known; however, the concentration of the free base form of ethanol, 2,2'-(butylimino)bis- used in cosmetics is not expected to be high when used as a buffering agent. Eye irritation effects are not expected from exposure to low concentrations of the chemical in cosmetic or domestic products.

Occupational Risk Characterisation

Given the critical health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise ocular exposure are implemented. The chemical should be appropriately classified and labelled to ensure that a

person conducting a business or undertaking 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 HCIS (Safe Work Australia) (see **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

Public Health

Products containing the chemical should be labelled in accordance with state and territory legislation.

Work Health and Safety

The chemical is recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Not Applicable	Causes serious eye damage - Cat. 1 (H318)

[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 ocular 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;
- 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.

References

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Last update 30 June 2017