Australian Government

Department of Health and Ageing

National Industrial Chemicals Notification and Assessment Scheme

INVENTORY MULTI-TIERED ASSESSMENT AND PRIORITISATION (IMAP)

HUMAN HEALTH TIER II ASSESSMENT FOR

Ethanol, 2-(2-butoxyethoxy)-

CAS Registry Number: 112-34-5

PREFACE

As part of the reform regarding assessment of Existing Chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is implementing a new framework to address the human health and environmental impacts of industrial chemicals, not yet assessed, on the Australian Inventory of Chemical Substances (AICS).

The framework provides a more rapid, flexible and transparent approach for the assessment of existing chemicals.

The Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework was developed, with significant input from stakeholders, and will be applied in stages.

Stage One of this program, which will take four years, started 1 July 2012 and is examining 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This includes chemicals for which NICNAS already holds exposure information, chemicals identified as a concern or for which regulatory action has been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

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.

This chemical/group of chemicals is/are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.
For more detail on the new program please visit: www.nicnas.gov.au

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ACRONYMS & ABBREVIATIONS

ACToR	Aggregated Computational Toxicology Resource (US)
AICS	Australian Inventory of Chemical Substances
ASTDR	Agency for Toxic Substances and Disease Registry (US)
bw	bodyweight
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations (US)
CHO	Chinese hamster ovary
CosIng	Cosmetic Ingredients and Substances database (EU)
d	day
DNA	Deoxyribonucleic acid
EC	European Commission
EC3	Estimated concentration three
ECHA	European Chemicals Agency
ESIS	European Chemical Substances Information System
EU	European Union
EU RAR	European Union Risk Assessment Report
FDA	Food and Drug Administration (US)
FSANZ	Food Standards Australia and New Zealand
g	gram
g/mol	grams per mole
GHS	Globally Harmonized System of Classification and Labelling of Chemicals*
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GPMT	Guinea Pig Maximisation Test
h	hour
HGPRT	hypoxanthine guanine phosphoribosyltransferase
HPV	high production volume
HSDB	Hazardous Substances Data Bank
HSIS	Hazardous Substances Information System
HVICL	High Volume Industrial Chemicals List
IARC	International Agency for Research on Cancer
INCHEM	International Programme on Chemical Safety (also known as IPCS)
INCI	International Nomenclature of Cosmetic Ingredients
ip	intraperitoneal
IRIS	Integrated Risk Information System (US)
IUCLID	International Uniform Chemical Information Database
iv	intravenous
kg	kilogram
L	litre
LC50	median lethal concentration
LD50	median lethal dose
LCLo	lowest published lethal concentration
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
m^3	cubic metre
mg	milligram
mg/cm^3	milligrams per cubic centimetre
mg/kg bw/d	milligrams per kilogram bodyweight per day
min	minute
mL	millilitre
µg	microgram
µL	microlitre
(m)SDS	(material) Safety Data Sheet

NIOSH	National Institute for Occupational Safety and Health (US)
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOHSC	National Occupational Health and Safety Commission
NTP	National Toxicology Program (US)
OECD	Organisation for Economic Cooperation and Development
OEL	occupational exposure limit
PCBU	person conducting a business or undertaking
PEL	permissible exposure limit
PND	postnatal day
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
REACH	Registration Evaluation Authorisation of Chemicals (ECHA)
SD	Sprague Dawley
SIAP	SIDS Initial Assessment Profile (OECD)
SIAR	SIDS Initial Assessment Report (OECD)
SIDS	Screening Information Data Set (OECD)
SMILES	simplified molecular-input line-entry system
SPIN	Substances in Preparations In the Nordic countries
STEL	short-term exposure limits
STV	short-term value
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (The Poisons Standard**)
TCLo	lowest published toxic concentration
TEEL	temporary emergency exposure limits
TSCA	Toxic Substances Control Act (US EPA)
TG	test guideline
TGA	Therapeutic Goods Administration
TLV	threshold limit values
TWA	time weighted average
UN	United Nations
US	United States of America
US EPA	United States Environmental Protection Agency
WHS	Work, Health and Safety
wt	weight
w/w	weight per weight

Glossary

NICNAS uses the IPCS Risk Assessment Terminology (IPCS, 2004) glossary, which includes:
Part 1: IPCS/OECD Key Generic Terms used in Chemical Hazard/Risk Assessment; and
Part 2: IPCS Glossary of Key Exposure Assessment Terminology.
The IPCS Risk Assessment Terminology can be accessed at:
http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf

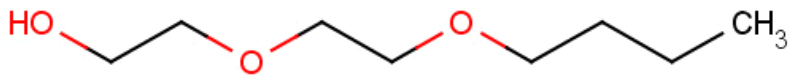
*Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third edition. Can be accessed at: http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

**The Poisons Standard (the SUSMP) can be accessed at: http://www.tga.gov.au/industry/scheduling-poisons-standard.htm

Ethanol, 2-(2-butoxyethoxy)-

CAS No: 112-34-5

Chemical Identity

Synonyms	Butyldiglycol Diethylene glycol monobutyl ether Butoxy diethylene glycol Butoxydiglycol Butoxyethoxyethanol
Structural Formula	
Molecular Formula	C8H18O3
Molecular Weight (g/mol)	162.23
Appearance and Odour (where available)	Colourless liquid with a faint fruity (banana/apple) smell.
SMILES	C(CCC)OCCOCCO

Import, Manufacture and Use

Australian

The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total annual reported volume between 1000 and 10000 tonnes (NICNAS, 2006).

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

The chemical has reported domestic use including:

- as a cleaning and washing agent/additive.

The chemical has reported commercial use including as a:

- solvent; and
- flame retardent.

The chemical has reported site-limited use including:

- in chemical manufacturing.

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; 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, the US Environmental Protection Agency's Aggregated Computer Toxicology Resource—ACToR, 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 function as a masking agent, solvent in hair dye products and to control viscosity. However, the chemical appears to be used in Europe only as a solvent in hair dyes up to a concentration of 9 % (SCCP, 2006).

The chemical has reported domestic use (Household Products Database, US Department of Health and Human Services; EU RAR, 1999). The chemical is reported to be present in a range of:

- home maintenance products, such as paints, sealants and adhesives (spray and liquid), up to a concentration of 10 % (typically 5 %) ; and
- cleaning products (spray, liquid and wipes) up to a concentration of 30 % (typically 10 %).

The chemical has reported commercial use including in:

- automotive products such as brake fluid; and
- heavy-duty de-greasers.

The chemical has reported site-limited use including as:

- an intermediate to produce other chemicals such as diethylene glycol dibutyl ether, diethylene glycol monobutyl ether acetate, and piperonyl butoxide; and
- a solvent in various manufacturing industries (textile, coating, oils and paint).

Restrictions

Australian

This chemical is listed in the Standard for the Uniform Scheduling of Medicines and Posions (SUSMP) in Schedule 5, except in preparations containing 10 % or less of diethylene glycol monobutyl ether.

Schedule 5 chemicals are labelled with 'Caution'. These are substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

International

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

EU Cosmetic Directive 76/768/EEC Annex III Part 1: *List of substances which must not form part of the composition of cosmetic products except subject to the restrictions and conditions laid down*:

- restricted as a solvent in hair dye products;
- maximum authorised concentration in the finished cosmetic product should not be greater than 9 %; and
- no use in aerosol dispensers (sprays).

Existing Worker 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; R36 (Irritating to eyes)

Exposure standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit (TWA) of 50–100 mg/m3 (7–10 ppm) in different countries such as USA (Alaska, Hawaii), Canada (Yukon), Norway and Switzerland.

Health Hazard Information

Toxicokinetics

In a 24-hour absorption study, carbon-14 labelled chemical (200 and 2000 mg/kg bw) was absorbed through the skin of Sprague Dawley rats (30 %—low dose, and 50 %—high dose).The chemical was detectable in urine within 24 hours. 60–80 % of the urinary radioactivity was observed in the form of the primary metabolite; (2-(2-butoxyethoxy)- acetic acid. Glucuronidated chemical metabolites were also recovered in the urine (5–8 %) (EU RAR, 1999).

In a study using excised human skin, the maximum absorbtion rate was achieved at five hours after application. The rate of absorption was determined to be 0.035 mg/cm2/hr, based on nine samples (REACH). In comparison, using rat skin, the rate of absorption was determined to be 0.51mg/cm2/hr. The large discrepancy is related to the fact that rat skin is significantly more permeable than human skin (REACH).

Acute Toxicity

Oral

The chemical exhibits low acute toxicity as evidenced by reported oral LD50 in rats is >2000 mg/kg bw. Observed sublethal effects included laboured breathing, rapid respiration, anorexia, slight to moderate weakness, tremors and prostration (EU RAR, 1999).

Dermal

The chemical exhibits low acute toxicity as evidenced by reported dermal LD50 in rats is >2000 mg/kg bw. Observed sublethal effects (at lower doses: 1700 and 3400 mg/kg) included anorexia, slight depression, cyanosis, ataxia, soft faeces, and at higher doses (6800 and 13600 mg/kg) salivation, nasal discharge, iritis, significant depression, laboured breathing, and prostration (REACH).

Inhalation

Limited data are available for acute inhalation toxicity. No mortalities were observed in rats exposed for seven hours to saturated vapour concentration (approximately 18 ppm) (EU RAR, 1999).

Observation in humans

It has been estimated that a single lethal oral dose of ethanol, 2-(2-butoxyethoxy)- for humans is approximately 1 ml/kg (HSDB). Cyanosis, tachypnoea, and slight uraemia have been reported (SCCP, 2006).

Corrosion / Irritation

Skin irritation

The chemical produced slight to moderate skin erythema and slight to marked oedema in New Zealand White rabbits when tested for four hours under semi-occlusive conditions according to OECD Test Guideline (TG) 404. The skin reactions (erythema and oedema) were reversible in all animals eight days after removal of the patch (REACH). The effects were not sufficient to warrant a hazard classification.

Eye irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to eyes' (Xi; R36) in HSIS (Safe Work Australia). The majority of available data support this classification.

In an eye irritation study in rabbits, the chemical was found to cause moderately severe conjunctivitis and mild corneal injury observed at 24, 48 and 72 hours. Effects were reversible within 14 days (REACH). In a similar study conducted in rabbits, application of the chemical caused lesions, notably in the iris and cornea, which persisted until the end of the 21-day study. Conjunctival redness and oedema were

reversible within 14 days (REACH). It is noted that washing the eyes was delayed in this study (washed at 72 hours), which may have resulted in the persistence of the effects. In a third study, involving two animals, reversible effects in the conjunctivae and no effects on the cornea and iris were reported.

Sensitisation

Skin sensitisation

The chemical was not found to induce dermal sensitisation when tested using the guinea pig maximisation test (EU RAR, 1999).

Repeat Dose Toxicity

Oral

In a 90-day oral gavage study on Fischer 344 rats, a no observed adverse effect level (NOAEL) of 250 mg/kg bw/day was reported. Effects observed at higher concentrations (1000 mg/kg bw/day) included: decreases of around 3–8% in erythron (red blood cell count, haemoglobin and haematocrit), decreases in serum levels of liver enzymes, total protein and cholesterol (REACH).

In a 6-week oral study in male rats a low observed adverse effect level (LOAEL) for systemic effects of 891 mg/kg bw/day was reported. Effects observed at this dose included local effects in the stomach and increased liver weights. At higher doses, effects to haematological parameters (reduced red blood cell count, haemoglobin level and mean cell haemoglobin), increased spleen and liver weights and histopathological changes to the spleen and kidney were observed (EU RAR, 2002).

Similar effects were not observed in another 13-week study on rats in which a majority of the high dose group (1270–1360 mg/kg bw/d) died, possibly due to irritant effects in the stomach. Effects observed in female rats at the lowest two doses were decreased white blood cells and lymphocytes.

Dermal

Considering the no observed adverse effect levels (NOAELs) available from 13-week rat studies (2000 mg/kg bw/d) reported in various repeat-dose toxicity studies, the chemical is not considered to cause serious damage to health through repeated dermal exposure. No systemic effects were observed. Irritation effects were observed at all doses tested (lowest dose 200 mg/kg bw/d) (EU RAR, 1999).

Inhalation

Several repeat-dose toxicity studies are available for the chemical (EU RAR, 1999). Signs of toxicity were not consistent; however, based on the available data, the chemical is not considered to cause serious damage to health through repeated inhalation exposure.

In a 90-day repeat-dose inhalation study (whole body exposure) no signs of toxicity were noted at any doses (NOAEC 94 mg/m3).

In a 5-week repeat-dose inhalation toxicity study in male and female Fischer 344 rats, the no-observed adverse effect concentration (NOAEC) for the chemical was reported to be 39 mg/m3. Hypertrophy of the liver was observed at higher doses.

Histopathological changes in the lungs were noted in rats exposed to vapour (concentration 100 mg/m3) and aerosol (>350 mg/m3) of the chemical for a period of two weeks. The effects appeared reversible. Increased spleen weights were also noted.

Genotoxicity

The chemical tested negative in several in vitro (mammalian chromosome aberration test, bacterial reverse mutation assay and the mammalian cell gene mutation test) and in vivo (mammalian bone marrow chromosome aberration test, sex-linked recessive lethal test in *Drosophila melanogaster*) tests for gene

mutation and clastogenicity (REACH). Although a weak positive response was observed in an in vitro mouse lymphoma assay, this was in the absence of metabolic activation. Overall, the weight of the evidence indicates that the chemical has no mutagenic or genotoxic potential.

Carcinogenicity

There are no data available for animal or human carcinogenic studies (EU RAR, 1999). However, considering similar chemicals (CAS No. 111-76-2), there is limited evidence of a carcinogenic effect (REACH).

Reproductive and developmental toxicity

Results of developmental toxicity studies conducted in rabbits and rats through oral and dermal exposure indicate that the chemical does not show specific reproductive or developmental toxicity (EU RAR, 1999).

In a one-generation oral gavage study with rats, no effects on fertility were observed (NOAEL 1000 mg/kg bw/d). The only effect on offspring was reduced bodyweight gain (NOAEL 500 mg/kg bw/d). In a one-generation dermal study with rats, no effects were observed (NOAEL 2000 mg/kg bw/d).

Other Health Effects

Neurotoxicity

Male and female Sprague Dawley rats treated dermally for 13 weeks with up to 2000 mg/kg bw/day of the chemical showed no neurotoxic effects (EU RAR, 1999).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local effects (eye irritation and potential skin irritation following repeated exposure to the chemical). Reversible changes in the lungs have been observed in animals following exposure to >100 mg/m3.

The chemical does not appear to produce the haemolytic effects observed with the shorter chain ethylene glycol butyl ether, 2-butoxyethanol. Changes to haematological parameters were only noted following oral exposure to high doses (1000 mg/kg bw/d).

Public Risk Characterisation

Although use in cosmetic products in Australia is not known, the chemical is reported to be used as a solvent in hair dyes overseas at concentrations up to 9%. The chemical is also reported to be used in domestic products such as paints and cleaning products both in Australia and overseas.

The European Scientific Committee on Consumer Products concluded that the use of diethylene glycol monobutyl ether (DEGBE) as a solvent in hair dye formulations at concentrations up to 9.0% does not pose a risk to the health of the consumer (SCCP, 2006). Other cosmetic products including those applied by spray or aerosol were not considered.

The margins of exposure estimated in a risk assessment conducted internationally for the chemical (EU RAR, 2006) for uses in paints and hard surface cleaners indicate that the chemical does not pose an unreasonable risk to the public except in the scenario where paint is spray-applied. The estimated margins of exposure are considered applicable in the Australian context.

The chemical is listed on Schedule 5 of the SUSMP for preparations containing more than 10% of the chemical. However no first aid instructions or safety directions appear to be specifically listed for the chemical.

Overall, for typical use scenarios identified, the risk to public is not considered to be unreasonable. The addition of safety directions relating to skin and eye contact, the avoidance of breathing aerosols and use of products in well ventilated area may minimise risk for products with higher concentrations (> 10%) of the chemical or for products that are spray-applied.

Occupational Risk Characterisation

During product formulation, dermal and ocular 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 local health effects, the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise 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 or an employee at a workplace has adequate information to determine appropriate controls.

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

NICNAS Recommendation

Further risk management is required. Sufficient information is available to recommend that risks to public health and safety from the potential use of the chemical in cosmetics and/or domestic products be managed through changes to poisons scheduling.

Assessment of the chemical is considered to be sufficient provided that risk management recommendations are implemented and all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

The chemical is listed on Schedule 5 of the SUSMP for preparations containing more than 10% of the chemical. Whilst this entry is considered appropriate, the addition of safety directions relating to, avoiding skin and eye contact and the breathing aerosols and use of products in well ventilated area, may further mitigate risk for products with higher concentrations (> 10%) of the chemical or for products that are spray-applied.

Work Health and Safety

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

	Approved Criteria (HSIS)[a]	*GHS Classification*
Irritation / Corrosivity	Irritating to eyes (Xi; R36)*	Causes serious eye irritation - Cat. 2A (H319)

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

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

Advice for consumers

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

Advice for industry

Control measures

Control measures to minimise the risk from 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 local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker (for spray applications);
- 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. *The Model Code of Practice - Spray Painting and Powder Coating* which provides practical guidance on how to manage health and safety risks associated with spray painting and powder coating is also available on this 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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