Australian Government
Department of Health and Ageing
NICNAS

INVENTORY MULTI-TIERED ASSESSMENT AND PRIORITISATION (IMAP)

HUMAN HEALTH TIER II ASSESSMENT FOR

Ethanol, 2-(diethylamino)-

CAS Registry Number: 100-37-8

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 three 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

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
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
m3	cubic metre
mg	milligram
mg/cm3	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)
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
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

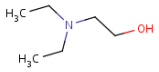
Glossary

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

Ethanol, 2-(diethylamino)-

CAS No: 100-37-8

Chemical Identity

Synonyms	2-(Diethylamino)ethanol Diethylaminoethanol 2-Hydroxytriethylamine (2-Hydroxyethyl)diethylamine Diethyl ethanolamine
Structural Formula	
Molecular Formula	C6H15NO
Molecular Weight (g/mol)	117.19
Appearance and Odour (where available)	Colorless liquid
SMILES	C(O)CN(CC)CC

Import, Manufacture and Use

Australian

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

International

The following international uses have been identified via the Registration Evaluation and Authorisation of Chemicals (REACH) Dossiers, the Organisation for Economic Cooperation and Development (OECD), Galleria Chemica, the Cosmetic Ingredients and Substances (CosIng) database, Personal Care Council Website (INCI Dictionary) & eChemPortal (Aggregated Computational Toxicology Resource (ACToR) and the Hazardous Substances Data Bank (HSDB)):

The chemical has reported cosmetic use:

- as a buffering agent in cosmetics.

The chemical has reported domestic use including:

- as a component of filler/sealing compounds and household cleaners/polishers (e.g. in shoe, leather, car).

The chemical has reported commercial use including:

- as a catalyst for the synthesis of polymers;
- as a pH stabiliser;
- as a component of corrosion inhibitors in closed systems, surface-active agents, cleaning/washing agents, cutting fluids, paint, lacquers and varnishes and surface treatment agents;
- in metal working fluids;
- as an additive in coatings, concrete and cement; and
- in the manufacture of emulsifying agents and special soaps.

The chemical has reported site-limited use including:

- as an intermediate in petroleum and gas processing chemicals; and
- in the production of pharmaceutical ingredients.

The chemical has reported uses as a food additive: use as a flavoring agents in Japan and Taiwan and in the USA up to 15 ppm is allowed; in steam contacting food except milk and milk products under US Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition.

Restrictions

Australian

No known restrictions have been identified.

International

No known restrictions have been identified.

Existing worker health and safety controls

Hazard classification

The chemical is currently classified on the Hazardous Substances Information System (HSIS) (may be accessed at http://hsis.safeworkaustralia.gov.au/HazardousSubstance) with following:
Xn; R20/21/22 (Acute toxicity)
C; R34 (Corrosive)

Exposure standards

Australian

The chemical has an exposure standard of 48 mg/m³ (10 ppm) Time Weighted Average (TWA).

International

48 - 50 mg/m³ (10 ppm) (OEL, TWA, STEL, PEL or STV) [USA (Alaska, Hawaii, Idaho, Michigan, Minnesota, Oregon, Tennessee, Vermont, Wyoming), Canada (Yukon), Norway, Switzerland, France, Greece, Ireland, Mexico, China, Argentina, Bulgaria, Czech Republic, Philippines, South Africa, Spain, Finland and New Zealand];
24 mg/m³ (5 ppm) MAK (Maximale Arbeitsplatz-Konzentration, or maximum allowed concentration) [Germany and Austria];
9.6 - 9.7 mg/m³ (2 ppm) (TWA, OEL, TLV or PEL) [USA (California), Canada (Alberta), Denmark, Iceland, Korea (South), Indonesian, Malaysia, Peru, Belgium and Singapore];
5 mg/m³ PDK (Predelno Dopustimaya Koncentraciya, or maximum allowed concentration) [Russia].

Health hazard information

Toxicokinetics

2-Diethylaminoethanol was rapidly absorbed via the oral route. It is also likely to be absorbed by dermal and inhalation routes. In the rat it was widely distributed to many tissues. It was primarily excreted unchanged via the urine in rats. Excretion via the faeces was also observed in rats, but to a lesser extent. Urinary excretion was also reported in humans (OECD, 2004).

The chemical has been reported to be rapidly absorbed via the oral route in humans and rats (Rosenberg et al., 1949 and Schulte et al., 1972). Rosenberg et al. (1949) reported that in humans, approximately 25% of the orally administered 2-diethyaminoethanol-HCl (5.6 g) was excreted unchanged in the urine within 48 hours. The plasma concentration peaked at 3 hours following oral administration and was almost undetectable after 8 hours.

In an oral gavage study with rats, radiolabeled 14C-2-diethylaminoethanol-HCl (68 or 679 mg/kg doses) was rapidly absorbed into the blood stream. With 68 mg/kg dose, the maximum concentration in the blood was reached in 30 minutes and with 679 mg/kg dose it was reached within 1 hour. The chemical was mainly excreted via the kidneys (of the 679 mg/kg bw dose, 40% was eliminated after 6 hours of application, 58.5% was

eliminated within the first 24 hours and 90% was eliminated within 10 days after the application). In this study, autoradiography indicated that 2-diethylaminoethanol was widely distributed throughout the body after gavaging (Schulte et al., 1972).

Acute toxicity

Oral

The data available support the current hazard classification in Australia: "Harmful if swallowed" (Xn; R22) (Safe Work Australia; HSIS).

The chemical was reported to cause acute toxicity via the oral route (median lethal dose (LD50) in rats = 1300 mg/kg bw) (JIHTAB, 1944).

Dermal

The data available support the current hazard classification in Australia: "Harmful in contact with skin" (Xn; R21) (Safe Work Australia; HSIS).

Rabbit dermal LD50 = 1260 mg/kg bw (Union Carbide Data Sheet, 1963) and guinea pig LD50 = 1000 mg/kg bw (JIHTAB, 1944).

Inhalation

The data available support the current hazard classification in Australia: "Harmful by inhalation" (Xn; R20) (Safe Work Australia; HSIS).

The mouse median lethal concentration (LC50) was reported to be 5000 mg/m³. Toxic effects include convulsions or effect on seizure threshold (GTPZAB, 1970). The rat lowest published lethal concentration (LCLo) = 4500 mg/m³/4 h (GTPZAB, 1970).

Obervation in humans

The lowest published toxic concentration (TCLo) in humans = 200 ppm. Nausea or vomiting was reported at this dose (Toxicology of Drugs and Chemicals, 1969).

Corrosion/Irritation

Corrosivity

The available data support the current hazard classification in Australia: " Causes burns" (C; R34) (Safe Work Australia; HSIS).

Studies were performed in accordance to OECD Test Guideline (TG) 404, and reported that the chemical was corrosive to the rabbit skin after 4 hours of application, both occlusive and semi-occlusive (OECD, 2004).

Several other studies where the OECD TG were not followed demonstrated that the chemical has the potential of being severely irritating to the eyes or could cause serious damage to the eyes (OECD, 2004). Irreversible damage to corneal tissue and corrosion of the conjunctiva and eyelids were observed when 50 µl of the undiluted chemical was applied to the eye. These findings were also irreversible after 8 days (OECD, 2004).

Sensitisation

Skin sensitisation

The chemical was not sensitising to the skin of guinea pigs (OECD, 2004).

The chemical was tested for skin sensitisation in guinea pigs using the method of Draize and the method of

Magnusson and Kligman (OECD, 2004). The chemical was reported to be negative in both skin sensitisation methods. None of the 70 animals induced with 2-diethylaminoethanol showed signs of sensitisation.

Repeat dose toxicity

Oral

No data are available.

Dermal

No data are available.

Inhalation

No adverse systemic effects were reported in a 14-week inhalation toxicity study in rats.

Repeated exposure of rats to vapors of the chemical (up to 76 ppm or 0.365 mg/l) for 14 weeks caused local toxicity (irritation) at the upper respiratory tract and the eyes. However, systemic toxicity was not observed. No observed adverse effect concentration (NOAEC) for systemic toxicity = 0.365 mg/L (365 mg/m³ or 76 ppm) (OECD, 2004)). After inhalation exposure, the main finding described was respiratory irritation which led to noisy breathing (rales) and irritation of the eyes. The lowest observed adverse effect concentration (LOAEC) for local toxicity (irritation) to the respiratory tract was 0.120 mg/L (120 mg/m³ or 25 ppm). The NOAEC for local toxicity was 0.053 mg/L (53 mg/m³ or 10 ppm) based on a lack of histopathological effects in the nasal cavity at this dose. However, since an effect (rales) was seen at the lowest concentration a NOEC was not established (OECD, 2004).

Genotoxicity

Based on the data available, the chemical is not genotoxic.

The chemical was evaluated for mutagenicity in the *Salmonella* microsome preincubation assay using a standard protocol approved by the National Toxicology Program. Doses of 0, 33, 100, 333, 1000, 2500, and 3333 µg/plate were tested in four *S. typhimurium* strains (TA98, TA100, TA1535, and TA1537) in the presence and absence of metabolic activation. The chemical was negative in these tests and the highest ineffective dose level tested without total or slight clearing of the background lawn in any *S.* tester strain was 1000 µg/plate (OECD, 2004).

The chemical was also tested for its ability to induce micronuclei in bone marrow erythrocytes in mice in vivo using doses up to 500 mg/kg bw under guideline conditions and was found to be negative (OECD, 2004). The report also indicates that the highest dose tested was adequate since animals showed a hunched posture, piloerection, rales (an abnormal or pathological respiratory sound), irregular respiration and swollen abdomen. One animal was sacrificed *in extremis*. Data from the preliminary test indicated that the test substance can reach the bone marrow (OECD, 2004).

Carcinogenicity

While no reliable data are available, the chemical is not anticipated to be a carcinogen based on the negative data for genotoxicity (OECD, 2004) and lack of carcinogenicity for similar compounds such as Triethanolamine (OECD, 1996).

Reproductive and developmental toxicity

Based on the limited information available, the chemical is not likely to be a reproductive or developmental toxicant.

In a 14-week repeat dose toxicity study, inhalation of 365 mg/m³ (76 ppm) the chemical did not cause any adverse effects on the reproductive organs in rats under the conditions tested (OECD, 2004).

In pregnant rats treated with the chemical on gestational days 6 - 15 (6 hours/day) by gavage, the highest dose of 0.486 mg/L (100 ppm) produced maternally toxic effects (significant decrease in hypoplastic bones of the forepaw). There were no deaths observed in this study. No adverse developmental effects were reported at the lower dose of 0.160 mg/L (33 ppm). The NOAECs are 0.160 mg/L for maternal toxicity and 0.486 mg/L for developmental toxicity (OECD, 2004).

Risk characterisation

Critical Health Effects

The main critical effect from exposure is corrosivity. The chemical may cause harmful effects if ingested, inhaled or in contact with skin.

Public Risk Characterisation

The chemical is used only as a buffering agent in cosmetics (CosIng) and therefore public exposure to higher concentrations of the chemical is not expected through cosmetic uses.

The chemical is also used in domestic products such as filler/sealing compounds and household cleaners/polishers. The concentration of the chemical in these domestic products in Australia is not known. The general public may be exposed to the chemical through dermal and/or inhalation routes when using domestic products containing the chemical. However, the concentration in these products is not considered to be high to cause corrosive effects based on the limited US information derived from the National Library of Medicine (NLM) Household Products Database.

Currently there are no restrictions in Australia to use this chemical in cosmetics or domestic products. If the concentrations in cosmetics and domestic products are low, corrosive effects are not expected. Therefore, further risk management is not considered necessary for public safety.

The current Australian exposure standard may require reconsideration, as in the repeat dose inhalation study, the presence of rales, albeit not severe, was observed in animals exposed at 10ppm, which is equivalent to the current exposure standard.

Occupational Risk Characterisation

Given the corrosive and harmful effects of the chemical, the risk to workers is considered high if adequate control measures to minimise occupational exposure to the chemical are not implemented. Inhalation exposure should be avoided to the extent possible. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or an employee at a work place has adequate information to determine appropriate controls for worker safety.

NICNAS Recommendation

The chemical is recommended for Tier III assessment to examine the adequacy of the current exposure standard. All other aspects have been sufficiently assessed at the Tier II level provided that the recommendations for classification and labelling are followed.

Occupational Health and Safety

The chemical is recommended for classification and labelling under the current Approved Criteria and adopted Globally Harmonised System (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

	Approved Criteria (HSIS)[a]	*GHS*[b] *Classification*
Acute Toxicity	Harmful if swallowed (Xn; R22)* Harmful in contact with skin (Xn; R21)* Harmful by inhalation (Xn; R20)*	Harmful if swallowed - Cat. 4 (H302) Toxic in contact with skin - Cat. 3 (H311) Toxic if inhaled - Cat. 3 (H331)
Irritation / Corrosivity	Causes burns (C; R34)*	Causes severe skin burns and eye damage - Cat. 1 (H314)

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

[b] Globally Harmonised System

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

Advice for consumers

The domestic products containing the chemical should be used according to the label instructions.

Advice for industry

Work Health and Safety (WHS) legislation in each Australian state and territory imposes obligations on manufacturers and importers of hazardous chemicals to ensure that the chemicals are correctly classified, correctly labelled and (material) safety data sheets ((m)SDS) are prepared for those chemicals. These include:

- the (m)SDS for the chemical, or products and mixtures containing the chemical, must contain accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of a chemical, as well as instructions on the safe storage, handling, use and disposal of the chemical (a review of physical hazards of the chemical has not been undertaken as part of this assessment); and
- a copy of the (m)SDS must be easily accessible to employees.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals to meet duties under the WHS Regulations are provided in the *Preparation of Safety Data Sheets for Hazardous Chemicals—Code of Practice* and *Labelling of Workplace Hazardous Chemicals—Code of Practice*, respectively.

To comply with the WHS legislation, a person conducting a business or undertaking (PCBU) at a workplace must manage risks arising from storage, handling and use of a hazardous chemical. Other duties may apply to a PCBU involved in the storage, handling and use of hazardous chemicals at a workplace. Refer to the WHS legislation in the relevant jurisdiction for further information.

Guidance on managing risks from hazardous chemicals are provided in the *Managing Risks of Hazardous Chemicals in the Workplace—Code of Practice*.

It is recommended that a PCBU should ensure that:

- protective clothing or protective equipment is used. The protective clothing or equipment should be designed, constructed, and operated to ensure that, the person handling the chemical (at concentrations greater than 25%) does not come into contact with the chemical; and
- equipment used to handle the chemical retains the chemical, without leakage, at all temperatures and pressures for which the equipment is intended to be used; and dispenses or applies the substance, without leakage, at a rate and in a manner for which the equipment is designed.

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