Ethane, 1,1'-oxybis[2-methoxy-: Human health tier II assessment

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CAS Number: 111-96-6

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	Diethylene glycol dimethyl ether Bis(2-methoxyethyl) ether Diglyme Dimethoxydiglycol 2,5,8-Trioxanonane
Structural Formula	
Molecular Formula	C6H14O3
Molecular Weight (g/mol)	134.174
Appearance and Odour (where available)	Colourless liquid with a mild odour.
SMILES	C(COCCOC)OC

Import, Manufacture and Use

Australian

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

The chemical has reported commercial use including as a solvent/carrier for substances used in the textile industry.

The total volume introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was 0–0.5 tonnes.

International

The following international uses have been identified through European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening Information Dataset Initial Assessment Report (OECD SIAR); Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary; and eChemPortal: OECD High Production Volume chemical program (OECD HPV), the US Environmental Protection Agency's Aggregated Computational Toxicology Resource (ACToR), and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported cosmetic use as a solvent.

It is also noted that the chemical has been prohibited for use in cosmetic products in EU and in some other countries (see **Restrictions—international**).

As there is currently no documented use of this chemical in cosmetic as well as consumer products in the United States, the chemical is not likely to be widely available for cosmetic/domestic uses (Personal Care Products Council, 2011; US Household Products Database).

The chemical has reported domestic use including as a cleaning and/or washing agent.

The chemical has reported commercial use including in:

- rubber and plastic products;
- transport equipment; and
- fabricated metal products, except machinery and equipment.

The chemical has reported site-limited use including:

- as an auxiliary solvent in water-based paints, which are industrially applied on automobiles, metal furniture, household appliances, and machines;
- as an inert reaction medium in chemical synthesis and as a separating agent in distillations including uses in polymerisation reactions (e.g., of isoprene, styrene), manufacturing perfluorinated organic compounds, and reactions in boron chemistry; and
- in manufacturing integrated circuit boards, primarily as a solvent for the photoresists. These are used as photosensitive materials to coat the wafer during microlithographic patterning in the photo/apply process and in producing semiconductors.

The chemical has reported non-industrial use in the production of pharmaceuticals.

Restrictions

Australian

No known restrictions have been identified.

International

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

- EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products;
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain;
- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient "Hotlist"); and
- Association of Southeast Asian Nations (ASEAN) Cosmetic Directive Annex II (Part 1)—List of Substances which must not form part of the composition of cosmetic products.

The chemical is also restricted by Annex XVII to REACH Regulation. The chemical cannot be used in substances and preparations placed on the market for sale to the general public in individual concentrations ≥0.5 %.

Existing Work Health and Safety Controls

Hazard Classification

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

T; R60/61 (Reproductive toxicity: Cat. 2).

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica).

The chemical has an exposure standard of 5.5 mg/m^3 (1 ppm) time weighted average (TWA) in California; 10 mg/m^3 in Russia; 27 mg/m^3 (5 ppm) in Denmark and Switzerland; and 28 mg/m^3 (5 ppm) in Germany.

A short-term exposure limit (STEL) of 27 mg/m^3 (5 ppm) in California and 216 mg/m^3 (40 ppm) in Switzerland have also been reported.

Health Hazard Information

Toxicokinetics

The chemical has been reported to be readily absorbed via all routes of exposure. It has the highest dermal absorption rate among glycol ethers, either as liquids or vapours. Although data are limited regarding the distribution of the chemical within the body following absorption, glycol ethers in general are readily distributed throughout the body. The chemical's principal pathway of metabolism involves O-demethylation with subsequent oxidation to form the main metabolite: 2-methoxyethoxyacetic acid. This metabolite has been reported to account for about 60–70 % of the dose in the urine of rats. In rats, the majority of the chemical (90 %) has been reported to be eliminated through the urine; the remaining dose as carbon dioxide (3.6 %), and through faeces (2.9 %) (WHO, 2002; ECHA, 2011; HSDB; REACH).

The minor metabolite, 2-methoxyacetic acid, was indicated to be responsible for reproductive toxicity. Furthermore, 2-methoxyacetic acid was the sole metabolite in the foetus after female CD-1 mice were administered 3.73 mg/kg bw of the chemical at gestation day (GD) 11 or 12. The highest levels observed for the average embryo (whole embryos analysed) were detected six hours after dosing. Although the chemical itself has shown no bioaccumulation potential, this metabolite persisted longer, with a half-life in humans calculated as 77.1 hours.

An in vitro dermal absorption study of the chemical, using the Franz cell method, was conducted with human skin. The epidermal surface (3.14 cm^2) was subjected to 0.2 mL of the chemical. After a lag time of approximately 36 minutes, the steady state permeation rate of 0.952 mg/cm^2/hour was calculated.

Acute Toxicity

Oral

The chemical is reported to have low acute toxicity in animal tests following oral exposure. The median lethal dose (LD50) is >2000 mg/kg bw in rats. Observed sub-lethal effects included restlessness, disturbed equilibrium, prone position, and breathing difficulty. At high doses, there was red discharge from the eyes (US EPA, 2008a; HSDB; REACH).

Dermal

No data are available.

Inhalation

The chemical is reported to have low acute toxicity in animal tests following inhalation exposure.

In an acute inhalation toxicity study conducted similar to OECD Test Guideline (TG) 403, Wistar rats (male and female) were exposed (nose only) to a saturated vapour of the chemical at greater than 11000 mg/m^3 (11–14 mg/L) for seven hours and observed for 14 days. There was no mortality. Observed sublethal effects included restlessness, narrowing of palpebral fissures, and irregular breathing. As there was no mortality, the median lethal concentration (LC50) was reported to be as >11–14 mg/L (WHO, 2002; US EPA, 2008a; REACH).

Observation in humans

No data are available.

Corrosion / Irritation

Respiratory Irritation

Although specific information is not available, the chemical has been reported to be a mild respiratory irritant during short-term exposure. However, these effects are reversible and are not sufficient to warrant hazard classification (ICSC).

Skin Irritation

The chemical is reported to slightly irritate the skin in animal studies. The effects were not sufficient to warrant hazard classification.

In a skin irritation study on albino Himalayan rabbits, application of 0.5 mL of the undiluted chemical on abraded skin for 24 hours caused slight irritation at the end of the dosing period. A single animal (out of six) had isolated patches of dry chapped skin after 72 hours. The mean (24, 48, 72 hours) scores for erythema and oedema were 0.89 and 0.50, respectively. All observed effects were fully reversible within 72 hours (WHO, 2002; REACH).

Eye Irritation

The chemical is reported to be a slight eye irritant in animal studies. The effects were not sufficient to warrant hazard classification.

In an eye irritation study conducted according to the US Food and Drug Administration (FDA) guidelines, albino Himalayan rabbits were exposed to the undiluted chemical (0.1 mL). Slight irritation (redness and swelling) was observed in all animals at one hour following application. These signs were fully reversible within 72 hours (WHO, 2002; REACH).

Sensitisation

Skin Sensitisation

No data are available. The chemical structure does not have any features generally associated with sensitising potential.

Repeated Dose Toxicity

Oral

Limited data are available. However, as the most sensitive effects seen in repeated dose toxicity following oral exposure are associated with the reproductive and developmental toxicity, these are discussed further under that section (see **Reproductive and developmental toxicity**).

Dermal

No data are available.

Inhalation

The available data indicate that the chemical might cause damage to health following repeated inhalation exposure. As reproductive and developmental effects were mainly noted in these studies, they are reported in the **Reproductive and developmental toxicity** section. The target organs are the testes (decreased sperm production) and bone marrow (hypoplasia), with haematopoietic effects being the most sensitive effects seen in females, although at much higher doses than the reproductive effects in males (WHO, 2002; US EPA, 2008a–b; REACH).

Genotoxicity

The available data indicate that the chemical does not have mutagenic or genotoxic potential.

The chemical gave negative results in several in vitro tests (bacterial reverse mutation assays in *Salmonella typhimurium,* DNA damage and repair assay in human embryonic intestinal cells) and also in vivo tests (mammalian bone marrow chromosome aberration assays in rats) for gene mutation and chromosomal aberrations (clastogenicity) (WHO, 2002; US EPA, 2008a; REACH).

In a dominant lethal assay with rats, the dominant lethal effect or the reduced fertility of the males could be responsible for the reduced number of pregnancies and increase in pre-implantation losses. Considering the known effects of the chemical on fertility, the reduced fertility was concluded to be responsible for these effects (WHO, 2002; US EPA, 2008a; REACH).

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

The chemical is classified as hazardous, a Category 2 substance toxic to reproduction with the risk phrases ‘May impair fertility’ (T; R60) and ‘May cause harm to the unborn child’ (T; R61) in HSIS (Safe Work Australia). The available data support this classification. The metabolite of the chemical, 2-methoxyacetic acid, has been indicated as responsible for these effects on the male reproductive organs (see **Toxicokinetics**) (WHO, 2002; US EPA, 2008a–b; ECHA, 2011; REACH).

In a repeated dose inhalation toxicity study, groups of 20 male and 10 female Crl:CD rats were exposed (nose only) to the vapours of the chemical at 0, 110, 370, or 1100 ppm (0, 614, 2065, or 6138 mg/m³), six hours/day, five days/week, for two weeks. Male rats were euthanised immediately after the last exposure and 14, 42, or 84 days post-exposure. Female rats were euthanised immediately after the last exposure and 14 days post-exposure. Male rats were more sensitive than females; the primary target organs in males were the thymus and reproductive organs (testes, epididymes, seminal vesicles and prostate). Stage-specific germ cell damage occurred at all concentrations and the effects were both concentration and time-dependent. A no observed adverse effect level (NOAEL) could not be established in this study for male rats, and the lowest observed adverse effect level (LOAEL) was reported to be 110 ppm. The LOAEL was based on testicular atrophy, germ cell damage, reduced leukocyte count, and lower mean body weight. Other treatment-related effects noted in males at every test concentration were decreased leukocyte counts at the end of the exposure period and statistically lower mean body weights throughout the treatment period. The NOAEL for female rats was established as 370 ppm (2065 mg/m^3), based on haematopoietic system effects seen at the next higher dose (WHO, 2002; US EPA, 2008a; REACH).

In a similar study conducted at lower concentrations of the chemical, rats were exposed (nose only) to the vapours of the chemical at 0, 3, 10, 30, and 100 ppm (0, 16.7, 55.8, 167, and 558 mg/m³) (measured concentrations: 0, 3.1, 9.9, 30, and 98 ppm, corresponding to 0, 17.3, 55.2, 167, and 547 mg/m^3), five days/week, for two weeks. The post-exposure period was 14 days. There was no effect on weights of testes, seminal vesicles, prostate, and epididymis. Minimal to mild testicular atrophy was noted in the 100 ppm (558 mg/m³) group on microscopic examination. A NOAEL of 30 ppm (167 mg/m³) was established for the study (WHO, 2002). In a dominant lethal assay with rats, the reduced fertility was concluded to be due to the effects of the chemical (reduced number of pregnancies, increased pre-implantation loss) on fertility (WHO, 2002; US EPA, 2008a; REACH).

The chemical has been reported to cause developmental effects in several studies in rats, rabbits, and mice via inhalation and oral exposure. This has been attributed to the chemical's ability to disrupt normal morphogenesis in a wide variety of tissues and

organ systems, and exert a general toxic effect upon proliferating cells (WHO, 2002; US EPA, 2002; REACH). Some of these studies are described below.

In a developmental toxicity study (OECD TG 414), pregnant CD-1 mice were administered the chemical by oral gavage at doses of 62.5, 125, 250, and 500 mg/kg bw/day during gestation days (GD) 6–15 and were sacrificed on day 17. Adverse effects on foetal growth, percent implantations, post implantation losses, foetal viability and foetal morphological development were noted at doses of 125 mg/kg bw/day and above. At the highest tested dose, 94 % of the foetuses were malformed compared with 0.35 % in the control group. Developmental and maternal NOAELs of 62.5 and 500 mg/kg bw/day, respectively, were established in this study (WHO, 2002; US EPA, 2008; REACH).

In another developmental toxicity study, pregnant New Zealand White rabbits were administered the chemical by oral gavage at doses of 0, 25, 50, 100, and 175 mg/kg bw/day during GD 6–19. Adverse developmental effects and minimal maternal toxicity were observed at doses of 50 and 100 mg/kg bw/day. At the highest tested dose of 175 mg/kg bw/day, increased prenatal mortality and malformed foetuses (fusion of ribs, hydronephrosis) were observed. A developmental NOAEL of 25 mg/kg bw/day and a maternal NOAEL of 100 mg/kg bw/day were estabished (WHO, 2002; ECHA, 2011; REACH).

Several epidemiology studies were conducted at workplaces where the chemical was used as a solvent (paint) or in fabrication (semiconductors). The chemical was present in a composition or formulation. Based on the results of these studies, it was concluded that continuous exposure to the chemical could have adverse effects in the reproductive system (WHO, 2002; HSDB; REACH).

The exposure to ethylene glycol ethers (EGE) that included the chemical was determined using questionnaires from workers in 14 different semiconductor companies, mainly in the fabrication area. A prospective study of early foetal loss and fecundity (probability of conception per menstrual cycle) was conducted in a subset of female employees from five plants. Diaries and urinary human chronic gonadotropin (hCG) levels were monitored and measured daily for six months. In the retrospective study, the overall relative risk (RR) for spontaneous abortion was 1.43, for workers exposed to a higher level of EGEs (masking group); the risk for spontaneous abortion increased three-fold (RR = 3.38). In the prospective study, no statistically significant differences were detected in the overall rate of spontaneous abortions between fabrication and non-fabrication workers, or when pregnancy outcomes were examined by work group; however, the ability to conceive was lower among female workers exposed to EGEs (WHO, 2002; REACH).

Another retrospective study evaluated the reproductive outcomes among both women employed in and wives of men employed in two semiconductor plants. Among female employees, a dose-response relationship ($p = 0.02$) was established for both endpoints following EGE exposure. Among wives of male employees, an increased risk of subfertility was speculated. A prospective study of reproductive outcomes conducted at the same plants reported elevated possibilities of pregnancy loss (WHO, 2002).

A study on 2-methoxyacetic acid (the metabolite of the chemical) was conducted on semen samples from 73 shipyard painters. Apart from inhalation, skin contact was also taken into account as a possible route of exposure. Increased prevalence of oligospermia and azoospermia was observed. Separate studies on the haematological effects of the same metabolite in three occupational painter populations found abnormal haemoglobin levels and white blood cell counts (WHO, 2002; HSDB).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (reproductive and developmental toxicity).

Public Risk Characterisation

The use of the chemical in cosmetic and domestic products in Australia is not known. Although the chemical has been reported to be used in cosmetic and other domestic uses (see **Import, manufacture and use**), the available North American and European databases do not supply evidence for other uses of the chemical in consumer products. The chemical has been identified ‘as a substance of very high concern because of its CMR (carcinogenic, mutagenic and toxic for reproduction)

properties' and has also been restricted for its use by the general public by listing on Annex XVII to REACH Regulation (ECHA, 2011).

Therefore, the use of the chemicals in this group in cosmetic and consumer products is not anticipated in Australia. Hence, the public risk from chemicals in this group is not considered to be unreasonable.

Occupational Risk Characterisation

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

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

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

NICNAS Recommendation

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

Regulatory Control

Work Health and Safety

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

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Reproductive and Developmental Toxicity	Repro. Cat 2 - May impair fertility (T; R60)* Repro. Cat 2 - May cause harm to the unborn child (T; R61)*	May damage fertility. May damage the unborn child - Cat. 1B (H360FD)

[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 instruction on the label.

Advice for industry

Control measures

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

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- 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;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

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

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

Obligations under workplace health and safety legislation

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

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

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

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

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

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