Ethane, 1,2-dimethoxy-: Human health tier II assessment

01 September 2015

CAS Number: 110-71-4

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

NICNAS has made every effort to assure the quality of information available in this report. However, before relying on it for a specific purpose, users should obtain advice relevant to their particular circumstances. This report has been prepared by NICNAS using a range of sources, including information from databases maintained by third parties, which include data supplied by industry. NICNAS has not verified and cannot guarantee the correctness of all information obtained from those databases. Reproduction or further distribution of this information may be subject to copyright protection. Use of this information without obtaining the permission from the owner(s) of the respective information might violate the rights of the owner. NICNAS does not take any responsibility whatsoever for any copyright or other infringements that may be caused by using this information.

Acronyms & Abbreviations

Chemical Identity

Synonyms	1,2-dimethoxyethane (DME) ethylene glycol, dimethyl ether (EGDME) ethylene dimethyl ether monoglyme glycol dimethyl ether
Structural Formula	
Molecular Formula	C4H10O2
Molecular Weight (g/mol)	90.1
Appearance and Odour (where available)	colourless liquid with ether-like odour
SMILES	C(COC)OC

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) Environmental Protection Agency's Risk-Based Prioritization Document; the OECD High Production Volume chemical program (OECD HPV); the US EPA's Aggregated Computer Toxicology Resource (ACToR); the US National Library of Medicine's Hazardous Substances Data Bank (HSDB) and various international assessments including WHO Concise International Chemical Assessment Document (CICAD) 2002 and Clariant, 2008).

The chemical has reported commercial uses in the production of lithium batteries and as an industrial solvent in lacquers, varnishes, paints and printing inks.

The chemical has reported site-limited use in manufacture of other chemicals.

The chemical has reported non-industrial use as a solvent in pharmaceutical applications.

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—List of substances which must not form part of the composition of cosmetic products.

The chemical is restricted by Annex XVII of REACH Regulations. The chemicals cannot be used in substances and preparations placed on the market for sale to the general public above the concentration limit of 0.3 % (European Parliament & Council, 2012).

The chemical is listed on the candidate list of Substances of Very High Concern (SVHC) for inclusion on Annex XVI of REACH Regulations (ECHA, 2012).

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):

- Xn; R20 (acute toxicity); and
- Xn; R60/61 Repr. Cat 2 (Reproductive toxicity).

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit of 10-18 mg/m^3 (5 ppm) time weighted average (TWA) in Latvia and Canada (Ontario) and

10-25 ppm short-term exposure limit (STEL) in Russia and the United States of America (USA).

Temporary Emergency Exposure limits (TEELs) defined by the US Department of Energy (DOE) are reported as:

TEEL-1 = 0.54 mg/m^3;

TEEL-2 = 5.9 mg/m^3; and

TEEL-3 = 76 mg/m^3.

Health Hazard Information

Both monoglyme (CAS No. 110-71-4) and diglyme (CAS No. 111-96-6) have similar metabolism, with the common active metabolite 2- methoxyethanol (2-ME) (CAS No. 109-86-4), and ultimately 2-methyoxy acetic acid. Toxicokinetics are expected to be similar for monoglyme and diglyme for hydrolysis to 2-ME and so data for diglyme are used for read across in the absence of information for monoglyme (OECD 2014). The chemical 2-ME has been previously assessed in IMAP, and information on this chemical is provided as supporting data (CICAD, 2002; US EPA HPVIS, 2008; NICNAS a & b; REACH).

Toxicokinetics

Glycol ethers are well absorbed by all routes of exposure. Dermal absorption of glycol ethers in liquid form or as vapour is very high (CICAD, 2002; US EPA HPVIS, 2008). No toxicokinetic studies are available for monoglyme. Monoglyme and diglyme are considered to be metabolised by the same enzymatic metabolic pathway and demonstrated similarity of metabolic products. In general, glycol ethers are widely distributed throughout the body (CICAD, 2002; US EPA HPVIS, 2008; NICNAS a & b; REACH).

Numerous studies have reported that 2-methyoxyacetic acid is the toxic metabolite, responsible for the reproductive toxicity of glycol ethers (CICAD, 2002; SVHC, 2012). The chemical 2-methyoxyacetic acid was the only metabolite found in the foetus of female mice exposed to diglyme. Although diglyme has shown no bioaccumulation potential, 2-methyoxyacetic acid persisted

longer with a half-life in humans calculated as 77.1 hours (CICAD, 2002; US HPVIS, 2008; SVHC, 2012; REACH). Excretion of diglyme is mainly through the urine and small amounts in the faeces. Approximately 2 % of the administered dose is found remaining in the carcass (CICAD, 2002; US HPVIS, 2008; SVHC, 2012; REACH).

Acute Toxicity

Oral

The chemical has low acute oral toxicity based on the results from animal tests following acute oral exposure. The median lethal dose (LD50) in female rats was reported to be >4000 mg/kg bw (US EPA HPVIS, 2008; REACH).

In a range finding study conducted in female Sprague Dawley (SD) rats, the chemical was administered to four animals/group by oral gavage at 500, 1000, 2000 or 4000 mg/kg bw. Animals were observed for 14 days post administration. No mortality was reported. At 2000 and 4000 mg/kg bw, the animals were unbalanced and lethargic after treatment. An LD50 of >4000 mg/kg bw was reported (US EPA HPVIS, 2008; REACH).

Dermal

The chemical has low acute dermal toxicity based on results from animal tests following dermal exposure. The reported LD50s were >5000 mg/kg bw in rats, and approximately 2000 mg/kg bw in rabbits.

In a study conducted according to OECD Test Guideline (TG) 402, the chemical was applied to the skin of female Wistar rats (six animals/dose) at a single concentration of 5000 mg/kg bw for 24 hours under occlusive conditions. No mortality and no clinical symptoms were observed. The dermal LD50 was >5000 mg/kg bw (REACH).

In another study, the chemical was applied to the skin of New Zealand White female rabbits (two animals/group) at doses of 1000 or 2000 mg/kg bw. One animal at 2000 mg/kg bw died. No other observations were reported from the study. The LD50 was reported to be approximately 2000 mg/kg bw (US EPA HPVIS, 2008; REACH).

Inhalation

The chemical is classified as hazardous with the risk phrase ‘Harmful by inhalation’ (Xn; R20) in the HSIS (Safe Work Australia). The available data do not support this classification but there is not sufficient evidence for an amendment.

The chemical has low to moderate acute toxicity based on the results from animal tests following inhalation exposure. In an inhalation study, rats were exposed to 20 or 63 mg/L of monoglyme for 6 hours via whole-body inhalation exposure. At 20 mg/L, no mortalities were reported, but slight ataxia and irritation were observed. At

63 mg/L, severe signs of irritation with progression to prostration were reported. All animals in this group died within 72 hours after exposure. The LC50 was determined to be between 20 mg/L and 63 mg/L (US EPA HPVIS, 2008).

In an inhalation study similar to OECD TG 403, Wistar rats (six animals/sex/dose) were exposed by nose-only inhalation to the chemical at concentrations of 240 mg/L for either one hour (group 1) or three hours (group 2) and 200 mg/L for six hours (group 3), and observed for 14 days. No mortalities were observed at 240 mg/L for one hour exposure. Clinical signs including ataxia, salivation and irregular respiration were reported. Eleven animals at 240 mg/L (group 2) and all animals at 200 mg/L (group 3) died following exposure. White foam in the stomach was reported at necropsy. No LC50 values were determined from the study (REACH).

Corrosion / Irritation

Respiratory Irritation

No data are available.

Skin Irritation

Based on the available data, the chemical is a skin irritant and warrants hazard classification.

In a skin irritation study conducted according to OECD TG 404, 0.5 mL of the chemical was applied on the shaved skin of six Himalayan rabbits for 24 hours under occlusive conditions. Observations were made at 24, 48 and 72 hours post application. Severe erythema to slight eschar formation (total mean score of 2.33) and slight oedema (total mean score of 0.72) were seen in all animals. Other effects reported after 48 hours included dry, rough, hardened, raised skin and greenish discolouration and haematoma of the lower skin layers at the site of application. The signs of irritation were not reversible within the 72 hour observation period (REACH).

Eye Irritation

Based on the available data, the chemical is not an eye irritant.

In an eye irritation study similar to OECD TG 405, 0.1 mL of the chemical was instilled in the eyes of six New Zealand White rabbits. The treated eyes were washed 24 hours after treatment. Observations were made at one, seven, 24, 48 and 72 hours after application. Redness and swelling were observed in all animals one hour after application, but these decreased significantly after 72 hours. All treatment related effects were fully reversed after 14 days (REACH).

Sensitisation

Respiratory Sensitisation

No data are available.

Skin Sensitisation

No data are available.

Repeated Dose Toxicity

Oral

No data are available for the chemical. However, a number of repeated dose oral toxicity studies on the metabolite, 2-methoxyethanol (CAS No. 109-86-4), are available. Adverse effects in studies in rats treated with 2-methoxyethanol for 13 weeks included reduced thymus weights, testicular degeneration, progressive anaemia and histopathological changes in the haematopoietic tissues including spleen, bone marrow and liver. The lowest observed adverse effect level (LOAEL) was reported as 750 ppm (approximately 70 mg/kg bw/day) based on testicular degeneration in males and decreased weight of the thymus in both sexes (CICAD, 2002; US EPA HPVIS, 2008; NICNASa; REACH).

In another study, male and female B6C3F1 mice (10 animals/sex/dose) were administered 2-methoxyethanol in drinking water at doses of 0, 2000, 4000, 6000, 8000 or 10,000 ppm (300 to 1800 mg/kg bw/day) for a period of 13 weeks. The LOAEL was determined to be 2000 ppm (approximately 300 mg/kg bw/day) based on reduced sperm concentrations and motility in male mice, and histological changes in the spleen and adrenal in female mice at all doses (CICAD, 2002; US EPA HPVIS, 2008; REACH).

Dermal

No data are available.

Inhalation

Based in the available information, the chemical is not considered to cause severe damage to health in animal studies following repeated inhalation exposure, excepting reproductive and developmental toxicity. This is discussed further under that section (see **Reproductive and developmental toxicity**).

In a repeated inhalation study conducted according to OECD TG 412, Hoechst rats (10 animals/sex/dose) were exposed by whole body inhalation to monoglyme vapours at doses of 0, 10, 50 or 250 ppm (approximately 0, 0.037, 0.187 or 0.935 mg/L, respectively) for six hours/day, five days/week for two weeks. The exposure period was followed by a recovery period of 36 days. No mortality or clinical signs of toxicity were reported at any dose. The no observed effect concentration (NOEC) was 50 ppm (0.187 mg/L) based on slight changes in the testes observed at 250 ppm (Ferro, 2001; SVHC, 2011; REACH).

In another repeated dose inhalation study conducted according to OECD TG 412, male and pregnant female Hoechst rats (five animals/group) were exposed by whole body inhalation to monoglyme vapours at doses of 0, 100 or 500 ppm for six hours/day, five days/week for two weeks. The exposure period was followed by a recovery period of three days. At 500 ppm, three female rats had decreased body weights. Decreased leucocyte counts were reported for all treated groups. The NOAEC was <100 ppm based on oligospermia, retardation of foetal development and resorption of embryos observed at 100 ppm (Ferro, 2001; US EPA HPVIS, 2008; SVHC, 2011).

In a study in rabbits conducted according to OECD TG 412, SPF Wiga rabbits (six/sex/group) were exposed by whole body inhalation to monoglyme vapours at doses of 0, 10, 50 or 250 ppm for six hours/day, five days/week for two weeks. The exposure period was followed by a recovery period of 36 days. Food consumption was decreased for treated groups during the exposure period. At 250 ppm, irreversible changes to the seminiferous epithelium of the testes were reported. A NOEC of 10 ppm was established in this study (Ferro, 2001; US EPA HPVIS, 2008; SVHC, 2011).

Genotoxicity

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

In vitro studies

In an Ames test conducted according to OECD TG 471, the chemical was tested at 0, 0.004, 0.02, 0.1, 0.5, 2.5 or 10 µL per plate for point mutations in *Salmonella typhimurium* strains TA 98, 100, 1535, 1537 and 1538 with and without metabolic activation. The chemical did not cause increases in the number of revertant colonies in any of the strains tested (REACH).

In an unscheduled DNA synthesis (UDS) assay conducted according to OECD TG 482, the chemical was tested for genotoxicity in human cell line A549 at concentrations ranging from 0.1 µg/mL to 1000 µg/mL. The chemical was not mutagenic in this assay (REACH).

In a sister chromatid exchange (SCE) assay conducted according to OECD TG 479, the chemical was tested in Chinese hamster ovary (CHO) cells with and without metabolic activation at concentrations of 2, 3, 4, 5 or 5.5 % (v/v). The chemical produced increases in the mean number of SCEs per cell with and without metabolic activation (REACH).

No data from in vivo studies are available.

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

The chemical is classified as hazardous—Category 2 substance toxic to reproduction—with the risk phrase ‘May impair fertility’ (T; R60) and Category 2 substance toxic to reproduction—with the risk phrase 'May cause harm to the unborn child' (T; R61) in the HSIS (Safe Work Australia). The available data support this classification.

Monoglyme, diglyme and 2-methoxyethanol share a common metabolite, 2-methyoxyacetic acid, which is considered to be responsible for reproductive toxicity (CICAD, 2002; SVHC, 2012). Diglyme and 2-methoxyethanol have been previously assessed by NICNAS and both are classified as reproductive toxicants (NICNAS a & b).

Oral

In a reproductive toxicity study, monoglyme was administered to 50 pregnant female Charles River (CD-1) mice at 2000 mg/kg by oral gavage for 14 days. No viable litters were produced by mice dosed at 2000 mg/kg. Examination of the uteri showed significant embryotoxicity. A LOAEL of 2000 mg/kg bw/day was established in this study (Ferro, 2001; NTP).

In a developmental toxicity study, pregnant female Harlan SD rats (six to 28 animals/group/dose), were administered the chemical by oral gavage at doses of 0, 30, 60, 120, 250, 500 or 1000 mg/kg bw/day on gestation days eight to 18. All dams were euthanised and the offspring were examined for developmental effects. Necrotic masses were reported in dams treated at the three highest doses, suggesting that embryonic deaths occurred shortly after the treatment initiation. A non-significant reduction in the number of litters and retarded ossification in the live pups were seen at 30 mg/kg bw/day. A seven-fold increase in resorptions per litter was seen at

60 mg/kg bw/day compared with controls and less than one pup per litter survived. Complete early foetal death together with limited maternal toxicity was observed at 120 mg/kg bw/day and above. The LOAEL for maternal toxicity was 120 mg/kg bw/day based on decreased maternal body weights and a NOAEL of 60 mg/kg bw/day was established for maternal toxicity. The LOAEL for developmental toxicity was 30 mg/kg bw/day. A NOAEL for developmental toxicity was not established (Ferro, 2001; US EPA HPVIS, 2008; REACH).

Inhalation

Repeated dose inhalation studies in rats and rabbits resulted in testicular effects and foetotoxicity following vapour inhalation exposure to the chemical.

At 250 ppm, reduction of cell layers in seminiferous epithelium of the testes was seen in rats. In another rat study, severe lesions of the seminiferous epithelium of the testes and increased resorption in pregnant females were reported at 500 ppm. At 100 ppm, oligospermia was noted in the microscopic examination of the testes and epididymis. Foetal retardation was also reported (Ferro, 2001; US EPA HPVIS, 2008; REACH).

In a study in rabbits, repeated exposure to monoglyme vapours caused irreversible changes to the seminiferous epithelium of the testes at 250 ppm (Ferro, 2001; US EPA HPVIS, 2008; SVHC, 2011).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation are systemic long-term effects (reproductive toxicity, developmental toxicity). Systemic acute effects (acute toxicity from inhalation exposure) and local effects (skin irritation) have also been reported.

Public Risk Characterisation

Given the uses identified for the chemical, it is unlikely that the public will be exposed.

Many countries such as Canada, New Zealand and in the European Union have restricted the use of this chemical in cosmetics. The chemical is not known to have cosmetic or domestic use internationally and the use of the chemical in cosmetics and domestic products in Australia is not expected. Therefore, the chemical is not considered to pose an unreasonable risk to the public.

Occupational Risk Characterisation

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

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

NICNAS Recommendation

Assessment of this 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. No further assessment is required unless information becomes available to indicate domestic and 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 and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful by inhalation (Xn; R20)*	Harmful if inhaled - Cat. 4 (H332)
Irritation / Corrosivity	Irritating to skin (Xi; R38)	Causes skin irritation - Cat. 2 (H315)
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 or 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 and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemical, if valid techniques are available to monitor the effect on the worker's health;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

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

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

Obligations under workplace health and safety legislation

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

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

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

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

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

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