2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester: Human health tier II assessment

18 September 2014

CAS Number: 868-77-9

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

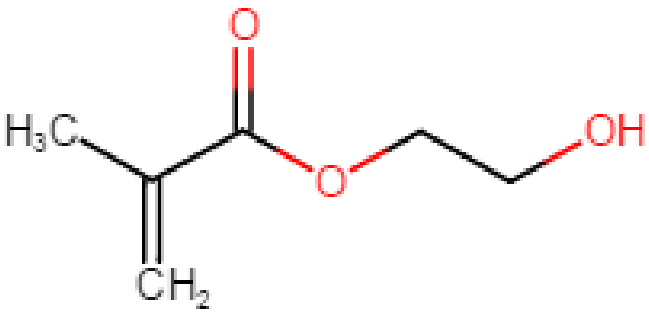
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	2-hydroxyethyl methacrylate ethylene glycol mono methacrylate HEMA
Structural Formula	
Molecular Formula	C6H10O3
Molecular Weight (g/mol)	130.14
Appearance and Odour (where available)	Colourless liquid
SMILES	C(=O)(C(=C)C)OCCO

Import, Manufacture and Use

Australian

No specific Australian import or manufacturing information has been identified.

The chemical has been listed in Australian safety data sheets (SDS) with the following industrial uses:

- cosmetics—as a nail binding agent (< 10 %)
- domestic products—in windshield repair kits (70–80 %)
- commercial products—in anaerobic adhesives (10–35 %) and compound mortar (< 20 %)

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; 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; 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 including:

- in artificial nail builders;
- in finger paints; and
- as a film forming agent.

The chemical is listed in the Compilation of Ingredients Used in Cosmetics in the United States (CIUCUS, 2011), indicating its use in 25 cosmetic products.

The chemical has reported domestic use including in:

- adhesives and sealants;
- paint, thinners and paint removers;
- washing and cleaning products;
- anti-freeze and de-icing products;
- colouring agents;
- corrosion inhibitors;
- surfactants; and
- insulating materials.

Although the chemical has reported domestic uses in the SPIN database, it should be noted that SPIN does not distinguish between direct use of the chemical or use of the materials that are produced from chemical reactions involving the chemical.

OECD (2001) stated that low levels of residual, unpolymerised chemical may be present in consumer products containing polymers made with the chemical. The Household Products Database (US Department of Health and Human Services) indicates the presence of the chemical in several domestic products up to 50 % concentration. These include home maintenance products such as bonding agents and auto products (e.g. windshield repair products).

The chemical has reported commercial use including in:

- plastic films;
- construction materials;
- process regulators;
- binders and monomers;
- reprographic and photographic agents; and
- viscosity adjustors.

The chemical has reported site-limited use including:

- as a chemical intermediate;
- as a monomer in polymerisation;
- in the manufacture of thermoplastics;
- as a laboratory reagent; and
- in electroplating agents.

The chemical has reported non-industrial use including in:

- biocidal products (e.g. disinfectants and pest control products)
- non-agricultural pesticides;
- dental adhesives; and

- pharmaceuticals.

Restrictions

Australian

No known restrictions have been identified for the chemical.

International

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

Plastics materials and articles intended to come in contact with food. The chemical may be used with a specific migration limit (SML) of 23 mg/kg in food packaging, under Annex I of the European Commission Regulation (EU) No 10/2011 of 14 January 2011.

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):

Xi; R36/38 (irritation)

Xi; R43 (skin sensitisation)

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica):

- Time weighted average (TWA) of 11 mg/m^3 (2 ppm) in Norway; and
- Short-term exposure limit (STEL) of 20 mg/m^3 in Russia.

Health Hazard Information

Toxicokinetics

The chemical is readily absorbed by oral and dermal routes of exposure in mice and guinea pigs and is rapidly distributed throughout the body (REACH).

The ability for the chemical to be hydrolysed in vitro was evaluated using nonspecific porcine liver esterase. More than 80 % of the chemical was hydrolysed in one day, with a half–life for ester hydrolysis being calculated as 9.3 hours (OECD, 2001; REACH). The expected hydrolysis products are ethylene glycol (CAS No. 107-21-1) and methacrylic acid (CAS No. 79-41-4), with the later being previously assessed under IMAP (NICNAS).

Dunkin-Hartley Pirbright white guinea pigs administered solution containing radiolabelled chemical at 0.02 mmol/kg bw (equivalent to ca. 2.60 mg/kg bw) via oral gavage or subcutaneous injection showed almost complete excretion by 24 hours. The excretion rates observed with gavage and injection doses were: 68 % and 75 %, respectively as expired CO_2; 17 % and 14 %, respectively in the urine and 1 % and 2 %, respectively in faeces). The organs contained about 8 % of the applied dose (REACH).

Acute Toxicity

Oral

The chemical has low acute oral toxicity based on animal studies.

The median lethal dose (LD50) in rats and mice is greater than 2000 mg/kg bw. Observed sublethal effects included reduced activity, tremor, ataxia (failure of muscle coordination), piloerection and increased body temperature (OECD, 2001).

Dermal

The chemical has low acute toxicity in rabbits following dermal exposure.

The dermal LD50 in rabbits is greater than 2000 mg/kg bw (OECD, 2001). Observed sublethal effects included local irritant effects (REACH).

Inhalation

No data are available for the chemical.

The results of studies conducted on a variety of methacrylates indicate that they are of low acute inhalation toxicity (Patty's Toxicology, 2012).

Corrosion / Irritation

Respiratory Irritation

Irritation of the respiratory tract has been noted in humans and test animals following exposure to vapours of other methacrylates (CIR, 2005). Other methacrylates have been shown to cause nasal lesions upon inhalation due to hydrolysis to methacrylic acid, but this effect has not been observed for the chemical (OECD, 2001).

Although the mechanism of action for respiratory irritation may be relevant for the chemical, the low volatility (estimated 0.02 kPa) will limit inhalation exposure to vapours.

Skin Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in HSIS (Safe Work Australia). The available data do not support this classification. However, in the absence of more conclusive data, amendment of the existing classification is not recommended.

The chemical is reported to be 'not more than slightly irritating to the skin' (OECD, 2001). In several (non-guideline) studies in rabbits, primary dermal irritation index (PDII) values ranging from 0.34 (not irritating) to 1.3 (slightly irritating) were reported. One study concluded that the chemical is corrosive. However, the test material had a pH value of 3, which is inconsistent with the properties of the chemical, thus this study was not considered reliable (OECD, 2001; EPA, 1992).

Eye Irritation

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

The OECD (2001) report indicated the chemical as a moderate eye irritant. Three rabbit studies conducted before the establishment of OECD TG 405 (but consistent with the TG 405) indicated similar results with 'corneal opaqueness that persist for a week' (OECD, 2001).

New Zealand White rabbits (n = 3) were treated with the undiluted chemical (0.1 mL) in the conjunctival sac for four hours. The chemical produced corneal opacity (score = 66.7/80), which persisted to 21 days. The scores for iris irritation and conjunctival reaction were 5/10 and 17.3/20, respectively. Although the study authors classified the chemical as corrosive, the purity of the test material was 88 % and it contained 2–5 % methacrylic acid (US EPA, 1981).

In another study, six New Zealand White rabbits were treated with the undiluted chemical (0.1 mL) in the conjunctival sac. The following mean scores (at 24, 48 and 72 hours) were determined using the Draize method: 1.22/4 for corneal opacity; 0.78/2 for iris irritation; 2.28/3 for conjunctival redness (with 2.83/3 maximum) and 1.33/4 for chemosis. The effects persisted for 2–5 days following treatment, but were reversible within the seven day observation period (OECD, 2001; REACH).

Sensitisation

Skin Sensitisation

The chemical is classified as hazardous with the risk phrase 'May cause sensitisation by skin contact' (R43) in HSIS (Safe Work Australia). The available data support the existing hazard classification.

In a maximisation study (Magnusson and Kligman), groups of female guinea pigs (strain SSC:AL) were treated intradermally with 25 % solution of the chemical (0.1 mL), with or without Freund's complete adjuvant. On day seven, the animals were topically treated with 10 % sodium dodecyl sulfate in petrolatum to induce slight inflammation and enhance potential absorption. On day eight, the animals were topically treated with the chemical (0.4 mL) under occlusive conditions for 48 hours. The animals were challenged on day 21 with 0.025 mL of 25–100 % solutions of the chemical. Positive skin responses were observed in 9/12 animals (OECD, 2001; REACH).

The chemical failed to exhibit a positive result when applied topically in two guinea pig sensitisation studies following the Buehler method (OECD, 2001).

Observation in humans

The chemical produced positive skin sensitisation reactions in several human patch tests (OECD, 2001).

There have been two cases where the chemical alone (cross–reactivity to other acrylates excluded for induction) was suspected of causing skin sensitisation:

- A laboratory technician handling 80 % the chemical in ethanol developed contact dermatitis with symptoms including nausea, diarrhoea and persistent paraesthesia of the fingertips. The gastrointestinal symptoms were reproduced following a patch test with the chemical. Cross reactions occurred with methyl-, ethyl-, propyl- and isopropyl methacrylate but not butyl- or isobutyl methacrylate (OECD, 2001); and
- Six dental personnel developed allergic contact dermatitis from a dentin adhesion promoter system containing the chemical and an epoxyacrylate (BIS-GMA). All six patients had a positive patch test to the chemical in 2 % petrolatum. Cross sensitisation is possible as positive reactions to other acrylates and methacrylates were observed. Three patients reported paraesthesia of the fingertips (OECD, 2001).

Many cases of allergic responses have been reported where humans have handled other acrylates or methacrylates together with the chemical (usually related to dental products or adhesive gels). Subsequent challenges with the chemical often gave a positive patch test result. These results are equivocal, as the chemical responsible for induction of the sensitisation is unclear (OECD, 2001).

Repeated Dose Toxicity

Oral

Based on the available data, the chemical is not considered to cause serious damage to health from repeated oral exposure.

In a combined repeated dose and reproductive and developmental toxicity study (OECD TG 422), Crj:CD(SD) rats (n = 12/sex/dose) were administered the chemical via oral gavage doses of 0, 30, 100, 300 or 1000 mg/kg bw/d for 49 days in males (no further details regarding mating period provided) and from day 14 before mating to day three post partum in females. A no observed adverse effect level (NOAEL) of 30 mg/kg bw/d was established, based on increased blood urea nitrogen (BUN) levels and increased kidney weights. Mortalities (reported to be due to low food consumption leading to general weakness) were observed at 1000 mg/kg bw/d in one male (on day 20) and six females (five before mating and one during gestation). Surviving animals in the highest dose groups showed decreased locomotor activity and triglyceride levels, slow breathing, dilation of renal tubules and increased kidney weights (OECD, 2001).

Dermal

Based on the limited data available, the chemical is not expected to cause serious health effects by repeated dermal exposure.

In a poorly documented repeated dose dermal study, rabbits were treated with 30 µL of a 35 % w/v aqueous solution of the chemical, twice daily, for seven days. Only slight skin irritation was observed (REACH).

In a 47-day repeated dose dermal study, female rats were treated daily with the chemical (details not available). No systemic effects were reported (REACH).

Inhalation

Based on the limited information available, the chemical is not considered to cause serious damage to health from repeated inhalation exposure.

The chemical has low vapour pressure (OECD, 2001), which limits inhalation exposure.

In a three-week inhalation study, rats were exposed to a saturated atmosphere of the chemical (0.5 mg/L or 90 ppm) for six hours per day, five days per week. No changes in histopathology or haematological parameters were observed apart from minor effects on clotting function (OECD, 2001; REACH).

Genotoxicity

Based on the results of the available in vitro and in vivo genotoxicity studies, the chemical is not considered to be genotoxic.

The chemical gave mixed results in several in vitro genotoxicity assays (OECD 2001; REACH):

- negative in bacterial reverse mutation assay (Ames test, OECD TG 471) with *Salmonella typhimurium* strains TA 98, 100, 1535 and 1537, with or without metabolic activation, up to 5000 µg/plate;
- negative in bacterial reverse mutation assay (Ames test, OECD TG 471) with *Escherichia coli* WP2 uvr A, with or without metabolic activation;
- negative in a DNA synthesis inhibition test in HeLa S3 cells at concentrations up to 40 mM;
- positive in a mammalian cell gene mutation assay (OECD TG 476) which used Chinese hamster lung fibroblasts (V79), with or without metabolic activation; and
- positive in DNA damage and repair assays in human gingival fibroblasts and human lymphocytes in peripheral blood.

The chemical gave negative results in two in vivo genotoxicity assays:

- gene mutation assays in Drosophila (REACH); and
- in a micronucleus test, the chemical did not induce increases of micronucleated polychromatic erythrocytes in bone marrow cells of rats at doses of 500–2000 mg/kg bw (OECD, 2001).

Carcinogenicity

There are no data available on the chemical. Based on the information available for other methacrylates and methacrylic acid, the chemical is not expected to be carcinogenic.

The results of carcinogenicity studies conducted on other methacrylates indicated that they are not carcinogenic (CIR, 2005). There was also no evidence of carcinogenicity in animals exposed to ethylene glycol (OECD, 2004).

Methacrylic acid (CAS No. 79-41-1; metabolite of the chemical) at 500 or 1000 ppm (2.05 or 4.1 mg/L), caused no significant neoplastic effects in B6C3F1 mice or Fischer 344 rats (n = 50/sex/dose) when exposed via inhalation (OECD TG 451) for two years (NICNAS).

Reproductive and Developmental Toxicity

Based on the available data, the chemical is not considered to have reproductive or developmental toxicity.

In a combined repeated dose and reproductive toxicity study (OECD TG 422), SD (Crj: CD) rats were administered the chemical by oral gavage doses of 0, 30, 100, 300 or 1000 mg/kg bw/d for 49 days in males and from 14 days before gestation to three days post partum in females. Maternal toxicity was observed at above 30 mg/kg bw/d (see **Repeated Dose Toxicity: oral**). No reproductive toxicity (including fertility index, conceiving days, length of gestation) or teratogenic effects (including number of dead pups, live birth index, viability index, external abnormalities) were observed. The NOAEL was established as 1000 mg/kg bw/d for both, reproductive and developmental toxicity (OECD, 2001).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include:

- local effects—skin sensitisation; and
- irritation of the eye and skin.

Public Risk Characterisation

Uses of the chemical in Australia at concentrations up to 10 % in cosmetic products and up to 80 % in domestic products have been identified through SDSs. Overseas information confirm the use of the chemical in cosmetics (25 products in CIUCUS, 2011) and domestic products (Household Products Database, US Department of Health and Human Services).

The main route of public exposure is expected to be through the skin, although the rate of polymerisation would be expected to limit the extent of exposure (CIR, 2005). When used in nail enhancement products, short-term small volume skin contact in the immediate vicinity of the fingernail may occur. Exposure is considered more probable for home use of the chemicals than in salon use by trained personnel. Dermal exposure to other parts of the body may occur during domestic use. The low volatility of the chemical limits the potential for exposure through vapour inhalation.

The Cosmetic Ingredient Review (CIR) concluded that methacrylate ester monomers 'are safe to use in nail enhancement products when skin contact is avoided. Products containing these ingredients should be accompanied with directions to avoid skin contact, because of the sensitising potential of methacrylates' (CIR, 2005).

There are currently no labelling requirements for products containing the chemical in Australia. Therefore, in the absence of any regulatory controls, the characterised critical health effects (skin sensitisation) have the potential to pose an unreasonable risk under the uses identified.

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. 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 (skin sensitisation), the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise dermal and ocular 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

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 the Poisons Schedule.

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

Appropriate scheduling and labelling should be undertaken to mitigate risk for the chemicals use in both domestic and cosmetic products. Due to the toxicity profile and concentrations reported to be in use in Australia, this chemical should be considered for listing in Schedule 5 of the SUSMP, consistent with the Scheduling Policy Framework guidelines. Matters to be taken into consideration include:

- skin sensitisation which may occur following exposure to the chemical and other structurally related methacrylates (cross–sensitisation); and
- the Cosmetic Ingredient Review recommendation that products containing the chemicals should be accompanied with directions to avoid skin contact.

Exemptions to scheduling may be applicable at low concentrations.

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]
Irritation / Corrosivity	Irritating to eyes (Xi; R36)* Irritating to skin (Xi; R38)*	Causes serious eye irritation - Cat. 2A (H319) Causes skin irritation - Cat. 2 (H315)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)*	May cause an allergic skin reaction - Cat. 1 (H317)

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

- 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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