



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

29 June 2018

CAS Number: 79-41-4

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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.

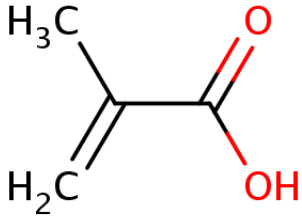
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

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Chemical Identity

Synonyms	2-methyl-2-propenoic acid methacrylic acid
Structural Formula	
Molecular Formula	C4H6O2
Molecular Weight (g/mol)	86.09
Appearance and Odour (where available)	Colourless, viscous liquid with an acrid odour
SMILES	<chem>C(=O)(O)C(=C)C</chem>

Import, Manufacture and Use

Australian

The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL).

The chemical has reported domestic and commercial uses in:

- lubricants and additives; and
- adhesives and binding agents.

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 Chimica; 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 including:

- in personal care products;
- in perfumes; and
- as a film forming substance.

The chemical has reported domestic use including in:

- adhesives and sealants;
- disinfectants;
- paint, thinners and paint removers;
- washing and cleaning products;
- finger paints;
- colouring agents;
- 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.

The chemical is produced by industry almost exclusively to manufacture polymers (Evonik Industries, 2013).

The chemical has reported commercial uses including:

- in inks and toners;
- in anti-freeze and de-icing products;
- in leather tanning, textile and paper coatings;
- in formulations;
- as a corrosion inhibitor;
- in plastic films;
- in construction materials;
- as a process regulator;
- in reprographic and photographic agents; and
- as a viscosity adjustor.

The chemical has reported site-limited uses including:

- as a chemical intermediate;
- as a monomer in polymerisation;
- in manufacturing thermoplastics;
- as a laboratory reagent; and
- as an electroplating agent.

The chemical has reported non-industrial uses including in:

- non-agricultural pesticides;

- pharmaceuticals; and
- orthopaedic surgery, to make bone cement.

Restrictions

Australian

No known restrictions have been identified for the chemical.

International

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

- The Canadian list of prohibited and restricted cosmetic ingredients (the cosmetic ingredient "Hotlist").

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; R21/22 (acute toxicity)

C; R35 (corrosivity)

Exposure Standards

Australian

The chemical has an exposure standard of 70 mg/m³ (20 ppm) time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica):

TWA:

- 10 mg/m³ (3 ppm) in Latvia and Russia;
- 18 mg/m³ (5 ppm) in Switzerland and Germany;
- 70 mg/m³ (20 ppm) in Austria, Belgium, Bulgaria, Canada, China, Denmark, Columbia, Croatia, France, Finland, Greece, Ireland, Iceland, Indonesia, Italy, Korea, Malaysia, Nicaragua, Norway, Peru, Portugal, New Zealand, Singapore, the UK, the US, Spain, Sweden, Taiwan, the United Arab Emirates, Venezuela and South Africa.

Short-term exposure limits (STEL):

- 36 mg/m³ (10 ppm) in Switzerland;
- 140 mg/m³ (40 ppm) in South Africa.

Health Hazard Information

Following absorption, methacrylates are rapidly metabolised to methacrylic acid. Methyl methacrylate (MMA) is an alkyl ester of methacrylic acid, and has been used in the hazard assessment for systemic toxicity effects where there were no hazard data for the chemical.

Toxicokinetics

The chemical is readily absorbed by oral, dermal and inhalation routes and is rapidly metabolised with a half-life of 1.7 minutes in rats (REACH; OECD, 2001).

Metabolism occurs by two main pathways, conjugation with glutathione to form thioesters, and conversion to carbon dioxide through the citric acid cycle (REACH).

Acute Toxicity

Oral

The chemical is classified as hazardous with the risk phrase 'Harmful if swallowed' (Xn; R22) in HSIS (Safe Work Australia). The available data support this classification.

The median lethal doses (LD50s) are:

- 1060–2400 mg/kg bw in rats;
- 1250–1332 mg/kg bw in mice; and
- 1200 mg/kg bw in rabbits (OECD, 2001; REACH).

Dermal

The chemical is classified as hazardous with the risk phrase 'Harmful in contact with skin' (Xn; R21) in HSIS (Safe Work Australia). The available data support this classification.

The LD50 is 500–1000 mg/kg bw in rabbits (OECD, 2001; REACH).

Inhalation

The available data indicate low acute inhalation toxicity in rats when exposed to the chemical vapour (median lethal concentration (LC50) above 3.7 mg/L).

The median lethal concentration (LC50) in rats was 7.1 mg/L/four hours when exposed to air containing a vapour/aerosol mixture of the chemical (OECD, 2001; REACH). The saturated vapour pressure was provided as 3.4–3.7 mg/L for all test doses used in this study (4.3, 5.9, 7.3, 8.2 mg/L). The mortalities that occurred at 5.9 mg/L (1/10) and above were due to the aerosol exposure (REACH). The REACH dossier stated that, 'Exposure to vapour alone was not associated with mortality, while exposure to aerosol increased (0.9–4.7 mg/L) in parallel to an increase in mortality'. However, both the vapour and the aerosol are considered to contribute to the observed toxicity.

Corrosion / Irritation

Corrosivity

The chemical is classified as hazardous with the risk phrase 'Causes severe burns' (Xi; R35) in HSIS (Safe Work Australia). The available data support this classification.

'The undiluted acid causes skin and eye corrosion and respiratory tract lesions' (OECD, 2001).

Studies performed in rabbits (OECD Test Guideline (TG) 404) indicate irreversible damage of the dermis following a three minute exposure to the chemical. The chemical on intact rabbit skin produced severe erythema and oedema after four hours. After 14 days, the exposed areas had effects that were not reversible. Primary dermal irritation indexes (PDII) of 6.1 in 7/8 and 8/8 have been reported (REACH).

Sensitisation

Skin Sensitisation

The chemical is not considered to be a skin sensitiser.

The chemical was not sensitising based on human experience and from the results of animal testing (OECD, 2001).

In a Magnusson and Kligman maximisation test, guinea pigs (n = 5/group) were induced with the chemical intradermally (at concentrations of 0.02, 0.1, 0.2, 0.5, 1.0 and 5.0 %) and topically (one week later with 0.2 mL of the chemical). The animals were challenged after 22 days with the chemical (0.1 mL) at concentrations (in olive oil and acetone at 7:3) of 10, 25, 50 and 100 %. Only positive skin irritation reactions (strong redness of skin and scab formation) were observed in all animals tested (REACH).

In a Buehler test (OECD TG 406), male Hartley guinea pigs (n = 20) were induced three times, with a 20 % aqueous solution of the chemical (0.4 mL), followed by two applications of a 15 % aqueous solution of the chemical. The animals were then challenged by applying a 10 % aqueous solution of the chemical on shaved skin. No dermal irritation was observed in the induction phase, and only 'slight patchy redness' was observed in 2/20 animals 48 hours following the challenge (REACH).

The chemical 'was not a dermal sensitizer in albino guinea pigs. Methacrylic acid did appear to be a skin irritant at concentrations of 15 % and above' (REACH).

Repeated Dose Toxicity

Oral

The studies available are of limited value. Considering the corrosive nature of the chemical, only low oral doses have been tested in animals. Although there were treatment-related effects reported in six-month studies in rats and rabbits at 0.5 mg/kg bw/d, the information available is not sufficient to warrant a hazard classification. The data available for an alkyl ester of the chemical (methyl methacrylate (MMA)), do not show significant toxicity from repeated oral exposure in animals.

In a 10-day oral gavage study, rats received the chemical at 0, 5 or 10 mg/kg bw/d. Slight to moderate alveolar haemorrhage, lipid granuloma in the lungs and moderate to severe granularity of liver cytoplasm were reported (dose not specified) (REACH).

In a six-month oral gavage (non-guideline) study, rats were administered the chemical at concentrations of 0, 0.05, 0.5 or 5 mg/kg bw/d. A no observed adverse effect level (NOAEL) of 0.05 mg/kg bw/d was reported based on dystrophic changes in the liver and adrenals observed at 0.5 mg/kg bw/d. Reduced reflexes, changes to liver enzymes and electrolytes, anaemia and decreased liver and adrenal weights were observed at 5 mg/kg bw/d (REACH). The severity of the systemic toxicity effects are not clear from the information available.

In a six-month oral gavage (non-guideline) study, rabbits were administered the chemical at 0, 0.05, 0.5 or 5 mg/kg bw/d. A NOAEL of 0.05 mg/kg bw/d was reported based on dystrophic changes in the liver and adrenals observed at 0.5 mg/kg bw/d. Loss of reflexes to positive stimulators, slight acidosis, anaemia and decreased spleen and adrenal weights, decreased catalase activity and increased alkaline phosphatase levels were observed (doses not specified) (REACH).

An alkyl ester of the chemical, methyl methacrylate (MMA), which rapidly metabolised to methacrylic acid, has low repeated dose oral toxicity in animals. For MMA, the oral NOAEL in rats was 2000 ppm (~146 mg/kg bw/day (females) and ~121 mg/kg bw/day (males)). Similarly, no treatment-related effects were observed in beagle dogs exposed to ~1500 ppm MMA in their feed for two years (~38 mg/kg bw/day). Both human and animal studies indicated that MMA does not accumulate in tissues (EU RAR 2002).

Dermal

Only limited data are available.

In a three-week repeated dose dermal study, male ICR mice (n = 8/group) were treated with a 4 % aqueous solution of the chemical or 4.8–19.2 % (approx. 150–600 mg/kg bw) solution of the chemical in acetone, on shaved intact skin for nine treatment days. Moderate to severe irritation was observed from 9.6 % (approx. 300 mg/kg bw). No systemic toxicity effects were observed at any dose level (REACH).

Inhalation

Based on the available data, the chemical is not considered to cause serious systemic toxicity effects following repeated inhalation exposure. All studies indicated local inflammatory effects in animals repeatedly exposed to the chemical.

There are a few 90-day inhalation toxicity studies available in rats and mice.

In a 90-day repeated dose inhalation study (OECD TG 413), Sprague Dawley (SD) rats (n = 10/sex/group) were exposed to the chemical at concentrations of 0, 20, 40, 100 or 350 ppm (equivalent to 0, 70, 141, 352 or 1232 mg/m³) for six hours/day five days/week. A no observed adverse effect concentration (NOAEC) of 100 ppm (352 mg/m³) was reported based on decreased body weight gain and food consumption, and local irritation effects at 350 ppm. Irritation of the respiratory epithelium in the nasal cavity (hypertrophy/hyperplasia) was observed in two females at 350 ppm (REACH).

In another 90-day study, SD (strain CD) rats (n = 20/sex/group) were exposed to the chemical at 0, 20, 100 or 300 ppm (equivalent to 0, 0.07, 0.3 or 0.9 mg/L) for six hours/day, five days/week. A lowest observed adverse effect concentration (LOAEC) of 20 ppm was reported based on local irritation effects (REACH).

In a 90-day inhalation study, Fischer 344 (CDF) rats (n = 20/sex/group) that were exposed to the chemical at 0, 20, 100 or 300 ppm; equivalent to 0, 0.07, 0.3 or 0.9 mg/L for six hours/day five days/week) showed decreased body weight gain, liver weights and food consumption at 300 ppm. Except for the local inflammatory effects (limited to nasal turbinates), there were no systemic toxicity effects observed in treated animals (REACH).

In a 90-day inhalation study, B6C3F1 mice (n=20/sex/group) were exposed to the chemical at 0, 20, 100 or 300 ppm (equivalent to 0, 0.07, 0.3 or 0.9 mg/L) for six hours/day, five days/week. A lowest observed adverse effect level (LOAEL) of 100 ppm was reported based on a local irritation effect such as eosinophilic globules in olfactory epithelium. Decreased liver weights were observed at 300 ppm. There were no treatment-related effects on haematology or clinical chemistry parameters at any dose level tested (OECD, 2001; REACH).

Genotoxicity

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

The chemical showed negative results in two in vitro genotoxicity tests (REACH):

- bacterial reverse mutation assay (Ames test, OECD TG 471) with *Salmonella typhimurium* (TA 98, 100, 1535 and 1537), with or without metabolic activation;
- mammalian cell gene mutation assay (OECD TG 476) that used Chinese hamster lung fibroblasts (V79), with or without metabolic activation.

Positive results were reported for one in vitro test (REACH):

- DNA cell binding assay in *Escherichia coli*, with or without metabolic activation.

No in vivo genotoxicity data are available for the chemical.

Negative results were reported for methyl methacrylate (MMA) in the following in vivo assays (REACH):

- a chromosome aberration assay in mammalian bone marrow cells (OECD TG 475) where SD rats were exposed to the chemical by inhalation up to 4 mg/L;
- a dominant lethal assay (OCED TG 478) in CD-1 mice at doses up to 9000 ppm (equivalent to 36.45 mg/L); and
- a mammalian erythrocyte micronucleus assay (OECD TG 474) in mice at oral gavage doses up to 4520 mg/kg bw.

Based on the negative in vivo genotoxicity results for MMA, the OECD report (2001) concluded that no further in vivo genotoxicity testing was required for methacrylic acid.

Carcinogenicity

No data are available for the chemical. Based on the data available for methyl methacrylate (MMA), the chemical is not considered to be carcinogenic.

In a two-year carcinogenicity study (OECD TG 451), Fischer 344 rats (n = 50/sex/dose) were exposed to MMA via inhalation for six hours/day, five days/week at concentrations of 0, 500 or 1000 ppm (0, 2.05 or 4.1 mg/L) for males and at 0, 250 or 500 ppm (0, 1.03 or 2.05 mg/L) for females. No significant neoplastic changes were observed (REACH).

In a two-year carcinogenicity study (OECD TG 451), B6C3F1 mice (n = 50/sex/dose) were exposed to MMA via inhalation for six hours/day, five days/week at concentrations of 0, 500 or 1000 ppm (0, 2.05 or 4.1 mg/L). No significant neoplastic changes were observed (REACH).

Reproductive and Developmental Toxicity

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

In a prenatal developmental toxicity study (OECD TG 414), female SD rats (n = 22–25/dose) were exposed to the chemical (via inhalation) at concentrations of 0, 50, 100, 200 or 300 ppm for six hours/day during gestation days (GD) 6–20. A NOAEL of 200 ppm for maternal toxicity was established based on decreased body weight gain and food consumption observed at 300 ppm. No developmental or teratogenic effects were observed in the pups at the doses tested (REACH).

In a 90-day repeated dose inhalation toxicity study SD rats (n = 10/sex/dose) showed no gross reproductive pathology (in reproductive systems and fertility parameters) up to 350 ppm (1232 mg/m³) (REACH).

Risk Characterisation

Critical Health Effects

The main critical health effect for risk characterisation includes local effects (corrosivity).

The chemical could also cause systemic effects by acute exposure from oral and exposure.

Public Risk Characterisation

Domestic use has been reported both in Australia and internationally, and there have been international reports of cosmetic use. However, international reports of cosmetic use do not distinguish between direct use of the chemical or use of the materials/polymers that are produced from chemical reactions involving the chemical.

A producer of the chemical stated that 'Consumer exposure is unlikely' to the chemical as it is 'almost exclusively' used in polymer manufacturing. The producer has recommended that it not be used in 'artificial nail products and other non-medical/dental applications involving direct skin/nail contact with the liquid monomer' (Evonik Industries, 2013).

Currently, there are no restrictions in Australia on using this chemical in cosmetics or domestic products. Based on the information available, public exposure to high amounts or concentrations of the chemical is not expected through cosmetic or domestic uses in Australia. Therefore, this chemical is not considered to pose an unreasonable risk to public under the uses identified.

Occupational Risk Characterisation

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

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.

If any information becomes available to indicate significant consumer exposure to the chemical in Australia (i.e. higher concentrations or quantities in cosmetics or domestic products), risks to public health and safety may have to be managed by changes to poisons scheduling.

Regulatory Control

Public Health

Products containing the chemical should be labelled in accordance with state and territory legislation (SUSMP, 2013).

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
Acute Toxicity	Harmful if swallowed (Xn; R22)* Harmful in contact with skin (Xn; R21)*	Harmful if swallowed - Cat. 4 (H302) Toxic in contact with skin - Cat. 3 (H311)
Irritation / Corrosivity	Causes severe burns (C; R35)*	Causes severe skin burns and eye damage - Cat. 1A (H314)

^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 oral, 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;
- 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 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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