

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

18 September 2014

CAS Number: 96-33-3

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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.

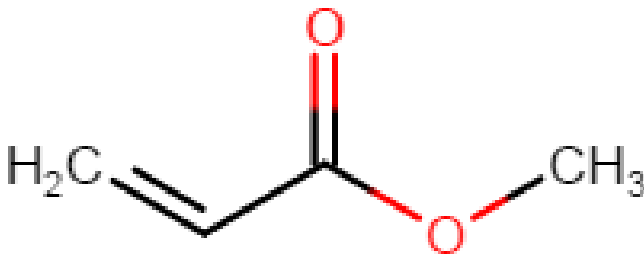
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

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.

Chemical Identity

Synonyms	methyl acrylate methyl propenoate methyl 2-propenoate acrylic acid, methyl ester
Structural Formula	
Molecular Formula	C4H6O2
Molecular Weight (g/mol)	86.09
Appearance and Odour (where available)	Colourless volatile liquid with an acrid odour
SMILES	C(=O)(C=C)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 Registration, Evaluation, Authorisation and Restriction of Chemicals (EU REACH) dossiers and Substances and Preparations in the Nordic countries (SPIN) database.

The chemical has reported domestic use including in:

- adhesives and binding agents; and
- paints, lacquers and varnishes.

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 has reported commercial use including in reprographic agents.

The chemical has reported site-limited use including as a:

- laboratory chemical; and
- chemical intermediate in polymer production.

Restrictions

Australian

No known restrictions have been identified.

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 22 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):

Xn; R20/21/22 (acute toxicity)

Xi; R36/37/38 (irritation)

R43 (skin sensitisation)

Exposure Standards

Australian

The chemical has an exposure standard of 35 mg/m³ (10 ppm) time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica):

- A time weighted average (TWA) of 7–35 mg/m³ (2–10 ppm) in different countries such as Canada, France, Germany, Greece, Iceland, Mexico, Norway, South Africa, Spain, Sweden, the UK and the USA.
- Short term exposure limit (STEL) of 36–50 mg/m³ (10–15 ppm) in different countries such as Canada, France, Ireland, Latvia, Sweden and the UK.

Health Hazard Information

Toxicokinetics

The chemical is readily absorbed through oral, dermal and inhalation exposure and rapidly metabolised by two main pathways: conjugation with glutathione (GHS) to form thioesters; and hydrolysis via esterases to yield acrylic acid (CAS No. 79-10-7) and methanol (CAS No. 67-56-1).

The excretion is almost complete (90 %) within 72 hours of administration, with the primary routes being the lungs (>50 %) as CO₂, and the kidneys (40–50 %) as glutathione conjugates (OECD, 2003).

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.

In an acute oral toxicity study equivalent to the Organisation for Economic Cooperation and Development test guideline (OECD TG) 401, a median lethal dose (LD50) of 768 mg/kg bw was determined. Reported signs of toxicity included staggering and prone position in the highest dose group. (OECD 2003; REACH).

Two poorly-documented studies have reported LD50 values of 277 and 300 mg/kg bw in rats. LD50 values of 826–840 mg/kg and 180–280 mg/kg bw have been reported for mice and rabbits, respectively (OECD, 2003).

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.

In rabbits (n = 6) exposed to the chemical via occlusive dermal application for 24 hours, an LD50 of 1250 mg/kg bw was determined (OECD 2003; REACH).

Inhalation

The chemical is classified as hazardous with the risk phrase 'Harmful by inhalation' (Xn; R20) in HSIS (Safe Work Australia). The available data support this classification.

In an acute inhalation toxicity study (equivalent to OECD TG 403), Sprague Dawley (SD) rats (n = 10/sex/dose) were exposed to vapours of the chemical at 2.8, 4.8, 5.8, 7.5, 7.6 and 9.8 mg/L for four hours. A median lethal concentration (LC50) of 5.7 mg/L/4-hours was calculated (average for male and female rats). Reported signs of toxicity included strong irritation of the eyes and respiratory tract, and dyspnoea (shortness of breath) in surviving rats, although the specific concentrations for these effects were not mentioned (OECD, 2003; REACH).

The LC50 in mice was 5.7 mg/L/4-hours and in hamsters, 2.5 mg/L/4-hours (OECD, 2003).

Corrosion / Irritation

Respiratory Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to respiratory system' (Xi; R37) in HSIS (Safe Work Australia). The limited data available support this classification.

The chemical was reported to be highly irritating to the 'mucous membranes of animals and humans' (OECD, 2003).

In an acute inhalation toxicity study (equivalent to OECD TG 403), SD rats exposed to the chemical up to 9.8 mg/L for four hours showed strong irritation to the respiratory tract (OECD, 2003) (see **Acute toxicity: inhalation**). Dose dependent local effects in the respiratory tract of SD rats have been observed in a repeated dose inhalation toxicity study at doses in the range of 5–45 ppm (see **Repeat dose toxicity: Inhalation**).

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 support this classification.

In a dermal irritation study (equivalent to OECD TG 404), a semi-occlusive dermal application of the chemical (0.5 mL, undiluted) was highly irritating to the skin of rabbits. A mean erythema score of 2.17/3 and oedema score of 2.44/4 were reported.

In another study (equivalent to OECD TG 404), rabbits were exposed (n = 2 per treatment time) to the chemical (0.5 mL) via an occlusive dermal application, for four hours or eight days. A mean erythema score of 3.5/4 and a mean oedema score of 3.5/4 were obtained after four hours (OECD, 2003; REACH).

Eye Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to eyes' (Xi; R36) in HSIS (Safe Work Australia). The limited data available support a hazard classification. Although a higher classification might be required for the chemical, the available details are not sufficient to upgrade the existing classification.

The chemical 'may cause serious eye damage' (OECD, 2003). The chemical was 'instilled into the eye of one rabbit and caused corneal damage, slight iritis and severe lesions of the conjunctivae. After 7 days the cornea showed moderate to severe opacity' (OECD, 2003). Only limited information is available.

The chemical was reported to be irritating to the eyes, based on a study conducted with one New Zealand White rabbit (exposed to the undiluted chemical (0.1 mL) and observed for seven days). The following mean scores were documented after 72 hours: cornea 2.33/3, iris 1/1, conjunctival redness 2/2 and chemosis 3/3. The effects were not reversible by day seven, with moderate to severe opacity of the cornea, moderate to severe lesions of the conjunctivae and slight iritis being observed (REACH).

In another study, the chemical (50 µL) administered to the eye of Vienna White rabbits (n = 2), resulted in severe swelling and conjunctivitis, and transient corneal opacity after 24 hours. These effects were reversible within three to five days (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 this classification.

The chemical was reported 'to induce contact sensitivity in animals and humans' (OECD, 2003).

The skin sensitising potential of the chemical was studied in a local lymph node assay (LLNA) (OECD TG 429) using female CBA mice (n = 4/dose) at concentrations of 1.0, 2.5, 5.0, 10 and 20 % of the chemical (in acetone/olive oil at 4:1 v/v). The chemical was determined to be a weak skin sensitiser based on the effective concentration needed to produce a three-fold increase in lymphocyte proliferation (EC3) of 19.6 % (Dearman et al., 2007; REACH).

The chemical also gave positive skin sensitisation results in several studies including split adjuvant, Polak, modified Draize and modified maximisation tests in guinea pigs (REACH).

Observation in humans

The chemical (at 1 % in petrolatum or 20 % in olive oil) produced positive results for sensitisation in patch tests in humans. Cross-sensitisation of the chemical with other acrylates and methacrylates has also been reported in humans (OECD, 2003).

Repeated Dose Toxicity

Oral

Limited data are available. A 90-day rat study only used the chemical at doses up to 20 mg/kg bw/d (within the classifiable range for repeated dose oral toxicity). The chemical is not considered to cause serious damage to health from repeated oral exposure up to 20 mg/kg bw/d.

In a 90-day oral drinking water study (comparable with OECD TG 408), CDF Fischer 344 rats (n = 15/sex/group) were exposed to the chemical at 0, 1, 5 or 20 mg/kg bw/d. No mortalities were observed and a lowest observed adverse effect level (LOAEL) of 20 mg/kg bw/d was established based on slight kidney effects (increased mean kidney weight, dilated renal tubules and eosinophilic cast formation). Water consumption was decreased in rats and believed to be due to the unpalatability of the drinking water. No severe lesions or histopathological changes were observed and the no observed adverse effect level (NOAEL) was reported as 5 mg/kg bw/d (OECD, 2008; REACH).

In a two-week oral gavage study, rabbits (n = 3–4/dose) were administered the chemical at 0, 95, 190 or 380 mg/kg bw/d. Mortalities were observed in the 190 and 380 mg/kg bw/d dose groups (4/4 and 1/3, respectively) due to substantial damage to the gastric mucosa, while no effects were observed in the surviving animals (REACH).

Neither of the hydrolysis products of the chemical are considered toxic after repeated oral exposure, with NOAELs of 150 mg/kg bw/d for acrylic acid (NICNAS a) and 500 mg/kg bw/d for methanol (NICNAS b).

Dermal

Limited data are available.

In a poorly-described 30-day repeated dose dermal study, rabbits were treated twice a day (five hours per application) with the undiluted chemical (1 mL). No systemic toxicity effects were reported. Local necrotic changes that occurred were reversible within 30 days (REACH).

Inhalation

No adverse systemic toxicity effects were reported in repeated dose inhalation studies in rats. Therefore, the chemical is not considered to cause severe systemic effects from repeated inhalation exposure. Based on the local irritation effects, the chemical is classified as an irritant to the respiratory system.

In a 12-week repeated dose inhalation study (OECD TG 413), SD rats (n = 10/sex/dose) were exposed to vapours of the chemical at concentrations of 0, 23, 124, 242 or 626 ppm (0, 0.082, 0.44, 0.86 or 2.24 mg/L) for six hours a day, five days a week. At the highest dose, the animals showed laboured breathing, irritation of the mucosa and haemorrhagic discharge from the eyes and nose. All animals in the highest dose group died during the study due to strong irritation effects in the respiratory system. The no observed effect concentration (NOEC) for local effects was 23 ppm (0.082 mg/L). Absolute organ weights (heart, liver, kidney and spleen) were decreased in males at 242 ppm. Absolute spleen weight was also reduced in males at 124 ppm (OECD, 2003).

A two-year inhalation study exposed SD rats to the chemical (>99.8 % purity) for six hours a day, five days a week at 0, 5, 15 and 45 ppm (equivalent to 0, 0.019, 0.058 and 0.173 mg/L) for the first 13 weeks, and then at 0, 15, 45 and 135 ppm (0, 0.058, 0.173 and 0.519 mg/L) until the end of the study. Dose-dependent local effects were observed (attributed to the irritant effects of the chemical). There were no systemic toxicity effects detectable by haematological and histopathological examinations (OECD, 2008).

Genotoxicity

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

The chemical gave mixed results for in vitro genotoxicity testing:

- negative results were observed in several in vitro bacterial reverse mutation assays (Ames test) with *Salmonella typhimurium* (strains TA 98, 100, 1535, 1537 and 1538), with or without metabolic activation (OECD, 2008);
- positive results were observed in mammalian chromosome aberration assays using Chinese hamster fibroblast, lung or ovary cells as well as mouse lymphoma (L5178Y) cells (OECD, 2008); and
- two gene mutation assays using mouse lymphoma (L5178Y) cells, gave positive results without metabolic activation (OECD, 2008; REACH).

The chemical gave mixed results for genotoxicity in the following in vivo assays:

- male ddY mice (n = 2/dose) exposed to vapours of the chemical at 1300 or 2100 ppm (4.64 or 7.50 mg/L) for three hours showed no chromosome aberrations in bone marrow samples taken at 18, 24, 30, 48 and 72 hours following exposure (OECD, 2008);
- no chromosome aberrations were observed in male ddY mice exposed to a single oral gavage dose of the chemical at 62.5, 125 or 250 mg/kg bw (n = 6/dose) or a repeated oral dose of 125 mg/kg bw for four days (n = 4) (OECD, 2008; REACH);
- male Balb/C mice exposed to the chemical at 37.5, 75, 150 or 300 mg/kg bw (n = 4/dose) via intraperitoneal injection showed increased micronuclei at toxic dose levels. However, this study was poorly described and the results were reported to be questionable, as other laboratories could not replicate this positive result (OECD, 2008); and
- a gene mutation test on *Drosophila melanogaster* produced negative results for the chemical at 500 ppm.

Carcinogenicity

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

The International Agency for Research on Cancer (IARC) reviewed animal carcinogenicity studies on the chemical and concluded that there is inadequate evidence for carcinogenicity in experimental animals, and classified the chemical as Group 3—not classifiable as to its carcinogenicity to humans (IARC, 1999).

In a two-year combined repeated dose and carcinogenicity study (OECD TG 453), SD rats (n = 86/sex/dose) were exposed (via inhalation) to the chemical for six hours a day, five days a week at concentrations of 0, 5, 15, 45 or 135 ppm (0, 0.019, 0.058, 0.173 or 0.519 mg/L). No significant neoplastic changes were observed (OECD, 2008).

The main hydrolysis products, acrylic acid and methanol, were also not considered carcinogenic (NICNASa; NICNASb).

Reproductive and Developmental Toxicity

The chemical is not considered to have reproductive or developmental toxicity.

In a two-generation reproductive toxicity study (OECD TG 416), Crl:CD(SD) rats (n = 27/sex/dose) were exposed to the chemical vapours at concentrations of 0, 5, 25 or 75 ppm (0, 19, 92 or 269 mg/m³) for six hours a day, from 10 weeks before breeding and continuing through breeding (two weeks), gestation (three weeks) and lactation (four weeks) for each of the two generations. Maternal rats were not exposed to the chemical after gestation day (GD) 20 through to lactation day four to allow for parturition and initiation of lactation. A no observed adverse effect concentration (NOAEC) of 5 ppm for parental systemic toxicity and 25 ppm for developmental toxicity were reported based on histopathological changes to the nasal epithelium and decreased body weight observed in pups, respectively. No specific reproductive toxicity effects were observed (REACH).

In a prenatal developmental toxicity study (OECD TG 414), Himalayan rabbits (n=25 inseminated females/dose) were exposed to the chemical vapour at 0, 5, 15 or 45 ppm (21.9, 57.2 or 176.5 mg/m³) for six hours a day, five days a week from GD six to 28. There were no prenatal developmental toxic effects observed up to the highest concentration tested. In a second prenatal development study (equivalent to OECD TG 414), SD rats (n = 20/sex/dose) were exposed to the chemical at concentrations of 0, 25, 50 or 100 ppm (0, 0.089, 0.179 or 0.357 mg/L) for six hours a day during GD 6–20. A NOAEC of 0.089 mg/L was determined for maternal toxicity based on decreased body weight. A lowest observed adverse effect concentration (LOAEC) of 100 ppm was reported based on decreased foetal body weight (-17 % compared with controls). One case of craniorachischisis (fissure of the skull and spine) and malformations of foetal skeletons in all test groups, including the control, were observed. There was no statistically significant difference between the treated groups and the control, nor was a dose-response relationship noted (OECD, 2008; REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include:

- local effects—skin sensitisation and irritation to the eyes, skin and respiratory system; and
- systemic acute effects from oral, dermal and inhalation exposure.

Public Risk Characterisation

Given the uses identified for the chemical, it is unlikely that the public will be exposed to the chemical. Although the public might come into contact with articles/coated surfaces containing the chemical, it is expected that the chemical will be bound within the article/coated surface and hence will not be bioavailable. Therefore the risk to the public 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. 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 (skin sensitisation and irritation), the chemical could 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.

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.

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
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Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Acute Toxicity	Harmful if swallowed (Xn; R22)* Harmful in contact with skin (Xn; R21)* Harmful by inhalation (Xn; R20)*	Harmful if swallowed - Cat. 4 (H302) Harmful in contact with skin - Cat. 4 (H312) Toxic if inhaled - Cat. 3 (H331)
Irritation / Corrosivity	Irritating to eyes (Xi; R36)* Irritating to skin (Xi; R38)* Irritating to respiratory system (Xi; R37)*	Causes serious eye irritation - Cat. 2A (H319) Causes skin irritation - Cat. 2 (H315) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)
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 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 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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