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

18 September 2014

CAS Number: 103-11-7

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.

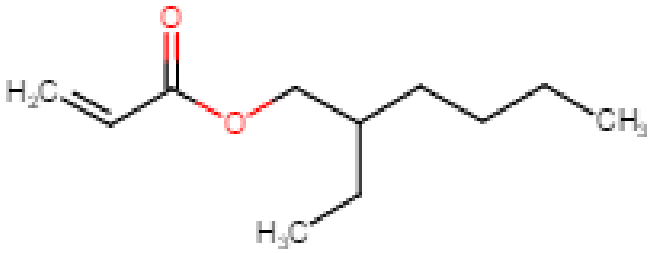
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	2-ethylhexyl 2-propenoate 2-ethylhexyl acrylate acrylic acid, 2-ethylhexyl ester 2-propenoic acid 2-ethylhexyl ester 2-EHA
Structural Formula	
Molecular Formula	C11H20O2
Molecular Weight (g/mol)	184.28
Appearance and Odour (where available)	Colourless liquid with a pleasant odour
SMILES	C(=O)(C=C)OCC(CCCC)CC

Import, Manufacture and Use

Australian

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

The chemical has reported domestic use in adhesives and binding agents.

The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume of 1000–9999 tonnes.

Australian safety data sheets (SDS) indicate that the chemical is used in commercial and domestic binding resins and agents, and long-life surface paint coatings, up to 60 % concentration (concentrations are typically below 10 %) (see **References** on SDS).

International

The following international uses have been identified through the Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; and the United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary:

The chemical has reported cosmetic use as a binding agent, however the chemical is not listed in the Compliation of Ingredients Used in Cosmetics in the United States (CIUCUS, 2011).

The chemical has reported domestic use including in:

- adhesives (including general purpose tape and pressure sensitive adhesives);
- binding agents;
- colouring agents;
- corrosion inhibitors;
- fillers;
- paints, lacquers and varnishes; and
- surfactants.

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 construction materials;
- in hydraulic fluids and additives;
- in impregnation materials;
- as a process regulators;
- in reprographic agents; and
- in solvents.

The chemical has reported site-limited use including as a chemical intermediate for polymers.

The chemical has reported non–industrial use including in non–agricultural pesticides and preservatives.

Restrictions

Australian

No known restrictions have been identified.

International

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

For use in food packaging — the chemical is regulated under Annex I of the European Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come in contact with food. The chemical may be used with a specific migration limit (SML) of 0.05 mg/kg.

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; R37/38 (irritation)

R43 (sensitisation)

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica).

Time weighted average (TWA) of 5 ppm (38 mg/m^3) in Germany; and

TWA of 35 mg/m^3 and short term exposure limit (STEL) of 100 mg/m^3 in Poland.

Health Hazard Information

Toxicokinetics

Following oral administration in rats, the chemical is rapidly absorbed, extensively distributed and readily eliminated. Studies in rats have indicated that short-chain acrylates such as this chemical undergo metabolism via carboxylesterase-catalysed hydrolysis to acrylic acid (CAS No. 79-7-10) and 2-ethylhexanol (CAS No. 104-76-7) (OECD, 2003).

In male Wistar rats that received an oral dose of a radiolabelled [2,3-^{14}C] sample of chemical at 100 mg/kg bw, 90 % of the administered dose was excreted 72 hours after administration via respiration (50 %) and in urine (40 %). Distribution of the chemical was mainly to the liver, kidneys and lungs, with concentrations peaking at three hours after administration. The chemical did not show bioaccumulation potential in rats (EU RAR, 2005; REACH).

Acute Toxicity

Oral

The chemical had low acute oral toxicity in an animal study.

The median lethal dose (LD50) value in rats was greater than 2000 mg/kg bw. In an acute oral toxicity study, (equivalent to the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 401), rats were administered the chemical in an aqueous emulsion (with 10 % tragacanth gum) at 1810 or 2903 mg/kg bw (n = 5 rats), or at 4444 mg/kg bw (n = 10 rats) via oral gavage. Four out of 10 rats died 24 hours after administration of the highest dose. An LD50 of 4435 mg/kg bw was determined for rats. Observed sublethal effects included apathy, narcosis and diarrhoea, with no histopathological alterations (EU RAR, 2005).

Dermal

The chemical had low acute dermal toxicity in an animal test.

The dermal LD50 is greater than 2000 mg/kg bw in rats and rabbits (EU RAR, 2005). Observed sublethal effects in rats included apathy, disturbances of equilibrium, accelerated respiration and anorexia (REACH).

Inhalation

Based on the limited data available, the chemical is expected to have low acute inhalation toxicity.

In a test with rats (n = 6), after eight hours of exposure to an atmosphere saturated with the chemical (no further details provided) at 20 °C, no mortalities or clinical signs were observed (OECD, 2003; EU RAR 2005).

Another poorly-documented study exposed rats (n = 6/sex/dose) to a saturated atmosphere (no concentration determined) of the chemical vapour for a period ranging from 15 minutes to eight hours. No mortalities were observed and the only clinical signs were nasal and ocular irritation in rats exposed for eight hours (EU RAR, 2005; REACH).

Corrosion / Irritation

Respiratory Irritation

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

Nasal irritation was observed in rats during an acute inhalation toxicity test (see **Acute toxicity: Inhalation**). Local irritant effects in the respiratory tract of rats were observed when they were exposed to low doses of the chemical during a repeated dose inhalation toxicity study (see **Repeated dose toxicity: Inhalation**) (EU RAR, 2005).

Skin Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in the Hazardous Substances Information System (HSIS) (Safe Work Australia). The available data support this classification.

Application of the chemical (0.5 mL, undiluted) on the unabraded skin of New Zealand White rabbits (n = 6) for four hours produced severe erythema (mean scores for 24 and 72 hours post application were 3.2 and 2.7, respectively) and oedema (mean scores for 24 and 72 hours post application were 2.7 and 1.2, respectively). After three days, the exposed areas were still inflamed. However this effect was reversible within eight days for 5/6 rabbits. No necrosis was observed (EU RAR, 2005; REACH).

In order to investigate the severity of skin lesions following exposure, the chemical was assessed in an EpiDerm™ skin corrosivity test (OECD TG 431) using a reconstructed three dimensional human epidermis model. It was demonstrated that the chemical reacts like the negative control (doubly distilled water), while a caustic compound (8 N potassium hydroxide) used as a positive control proved that this test is able to detect caustic chemicals. Based on the observed results and applying the evaluation criteria of the test, the chemical was not a corrosive compound (EU RAR, 2005; REACH).

Eye Irritation

The chemical is not an eye irritant.

The chemical was reported to be non–irritating to the eyes of rabbits when tested according to OECD (TG) 405. The following mean scores were documented after 72 hours of exposure: cornea 0.1, iris 0; conjunctival redness 0.2; and conjunctival chemosis 0.1. The effects were reversible within 72 hours after application (EU RAR, 2005).

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 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 0.5, 1.0, 2.5, 5.0 and 10 % (in acetone/olive oil at 4:1 v/v). The chemical was determined to be a moderate skin sensitiser based on the effective concentration needed to produce a three-fold increase in lymphocyte proliferation (EC3) value of 9.7 %. The chemical was determined to be a weak skin sensitiser (Dearman et al., 2007; REACH).

In several tests in guinea pigs, the chemical showed sensitising properties, with and without adjuvants. In a Freud's Adjuvant test (FCA test), guinea pigs (n = 10/group) were exposed to a 0.1 % aqueous solution of the chemical via intradermal and topical application on three days over three consecutive weeks. A challenge was performed at the same concentration 10 days after the last application. Intense redness and oedema were observed after 48 hours in 10/10 animals in the topical application group and 5/10 in the intradermal injection group (EU RAR, 2005).

The sensitising potential of the chemical was also demonstrated in a skin sensitisation study using the Polak method. Guinea pigs (n = 6/dose) received four footpad injections of 0.1 mL containing the chemical at 2 mg/mL (in acetone/olive oil at 4:1 v/v). Seven days after the last treatment, the animals showed positive skin reactions when challenged with 0.2 % and 0.8 % of the chemical (EU RAR, 2005).

Observation in humans

The positive animal data are supported by the human case reports detailed below:

- seven male volunteers developed allergic contact dermatitis to an acrylic acid-based adhesive, with all subjects being strongly positive to the chemical. Test concentrations were 5 % in olive oil (EU RAR, 2005);
- a 51-year-old engineer developed hand eczema after contact with products used as anaerobic sealants in metal manufacturing. Positive patch test results were seen with several acrylates, including the chemical at 0.5 % in ethanol (EU RAR, 2005);

- four patients developed dermatitis from working with UV-cured inks in printing plants. Patch tests with various acrylate monomers yielded positive results, including two patients who tested positive to the chemical (EU RAR, 2005);
- six patients developed contact dermatitis to various acrylates after exposure to tape or glues. All patients tested positive to various acrylates. One of these patients developed eczema after surgery. The wound had been dressed with a tape, and the eczema was strictly localised under the tape. Positive patch test reactions were seen for the chemical at a concentration of 2 % in petrolatum (EU RAR, 2005); and
- a 51-year-old man with a limb prosthesis developed contact sensitivity in the area of the amputation stump and in other areas after readjustment of the prosthesis to have it revarnished. He had a positive reaction to the chemical at 0.1 % in petrolatum (EU RAR, 2005).

Repeated Dose Toxicity

Oral

Limited data are available. There are no reliable repeated dose oral toxicity studies available for the chemical (EU RAR, 2005).

In a poorly-documented subacute oral toxicity study, rabbits were administered the chemical via oral gavage at doses of 887 mg/kg bw/day (n = 4) and 1774 mg/kg bw/d (n = 2) for five days a week over two weeks. In the second group, both animals died following administration of six or eight doses, respectively, of the chemical at 1774 mg/kg bw/d (REACH).

Dermal

Limited data are available. There are no reliable repeated dose dermal toxicity studies available for the chemical (OECD, 2003).

A subchronic repeated dose dermal toxicity study investigated the effects of epicutaneous application of the chemical in two strains of mice (C3H and NMRI) over a three-month period. The mice (n = 10/sex/dose) were administered the chemical on clipped dorsal skin at 170 or 758 mg/kg bw/d for three days a week. C3H mice were found to be more sensitive to skin irritation than NMRI mice. No significant clinical abnormalities were observed in mice and a no observed adverse effect level (NOAEL) for systemic effects could not be drawn from this study (EU RAR, 2005; REACH).

Inhalation

Based on the data available, the chemical is not considered to cause serious systemic effects from repeated inhalation exposure. However, local irritation effects are expected.

In a 90-day repeated dose inhalation toxicity study (OECD TG 413) Wistar rats (n = 10/sex/dose) were exposed to the chemical vapour (99.7 % purity) at 0, 10, 30 or 100 ppm (equivalent to 0, 0.075, 0.226 or 0.753 mg/L) for six hours a day (6-h/d), five days a week. There were no treatment-related mortalities or systemic effects on body and organ weights, ophthalmology, haematology or gross pathology. The no observed adverse effect concentration (NOAEC) was reported to be 0.226 mg/L/6-h/d and the lowest observed adverse effect concentration (LOAEC) was reported as 0.753 mg/L/6-h/d based on elevated activities of transaminase and alkaline phosphatase. An LOAEC of 0.226 mg/L was calculated for local effects, based on degeneration of the olfactory epithelial layer in the cranial part of the nasal cavity (EU RAR, 2005; REACH).

Genotoxicity

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

The chemical gave negative results for genotoxicity in three in vitro bacterial reverse mutation assays (Ames test) with *Salmonella typhimurium* strains (TA 98, 100, 1535, 1537 and 1538), with or without metabolic activation, at doses up to 10000 µg/plate (EU RAR, 2005). However, positive results were observed for gene mutations and DNA damage in several other in vitro tests:

- in mammalian gene mutation tests using mouse lymphoma cells (L5178Y), with or without metabolic activation, the chemical was considered to be weakly positive at doses in the toxic range and effects were more pronounced with microsomal activation (EU RAR, 2005); and
- in a sister chromatid exchange (SCE) assay in mammalian cells using Chinese hamster ovary cells with or without metabolic activation, no statistically significant increase in SCE was observed without activation. However, the chemical was weakly positive with metabolic activation (EU RAR, 2005, REACH).

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

- in an unscheduled DNA synthesis test (OECD TG 486) in Wistar rats which received the chemical orally at 1000 or 2000 mg/kg bw (REACH); and
- in a chromosome aberration assay in CD1 mice which received the chemical orally at 0, 250, 1000 or 2500 mg/kg bw (EU RAR, 2005; REACH).

Carcinogenicity

No oral carcinogenicity studies are available. Based on the limited data available, the chemical is not expected to be carcinogenic from dermal exposure.

In a two-year carcinogenicity study, NMRI mice (n = 80/dose) received the chemical dermally at doses of 21.5, 43 or 85 % (w/w) in acetone (corresponding to 217, 444 or 919 mg/kg bw/d), three times a week. No treatment-related histopathological changes or neoplastic lesions of the skin were observed in any dose group. A NOAEL of 919 mg/kg bw/d was determined (EU RAR, 2005; REACH).

Male C3H mice (n = 80/dose) were dermally administered the chemical at 2.5, 21, 43 and 86.5 % (w/w) in acetone (corresponding to 24.8, 212, 444 and 937 mg/kg bw/d) three times a week over their lifetime. The lowest observed adverse effect level (LOAEL) was 24.8 mg/kg bw/d for local non–neoplastic skin effects (EU RAR, 2005).

There are no oral carcinogenicity studies available in animals. However, there are no carcinogenicity concerns for the hydrolysis products of the chemical (acrylic acid, CAS no. 79-10-7 and 2-ethylhexanol, CAS no. 104-76-7) (EU RAR, 2005).

Reproductive and Developmental Toxicity

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

In a 90-day study (OECD TG 413), Wistar rats (n = 10/sex/dose) received the chemical via inhalation at 10, 30 or 100 ppm (0.075, 0.226 or 0.753 mg/L) for six hours a day, five days a week with no evidence of impaired reproductive organs in either sex (EU RAR, 2005, REACH).

In a developmental toxicity study (non-guideline), female Sprague Dawley (SD) rats (n = 20/dose) were exposed (whole body for 6-h/d) to the chemical vapour (99.7 % purity) at 0, 50, 75 or 100 ppm (approximately 0.375, 0563 or 0.750 mg/L) during gestation days 6–20. An NOAEC of 0.563 mg/L/6-h/d was determined for maternal systemic toxicity based on reduced body weight and food intake observed at the next dose level. No developmental effects were observed at the highest concentration tested, thus the NOAEC of 0.750 mg/L/6-h/d was derived (EU RAR, 2005; REACH).

One of the hydrolysis products of the chemical, 2-ethylhexanol (CAS No. 104-76-7) has been assessed and is classified as a reproductive toxin category 3—'possible risk of harm to the unborn child' (Xn; R63) in HSIS (Safe Work Australia). The NOAEL for 2-ethylhexanol for reproductive toxicity was determined to be 130 mg/kg bw/d (NICNAS).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local effects — skin sensitisation and irritation of the skin and respiratory tract.

Public Risk Characterisation

The chemical is reported to be used in domestic products in Australia at concentrations usually below 10 %. However, concentrations up to 60 % in surface coatings are possible according to some Australian SDSs. Product use in a domestic setting is not known. Although use in cosmetics in Australia is not known, the chemical is reported to be used in cosmetics overseas (concentrations not specified). The chemical is not listed in the Compilation of Ingredients Used in Cosmetics in the United States (CIUCUS, 2011).

Given the uses identified for the chemical, it is unlikely that the public will be exposed. 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 and inhalation 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, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise dermal 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.

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 the Poisons Schedule.

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]
Irritation / Corrosivity	Irritating to skin (Xi; R38)* Irritating to respiratory system (Xi; R37)*	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 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 which could 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;
- 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.

References

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