Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-(2-methyl-1-oxo-2-propenyl)-.omega.-hydroxy-: Human health tier II assessment

07 February 2014

CAS Number: 39420-45-6

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.

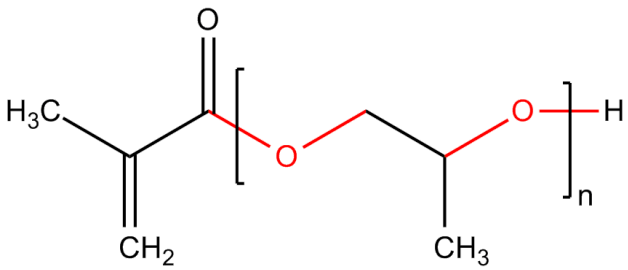
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	Polypropylene glycol monomethacrylate PPG-5 methacrylate Poly(propylene oxide) monomethacrylate Poly[oxy(methyl-1,2-ethanediyl)], a-(2-methyl-1-oxo-2-propen-1-yl)-?-hydroxy-
Structural Formula	
Molecular Formula	(C3H6O)nC4H6O2
Appearance and Odour (where available)	clear colourless liquid
SMILES	CC(=C)C(=O)OCCCO

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 potential domestic or commercial use as a surfactant.

The chemical has reported site-limited use as a monomer for polymer manufacture.

International

The following international uses have been identified through European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR); Galleria Chemica; 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 Computer Toxicology Resource—ACToR, and the US National Library of Medicine's Hazardous Substances Data Bank—HSDB.

The chemical has reported cosmetic use including:

- film forming; and
- nail conditioning.

Available data indicate that there is not widespread use of the chemical in cosmetics as it is reported to be present in only 14 cosmetic products in the United States (Personal Care Products Council 2011).

The chemical has reported domestic use including in paints, lacquers and varnishes. Available North American databases do not give evidence for use of this chemical in consumer products, indicating that the chemical is not likely to be widely available for domestic uses.

The chemical has reported site-limited use as a monomer for polymer manufacture.

Restrictions

Australian

No known restrictions have been identified.

International

No known restrictions have been identified.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Substances Information System (HSIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

Toxicity data for the chemical are not available. There are limited data available for the chemicals 2-hydroxypropyl methacrylate and 2-propenoic acid, 2-methyl-, monoester with 1,2-propanediol (CAS Nos. 923-26-2 and 27813-02-1) which are related to the chemical. These chemicals (collectively known as HPMA) are the mono-propoxylate ester of methacrylic acid, while the chemical is the poly-proproxylate ester with an average of five propoxylate units. The potential metabolite polypropylene glycol (CAS 25322-69-4) is not considered to pose an unreasonable risk to the health of workers and public health (NICNASb). Based on the similarity and lower molecular weight of HPMA, toxicity data for this analogue are expected to represent the highest toxicological hazard for the chemical (NICNASa).

Toxicokinetics

No data are available for the chemical.

Based on the calculated water solubility (1.091 x 10^3 mg/L at 25 °C), the calculated partition coefficient (log Kow = 1.29) and low molecular weight (< 500 Da) of the chemical, passive diffusion across the gastrointestinal (GI) tract and dermal absorption may occur. The expected irritant effects of the chemical may increase the dermal absorption potential. The chemical may also be absorbed through the respiratory tract.

Methacrylates are detoxified predominantly by conjugation with glutathione by the Michael addition reaction or by glutathione-*S*-transferase. The ester functionality is likely to be hydrolysed by carboxylesterases, as indicated by an in vitro hydrolysis study on HPMA (CAS No. 27813-02-1) (NICNASa). Methacrylates of lower molecular weight are rapidly metabolised and eliminated and are not likely to cause cumulative toxicity (Patty’s Toxicology 2012). The polypropylene glycol group resulting from hydrolysis of the chemical is likely to be metabolised similarly to other propoxylates (HERA 2009; REACH).

Acute Toxicity

Oral

The chemical is expected to be of low acute toxicity following oral exposure based on the data available for the related chemical, HPMA (NICNASa). In general methacrylates are of low acute toxicity by the oral route (Patty's Toxicology 2012).

Dermal

The chemical is expected to be of low acute toxicity following dermal exposure based on the data available for the related chemical, HPMA (NICNASa).

Inhalation

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

Respiratory irritation has been observed in both test animals and in humans following exposure to vapours of other methacrylates (CIR 2005). Respiratory irritation from inhalation of other methacrylates is ascribed to methacrylic acid formation due to carboxylesterase hydrolysis of the methacrylate esters in the nasal tissues.

Although the mechanism of action for respiratory irritation may be relevant for the chemical, the low vapour pressure (estimated 0.01 kPa) will limit inhalation exposure to vapours.

Skin Irritation

The chemical is considered to be at the most slightly irritating to the skin based on the data available for the related chemical, HPMA (NICNASa).

Eye Irritation

The results of studies conducted on a variety of methacrylates including the related chemical HPMA indicate that they are eye irritants (NICNASa). Therefore, based on the available information the chemical is expected to be irritating to the eye, although data are not sufficient to warrant classification.

Sensitisation

Skin Sensitisation

Skin sensitisation has been observed in both test animals and in humans following exposure to other methacrylates (CIR 2005). The related chemical HPMA elicited a weak, but not classifiable, sensitisation response in two guinea pig maximisation tests (GMPT) (1/10 and 3/12 animals sensitised) and in a local lymph node assay (LLNA) (NICNASa). Therefore, based on the available information, the chemical may be sensitising to the skin, although data are not sufficient to warrant classification.

Exposure to one methacrylate may induce sensitisation to other structurally related methacrylates, also known as skin sensitisation cross-reactivity. This has been observed with the related chemical HPMA (Rustemeyer et al. 1998). Skin sensitisation cross-reactivity by the chemical cannot be ruled out.

Repeated Dose Toxicity

Oral

The chemical is not considered to cause serious damage to health from repeated oral exposure based on the data available for the related chemical, HPMA (NICNASa).

Dermal

No data are available.

Inhalation

Following subchronic exposures to atmospheres of excessive concentrations of acrylates and/or methacrylates, pulmonary congestion or haemorrhage and cloudy swelling and organ weight changes of the liver and kidney have been reported (Patty’s Toxicology 2012). Repeat dose inhalation toxicity from the chemicals cannot be ruled out, although the low vapour pressure of the chemical (estimated 0.01 kPa) will limit inhalation exposure to vapours.

Genotoxicity

The results of mutagenicity studies on acrylates and methacrylates have been evaluated (Johannsen et al. 2008). In general, it was found that compounds were negative in bacterial reverse mutation assays (and other in vitro mammalian point mutation assays). While positive results were noted in some in vitro mammalian clastogenicity assays, the results of in vivo assays were negative.

The related chemical HPMA was considered not to be genotoxic in vivo based on the weight of evidence from the available genotoxicity studies (NICNASa).

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

Based on the information available for the related chemical HPMA, the chemical is not expected to show specific reproductive or developmental toxicity (NICNASa).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local effects (weak skin sensitisation). The chemical may also cause eye irritation. Skin sensitisation cross reactivity may occur following exposure to other structurally related methacrylates.

Public Risk Characterisation

The use of this chemical in cosmetic/domestic products in Australia is not known. However, use in domestic products overseas at a concentration up to 30 % has been identified. While the chemical may have weak sensitisation potential, it is expected to be less sensitising than the majority of alternate methacrylate monomers. International information indicates that the chemical is not likely to be widely available for domestic and cosmetic use. Hence, the public risk from this chemical is not considered to be unreasonable.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. 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 may pose an unreasonable risk to workers unless adequate control measures to minimise dermal 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.

The chemical is stable in the presence of an inhibitor. High temperatures, inhibitor depletion, accidental impurities, or exposure to radiation or oxidising agents may cause spontaneous polymerisation reactions generating heat/pressure. Closed containers

may rupture or explode during runaway polymerisation.

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. The chemical is not recommended for classification and labelling under the current approved criteria and adopted GHS. This does not consider classification of physical hazards and environmental hazards. No further assessment is required.

Regulatory Control

Advice for consumers

Products containing the chemical should be used according to the instruction on the label.

References

Bingham, E. and Cohrssen, B. (eds.) Patty's Toxicology: Volume 4 (Chapter 57) Esters of Mono- and Alkenyl Carboxylic Acids and Mono- and Polyalcohols. 6th ed. New York: John Wiley & Sons, 1999-2012.

Cosmetic Ingredient Review 2005. Final report of the safety assessment of methacrylate ester monomers used in nail enhancement products. International Journal of Toxicology, Volume 24, Supplement 5, 53-100.

Human& Environmental Risk Assessment on ingredients of European household cleaning products 2009. Alcohol Ethoxylates Human Health Risk Assessment. Accessed May 2013 at http://www.heraproject.com

Johannsen FR, Vogt B, Waite M& Deskin R 2008. Mutagenicity assessment of acrylate and methacrylate compounds and implications for regulatory toxicology requirements. Regul. Toxicol. Pharm. 50: 322-335.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (NICNAS a). Inventory Multi-tiered Assessment and Prioritisation (IMAP) Human Health Tier II Assessment for 2-hydroxypropylmethacrylate (CAS Nos 923-26-2 and 27813-02-1). Available at http://www.nicnas.gov.au

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (NICNAS b). Inventory Multi-tiered Assessment and Prioritisation (IMAP) Human Health Tier I Assessment for poly[oxy(methyl-1,2-ethanediyl)], .alpha.-hydro-.omega.-hydroxy- (CAS No. 25322-69-4). Available at http://www.nicnas.gov.au

REACH Dossier. Propane-1,2-diol, propoxylated (CAS No. 25322-69-4). Accessed November 2013 at http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Rustemeyer T, de Groot J, von Blomberg E, Frosch PJ& Scheper RJ 1998. Cross-reactivity patterns of contact-sensitizing methacrylates. Toxicol. Appl. Pharm. 148: 83-90.

Last update 07 February 2014

Share this page