Australian Government



Department of Health and Aged Care Australian Industrial Chemicals Introduction Scheme

Polymers incorporating glycidyl methacrylate

Evaluation statement

22 December 2022



Table of contents

Contents

AICIS evaluation statement	
Subject of the evaluation	3
Chemicals in this evaluation	
Reason for the evaluation	
Parameters of evaluation	
Summary of evaluation	
Summary of introduction, use and end use	
Human health	
Proposed means for managing risk	5
Workers	5
Conclusions	7
Supporting information	
Chemical identities	
Introduction and use	
Australia	14
International	
Existing Australian regulatory controls	15
AICIS	15
Public	15
Workers	15
International regulatory status	
Exposure Standards	15
Europe	15
- /	40

AICIS evaluation statement

Subject of the evaluation

Polymers incorporating glycidyl methacrylate

Chemicals in this evaluation

Name	CAS registry number
2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, homopolymer	25067-05-4
2-Propenoic acid, 2-methyl-, methyl ester, polymer with oxiranylmethyl 2-methyl-2- propenoate	26141-88-8
2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with ethyl 2-propenoate	26591-04-8
Methacrylic acid, 2,3-epoxypropyl ester, polymer with ethylacrylate and methyl acrylate	28963-71-5
2-Propenoic acid, 2-methyl-, methyl ester, polymer with ethenylbenzene and oxiranylmethyl 2-methyl-2-propenoate	29564-58-7
Methacrylic acid, 2,3-epoxypropyl ester, polymer with acrylonitrile and 2-ethylhexyl acrylate	30586-92-6
2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with ethene and ethenyl acetate	36604-80-5
2-Propenoic acid, 2-methyl-, methyl ester, polymer with butyl 2-propenoate, ethenylbenzene and oxiranylmethyl 2- methyl-2-propenoate	37953-21-2
2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with butyl 2-propenoate and ethyl 2-propenoate	41259-37-4
2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with butyl 2-propenoate and ethene	51109-15-0
2-Propenoic acid, 2-methyl-, methyl ester, polymer with butyl 2-propenoate, ethenylbenzene, methyl 2-propenoate and oxiranylmethyl 2-methyl-2-propenoate	60190-38-7
2-Propenoic acid, 2-methyl-, methyl ester, polymer with butyl 2-propenoate, ethenylbenzene, (1-methylethenyl)benzene and oxiranylmethyl 2-methyl-2-propenoate	60621-79-6
2-Propenoic acid, 2-methyl-, butyl ester, polymer with butyl 2-propenoate and oxiranylmethyl 2-methyl-2-propenoate	61156-85-2

Reason for the evaluation

Evaluation Selection Analysis indicated a potential human health risk.

Parameters of evaluation

Chemicals in this evaluation are a group of acrylic polymers incorporating glycidyl methacrylate (GMA) (CAS No. 106-91-2), with epoxide functional groups that are expected to be unreacted. These chemicals are listed on the Australian Inventory of Industrial Chemicals (the Inventory). This evaluation is a human health risk assessment for all identified industrial uses of these chemicals. This group of chemicals has similar use patterns and are expected to have similar toxicological properties, which are mainly expected to result from unreacted epoxide groups of glycidyl methacrylate within the polymers.

Summary of evaluation

Summary of introduction, use and end use

There is currently no specific information about the introduction, use and end use of these chemicals in Australia.

Based on international use information, polymers incorporating glycidyl methacrylate are used in several industrial products including:

- powder and metal coatings
- paints and coating products
- adhesive products
- 2-part resins
- printing inks
- rubber and plastic products
- food contact materials.

Human health

Summary of health hazards

No toxicological data are available for the chemicals in this group. The polymers contain reactive epoxide functional groups. The polymers are not expected to contain acrylate functional groups. The systemic health concerns for epoxide functionality are cancer and reproductive effects (US EPA 2010). Health effects arising from absorption and systemic exposure will depend on the amount of low molecular weight species present and the nature of exposure. The main health concerns are restricted to species with molecular weights less than 1000 g/mol, and less than 500 g/mol if exposure is limited to the dermal route. Systemic effects are not expected where concentrations of low molecular weight species are low.

There are no data available on the polymers for local effects. However, the epoxide group of these chemicals is highly reactive, leading to local effects at the point of contact. Local effects arise from the reactivity of the epoxide group, including severe skin and eye irritation. The epoxy functional groups are also structural alerts for sensitisation. Due to its reactivity, residual levels of GMA are expected to be extremely low.

Hazard classifications relevant for worker health and safety

These chemicals do not satisfy the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE 2017) for hazard classes relevant for work health and safety. This does not consider classification of physical hazards and environmental hazards.

Summary of health risk

Public

Based on the available use information it is unlikely that the public will be significantly exposed to these chemicals. Although the use in epoxy resins available to consumers is not expected to be widespread this use requires labelling in accordance with the *Poisons Standard - the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP). The public could come into contact with articles/coated surfaces containing these chemicals; however, it is expected that these chemicals will be bound within articles/coated surfaces and hence will not be bioavailable. Exposure to residual levels of GMA is not expected. Migration studies on food contact materials manufactured with GMA polymers support this, as indicated by migration of GMA being below the limit of detection (EFSA 2011; EFSA 2012a; EFSA 2012b). Therefore, there are no identified risks to the public that require management.

Workers

During product formulation, dermal, ocular and inhalation exposure might occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment.

The risks from exposure will depend on the amount of low molecular weight species present. Where low molecular weight species are present, these chemicals may pose a risk to workers, unless adequate control measures to minimise dermal, ocular and inhalation exposure are implemented (see Proposed means for managing risk section).

Proposed means for managing risk

Workers

Information relating to safe introduction and use

The information in this statement, should be used by a person conducting a business or undertaking at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws. In determining controls, the presence of low molecular weight species below 1000 g/mol should be considered.

Control measures that could be implemented to manage the risk arising from exposure to these chemicals include, but are not limited to:

- using closed systems or isolating operations
- using local exhaust ventilation to prevent these chemicals from entering the breathing zone of any worker
- minimising manual processes and work tasks through automating processes

- adopting work procedures that minimise splashes and spills
- cleaning equipment and work areas regularly
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with these chemicals.

Measures required to eliminate or manage risk arising from storing, handling and using these hazardous chemicals depend on the physical form and how these chemicals are used.

These control measures may need to be supplemented with:

• conducting health monitoring for any worker who is at significant risk of exposure to these chemicals if valid techniques are available to monitor the effect on the worker's health.

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.

Model codes of practice, available from the Safe Work Australia website, provide information on how to manage the risks of hazardous chemicals in the workplace, prepare an SDS and label containers of hazardous chemicals. Your Work Health and Safety regulator should be contacted for information on Work Health and Safety laws and relevant Codes of Practice in your jurisdiction.

Conclusions

The conclusions of this evaluation are based on the information described in this statement.

Considering the proposed means of managing risks, the Executive Director is satisfied that the identified human health risks can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory and the proposed means of managing the risks identified during this evaluation are implemented.

Note: Obligations to report additional information about hazards under *section 100 of the Industrial Chemicals Act 2019* apply.

Supporting information

Chemical identities

Chemical name	2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, homopolymer
CAS No.	25067-05-4
	polyglycidyl methacrylate
Synonyms	methacrylic acid, 2,3-epoxypropyl ester, polymers
	2,3-epoxypropyl methacrylate polymer
Structural formula	No structural diagram available
Molecular formula	(C7H10O3)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OCC1OC1)C(=C)C
Chemical description	-

Chemical name	2-Propenoic acid, 2-methyl-, methyl ester, polymer with oxiranylmethyl 2-methyl-2-propenoate
CAS No.	26141-88-8
	1-propanol, 2,3-epoxy-, methacrylate, polymer with methyl methacrylate
Synonyms	glycidyl methacrylate, methyl methacrylate copolymer
	2-propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with methyl 2-methyl-2-propenoate
Structural formula	No structural diagram available
Molecular formula	(C7H10O3.C5H8O2)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OC)C(=C)C.O=C(OCC1OC1)C(=C)C
Chemical description	-

Chemical name	2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with ethyl 2-propenoate
CAS No.	26591-04-8
	ethyl 2-propenoate, oxiranylmethyl 2-methyl-2- propenoate copolymer
Synonyms	2-propenoic acid, ethyl ester, polymer with oxiranylmethyl 2-methyl-2-propenoate
	acrylic acid ethyl ester, polymer with 2,3-epoxypropyl methacrylate
Structural formula	No structural diagram available
Molecular formula	(C7H10O3.C5H8O2)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OCC)C=C.O=C(OCC1OC1)C(=C)C
Chemical description	-

Chemical name	Methacrylic acid, 2,3-epoxypropyl ester, polymer with ethylacrylate and methyl acrylate
CAS No.	28963-71-5
Synonyms	2-propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with ethyl 2-propenoate and methyl 2-propenoate
	2-propenoic acid, ethyl ester, polymer with methyl 2- propenoate and oxiranylmethyl 2-methyl-2-propenoate
	2-propenoic acid, methyl ester, polymer with ethyl 2- propenoate and oxiranylmethyl 2-methyl-2-propenoate
	acrylic acid, ethyl ester, polymer with 2,3-epoxypropyl methacrylate and methyl acrylate
Structural formula	No structural diagram available
Molecular formula	(C7H10O3.C5H8O2.C4H6O2)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OC)C=C.O=C(OCC)C=C.O=C(OCC1OC1)C(=C) C
Chemical description	-

Chemical name	2-Propenoic acid, 2-methyl-, methyl ester, polymer with ethenylbenzene and oxiranylmethyl 2-methyl-2- propenoate
CAS No.	29564-58-7
Synonyms	styrene, methyl methacrylate, glycidyl methacrylate polymer
Structural formula	No structural diagram available
Molecular formula	(C8H8.C7H10O3.C5H8O2)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OC)C(=C)C.O=C(OCC1OC1)C(=C)C.C=CC=1C= CC=CC1
Chemical description	-
	•

Chemical name	Methacrylic acid, 2,3-epoxypropyl ester, polymer with acrylonitrile and 2-ethylhexyl acrylate
CAS No.	30586-92-6
Synonyms	-
Structural formula	No structural diagram available
Molecular formula	(C11H20O2.C7H10O3.C3H3N)x
Molecular weight (g/mol)	Unspecified
SMILES	N#CC=C.O=C(OCC(CC)CCCC)C=C.O=C(OCC1OC1) C(=C)C
Chemical description	-

Chemical name	2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with ethene and ethenyl acetate
CAS No.	36604-80-5
Synonyms	acetic acid ethenyl ester, polymer with ethene and oxiranylmethyl 2-methyl-2-propenoate
Structural formula	No structural diagram available
Molecular formula	(C7H10O3.C4H6O2.C2H4)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OCC1OC1)C(=C)C.O=C(OC=C)C.C=C
Chemical description	-

Chemical name

CAS No.

Synonyms

Structural formula

Molecular formula

Molecular weight (g/mol)

SMILES

Chemical description

2-Propenoic acid, 2-methyl-, methyl ester, polymer with butyl 2-propenoate, ethenylbenzene and oxiranylmethyl 2-methyl-2-propenoate

37953-21-2

methyl methacrylate, styrene, butyl acrylate, glycidyl methacrylate copolymer

No structural diagram available

(C8H8.C7H12O2.C7H10O3.C5H8O2)x

Unspecified

_

O=C(OCCCC)C=C.O=C(OC)C(=C)C.O=C(OCC1OC1)C(=C)C.C=CC=1C=CC=CC1

and

Chemical name	2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with butyl 2-propenoate and ethyl 2- propenoate
CAS No.	41259-37-4
Synonyms	-
Structural formula	No structural diagram available
Molecular formula	(C7H12O2.C7H10O3.C5H8O2)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OCC)C=C.O=C(OCCCC)C=C.O=C(OCC1OC1)C(=C)C
Chemical description	-

Chemical name	2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with butyl 2-propenoate and ethene
CAS No.	51109-15-0
Synonyms	butyl acrylate, ethylene, glycidyl methacrylate copolymer
Structural formula	No structural diagram available
Molecular formula	(C7H12O2.C7H10O3.C2H4)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OCCCC)C=C.O=C(OCC1OC1)C(=C)C.C=C
Chemical description	-
	-

Chemical name	2-Propenoic acid, 2-methyl-, methyl ester, polymer with butyl 2-propenoate, ethenylbenzene, methyl 2- propenoate and oxiranylmethyl 2-methyl-2-propenoate
CAS No.	60190-38-7
Synonyms	butyl acrylate, glycidyl methacrylate, methyl acrylate, methyl methacrylate, styrene copolymer
Structural formula	No structural diagram available
Molecular formula	(C8H8.C7H12O2.C7H10O3.C5H8O2.C4H6O2)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OC)C=C.O=C(OCCCC)C=C.O=C(OC)C(=C)C.O= C(OCC1OC1)C(=C)C.C=CC=1C=CC=CC1
Chemical description	-

Chemical name	2-Propenoic acid, 2-methyl-, methyl ester, polymer with butyl 2-propenoate, ethenylbenzene, (1- methylethenyl)benzene and oxiranylmethyl 2-methyl-2- propenoate
CAS No.	60621-79-6
	2-propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with butyl 2-propenoate, ethenylbenzene, (1- methylethenyl)benzene and methyl 2-methyl-2- propenoate
Synonyms	2-propenoic acid, butyl ester, polymer with ethenylbenzene, (1-methylethenyl)benzene, methyl 2- methyl-2-propenoate and oxiranylmethyl 2-methyl-2- propenoate
	benzene, (1-methylethenyl)-, polymer with butyl 2- propenoate, ethenylbenzene, methyl 2-methyl-2- propenoate and oxiranylmethyl 2-methyl-2-propenoate
	butyl acrylate, glycidyl methacrylate, methyl methacrylate, .alphamethylstyrene, styrene copolymer
Structural formula	No structural diagram available
Molecular formula	(C9H10.C8H8.C7H12O2.C7H10O3.C5H8O2)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OCCCC)C=C.O=C(OC)C(=C)C.O=C(OCC1OC1) C(=C)C.C=CC=1C=CC=CC1.C=C(C=1C=CC=CC1)C
Chemical description	-

Chemical name	2-Propenoic acid, 2-methyl-, butyl ester, polymer with butyl 2-propenoate and oxiranylmethyl 2-methyl-2- propenoate
CAS No.	61156-85-2
Synonyms	-
Structural formula	No structural diagram available
Molecular formula	(C8H14O2.C7H12O2.C7H10O3)x
Molecular weight (g/mol)	Unspecified
SMILES	O=C(OCCCC)C=C.O=C(OCCCC)C(=C)C.O=C(OCC1 OC1)C(=C)C
Chemical description	-

Introduction and use

Australia

No specific information is available on the introduction, use and end use of these chemicals in Australia.

International

Limited specific information is available on the introduction, use and end use of these chemicals internationally. The following international uses have been identified for polymers and pre-polymers manufactured from GMA through European Food Safety Authority Scientific opinions (EFSA); the European Union Registration, Evaluation and Authorisation of Chemicals (REACH); European Chemicals Agency (ECHA) CLP report; ChemWatch; United States Environmental Protection Agency (US EPA); International Agency for Research on Cancer (IARC) monograph volume 125; Organisation for Economic Co-operation and Development (OECD) SIDS Initial Assessment Report (2000); and FCCdb: Food Contact Chemicals database (FCCdb).

- powder and metal coatings
- paints and coating products
- adhesive products
- 2-part resins
- printing inks
- rubber and plastic products.

North American databases did not identify use of the chemicals in home maintenance products sold to consumers.

The following chemicals are used in food contact materials:

- CAS No. 25067-05-4
- CAS No. 26141-88-8
- CAS No. 29564-58-7

- CAS No. 36604-80-5
- CAS No. 37953-21-2
- CAS No. 51109-15-0

GMA is reported to have non-industrial uses in the manufacture of polymers and prepolymers used in medical applications such as:

- dental sealants and bone composite materials
- hydrogel lenses.

Existing Australian regulatory controls

AICIS

No specific controls are currently available for these chemicals.

Public

These chemicals are not specifically listed in the *Poisons Standard* (SUSMP). However, there is a group entry for 'Epoxy resins, liquid' in Schedule 5 (TGA 2022).

Schedule 5 chemicals are labelled with 'Caution' and are described as 'Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label'. Depending on their use, the chemicals in this evaluation may be covered by this entry.

Workers

These chemicals are not listed on the Hazardous Chemical Information System (HCIS) and no specific exposure standards are available in Australia (SWA).

International regulatory status

Exposure Standards

No specific exposure standards were identified for the chemicals in this group.

Europe

GMA is authorised for use in the manufacture of plastic food contact materials and articles, with a specific migration limit of 0.02 mg/kg (Annex I of Commission regulation (EU) No. 10/2011) (EC 2011). One of the chemicals in this group (CAS No. 37953-21-2) is listed in Annex I Plastic Food Contact Materials (FCMs) for use in rigid poly(vinyl chloride) (PVC) with a maximum allowable level of 2 % at room temperature or below (EC 2011; EFSA 2011; ECHA 2015).

References

AICIS (Australian Industrial Chemicals Introduction Scheme) (2022) <u>Glycidyl acrylate and</u> <u>glycidyl methacrylate</u>, AICIS, accessed July 2022.

Chemwatch (n.d.) Galleria Chemica, Chemwatch website, accessed July 2022.

EC (European Commission) (2011) <u>Commission Regulation (EU) No 10/2011 of 14 January</u> <u>2011 on plastic materials and articles intended to come into contact with food</u>, EC, accessed July 2022.

ECHA (European Chemicals Agency) (n.d.) <u>Substance Infocard for CAS No.106-91-2</u>, ECHA website, accessed July 2022.

ECHA (European Chemicals Agency) (2015) <u>Proposal for Harmonised Classification and</u> <u>Labelling. CLP report for 2,3 –epoxypropyl methacrylate (Glycidyl methacrylate, GMA)</u>, accessed February 2022.

EFSA (European Food Safety Authority) (2011) <u>Scientific Opinion on the safety evaluation of</u> <u>the substance, (methyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate)</u> <u>copolymer, CAS No. 37953-21-2, for use in food contact materials</u>, EFSA Journal, 9(4): 2124, accessed July 2022.

EFSA (European Food Safety Authority) (2012a) <u>Scientific Opinion on the safety evaluation</u> of the substance, Methacrylic acid, 2,3-epoxypropyl ester, copolymer with acrylic and/or <u>methacrylic acid alkyl (C1-C4) esters, for use in food contact materials</u>, EFSA Journal, 10(5): 2744, accessed March 2022.

EFSA (European Food Safety Authority) (2012b) <u>Scientific Opinion on the safety evaluation</u> of the active substances, terephthalic acid, dimethyl ester, polymer with 1,4-butanediol, cyclized, polymers with glycidyl methacrylate, hydroxyl-terminated polybutadiene, methyl methacrylate and styrene, and cobalt stearate for use in food contact materials, EFSA Journal, 10(10): 2905, accessed March 2022.

FCCdb (Food Contact Chemicals database) (n.d.) *Food contact chemicals database ver 5.0*, accessed July 2022.

IARC (International Agency for Research on Cancer) (2020) *International Agency for Research on Cancer (IARC)* <u>Monograph on Some Industrial Chemical Intermediates and</u> <u>Solvents</u>. Volume 125, accessed February 2022.

OECD (Organisation for Economic Co-operation and Development) (2020), <u>SIDS Initial</u> <u>Assessment Report for Glycidyl Methacrylate (CAS No. 106-91-2)</u>, accessed December 2021.

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) (n.d.). <u>Registered Dossier for 2,3-epoxypropyl methacrylate (CAS No. 106-91-2)</u>, European Chemicals Agency website, accessed December 2021. SWA (Safe Work Australia) (2016) *Model Work Health and Safety Regulations,* accessed July 2022.

SWA (Safe Work Australia) (n.d.) *Hazardous Chemical Information System*, SWA website, accessed July 2022.

TGA (Therapeutic Goods Administration) (2022) <u>Standard for the Uniform Scheduling of</u> <u>Medicines and Poisons No.36 (Poisons Standard June 2022)</u>, TGA, accessed July 2022.

UNECE (United Nations Economic Commission for Europe) (2017), <u>Globally Harmonized</u> <u>System of Classification and Labelling of Chemicals (GHS) Seventh Revised Edition</u>, accessed July 2022.

US EPA (United States Environment Protection Agency) (2010) <u>New Chemicals Program</u> <u>Chemical Categories Document</u>, US EPA website, accessed July 2022.

