Australian Government
Department of Health and Aged Care
Australian Industrial Chemicals Introduction Scheme

Fatty acids, dimers, hydrogenated, polymers with alkanediol and methylenebis[isocyanatobenzene]

Assessment statement

20 January 2023

Table of contents

Contents

AICIS assessment

Chemical in this assessment

Name	CAS registry number
Fatty acids, dimers, hydrogenated, polymers with alkanediol and methylenebis[isocyanatobenzene]	AICIS Approved Chemical Name (AACN)

Reason for the assessment

An application for an assessment certificate under section 31 of the *Industrial Chemicals Act 2019* (the Act).

Certificate Application type

Health focus

According to information submitted by the applicant and criteria in the *Industrial Chemicals (General) Rules 2019* and the *Industrial Chemicals Categorisation Guidelines*, this introduction is in the **assessed** category. The reason is that this introduction has **medium to high** indicative risk for **human health** because it is in:

- human health exposure band 4
- human health hazard band B

The introduction of this chemical has very low indicative risk for the environment because it is in:

- environment exposure band 3
- no environment hazard band

Defined scope of assessment

The polymer was assessed for industrial adhesive and sealant use (non-spray):

- imported into Australia at up to 35 tonnes per year
- imported at a concentration of 20% or less, in finished end-use products
- as having low molecular weight species less than 1000 g/mol below 7% and less than 500 g/mol below 1%

Summary of assessment

Summary of introduction, use and end use

The polymer will be imported into Australia as a component of finished adhesive/sealant products at up to 20% concentration in 310 mL sealed cartridges or 600 mL sausage packs.

The imported finished sealant/adhesive products will be used in industrial settings for automotive windscreen replacement, caulking applications (including marine) and general construction.

Human health

Summary of health hazards

The assessed polymer contains isocyanate functional groups that are of concern for irritation, dermal and respiratory sensitisation, and pulmonary toxicity (Barrett, 1994; US EPA, 2010; Kirk-Othmer, 1995). The United States Environmental Protection Agency (US EPA) specifies that chemical structures with isocyanate equivalent weights of greater or equal to 5000 g/mol are presumed not to pose a health hazard under any conditions. In addition, concerns are generally confined to species with molecular weights less than 1000 g/mol. The isocyanate functional group equivalent weight of the assessed polymer is less than 5000 g/mol; however, a relatively low proportion of low molecular weight species (less than 7% of molecular weight species less than 1000 g/mol and less than 1% of molecular weight species less than 500 g/mol) are present in the assessed polymer. Polymeric isocyanates tend to be non-volatile and are therefore expected to be less of an inhalation hazard compared to non-polymeric isocyanates.

Based on the positive and negative local lymph node assay (LLNA) results, it is possible to conclude that the isocyanate impurity (residual monomer) in the polymer tested has contributed to the skin sensitisation outcome in the two LLNA studies.

Based on the available skin sensitisation studies, the assessed polymer having low molecular weight species less than 1000 g/mol below 7% and less than 500 g/mol below 1% is not classified as a skin sensitiser. The applicant confirmed that the polymer will contain an impurity that is classified as hazardous for skin and respiratory sensitisation according to the GHS at less than 0.1% due to the processes that will be implemented during manufacture. The reduction in the concentration of this impurity from 0.2% to 0.05% in the polymer, resulted in no skin sensitisation in the second LLNA, compared to the positive results in the first LLNA.

The negative LLNA result indicate that the assessed polymer as introduced having low molecular weight species less than 1000 g/mol below 7% and less than 500 g/mol below 1% is unlikely to cause respiratory sensitisation (see **Supporting information** section). However, there is still uncertainty regarding the respiratory sensitisation potential of the assessed polymer. Therefore, further evaluation may be required when relevant data becomes available.

The available toxicity data also indicate that the assessed polymer:

- is likely to be of low acute oral toxicity;
- is non-irritating to skin and eyes;
- is not genotoxic.

Hazard classifications relevant for worker health and safety

Based on the data provided, the assessed polymer does not satisfy the criteria for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017), for hazard classes relevant for worker health and safety as adopted for industrial chemicals in Australia.

Summary of health risk

Public

The products containing the assessed polymer will not be available for use by the public. When introduced and used in the proposed manner, it is unlikely that the public will be exposed to the assessed polymer. No risks are identified for public health, if the assessed polymer is introduced and used by workers only, in accordance with the terms of the assessment certificate.

Workers

Workers will be dermally exposed to the assessed polymer at up to 20% concentration in end-use products when applying adhesives/sealants in industrial settings. Inhalation exposure may also occur during handling, application or cleaning activities. Based on the hazard information provided, this assessment does not identify any risks to the health of workers that would require specific risk management measures when the assessed polymer is introduced in accordance with the terms of the assessment certificate. General controls relating to isocyanates apply (see **Means for managing risk**).

Environment

Summary of environmental hazard characteristics

According to domestic environmental hazard thresholds and based on the available data the polymer is:

- Persistent (P)
- Not Bioaccumulative (not B)
- Not Toxic (not T) based on two ecotoxicological endpoints

Environmental hazard classification

Data on two acute endpoints were available. Based on the ecotoxicological endpoints for the assessed polymer, it is not expected to be harmful to aquatic life up to its water solubility limit. Therefore, the assessed polymer is not formally classified for acute and chronic toxicities according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017).

Summary of environmental risk

No significant release of the assessed polymer is expected to occur as a result of its use as a cross-linking agent in industrial adhesives and sealants. The assessed polymer is expected to share the fate of the product it is incorporated into and be disposed to landfill at the end of its useful life.

The assessed polymer is not readily biodegradable and is considered to be persistent. The assessed polymer has a low potential for bioaccumulation due to its high molecular weight and is not harmful to aquatic organisms based on data supplied for two trophic levels.

Based on its low hazards and assessed use pattern, the assessed polymer is unlikely to cause environmental risk.

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 (PCBU) at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

- AICIS notes that the assessed polymer contains an impurity that is classified as hazardous according to the GHS, as adopted for industrial chemicals in Australia.

- Workers must not be exposed to isocyanates at atmospheric concentrations greater than the workplace exposure standard for isocyanates. Air monitoring may be required to ensure exposure standards for isocyanates (SWA, 2018) are not exceeded.

- When handling products containing the assessed polymer, the Safe Work Australia Guide to Handling Isocyanates (SWA, 2015) should be followed.

Specific requirements to provide information

Introducers of the assessed chemical, including assessment certificate holders or persons covered by an assessment certificate, must advise the Executive Director within 20 working days if additional information has become available to the person as to reports of an adverse effect of the assessed chemical on worker health and safety.

Conclusions

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

Considering the proposed means of managing risks, the Executive Director is satisfied that when the assessed polymer is introduced and used in accordance with the terms of the assessment certificate the human health and environment 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 for managing the risks identified during this assessment are implemented.

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

Supporting information

Chemical identity

Chemical name	Fatty acids, dimers, hydrogenated, polymers with alkanediol and methylenebis[isocyanatobenzene] (AACN)
Synonyms	Prepolymer 4 V4
Molecular weight (g/mol)	Greater than 1000
Chemical description	Polymer

Relevant physical and chemical properties

A measured value was provided for the flash point based on a study conducted according to ASTM D7094 standard test guidelines. The other information is from the SDS of the polymer product containing the assessed polymer (marked with *).

Physical form	Colourless viscous liquid at 20 ºC and 101.3 kPa (polymer product)
Density	1200 kg/m^3 at 20 °C*
Flash Point	greater than 200 °C at 101.3 kPa
Water solubility	Insoluble*
Hydrolysis as a function of pH	Not determined (Expected to react and crosslink in water)
Dissociation constant (pKa)	Not determined (Expected to react and crosslink in water)
Octanol-water partition coefficient (log K_{ow})	Not determined (Expected to react and crosslink in water)
Adsorption coefficient (log K_{oc})	Not determined (Expected to react and crosslink in water)

Introduction and use

The assessed polymer will be imported by sea as a component of finished adhesive/sealant products at up to 20% concentration in 310 mL cartridges or 600 mL sausage packs. From the port, the finished adhesive/sealant products will be transported by road to the applicants' warehouse facilities and then distributed to end users.

The assessed polymer will be used as a hardener in adhesives/sealants at up to 20% concentration. The finished sealant/adhesive products will be used in automotive windscreen replacement, corking applications (including marine) and general construction.

At the end-use sites, the adhesive/sealant products will be applied to surfaces or cavities using either a manual application gun or a compressed air-assisted gun. Any excess product will be

removed using a scraper and cloth. The adhesive/sealant will be cured within 2-4 hours following application.

Human exposure

Workers

Category of Workers

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	2-4	12-14
End users (professional applicators)	8	100-200

Exposure Details

Transport and storage

Transport and storage workers may come into contact with the assessed polymer at up to 20% concentration in adhesive/sealant products only in the unlikely event of an accidental rupture of the packaging.

End users

At end-use sites, dermal exposure to the assessed polymer at up to 20% concentration may occur during application of adhesives/sealants. Inhalation exposure to the assessed polymer is not expected given the expected low vapour pressure of the assessed polymer and high viscosity of the adhesives/sealants. According to the applicant, potential for exposure to the assessed polymer is expected to be minimised through the use of personal protective equipment (PPE) including protective clothing and gloves.

Once the adhesives/sealants are cured and dried, the assessed polymer will be bound within a polymer matrix and is not expected to be available for exposure.

Public

Products containing the assessed polymer at up to 20% concentration are intended for industrial use only and will not be sold to the public. The public may come into dermal contact with the surfaces containing the cured sealants/adhesives containing the assessed polymer after application. However, once the adhesives/sealants are cured and dried, the assessed polymer will be bound within a polymer matrix and is not expected to be available for exposure.

Health hazard information

Toxicokinetics

Based on the high molecular weight (greater than 1000 g/mol) of the assessed polymer and low percentage (less than 7%) of low molecular weight species (less than 1000 g/mol) in the assessed polymer, absorption across biological membranes is expected to be limited.

Acute toxicity

Oral

Based on an acute oral toxicity study of the assessed polymer (OECD TG 423), the assessed polymer was found to be of low acute oral toxicity in rats (LD50 greater than 2000 mg/kg bw).

No acute dermal or inhalation toxicity data are provided for the assessed polymer.

Corrosion/Irritation

Skin irritation

In an in vitro skin irritation study using the EpiSkin™ reconstructed human epidermis model (OECD TG 439) and based on the mean tissue viability of greater than 50%, the assessed polymer does not require classification as a skin irritant under the GHS.

Eye irritation

In an in vitro eye irritation study using the isolated chicken eye (ICE) test (OECD TG 438), the assessed polymer gave ICE Class 1 results for each of the three ICE classification criteria (mean percentage corneal swelling, maximum mean opacity score and mean fluorescein retention score at 30-minute post-treatment). The combination of the ICE result falls under 'no category' according to the test guideline, indicating that the assessed polymer does not require classification as an eye irritant under the GHS.

Sensitisation

Skin sensitisation

In the two mouse Local Lymph Node Assays (LLNA) provided with the application, there was a difference in concentrations of the isocyanate impurity (residual monomer) in the test substances. The concentration of the isocyanate impurity was reduced from 0.2% in the positive LLNA test (the first test conducted in 2019) to 0.05% in the negative LLNA test (the second test conducted in 2020).

The assessed polymer was found to be a moderate skin sensitiser in the first LLNA test (with stimulation indices of 1.3, 1.0, 2.1 and 8.1 at 1%, 2.5%, 5% and 10% concentrations, respectively). The EC3 value was calculated to be 5.8%.

The assessed polymer was not a skin sensitiser in the second LLNA test up to 25% concentration (with stimulation indices of 0.7, 1.5, 2.6 and 2.2 at 2.5%, 5%, 10% and 25% concentrations, respectively).

Respiratory sensitisation

Air-borne polymeric isocyanate may cause respiratory sensitisation similar to monomer vapours, and reports have shown that inhalation of relatively non-volatile isocyanates in the form of dusts and spray mists could cause adverse respiratory effects (HCIS, 2008). The mechanism by which sensitisation occurs is uncertain. In sensitised individuals getting exposed to small amounts of isocyanates can cause allergic respiratory reactions like asthma

and breathing difficulties. Isocyanates may also cause respiratory sensitisation by skin contact (US EPA, 2010).

There are no validated tests available for the identification of respiratory sensitisation. The characteristics of immune responses elicited by contact allergens and respiratory allergens differ qualitatively. However they are both associated with the activation and proliferation of T lymphocytes in lymph nodes draining the site of exposure. Known respiratory allergens including isocyanates tested positive in one or more standard tests used for the identification of skin-sensitising potential chemicals. This indicates that chemicals that fail to elicit positive responses in accepted skin-sensitisation test methods might also be regarded as lacking the inherent potential to cause allergic sensitisation of the respiratory tract (Arts 2020; Dearman 2013; Kimber, et al. 2018; expert opinion received for the assessment – 16 December 2022).

Repeat dose toxicity

No repeated oral, dermal or inhalation toxicity data are provided for the assessed polymer.

Due to high molecular weight of the polymer (as having low molecular weight species less than 1000 g/mol below 7% and less than 500 g/mol below 1%), limited dermal absorption is expected. Therefore, the assessed polymer is unlikely to cause systemic effects from repeated dermal exposure.

Genotoxicity

The assessed polymer was not mutagenic in a bacterial reverse mutation assay (OECD TG 471). There was no significant increase in revertant colony numbers of any of the tested strains of *Salmonella typhimurium* (TA98, TA100, TA1535, TA1537) and *Escherichia coli* (WP2 uvrA) observed following exposed to the test substance at any concentration level up to 5000 µg/plate, with or without metabolic activation.

Environmental exposure

The assessed polymer will be imported into Australia as a component of industrial adhesive and sealants. Significant releases of the assessed polymer to the environment are not expected because no reformulation or repackaging will occur in Australia. Spills or accidental release of the products containing the assessed polymer during import, storage and transport is only expected to occur if the cartridges or sausage packs are breached. If spills or accidental releases of the assessed polymer occur, they are expected to be collected by suitable absorbents and disposed of, in accordance with State and local government regulations.

The sealants and adhesives containing the assessed polymer will be applied to surfaces or cavities using either a manual application gun or a compressed air-assisted gun. The sealant or adhesive is not expected to be released to the environment once it is cured into a solid matrix. The assessed polymer is expected to share the fate of the product it is incorporated into and be disposed of to landfill at the end of its useful life.

The applicant has estimated that up to 5% of the import volume of the assessed polymer may be present in residual product in empty end-use cartridges and sausage packs. The assessed polymer present in these residues is expected to cure into an inert solid matrix and not be released to the environment.

Environmental fate

Partitioning

The assessed polymer is expected to cure during use. The cured polymer will share the fate of the substrates to which it has been applied, either being subjected to metal reclamation or disposed of to landfill at the end of their useful lives. Any assessed polymer that is wasted during application processes or present as residue in empty end-use cartridges or sausage packs is expected to be cured and disposed of to landfill, along with the empty cartridges or sausage packs.

Degradation

Based on its measured degradation in water, the assessed polymer is persistent. Degradation studies in water indicate that the assessed polymer is not readily biodegradable. The results of a supplied degradation study for the assessed polymer indicated 4.4% degradation after 28 days (OECD 301D).

Bioaccumulation

The assessed polymer has a NAMW >1000 g/mol and is not expected to be bioavailable, and hence is not expected to be bioaccumulative.

Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) has not been calculated as the assessed polymer is not released into environmental waters under the assessed use.

Environmental effects

Effects on Aquatic Life

Acute toxicity

The results from the supplied ecotoxicological studies conducted on the assessed polymer are summarised in the table below:

Taxon	Endpoint	Method
Invertebrate	48 h EC50 > 100 mg/L WAF	*Daphnia magna* (water flea) Immobility OECD TG 202 Static conditions Nominal concentration
Algae	72 h ErC50 > 100 mg/L WAF	*Raphidocelis subcapitata (formerly known as Pseudokirchneriella subcapitata)* (green algae) Growth rate OECD TG 201 Static conditions Nominal concentration

WAF: Water Accommodated Fraction

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) for the aquatic compartment was not calculated as the assessed polymer is not expected to be harmful to aquatic life up to its water solubility limit.

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed polymer according to domestic environmental hazard thresholds is presented below:

Persistence

Persistent (P). Based on measured degradation of 4% in 28 days under screening test conditions, the assessed polymer is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on its expected low bioavailability (NAMW >1000 g/mol), the assessed polymer is categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on supplied ecotoxicity data for two trophic levels, the assessed polymer is not harmful up to the water solubility limit and hence categorised as Not Toxic.

Environmental risk characterisation

The assessed polymer does not meet all three PBT criteria and is hence unlikely to have unpredictable long-term effects (EPHC 2009). The Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as release of the assessed polymer to the aquatic environment is not expected based on its assessed use pattern.

Therefore, based on the low toxicity, expected low bioavailability and limited environmental exposure from the assessed use pattern, the assessed polymer is unlikely to cause environmental risks.

References

Arts J (2020), How to assess respiratory sensitization of low molecular weight chemicals? International Journal of Hygiene and Environmental Health 225, 113469.

Barratt MD, Basketter DA, Chamberlain M, Admans GD and Langkowski JJ (1994), An Expert System Rulebase for Identifying Contact Allergens. Toxicology In Vitro 8(5), 1053-1060.

Dearman RJ, Basketter DA and Kimber I (2013) Inter-relationships between different classes of chemical allergens. Journal Applied Toxicology 33(7), 558-65.

EPHC (2009) Environment Protection and Heritage Council, Environmental Risk Assessment Guidance Manual for industrial chemicals, Prepared by: Chris Lee-Steere Australian Environment Agency Pty Ltd, February 2009. ISBN 978-1-921173-41-7.

HCIS (2008) Hazardous Chemical Information System. Exposure Standard Documentation. Isocyanates. Safe Work Australia. http://hcis.safeworkaustralia.gov.au/ExposureStandards/Document?exposureStandardID=1013.

Kimber I, Poole A and Basketter DA (2018), Skin and respiratory chemical allergy: confluence and divergence in a hybrid adverse outcome pathway. Toxicology Research 7, 586.

Kirk-Othmer Encyclopedia of Chemical Technology, 4th edition (1995) M Howe-grant (ed). Vol 14, p902 (Richter RH and Priester RD contributors). New York, John Wiley and Sons.

SWA (2015) Guide to Handling Isocyanates, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/guide-handling-isocyanates.

SWA (2018) Workplace Exposure Standards for Airborne Contaminants, Safe Work Australia, https://www.safeworkaustralia.gov.au/system/files/documents/1804/workplace-exposure-standards-airborne-contaminants-2018_0.pdf

UNECE (2017), Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 7th Revised Edition. United Nations Economic Commission for Europe, Geneva, Switzerland.

US EPA (2010) TSCA New Chemicals Program (NCP) Chemical Categories. Washington, D.C., https://www.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf.

US EPA (2012) Estimation Programs Interface (EPI) SuiteTM for Microsoft Windows®, v 4.1. US EPA. Available at https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.