Polymers with known genotoxic aromatic amine and isocyanate constituents: Human health tier II assessment

12 December 2019

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Benzenamine, 4,4'-methylenebis-, polymer with 1,3-diisocyanatomethylbenzene and .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)]	51888-37-0
2-Oxepanone, polymer with .alpha.-hydro-.omega.-hydroxypoly(oxy-1,4-butanediyl), 4,4'-methylenebis[benzenamine] and 1,1'-methylenebis[4-isocyanatobenzene]	59218-46-1
2-Oxepanone, polymer with .alpha.-hydro-.omega.-hydroxypoly(oxy-1,4-butanediyl), 4,4'-methylenebis[benzenamine], 1,1'-methylenebis[4-isocyanatobenzene] and 1,1'-methylenebis[4-isocyanatocyclohexane]	72928-66-6

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

Grouping Rationale

The chemicals covered by this assessment are polymers with multiple monomers (no. of monomer components ≤6) that are primarily grouped based on the risks associated with the release of genotoxic and/or carcinogenic amines due to the following aromatic amine monomers, 4,4-methylenedianiline (MDA, CAS No. 101-77-9) (NICNASa).

These polymers also contain the following isocyanate monomers (aliphatic and aromatic diisocyanates) (NICNASb):

- 4,4-methylenediphenyl diisocyanate (MDI, CAS No. 101-68-8);
- 4,4-methylenedicyclohexyl diisocyanate (HMDI, CAS No. 5124-30-1); or
- toluene diisocyanate (TDI, CAS No. 26471-62-5).

Local effects (including acute toxicity, irritation and sensitisation through the dermal and inhalation routes) associated with polymers containing isocyanate monomers are not expected to be at significant concentration levels for which local effects would be observed.

The polymers in the group are polyurethanes (PUR), from which the aromatic amine may be released by hydrolysis reactions. The aromatic amine, MDA is classified as carcinogens and is included in the European Union (EU) Regulation on Registration,

Evaluation, Authorisation and Restriction of Chemicals (REACH) list of 22 carcinogenic aromatic amines in Annex XVII Appendix 8 (ECHA, 2019) (see **International restrictions** section).

Aromatic amines are much smaller molecules than the polymers from which they are released and are reported to have more significant absorption through biological membranes, including the skin, or absorbed through the intestine (Kemi, 2015; Ollgaard et al., 1998; Stingley et al., 2010). These aromatic amines may potentially cause significant human health effects related to systemic toxicity including mutagenicity and/or carcinogenicity (Chung, 2016; ECHA, 2019; NICNASa).

These polymers are generally expected to be of low concern to human health. However, the products manufactured using these polymers may contain low levels of free MDA as an impurity, or free isocyanate groups as terminal groups following incomplete polymerisation. The chemicals are grouped based on their common sources of risk and end-related uses in the manufacture of polyurethanes, polyureas, related coatings and foams **(**Dias Vila, 2002; Frosch et al., 2010; Kawamura et al., 2014; CROW, 2015) (see **Import, manufacture and use** section).

Thermal decomposition of these polymers are not expected during normal use. Aliphatic and aromatic isocyanates are reported to revert only at very high temperatures of >160 °C, and >180 °C, respectively. At temperatures >250°C, thermal decomposition into free isocyanates, alcohols, free amines, olefins, and carbon dioxide is expected (Szycher, 2012).

In the worst-case scenario, due to the presence of the aromatic amine monomers, the polymers may contain free MDA from incomplete polymerisation reactions or hydrolytic reactions. Isocyanates readily decompose into amines, thus free isocyanate groups are not expected to be available under normal circumstances where complete hydrolysis of isocyanate is expected during end-use in products (Kawamura et al., 2014). Hazards of any unreacted isocyante groups are; therefore, only expected to be relevant for occupational uses where freshly exposed surfaces are present. The hazardous properties of aromatic amines are well characterised and are expected to be the key driver for systemic acute and chronic toxicity from all routes of exposure related to these polymers. These aromatic amines are expected to be genotoxic and/or carcinogenic. In comparison, the other monomer constituents (potential release of constituents as a result of incomplete polymerisation or hydrolysis from the polymers), are not expected to be at the same level of concern.

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified.

International

The polymers in this group mainly have domestic, commercial and site-limited uses in the manufacture of polyurethanes, polyureas, elastomers, related coatings and foams for industrial application (including potential food contact applications such as cushioning and absorbent pads for fruit and meat, gloves, and in kitchen sponges) (Frosch et al., 2010; Kawamura et al., 2014; CROW, 2015; ACC, 2019).

Polyurethane applications are dependent on the monomer compositions of the respective chemicals (Frosch et al., 2010; Kawamura et al., 2014; CROW, 2015; ACC, 2019):

- Aromatic diisocyanates (MDI and TDI) are reported to dominate the market as they are inexpensive, where MDI and TDI are used in the manufacture of flexible and rigid polyurethanes foams (including coatings, sealants, adhesives, binders and elastomers) due to its light weight properties. Potential applications include insulation used in homes or refrigerators. Aromatic diisocyanates are not used in certain applications due to their tendency to undergo oxidative discoloration upon exposure to light and moisture.
- Aliphatic isocyanates (HMDI) are used in the manufacture of polyurethane dispersions (PUDs), elastomers, and thermoplastic polyurethanes (TPUs) which are more UV-stable, do not discolour due and are less susceptible to oxidation and degradation. Potential applications include coatings for flooring, roofing, textiles, elastomers, optical products, adhesives, and sealants.

Restrictions

Australian

Where the polymers in this group contain terminal isocyanate groups, these polymers may be covered by the entry for 'Isocyanates', listed in the Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in Schedule 6 (SUSMP, 2019) as:

"ISOCYANATES, free organic, boiling below 300 °C, except in:

a) viscous polyurethane adhesives; or

b) viscous polyurethane sealants;

containing not more than 0.7 per cent of free organic isocyanates boiling below 300 °C."

Schedule 6 chemicals are described as 'Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label'. Schedule 6 chemicals are labelled with 'Poison' (SUSMP, 2019).

Where the polymers in this group contain terminal isocyanate groups, these chemicals are covered by the entry for 'Isocyanates', listed in the Safe Work Australia, Model Work Health and Safety Regulations, Hazardous Chemicals (other than lead) requiring health monitoring (SWA, 2016).

The following applies to food contact articles and packaging in Australia and New Zealand, where manufacturers are required to ensure food in contact with packaging is safe from contaminants.

According to Food Standards Australia New Zealand (FSANZ, 2014) as stipulated under the '*Australia New Zealand Food Standards Code - Standard 3.2.2 - Food Safety Practices and General Requirements':*

'Division 3 – Food handling controls: Food packaging

A food business must, when packaging food –

(a) only use packaging material that is fit for its intended use;

(b) only use material that is not likely to cause food contamination; and

(c) ensure that there is no likelihood that the food may become contaminated during the packaging process.'

International

No known restrictions specific to these polymers have been identified.

The following applies to food contact articles and packaging in the United States and Europe, where manufacturers are required to ensure food in contact with packaging is safe from contaminants.

United States:

These polymers are regulated for use as a component of food contact substances under the United States (US) Food and Drug Administration (FDA) - List of Indirect Additives Used in Food Contact Substances with the following restrictions (US FDA, 2019; Kawamura et al., 2014):

- primary aromatic amines should not be released into foods or food simulants in detectable quantities. For the purpose of analysis, the detection limit for amines is set at 0.01 mg/kg foods or food simulants; and
- PUR resins in indirect food additives can only to be used in dry solid foods with a surface containing no free fat or oil.

Europe:

The monomers are regulated for use as a component of food contact substances under the EU – Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (European Commission, 2011; Kawamura et al., 2014) with the following limitations:

Aromatic Amines (MDA):

'Plastic materials and articles shall not release primary aromatic amines, excluding those appearing in Table 1 of Annex I, in a detectable quantity into food or food simulant. The detection limit is 0.01 mg of substance per kg of food or food simulant. The detection limit applies to the sum of primary aromatic amines released.'

Isocyanates (MDI and HMDI, except TDI):

- 'authorised to be used as monomer or other starting substance but not as an additive or polymer production aid'; and
- 'restriction of use of a substance or migration limit or limit of content of the substance in the material or article: 0.01 mg/kg in final product expressed as isocyanate moiety.'

Existing Worker Health and Safety Controls

Hazard Classification

The polymers in this group are not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Where the polymers in this group contain free isocyanate groups, these chemicals are covered by the entry for 'Isocyanates', listed in the Safe Work Australia, Model Work Health and Safety Regulations, Hazardous Chemicals (other than lead) requiring health monitoring (SWA, 2016).

Exposure Standards

Australian

There are no specific exposure standards available for the polymers in this group.

Safe Work Australia has a group entry for all isocyanates. Where the polymers in this group contain free isocyanate groups, exposure standards of 0.02 mg/m³ time weighted average (TWA) and 0.07 mg/m³ short term exposure limit (STEL) apply (Safe Work Australia).

International

There are no specific exposure standards available for the polymers in this group.

Health Hazard Information

The chemicals in this group are polymers with monomers that include the aromatic amine, MDA (CAS No. 101-77-9); and isocyanates, MDI (CAS No. 101-68-8), HMDI (CAS No. 5124-30-1) and TDI (CAS No. 26471-62-5) and are expected to have similar end-related domestic and commercial uses in the manufacture of polyurethanes, polyureas, related coatings and foams.

No specific studies are available for the chemicals in this group. The bioavailability of these polymers is likely to be negligible due to their large molecular size. Free MDA may be released through their decomposition (whether from environmental degradation or during end use) and will generally be the main driver for systemic acute and chronic toxicity for all routes of exposure, as compared to the other monomer constituents (see **Grouping Rationale** section).

The critical health hazards of the polymers with the aromatic amine monomer, MDA, have been previously identified in the NICNAS Tier II Human Health assessments under the IMAP Framework (NICNASa), where monomer constitutent MDA is both genotoxic and carcinogenic in animals. The critical health effects for risk characterisation also include systemic acute and chronic toxicity from all routes of exposure.

These polymers with genotoxic amine impurities or breakdown products present similar issues to those that are azo dyes-based on the same aromatic amines (NICNASa).

Where the polymers in this group do not contain unreacted isocyanate groups, no significant health effects in the absence of impurities or degradation are expected. The isocyanate group is extremely reactive, and its key health hazards are those identified in the NICNAS Tier II Human Health assessment for polymers containing isocyanate monomers (NICNASb). Monomer constituents TDI, MDI and HDI have common critical health effects which include acute toxicity via the inhalation route; irritation to skin, eyes and the respiratory system; and sensitisation by inhalation and skin contact.

The polymer itself can be respiratory sensitisers if it has terminated isocyanates. It has been reported that pre-polymers with TDI, MDI and HDI contain less than 0.7 % residual monomer and are reportedly stable over time. No residual functional isocyanate groups are present in fully cured polyurethane. While some polyurethanes in this group may be terminated with isocyanate functional groups, these are not expected to convert back to TDI, MDI or HDI (NICNASb)

Risk Characterisation

Critical Health Effects

The polymers in this group may release the aromatic amine, MDA, and may include unreacted isocyanate groups under normal circumstances. Release of the other monomer constituents at toxic levels when in normal use is not expected.

Polymers in this group which do not readily release or produce free aromatic amines, MDA and ODA, are not expected to have significant health effects for downstream users. However, where the polymers in this group degrade to MDA, or are capable of releasing the free aromatic amine, the critical health effects for risk characterisation include genotoxicity and/or carcinogenicity.

Where the polymers in this group contain unreacted isocyanate groups, the critical health effect for risk characterisation is respiratory sensitisation. Other health effects include systemic acute effect (acute toxicity by the inhalation route of exposure) and local effects (skin and eye irritation; skin sensitisation and respiratory irritation).

Public Risk Characterisation

In the absence of Australian use information for the polymers in this group, international information indicate site-limited used in the manufacture of articles or domestic and commercial uses in the manufacture of polyurethane coatings (see **Import, manufacture and use** section).

Based on the current information available, the public could come into contact with food contact articles, packaging and coated surfaces where potential migration or leaching of MDA may occur. However, significant levels of MDA are not expected to be released (Kawamura et al., 2014) and related risks to the public are adequately mitigated under current food packaging standards: Food Standards Australia New Zealand (FSANZ): *Australia New Zealand Food Standards Code - Standard 3.2.2 - Food Safety Practices and General Requirements* (see **Australian Restrictions** section).

Occupational Risk Characterisation

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. Worker exposure to the chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

Based on the available data the amount of free MDA, and/or isocyanate groups, expected to be available from these chemicals is very low and; therefore, these polymers are unlikely to pose a risk to workers. Information in this report can be used by a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) to determine the appropriate controls.

Where the polymers in this group contain terminal isocyanate groups, given the critical health effects, the chemicals may pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemical are implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU), e.g. employer, at a workplace, has adequate information to determine appropriate controls.

Guidance on the Interpretation of workplace exposure standards for airborne contaminants advises that 'exposure to carcinogens should be eliminated or minimised so far as is reasonably practicable' (Safe Work Australia, 2019).

NICNAS Recommendation

Assessment of these polymers is considered to be sufficient, provided that all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

NICNAS recommends that formulators of products containing these polymers should take into account the availability of the aromatic amine, MDA, or free (terminal) isocyanate groups in the products when determining label instructions in order to take appropriate risk management measures to control the hazards stipulated in the HCIS, and the advice and controls in the SUSMP.

Companies using or marketing these polymers should have sufficient information to determine whether the polymer contains free aromatic amine MDA, or terminal isocyanate groups and take appropriate risk management measures to control the hazards associated with free aromatic amine, MDA, or free isocyanate groups.

Regulatory Control

Work Health and Safety

Where the polymers in this group contains free (terminal) isocyanate groups, these are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below.

The recommended classification and labelling entry should have the following note appended against the individual CAS numbers of the polymers: "Note 15: This chemical is a polymer. The hazards of a polymer may depend on a number of factors. For more information refer to the assessment report published on the website of the National Industrial Chemical Notification and Assessment Scheme."

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	Fatal if inhaled - Cat. 2 (H330)
Irritation / Corrosivity	Not Applicable	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)

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Sensitisation	Not Applicable	May cause allergy or asthma symptoms or breathing difficulties if inhaled - Cat. 1 (H334) 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 consumers

Products containing the polymers in this group should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular and inhalational exposure to the polymers in this group containing free aromatic amine, MDA, or free isocyanate groups, 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 closed systems or isolating operations;
- using local exhaust ventilation to prevent the polymer resin from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the polymer resin 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 polymer resin.

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.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet 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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Last Update 12 December 2019

Chemical Identities

Chemical Name in the Inventory and Synonyms	**Benzenamine, 4,4'-methylenebis-, polymer with 1,3-diisocyanatomethylbenzene and .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)]** polypropylene glycol, polymer with p,p-methylenedianiline and toluenediisocynate
CAS Number	51888-37-0
Structural Formula	

	
Molecular Formula	(C13H14N2.C9H6N2O2.(C3H6O)nH2O)x
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**2-Oxepanone, polymer with .alpha.-hydro-.omega.-hydroxypoly(oxy-1,4-butanediyl), 4,4'-methylenebis[benzenamine] and 1,1'-methylenebis[4-isocyanatobenzene]** poly(oxy-1,4-butanediyl), .alpha.-hydro-.omega.-hydroxy-, 4,4-methylenebis[benzeneamine
CAS Number	59218-46-1
Structural Formula	
Molecular Formula	(C15H10N2O2.C13H14N2.C6H10O2.(C4H8O)nH2O)x
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**2-Oxepanone, polymer with .alpha.-hydro-.omega.-hydroxypoly(oxy-1,4-butanediyl), 4,4'-methylenebis[benzenamine], 1,1'-methylenebis[4-**

	isocyanatobenzene] and 1,1'-methylenebis[4-isocyanatocyclohexane]
CAS Number	72928-66-6
Structural Formula	**No Structural Diagram Available**
Molecular Formula	(C15H22N2O2.C15H10N2O2.C13H14N2.C6H10O2.(C4H8O)nH2O)x
Molecular Weight	

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