Polymers incorporating bisphenol A and octylphenol: Human health tier II assessment

12 December 2019

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Carbonic dichloride, polymer with 4,4'-(1-methylethylidene)bis(phenol), (1,1,3,3-tetramethylbutyl)phenyl ester	104376-58-1
1,3-Benzenedicarbonyl dichloride, polymer with 1,4-benzenedicarbonyl dichloride, carbonic dichloride and 4,4'-(1-methylethylidene)bis[phenol], 4-(1,1,3,3-tetramethylbutyl)phenyl ester	117653-69-7
Carbonic dichloride, polymer with 4,4'-(1-methylethylidene)bis[phenol] and 4,4'-(3,3,5-trimethylcyclohexylidene)bis[phenol], 4-(1,1,3,3-tetramethylbutyl)phenyl ester	128754-66-5

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**

ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group are bisphenol A (BPA)-based polycarbonate polymers which also contain octylphenol (OP):

- 1,3-benzenedicarbonyl dichloride, polymer with 1,4-benzenedicarbonyl dichloride, carbonic dichloride and 4,4'-(1-methylethylidene)bis[phenol], 4-(1,1,3,3-tetramethylbutyl)phenyl ester (CAS No. 117653-69-7);
- carbonic dichloride, polymer with 4,4'-(1-methylethylidene)bis(phenol), (1,1,3,3-tetramethylbutyl)phenyl ester (CAS No. 104376-58-1); and
- carbonic dichloride, polymer with 4,4'-(1-methylethylidene)bis[phenol] and 4,4'-(3,3,5-trimethylcyclohexylidene)bis[phenol], 4-(1,1,3,3-tetramethylbutyl)phenyl ester (CAS No. 128754-66-5).

These polymers are non-hazardous in their polymeric form; however, products manufactured using these polymers may contain BPA and/or OP (from incomplete polymerisation) or may release BPA and/or OP (as a result of hydrolysis of the polymers) under certain conditions.

During polymerisation, chemically inert methylene bridges form between BPA monomers and; therefore, the polymers in this group are not expected to breakdown significantly following biological or chemical degradation (Kopf, 2002).

Import, Manufacture and Use

Australian

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

International

There is no specific use information for the polymers in this group.

The following international uses have been identified for similar BPA-based polycarbonate polymers, and similar OP-containing polymers (NICNASb; NICNASc; NICNASd), through Galleria Chemica and the Substances in Preparations in Nordic Countries (SPIN) database.

Reported domestic uses, including in:

- adhesives and binding agents;
- fillers; and
- paints, lacquers and varnishes.

Reported commercial uses, including as:

- process regulators;
- photo chemicals; and
- reprographic agents.

Reported site-limited uses, including:

- as intermediates;
- in test drilling and boring;
- in specialised construction;
- in combustion products; and
- in the manufacture of plastics.

Restrictions

Australian

No known restrictions have been identified for the polymers in this group.

International

International restrictions specifically relevant to the monomers released from polymeric substances are as follows:

Bisphenol A

In September 2018, regulations on the use of BPA in food contact materials in the EU came into effect (Regulation (EU) 2018/213). The regulations reduced the specific migration limit (SML) of BPA in food contact articles (including varnishes and coatings applied to these materials) to 0.05 mg/kg food. Specific regulations relating to the use of these materials in foods for infants and young children stipulate that no migration of BPA from these materials is permitted (European Commission, 2018).

In June 2011, restrictions banning the use of BPA in polycarbonate baby bottles came into effect in the EU (European Commission, 2011).

The US Food and Drug Administration (FDA) amended regulations to reflect the market abandoning use of BPA in polycarbonate baby bottles and packaging for infant formula in July 2012 and 2013, respectively (US FDA, 2014).

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals are not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

The polymers in this group contain BPA and OP. There are no specific data available on the health hazards of the polymers in this group. The bioavailability of the polymers is expected to be negligible based on their large molecular size. It is considered that OP and BPA released from the decomposition of these polymers (whether from environmental degradation or during end use) will generally be the critical driver of toxicity.

Bisphenol A

A Tier II Human Health risk assessment of BPA has previously been conducted by NICNAS under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework (NICNASa). An assessment of BPA-based polycarbonate polymers has also been conducted (NICNASb). These assessments are available at **www.nicnas.gov.au**.

BPA causes reproductive toxicity in animals at high doses. However, the available data are insufficient to prove a causal link between BPA exposure and reproductive effects in humans at current average exposure levels. The European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), using a weight of evidence approach, assigned BPA a likelihood level of “as likely as not” to cause reproductive and developmental effects at low doses (below the human equivalent dose (HED) of 3.6 mg/kg bw/day) (ESFA, 2015).

Increases in kidney weight (associated with nephropathy) and liver weight (associated with hepatocellular hypertrophy) changes were observed at high doses in animals. A benchmark dose lower bound (BMDL)10 of 8.96 mg/kg bw/day for changes in relative kidney weight was determined from a 2-generation reproductive toxicity study in mice. BPA is unlikely to have any neurological, neurodevelopmental, and or neuroendocrine effects. It is not mutagenic, genotoxic or carcinogenic. Although BPA produced mammary gland hyperplasia in a non-human primate study, the effects were insufficient to conclude that the chemical is likely to be carcinogenic in humans (EFSA, 2015; NICNASa).

Food Standards Australia New Zealand (FSANZ) has concluded that exposure to BPA in food does not present a significant human health and safety issue at current exposure levels (FSANZ, 2010). FSANZ supports the risk assessments conducted by other regulatory agencies, as well as with the tolerable daily intake (TDI) value of 50 µg/kg bw/day. A FSANZ survey of BPA in food and drinks in the Australian market found only a limited number of products with detectable levels of the chemical. The same study found no detectable levels of BPA in infant formula. FSANZ concluded that Australians of all ages are exposed to the chemical at extremely low levels (in the range of ng/kg food to µg/kg food) (FSANZ, 2010). Health Canada (2012) and the US Food and Drug Administration (US FDA, 2014) have drawn similar conclusions.

EFSA concluded that BPA poses no health risk to consumers of any age group (including unborn children, infants and adolescents) at the estimated levels of exposure. In addition to dietary exposure, the EFSA report also calculated 'average' and 'high' exposure levels for dust and toys, thermal paper, and cosmetics. Exposure from the diet or from a combination of all sources (diet, dust, cosmetics and thermal paper) is considerably below the safe exposure level (EFSA, 2015).

Incorporation of BPA into a phenol/formaldehyde type polymer by formation of carbon-carbon bonds is expected to reduce the likelihood of releasing the alkylphenols from the polymeric matrix compared with polymers where these are incorporated by hydrolysable links through oxygen.

The chemicals in this group are not expected to readily release BPA. When the polymers in this group do release BPA under extreme conditions, it is considered that the levels are unlikely to present a concern to either public or worker health and safety based on the above.

Octylphenol

A Tier II Human Health risk assessment of OPs has been conducted by NICNAS under the IMAP framework (NICNASc).

The critical health hazards of the alkylphenols and alkylphenol ethoxylates (which generally degrade to the alkylphenols) include local effects (corrosivity), acute effects from oral exposure, and systemic long-term effects (reproductive and developmental toxicity). The chemicals have been shown to have weak oestrogenic activity, but there are currently no established adverse outcome pathways for weak oestrogenic activity. At the concentrations likely to be present from polymer breakdown, local and acute effects are not expected.

The European Chemicals Agency (ECHA) lists phenol, 4-(1,1,3,3-tetramethylbutyl)- (CAS No. 140-66-9) as a Substance of Very High Concern (SVHC) for its environmental concerns and potential for endocrine disruption (ECHA, 2019).

Risk Characterisation

Critical Health Effects

The polymers in this group are not expected to readily release BPA and/or OP. The levels of BPA and/or OP are expected to be well below the levels where systemic or local effects would be observed. Therefore, no significant health effects are expected to occur as a result of the presence of BPA and OP in these polymers. Where OP and BPA are released due to environmental degradation, there is a potential for secondary human exposure via the environment.

Public Risk Characterisation

The use(s) of these polymers are not well known. Similar polymers are reported to be used domestically overseas. Potential consumer uses might include use of the polymers in food contact materials such as reusable beverage bottles, infant feeding bottles, tableware (plates and mugs) and storage containers. Small amounts of BPA and OP may migrate into food and beverages from containers. Migration is most probable under the hot alkaline conditions found in dishwashers.

Food Standards Australia New Zealand (FSANZ) has concluded that exposure to BPA in food does not present a significant human health and safety issue at current exposure levels (FSANZ, 2010). Health Canada (2012) and the US Food and Drug Administration (US FDA, 2014) have drawn similar conclusions. Exposure from the diet or from a combination of all sources (diet, dust, cosmetics and thermal paper) is estimated to be considerably under the suggested safe level for BPA (EFSA, 2015).

Based on the above information, the risk to public health is not considered to be unreasonable and further risk management of the chemicals is not considered necessary to protect public health.

Secondary exposure to OP may occur via the environment. OP has been measured in indoor air, house dust and human blood, breast milk and urine (ECHA, 2011). However, the available information indicates that adverse systemic effects are only observed at relatively high doses. Therefore, the chemicals are not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

During product formulation 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, 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 at a workplace (such as an employer) to determine the appropriate controls.

Based on available data, the amount of BPA and/or OP expected to be available from these chemicals is very low and; therefore, classification in the Hazardous Chemical Information System (HCIS) is not recommended. Should empirical data become available for the individual polymers indicating that a classification is appropriate, the data may be used to make recommendation(s) for classification.

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.

Companies using or marketing these polymers should have sufficient information to determine whether the polymer contains free BPA/OP or releases BPA/OP, and take appropriate risk management measures to control the hazards associated with the monomers.

Regulatory Control

Work Health and Safety

Based on available data, the amount of BPA/OP expected to be available from these polymers is very low and; therefore, the health risk to workers from these polymers is controlled when adequate control measures to minimise occupational exposure and protective clothing are implemented.

Based on the available data, the polymers in this group are not recommended for hazard classification in the HCIS (Safe Work Australia). Should data become available for the individual polymers in this group, further risk management may be required.

Advice for industry

Control measures to minimise the risk from exposure to the chemicals 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 chemicals are used. Examples of control measures that could minimise the risk include, but are not limited to:

- 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 chemicals.

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 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 chemicals 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 these chemicals has not been undertaken as part of this assessment.

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National Industrial Chemicals Notification and Assessment Scheme (NICNASb). Inventory Multi-tiered Assessment and Prioritisation (IMAP) Tier II Human Health assessment for BPA-based polycarbonate polymers. Australian Government Department of Health. Accessed August 2019 at **www.nicnas.gov.au**

National Industrial Chemicals Notification and Assessment Scheme (NICNASc). Inventory Multi-tiered Assessment and Prioritisation (IMAP) Tier II Human Health assessment for octylphenols. Australian Government Department of Health. Accessed September 2019 at **www.nicnas.gov.au**

National Industrial Chemicals Notification and Assessment Scheme (NICNASd). Inventory Muli-tiered Assessment and Prioritisation (IMAP) Human Health Tier II assessment for nonylphenol and octylphenol ethoxylates and related compounds. Australian Government Department of Health. Accessed August 2019 at **www.nicnas.gov.au**

Safe Work Australia (SWA). Hazardous Chemical Information System (HCIS). Accessed August 2019 at **http://hcis.safeworkaustralia.gov.au/**

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Chemical Identities

Chemical Name in the Inventory and Synonyms	**Carbonic dichloride, polymer with 4,4'-(1-methylethylidene)bis(phenol), (1,1,3,3-tetramethylbutyl)phenyl ester** phenol, 4,4-(1-methylethylidene)bis-, polymer with carbonic dichloride, (1,1,3,3-tetramethylbutyl)phenyl ester
CAS Number	104376-58-1
Structural Formula	**No Structural Diagram Available**

Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	**1,3-Benzenedicarbonyl dichloride, polymer with 1,4-benzenedicarbonyl dichloride, carbonic dichloride and 4,4'-(1-methylethylidene)bis[phenol], 4-(1,1,3,3-tetramethylbutyl)phenyl ester** carbonic dichloride, polymer with 1,3-benzenedicarbonyl dichloride, 1,4-benzenedicarbonyl dichloride and 4,4-(1-methylethylidene)bis[phenol
CAS Number	117653-69-7
Structural Formula	No Structural Diagram Available
Molecular Formula	(C15H16O2.C8H4Cl2O2.C8H4Cl2O2.CCl2O)x.xC14H22O
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	**Carbonic dichloride, polymer with 4,4'-(1-methylethylidene)bis[phenol] and 4,4'-(3,3,5-trimethylcyclohexylidene)bis[phenol], 4-(1,1,3,3-tetramethylbutyl)phenyl ester**
CAS Number	128754-66-5
Structural Formula	

	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	Unspecified

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