Bisphenol S (BPS)-based polymers: Human health tier II assessment

28 June 2019

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Poly(oxy-1,4-phenylenesulfonyl-1,4-phenylene)	25667-42-9
Benzene, 1,1'-sulfonylbis[4-chloro-, polymer with phenol, 4,4'-sulfonylbis- and 1,4-benzenediol	79293-56-4

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 in this group are polymers that contain bisphenol S (4,4'-sulfonyldiphenol (CAS No. 80-09-1)) as a monomer. Bisphenol S (BPS) is a close analogue of the widely studied bisphenol A (phenol, 4,4'-(1-methylethylidene)bis-, (CAS No. 80-05-7)). In the absence of data on BPS, given their close structural similarity and similar use profile, information (particularly for the critical reproductive toxicity endpoint) from BPA and its extrapolation to polymers is considered relevant for this assessment.

The polymers in this group are generally of low concern to human health. However, the products manufactured using these chemicals may contain BPS (from incomplete polymerisation) or may release BPS (as a result of hydrolysis from the polymers) under certain conditions. The hazardous properties of the polymers are expected to be mostly driven by the toxicity profile of BPS.

Bisphenol S is an industrial chemical that has been widely used as a monomer in the manufacturing of certain plastics, including can linings, which are widely used in consumer products. There may be other sources of exposure to BPS such as thermal rolls for printing paper receipts.

Import, Manufacture and Use

Australian

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

International

The following international uses have been identified through Galleria Chemica and the Substances in Preparations in Nordic Countries (SPIN) database.

The polymers in this group have reported domestic uses including in paints, lacquers and varnishes; cleaning products; and adhesives, binding agents.

The polymers in this group have reported commercial use including in construction materials.

The polymers in this group have reported site-limited uses including as an intermediate in manufacture of certain plastics.

Restrictions

Australian

No known restrictions have been identified for the chemicals in this group or for the monomer BPS (SUSMP, 2019).

International

No known restrictions have been identified.

Existing Worker Health and Safety Controls

Hazard Classification

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

The monomer BPS (CAS No. 80-09-1) is classified as hazardous, with the following hazard category and hazard statement for human health in the HCIS (Safe Work Australia):

Reproductive toxicity – Category 2; H361f (Suspected of damaging fertility).

Exposure Standards

Australian

There are no specific exposure standards available for individual polymers in this group or for the monomer BPS.

International

The following exposure standard was identified for one of the chemicals- benzene, 1,1'-sulfonylbis[4-chloro-, polymer with phenol, 4,4'-sulfonylbis- and 1,4-benzenediol (CAS No. 79293-56-4) (Galleria Chemica):

The chemical has an exposure limit of 3–10 mg/m³ time weighted average (TWA) in countries such as Canada and Spain.

Health Hazard Information

No specific studies are available for the chemicals in this group. The chemicals in this group are polymers of bisphenol S (BPS). Bisphenol S is structurally-similar to BPA but the 2 phenol groups are connected by a sulfonyl group instead of a

dimethylmethylene group. BPS was introduced, largely to replace BPA in industrial applications. Studies in general human populations found that BPS (free plus conjugated) was present in 81 % of 315 urine samples at concentrations ranging from 0.02 ng/mL to 21.0 ng/mL (NICNASa). BPS has been recorded in food (e.g. cereals, seafood, dairy, vegetables, canned products, meats), indoor dust, sediment and paper products (e.g., toilet paper, cashier's receipts, currency) (NTP, 2014).

There is a considerable amount of data available on BPA toxicity; however, very little is known about the potential replacement chemicals such as BPS. The bioavailability of the polymers is expected to be negligible due to their large molecular size. However, it is considered that bisphenol S released from the decomposition of these polymers under extreme conditions will generally be the critical driver of toxicity.

The critical health hazards of BPS, BPA and various polymers of BPA have been previously identified in the Tier II Human Health assessments under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework (NICNASa–e).

Bisphenol S is classified as hazardous with the risk phrase 'Suspected of damaging fertility – Cat. 2 (H361f)' (HCIS, SWA). The no observed adverse effect level (NOAEL) for reproductive and developmental toxicity is considered to be 60 mg/kg bw/day based on prolongation of oestrus cycle and dioestrus period, decreased fertility index and decreased implantation index (NICNASa).

The analogue bisphenol A was found to be a reproductive toxicant at high dose levels with a benchmark dose lower bound (BMDL)10 of 8.96 mg/kg bw/day for changes in relative kidney weight in mice (NICNASb). Bisphenol A is classified as hazardous with the risk phrase 'Suspected of damaging fertility – Cat. 2 (H361f)' (HCIS, SWA) (NICNASb).

Risk assessments by several regulatory agencies (FSANZ, 2010; Health Canada, 2012; US FDA, 2014; EFSA, 2015) found no health risk to consumers at the estimated levels of exposure to bisphenol A. Given the similarity between BPA and BPS, similar conclusions can be drawn for BPS and its polymers.

The polymers in this group are not expected to readily release BPS except under extreme conditions. It is considered that the levels may not be of concern to either public or worker health and safety based on the above data.

Risk Characterisation

Critical Health Effects

These polymers are not expected to readily release BPS. The levels of BPS are expected to be well within concentration levels where systemic or local effects would not be observed. Therefore, no significant health effects are expected from the presence of BPS in these polymers.

Public Risk Characterisation

The chemicals have no reported uses in Australia; however, some have reported to be used domestically overseas. Potential consumer uses might include use of the polymers in can linings and plastics for food storage. Small amounts of bisphenol S can migrate into food and beverages from containers. Migration is most probable under the hot alkaline conditions associated with dishwashers.

Risk conclusions for BPS can be drawn from its structurally similar analogue BPA. Food Standards Australia New Zealand (FSANZ) has concluded that exposure to bisphenol A 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 paper receipts) is estimated to be low when applying the suggested safe level for BPA (EFSA, 2015).

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

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 BPS 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.

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 BPS or releases BPS, and take appropriate risk management measures to control the hazards associated with BPS.

Regulatory Control

Work Health and Safety

Based on available data, the amount of BPS expected to be available from these chemicals is very low and; therefore, classification in the 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.

Advice for industry

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.

References

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U.S Food and Drug Administration (US FDA) (2014). Bisphenol A (BPA): Use in Food Contact Application. Accessed at **http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm064437.htm#summary**

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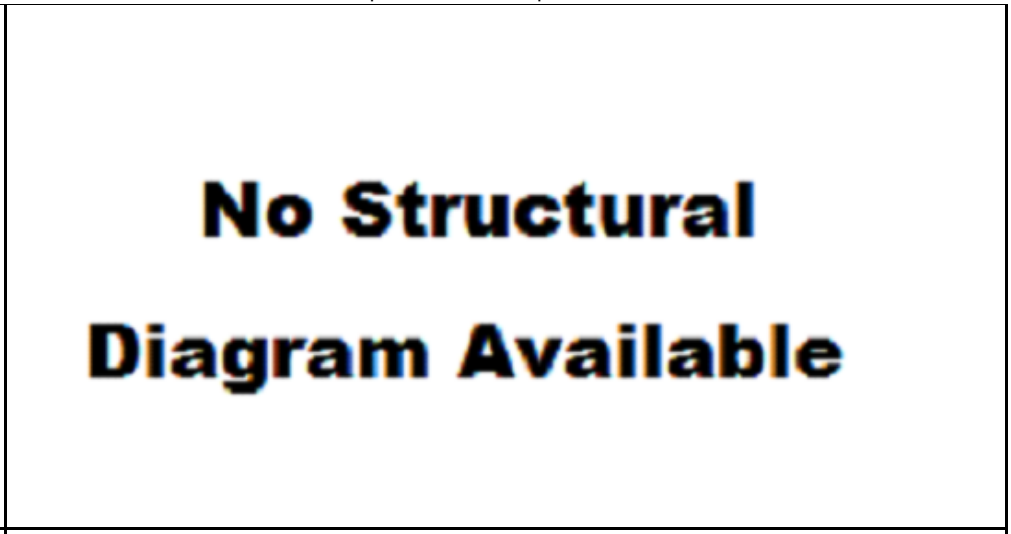
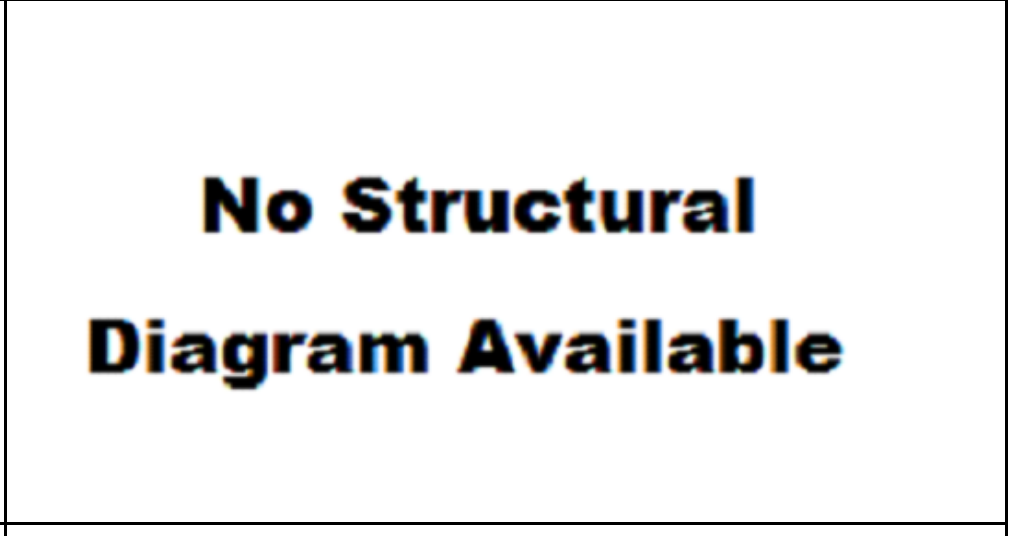
Chemical Identities

Chemical Name in the Inventory and Synonyms	**Poly(oxy-1,4-phenylenesulfonyl-1,4-phenylene)** polyethersulfone
CAS Number	25667-42-9

Structural Formula	
Molecular Formula	(C12H8O3S)n
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Benzene, 1,1'-sulfonylbis[4-chloro-, polymer with phenol, 4,4'-sulfonylbis- and 1,4-benzenediol**
CAS Number	79293-56-4
Structural Formula	
Molecular Formula	
Molecular Weight	

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