Australian Government

Department of Health Australian Industrial Chemicals Introduction Scheme

Pentabromodiphenyl ether (pentaBDE)

Evaluation statement

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AICIS evaluation statement

Subject of the evaluation

Pentabromodiphenyl ether (pentaBDE)

Chemical in this evaluation

Name	CAS registry number
Benzene, 1,1'-oxybis-, pentabromo derivative (Pentabromodiphenyl ether; PentaBDE)	32534-81-9

Reason for the evaluation

An evaluation or assessment recommended further evaluation of specific issues related to the chemical.

Parameters of evaluation

On 3 January 2006, the then Minister for Health and Ageing declared pentabromodiphenyl ether (pentaBDE), CAS Number 32534-81-9, a Priority Existing Chemical (PEC) for full risk assessment under Division 5 of the Industrial Chemicals Notification and Assessment (ICNA) Act 1989. PentaBDE was declared because of its use as a flame retardant, reported liver, thyroid hormone and neurobehavioural effects, and persistent, bioaccumulative and very toxic effects in the environment. PentaBDE was also found in human breast milk in Australia. On 6 March 2007, the Minister of Health and Ageing (Sections 51 and 61 of the ICNA Act) prohibited the manufacture and import of pentaBDE while the chemical remains a PEC.

The PEC assessment report for pentaBDE was published in May 2020. The PEC assessment report recommended the following:

- that pentaBDE be considered for evaluation under the Industrial Chemical (IC) Act 2019, to determine whether it should be removed from the Australian Inventory of Industrial Chemicals (the Inventory)
- that the Department of Agriculture, Water and the Environment (DAWE), in consultation with states and territories develop a plan to address the environmental risks of pentaBDE, including in existing products and articles, taking into account the information in the PEC report (NICNAS 2020).

The publication of the PEC assessment report revoked the declaration of this chemical as a PEC (Section 62 of the ICNA Act) and thus the prohibitions against the introduction of pentaBDE while the chemical remained a PEC (Section 61 of the ICNA Act). As two companies applied for the assessment of the chemical following the declaration of pentaBDE as a PEC, the chemical could not be removed from the Inventory under Section 63 of the ICNA Act. As a result, pentaBDE remains listed on the Inventory. There are no regulatory controls in place to prevent the re-introduction (by import or manufacture) of the chemical into Australia.

This evaluation examines the risks to workers, public and the environment identified in the PEC assessment report. This evaluation determined whether the human health and environment risks from any reintroduction by import or manufacture and subsequent use of the chemical can be managed within existing risk management frameworks. This evaluation also considered the recommendation from the PEC assessment report to determine whether pentaBDE should be removed from the Inventory.

This evaluation report should be read in conjunction with the <u>PEC Assessment Report No 43</u> <u>– Pentabromodiphenyl ether</u>.

Summary of evaluation

The chemical, pentaBDE, is a reaction products mixture produced by brominating diphenyl ether to approximately 5 bromine atoms per molecule. It consists of a number of individual tetra-, penta- and hexabrominated diphenyl ethers, referred to as congeners. The main components of pentaBDE are tetrabrominated BDE-47, pentabrominated BDE-99 and BDE-100, and hexabrominated BDE-153 and BDE-154.

Summary of introduction, use and end use

The chemical, pentaBDE, has never been manufactured in Australia. Consultation with the applicants for assessment of pentaBDE (known past importers of pentaBDE) in 2005 and in 2017 (one past importer), confirmed that importation of pentaBDE as a pure chemical or as a component in chemical products ceased in 2005.

In Australia, pentaBDE was used as an additive flame retardant for flexible polyurethane foam at a level of 2.5–15% of the polyol mixture (equivalent to a final pentaBDE concentration of 1.63–9.75%). The polyurethane foam containing pentaBDE was used in commercial furniture, such as transport seats, and domestic furniture, such as beds. The chemical, pentaBDE was also used as an additive flame retardant for rigid polyurethane, epoxy, unsaturated polyesters and flexible PVC compounds. Epoxy resin formulations containing pentaBDE were also supplied to the aerospace industry and used in potting agents, and in laminating and adhesive systems.

An unknown quantity of pentaBDE has been imported in articles in the past. These, as well as articles produced in Australia, are likely to remain in use for some time. These are mostly polyurethane foam containing articles, for example transport seats and mattresses.

PentaBDE is currently listed on the Inventory and may be reintroduced in Australia as a listed introduction under the IC Act.

Human health

Summary of health hazards

The critical health effects for risk characterisation include:

- liver effects, changes in neurobehavioural development, reproductive organs and thyroxine levels following repeated oral exposure
- presence in human breast milk in Australia.

The liver effects and enzyme induction in rats may be considered to be an adaptive change. However, a number of studies have shown that the enzyme induction may have further systemic effects, particularly at sensitive life stages, for example via mechanisms controlled by the thyroid hormones. The results of the in vitro and in vivo studies on the effect of pentaBDE or individual congeners on the thyroid hormones and related systems indicate that there is a clear reduction in T₄ (thyroxine) levels associated with exposure to the lower polybrominated diphenyl ethers. Following oral dosing of rat dams during gestation with a single dose of 60 µg BDE9–9/kg maternal body weight, adverse effects were seen on neurobehavioural development, sperm counts and ovarian microstructure in offspring. There is a wide range of studies that suggest that the neurodevelopment and sexual development effects are likely to be related to hypothyroidism following enzyme induction occurring at critical foetal development periods (NICNAS 2020).

The Australian biomonitoring study results indicate the presence of pentaBDE congeners in all the collected matrices (air, dust, human milk and human sera) (NICNAS 2020).

Health hazard classification

The chemical satisfies the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE 2017) for hazard classes relevant to work health and safety (see table below). This does not consider classification of physical hazards and environmental hazards. These are the current classifications listed in the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Health Hazard	Hazard Category	Hazard Statement
Specific target organ toxicity – repeated exposure	STOT Repeated Exposure 2	H373: May cause damage to organs through prolonged or repeated exposure
Reproductive toxicity	Effects on or via lactation	H362: May cause harm to breast-fed children

Summary of health risk

Public

Given the neurobehavioural, developmental and reproductive effects in the offspring of experimental animals exposed to pentaBDE, the potential for these effects to occur in humans cannot be ruled out. Repeated exposure to pentaBDE also resulted in perturbation of the thyroid hormone homeostasis. The biomonitoring studies, although not robust, indicate exposure to pentaBDE. Therefore, reintroduction by manufacture or import, and the subsequent use of pentaDBE could pose a risk to the public based on the critical health effects and potential for exposure.

There is a global phase-out of manufacture and use of pentaBDE; therefore, public exposure from use of articles containing pentaBDE is expected to decline to minimal levels as the articles reach the end of their useful life.

There are no current regulatory controls in place and risk management frameworks are limited to prevent the reintroduction of pentaBDE and articles containing pentaBDE into Australia while it remains listed on the Inventory. Regulatory controls should be in place to prohibit the reintroduction by manufacture in Australia or importation, and the subsequent use of pentaBDE.

Workers

While pentaBDE is no longer imported into Australia as a raw material, pentaBDE is likely to be present in Australia in articles manufactured or imported in the past.

The major route of occupational exposure is expected to be due to release from articles in use, and particularly foam furnishings manufactured or imported in the past. This is likely to be widespread, particularly among office workers. Articles containing pentaBDE are no longer imported into Australia. Occupational exposure from use of articles is expected to decline to minimal levels due to the global phase-out of pentaBDE.

Given the critical health effects and limited available risk management controls, pentaBDE could pose a risk to workers if the chemical is reintroduced in the form of pure chemical or chemical mixtures into Australia, or in articles containing pentaBDE.

Therefore, regulatory controls should be put in place to mitigate potential human and environmental risks associated with worker exposure resulting from the reintroduction by manufacture in Australia or importation, and the subsequent use of pentaBDE.

Environment

Summary of environmental hazard characteristics

Based on available ecotoxicity data, pentaBDE is considered to be very toxic to aquatic organisms. PentaBDE can bioaccumulate in fish, and biomagnification of the chemical can occur in birds that eat contaminated fish. Available test data confirm that the congeners found in pentaBDE are bioaccumulative and can biomagnify through the food chain. Sediment organisms also have the potential to accumulate congeners found in pentaBDE when exposed through sediment with bioaccumulation factors of 4 (BDE-99) to 9.1 (BDE-154) found for tetra- through to hexabrominated congeners (NICNAS 2020).

Modelled and measured levels of pentaBDE in remote regions that are far removed from major sources of emissions indicate that pentaBDE and the congeners in pentaBDE can undergo long range transport (LRT) in the environment. (NICNAS 2020).

Environmental hazard classification

The chemical satisfies the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE, 2017) for hazard classes relevant to the environment (see table below). This does not consider classification of physical hazards and health hazards. These are the current classifications listed in the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Environmental Hazard	Hazard Category	Hazard Statement
Acute Aquatic	Aquatic Acute 1	H400: Very toxic to aquatic life
Chronic Aquatic	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects

Summary of environmental risk

There is sufficient evidence to conclude that under environmental conditions, pentaBDE is persistent and bioaccumulative, and is very toxic to aquatic organisms. The chemical meets the persistence, bioaccumulation, potential for long-range environmental transport and adverse effects in aquatic life criteria of Annex D of the Stockholm Convention.

Therefore, on the basis of the current hazard information available and the combination of characteristics indicating that the chemical is a Persistent Organic Pollutant mean that there are very significant long term risks to the environment from the manufacture, import and use of the chemical.

Any reintroduction of the chemical would increase the already significant environmental risks identified from past environmental exposure to pentaBDE. Therefore, regulatory controls should be put in place to ensure that manufacture, importation and use of pentaBDE continues to be prohibited in Australia.

Conclusions

The conclusions of this evaluation are based on the information described in this statement and the PEC assessment for pentaBDE, which includes more detailed information on human health and environmental hazard and risk.

Considering the human health and environmental effects of pentaBDE and its fate in the environment identified in the PEC assessment report, there are risks from the reintroduction by import or manufacture, and the subsequent use of the chemical to the:

- environment
- public and workers via secondary exposure from their environment.

Advice on the existing risk management framework was sought from the Department of Agriculture, Water and the Environment (DAWE). There is a global agreement in place under the Stockholm Convention to eliminate production, use, importation and exportation of pentaBDE because of the risks it poses to the environment and human health. DAWE has advised that Australia is a Party to the Stockholm Convention, but does not currently have an associated mechanism to prevent the manufacture and/or importation of the chemical.

Based on the risk characteristics of this chemical and that it is a Persistent Organic Pollutant, DAWE advised that the risks to the environment posed by the use of the chemical cannot be managed within the current risk management frameworks. Thus, secondary risks to the public and workers from environmental exposures also cannot be managed.

The Executive Director is not satisfied that the human health and environmental risks identified in this Evaluation Statement (informed by the PEC Assessment Report No 43 – Pentabromodiphenyl ether), can be managed. Therefore, under Section 95 of the Act, the chemical may be removed from the Inventory listing by the Executive Director (refer to Recommendations)

Recommendations

Inventory listing

The Inventory listing for Benzene, 1,1'-oxybis-, pentabromo derivative (Pentabromodiphenyl ether; PentaBDE) (CAS No 32534-81-9) should be removed under Section 95 of the Industrial Chemicals Act 2019.

Scheduling for environmental management

Once the Industrial Chemicals Environmental Management Standard is operational, pentaBDE (CAS No 32534-81-9) is recommended for scheduling as a high risk chemical, with prohibitions, restrictions and risk management measures attached that will minimise further release to the environment from historical introductions of pentaDBE.

Supporting information

Chemical identity



Br



contain a mix of bromination levels ranging from tribrominated to hexabrominated. The average degree of bromination is close to 5 bromine atoms per molecule, with a bromine content of around 71%. The name 'pentabromo derivative' derives from the stoichiometry of the preparative reaction and does not necessarily reflect the actual composition of the final product, which may contain high levels of tetrabrominated congeners. PentaBDE contains mostly congeners in the tetrabrominated (BDE-47), pentabrominated (BDE-99 and BDE-100) and hexabrominated (BDE-153 and BDE-154) range.

For additional supporting information, refer to the <u>PEC Assessment Report No 43 –</u> <u>Pentabromodiphenyl ether (NICNAS, 2020)</u>.

References

NICNAS (National Industrial Chemicals Notification and Assessment Scheme) (2020) <u>Pentabromodiphenyl Ether: Priority Existing Chemical Assessment Report No. 43</u>, AICIS, accessed October 2021.

SWA (Safe Work Australia) (n.d.) *Hazardous Chemical Information System*, SWA website, accessed October 2021.

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>, UNECE, accessed October 2021.

