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

Isocyanic acid, polymethylenepolyphenylene ester, polymers with diethylene glycol, methoxylated dehydrochlorinated brominated 2-butyne-1,4-diol-epichlorohydrin polymer, phthalic anhydride and polypropylene glycol ether with glycerol (3:1)

Assessment statement (CA09775)

02 May 2024

Table of contents

AICIS assessment (CA09775)

Chemical in this assessment

Name	CAS registry number
Isocyanic acid, polymethylenepolyphenylene ester, polymers with diethylene glycol, methoxylated dehydrochlorinated brominated 2-butyne-1,4-diol-epichlorohydrin polymer, phthalic anhydride and polypropylene glycol ether with glycerol (3:1)	2484708-66-7

Reason for the assessment

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

Certificate Application type

AICIS received the application in a Health and Environment Focus type.

Defined scope of assessment

The polymer has been assessed as:

- imported into Australia at up to 50 tonnes per year
- imported at up to 65% concentration in finished end-use products for use only by industrial and professional workers
- used as a component of fire resistant foam adhesive

Summary of assessment

Summary of introduction, use and end use

The assessed polymer will not be manufactured, reformulated, or re-packaged in Australia. It will be imported into Australia at up to 50 tonnes per year at up to 65% concentration as a component of a fire resistant self-expanding foam in 750 mL pressurised canister with safety valve.

The assessed polymer will only be used by industrial and professional workers for indoor use in construction sites, where it is not accessible to the public, as fire resistant self-expanding foam.

Human health

Summary of health hazards

The submitted toxicological data on the assessed polymer and the analogue (see **Supporting information**) indicate that the assessed polymer is:

- of low acute oral toxicity
- non-irritating to the skin
- not genotoxic
- a strong skin sensitiser
- a respiratory sensitiser
- cause adverse health effects with repeated inhalation exposure
- suspected of causing cancer

The assessed polymer contains isocyanate functional groups that are of concern for irritation, skin and respiratory sensitisation, and pulmonary toxicity (Barratt, 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 of less than 1000 g/mol. The isocyanate functional group equivalent weight of the assessed polymer is less than 5000 g/mol; a relatively high proportion of low molecular weight species (higher than 10% of molecular weight species less than 1000 g/mol) are present in the assessed polymer warranting hazard classification of the assessed polymer as a respiratory sensitiser.

The data provided on eye damage/irritation indicate the assessed polymer requires classification for this end point. However, the two *in vitro* studies provided are inconclusive to differentiate the GHS classification criteria as category 1 or 2, however, eye corrosion/ irritation of the assessed polymer cannot be ruled out. No dermal toxicity data were provided for the assessed polymer.

Hazard classifications relevant for worker health and safety

Based on the data provided on the assessed polymer and the analogue polymer, the assessed polymer satisfies the criteria for classification for human health according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017), as adopted for industrial chemicals in Australia.

Health hazards	Hazard category	Hazard statement
Skin Sensitisation	Category 1A	H317: May cause an allergic skin reaction
Respiratory Sensitisation*	Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled
Carcinogenicity	Category 2	H351: Suspected of causing cancer
Specific target organ toxicity (repeated exposure)	Category 1	H373: May cause damage to organs through prolonged or repeated inhalation exposure

*classification based on free isocyanates in the assessed polymer

Summary of health risk

Public

The assessed polymer will not be available for use by the public and is intended for industrial and professional use only. Therefore, no public exposure is expected to occur. When introduced and used in the proposed manner, it is unlikely that the public will be exposed to the assessed polymer.

This assessment does not identify any risks to the public health that would require specific risk management measures.

Workers

Workers may experience dermal, ocular or inhalation exposure to the assessed polymer at up to 65% concentration during handling, transfer, and when applying as fire resistant in end-use products or during cleaning activities in industrial settings.

Given that risks of critical health effects of the assessed polymer (possible through inhalation of vapour, skin sensitisation, and the risk of respiratory sensitisation due to the presence of free isocyanates in the assessed polymer), control measures to minimise inhalation, dermal and ocular exposure are needed to manage the risk to workers) (see **Means for managing risk section**).

Environment

Summary of environmental hazard characteristics

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

- Persistent (P)
- Not Bioaccumulative (not B)
- Not Toxic (not T)

Environmental hazard classification

Based on the ecotoxicological information available for the assessed polymer, it is not expected to be harmful to aquatic life. Therefore, the assessed polymer does not satisfy the criteria for classification under the GHS for acute and chronic aquatic toxicities (UNECE, 2017).

Summary of environmental risk

The assessed polymer will be imported as a component of a fire resistant self-expanding foam that will be injected into walls or floors in building, that will be cured to form a three-dimensional high molecular weight polymer network that expands into a foam.

Based on its physical-chemical properties and assessed use pattern, no significant release to environmental compartments is expected to occur during use. The cured polymer is expected to share the fate of the material it is bound to and be disposed to landfill at the end of its useful life.

Information supplied by the applicant indicates that in landfill, similar products have the potential for brominated reactants to leach out of the cured material (blooming). However, as the brominated reactants in the assessed polymer are chemically bound to the polymer network, and are not volatile or water soluble, leaching into environmental compartments is expected to be negligible.

A Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as the currently available information indicates the assessed polymer is not harmful to aquatic organisms and will have limited bioavailability. Additionally, the assessed polymer is not expected to be released into the environment. Therefore, on the basis of low hazard and limited exposure, the risk from the assessed polymer can be managed.

Means for managing risk

Workers

Recommendation to Safe Work Australia

- It is recommended that Safe Work Australia (SWA) update the *Hazardous Chemical Information System* (HCIS) to include classifications relevant to work health and safety (see **Hazard classifications relevant for worker health and safety**).

Information relating to safe introduction and use

The information in this statement, including recommended hazard classifications, should be used by a person conducting a business or undertaking at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

- The following control measures could be implemented to manage the risk arising from exposure to the assessed polymer during application or use:
    - Use of engineering controls such as
        - Adequate workplace ventilation to avoid accumulation of aerosols
    - Use of safe work practices to
        - Avoid contact with skin and eye
        - Avoid inhalation of aerosols
    - Use of personal protective equipment (PPE)
        - Impervious gloves
        - Protective clothing
        - Eye protection
        - Respiratory protection where local ventilation may be inadequate
- The storage of the assessed polymer should be in accordance with the Safe Work Australia *Code of Practice for Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

- Atmospheric monitoring should be conducted to measure workplace concentrations of isocyanates during use of products containing the assessed polymer. Users of the products should ensure that the exposure standard for isocyanates (SWA, 2015), listed by Safe Work Australia in the *Hazardous Chemical Information System* (HCIS), is not exceeded for all areas where the assessed polymer is present.

- As the assessed polymer is a skin sensitiser and respiratory sensitisation, control measures may need to be supplemented with health monitoring for any worker who is at significant risk of exposure to the polymer, if valid techniques are available to monitor the effect on the worker's health.

- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

Conclusions

The Executive Director is satisfied that the risks to human health or the environment associated with the introduction and use of the industrial chemical can be managed.

Note:

- Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.

- You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

Chemical name	Isocyanic acid, polymethylenepolyphenylene ester, polymers with diethylene glycol, methoxylated dehydrochlorinated brominated 2-butyne-1,4-diol-epichlorohydrin polymer, phthalic anhydride and polypropylene glycol ether with glycerol (3:1)
CAS number	2484708-66-7
Molecular formula	Unspecified

Chemical description

Polymer (purity of the assessed polymer is approximately 85% and contains an impurity of unreacted excess isocyanate)

Relevant physical and chemical properties

Physical form	Brownish paste
Melting point	Decomposes before melting, decomposition starts at 300 °C at 101.3 kPa
Relative density	1.2 at 20 °C
Vapour pressure	0.001 kPa *
Flash point	> 150 °C *
Flammability	Not flammable
Viscosity, kinematic	> 20.5 mm^2/s at 40 °C *
Water solubility	insoluble
Ionisable in the environment	No

* SDS

Human exposure

Workers

The foam containing the assessed polymer will be injected via a supplied nozzle into walls or floors. The adhesive will cure and form a hard solid matrix within 20 minutes.

Dermal and ocular exposure to the assessed polymer at up to 65% concentration may occur during application of the liquid foam into walls and floors through an injection nozzle during construction work. According to the applicant, exposure to workers will be minimised through the use of PPE such as goggles/glasses, impervious gloves, overalls, and safety boots during application. Given the expected low vapour pressure of the assessed polymer (0.001 kPa, as indicated on the SDS), inhalation exposure to the vapours of the assessed polymer is not expected. In addition, workers will have previous experience with using similar adhesive foam and will know to avoid over application and contact with skin. As the foam has a red colouring, any skin contamination will be easily visible and will be wiped off immediately.

Health hazard information

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), the assessed polymer was administered by oral gavage to two individual groups of female Wistar rats (3 rats/group) at 2,000 mg/kg bw in polyethylene glycol 400. All treated animals showed expected bodyweight gains during the study. All animals survived until the end of the 14-day study period and no abnormalities were observed at necropsy. The acute oral LD50 value for the assessed polymer was determined to be > 2,000 mg/kg bw.

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

Corrosion/Irritation

Skin irritation

The assessed polymer was tested for skin corrosion potential using a reconstructed (three-dimensional) human epidermis model (EpiSkin SM) (OECD TG 431). Disks of EPISKIN (two units/test substance/incubation time) were treated with the assessed polymer (approx. 50 mg) and then incubated for 3 minutes, 1 hour (±5 min) and 4 hours (±10 min) at room temperature. The viability of each disk was determined by the MTT reduction assay. The assessed polymer would be considered to be non-corrosive to skin, if the mean relative viability after 3 minutes, 1 hour and 4 hours of exposure is equal or above to 35% of the negative control. The average test item treated tissue relative viabilities were 88%, 94% and 79% at 3 minutes, 1 hour and 4 hours exposure, respectively. Based on the results and as per the test guideline, the assessed polymer was considered non-corrosive to the skin.

In an *in vitro* skin irritation study using the EpiSkin™ reconstructed human epidermis model (OECD TG 439), the assessed polymer did not show significantly reduced cell viability in comparison to the negative control. The relative mean tissue viability of the test substance-treated tissues, as compared to the negative control tissues, was 88% (above the threshold for irritancy of ≤ 50%) after the treatment period. Under the conditions of the study and according to the test guideline, the assessed polymer was considered to be non-irritating to the skin.

Eye irritation

The assessed polymer was tested for eye irritation potential using the three-dimensional reconstructed human cornea model (EpiOcular™) (OECD TG 492). Disks of EpiOcular™ (two units) were incubated with the test material (approx. 50 mg) for 6 hours followed by an 18-hour post-incubation period. The disks treated with the assessed polymer showed significantly reduced cell viability in comparison to the negative control, with corrected final mean viability of 39%. As the mean tissue viability was ≤ 60% when treated with the assessed polymer, the assessed polymer is either a Category 1 corrosive or a Category 2 eye irritant according to the OECD TG 492. It is noted that further testing is required to differentiate between GHS Categories 1 and 2.

The assessed polymer was further tested for eye irritating potential using the isolated chicken eye (ICE) test method (OECD TG 438). The test measured the ability of the assessed polymer to cause corneal opacity, swelling and fluorescein retention in an enucleated chicken eye (three ICE classes). The observed maximal mean score for corneal opacity was 2 (ICE Class III), maximal corneal swelling observed was 6% within 240 minutes (ICE Class II), and the observed mean score for fluorescein retention was 1 (ICE Class II). The combination of the three endpoints (2x II, 1x III) fall under the 'No Prediction can be made' under the TG. Therefore, the degree of eye irritation (i.e. Category 1 or 2) cannot be confirmed using the GHS classification criteria (UNECE, 2017).

Sensitisation

Skin sensitisation

In a local lymph node assay (LLNA) (OECD TG 429), the assessed polymer in acetone/Olive Oil (4:1) was applied topically onto the dorsal part of both ears of female CBA/Ca mice (4 animals/group) at 0%, 0.25%, 0.5%, 1%, or 2.5% (w/v) concentrations (25 µL/ear) for 3 consecutive days. On day 6, 250 µL (20 µCi/mouse) of ^{3}HTdR (80 µCi/mL) solution was injected via the tail vein and the animals were euthanised approximately 5 hours afterward for further processing.

There was no mortality and the body weights of the animals were not affected by any treatment. No other signs of systemic toxicity were observed in any test group.

No erythema was observed in any test group during the test. A significant increase of ear thicknesses (i.e. ≥ 25% increase compared to the initial value) were observed only in the 2.5% (w/v) dose group on Day 6.

A significantly increased lymphoproliferation response, compared to the vehicle control, was noted for the test substance at all tested concentrations. The observed stimulation index (SI) values were 6.5, 8.4, 14.7, and 13.9 at test substance concentrations of 0.25%, 0.5%, 1%, and 2.5% (w/v), respectively. Under the conditions of this study and according to the test guideline, the assessed polymer is considered a skin sensitiser. The study also noted that an EC3 value could not be calculated because SI were all > 3 at the concentrations tested. However, as noted by the study authors, the assessed polymer is a strong skin sensitiser as the observed SI value at 0.25% (w/v) concentration was clearly over the threshold value of 3, indicating the EC3 should be below 0.25%.

Repeat dose toxicity

Inhalation

In a combined chronic inhalation toxicity and carcinogenicity study (non-guideline) of an analogue polymer, four groups of Wistar rats (n = 15/group/sex) were exposed by inhalation to the test substance as aerosol at 0, 0.2, 1.0, or 6.0 mg/m^3 respirable concentrations (93.5% < 4.2 µm) for 6 hrs/day, 5 days/week for up to 24 months. In addition, satellite groups of 10 rats/group/sex received the same treatment for 12 months.

There was no adverse effect on general health, survival, body weight, or haematological or clinical chemistry parameters and urinary analyses. However, lung weights were increased in both males and females treated at 6.0 mg/m^3 for 12 or 24 months; Gross examination revealed an increased incidence of spotted and discoloured lungs. Increased degree and incidences of changes in the nasal olfactory epithelium at 1.0 and 6.0 mg/m^3 were reported. Accumulations of alveolar macrophages laden with yellowish refractile pigment, were noted in males and females of the 1.0 and 6.0 mg/m^3 groups in subpleural regions, at the level of the alveolar duct and alveoli.

In addition, alveolar duct epithelialisation with fibrosis of tissues surrounding the macrophage accumulations were also noted at the 1.0 and 6.0 mg/m^3 exposure levels (both sex animals). Increased incidences of calcareous deposits and localized alveolar bronchiolisation were also seen in the 6.0 mg/m^3 group (both sex animals). Alveolar wall damage containing alveolar macrophages leads to alveolar bronchiolisation and finally to bronchioloalveolar tumours, warranting carcinogenicity classification (Cat 2) for the assessed polymer.

No lung tumours were found in the lower concentration groups and in the control group. The pulmonary tumours occurred only in animals of the high-concentration group that died or being euthanised towards or at the end of the 2-year exposure period (number not cited). Based on the pathogenesis of lung damage and lung tumour formation, it was reported that exposure to concentrations which do not lead to recurrent lung tissue injury, would not produce pulmonary tumours. The study authors determined a No Observed Adverse Effect Concentration (NOAEC) of 0.2 mg/m^3 for the analogue polymer, warranting classification of the assessed polymer for STOT-RE Category 1 based on this analogue data.

Genotoxicity

The assessed polymer was not mutagenic in a bacterial reverse mutation assay (Ames Test), when tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* strain WP2 uvrA, with and without metabolic activation (OECD TG 471). No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any tested concentration (16, 50, 160, 500, 800, and 1,200 µg/plate – with metabolic activation; 5, 16, 50, 160, 500, 800, and 1,200 µg/plate - without metabolic activation).

An analogue polymer was evaluated for its clastogenic potential as measured by its ability to increase the incidence of micronucleated polychromatic erythrocytes (mnPCEs) in bone marrow (OECD TG 474). Three groups of male Brown-Norway rats (BN/RijHsd) (n = 6/group) were exposed (whole-body) to filtered air (negative control) or to respirable aerosols of the test substance at actual breathing zone concentrations of 9.2 ± 1.5 and 118 ± 8.6 mg/m^3. One additional group was exposed (nose only) to actual breathing zone concentration of 110 ± 14.4 mg/m^3 of test substance. No mortality was observed at any tested dose level. Animals exposed to 118 and 110 mg/m^3 (NO) of the test substance exhibited signs of respiratory distress,

(hypothermia), and had increased lung weights. The intensity of changes appeared to be slightly more pronounced in animals exposed through the nose. There was no evidence of test substance induced effects on the frequency of mnPCEs. Under the conditions of this study, the analogue polymer did not induce any statistically significant increases in the frequency of mnPCEs in bone marrow cells. Even though the presence of the test substance was not demonstrated in the bone marrow, considering the symptoms/increased lung weights observed at high doses, it is likely that the test substance would have reached the bone marrow. Therefore, under these conditions, was concluded that the analogue polymer was not cytogenic.

In another study, the above analogue polymer was also evaluated for its clastogenic potential in bone marrow and peripheral blood of mice (OECD TG 474). Male C57Bl/6J mice (n = 8 animals/dose/group) were exposed to the aerosolised test substance in a nose-only exposure for one hour/day, for 5 consecutive days at air mean concentrations of 10.7, 20.9 and 23.3 mg/m^3. No mortality was observed at any dose level tested.

No statistically significant increases in the frequency of micronucleated PCEs was detected in the bone marrow or peripheral blood of the mice exposed to the test substance. Even though the presence of the test substance was not demonstrated in the bone marrow, considering the toxic effects observed (decreased respiratory frequency, decreased body weights, an influx of inflammatory cells into the lung) and the formation of analogue-specific adducts in haemoglobin, it is likely that the test substance would have reached the bone marrow. Therefore, under these conditions, it can be concluded that the analogue chemical was not clastogenic in mice.

Environmental exposure

The assessed polymer will be imported to Australia as a component of a fire resistant self-expanding foam in 750 ml pressurised aerosol cans with safety valves. No reformulation, repackaging, dosing, and pre-mixing of the assessed polymer will occur, domestically. The assessed polymer will be contained in a closed system until application. During application, the assessed polymer will be injected via a nozzle into building walls and floors. Following application, the assessed polymer undergoes rapid polymerisation, forming a skin within 5 to 10 minutes and after approximately 20 minutes, the expanding foam is fully cured into an insoluble solid mass.

During application:

The assessed polymer is expected to have minimal environmental exposure, based on the assessed use pattern. It is a one component, ready-to-use product, for use by professionals in interior applications only. Any excess product will be collected and disposed of to landfill.

The cured assessed polymer is not soluble in water and as most of the constituents are cured and bound within the crosslinked polymer matrix, minimal chemical exposure is expected, if the cured assessed polymer is released to water. However, there is some potential for the unreacted excess isocyanate component of the assessed polymer which is not bound to the cured polymeric network to be released into the environment.

In landfill:

In landfill the assessed polymer may degrade, resulting in the leaching of tetrabromo phthalic acid (CAS RN 13810-83-8) or its salts. Under typical environmental conditions as demonstrated in a hydrolysis test, saponification of ester structures may lead to an abiotic

degradation of the polymer. Saponification is expected to be limited only to the surface molecules of the polymer structure that is formed immediately after application. Saponification of the cured polymer surface may result in the release of the degradation products tetrabromo phthalic acid or its salts. No bioavailable Phthalic esters from polymer degradation are expected to be released.

There is evidence that tetrabromo phthalic acid and its potassium, sodium and aluminium salts may be potentially very persistent and very bioaccumulative (vPvB), according to a Public Activities Coordination Tool (PACT) report. Although, it is also noted that no data generation is currently possible to clarify these potential hazards (ECHA, 2022).

Environmental fate

Partitioning

The assessed polymer will readily react and undergo cross linking immediately when in contact with or exposed to water. The cured polymer is a polyurethane network, which is highly stable in water. Hence, no release of educts is expected if the assessed polymer is released to water, except for small amounts of unreacted excess of the isocyanate component which are not bound to the cured polymeric network.

Due to its high molecular weight (MW > 1000 g/mol) and rapid curing, the assessed polymer is not expected to evaporate and partition to air and is expected to partition to soil or sediment if released into the environment.

Degradation

Based on its lack of ready biodegradability in water, and potential production of persistent degradants, the assessed polymer is considered persistent.

Results from a supplied biodegradation study for the assessed polymer showed 25% degradation (OECD 301D) over 28 days. The 10-day window criterion was not fulfilled. Hence the assessed polymer is expected to be not readily biodegradable in aquatic environments.

Applicant supplied data reports an average hydrolysis half-life of 20 hours for the isocyanate component of the assessed polymer based on an experimental study. As this value is below the domestic threshold value of 60 days, the excess isocyanate component in assessed polymer is not expected to persist in aquatic environments. However, its hydrolysis products, high molecular weight polyureas and 4,4′-methylenedianiline (MDA) are likely to be persistent in aquatic environments, based on read-across information provided on an analogue chemical.

Bioaccumulation

Based on weight of evidence, the assessed polymer is not expected to bioaccumulate in aquatic environments.

- The main constituent of the assessed polymer which is an isocyanate component is expected to be present in excess and may be released from the cured polymer, is not expected to be bioaccumulative, based on read-across information provided for analogue chemicals.
- The cured assessed polymer has a high molecular weight, is insoluble in water and is highly stable. Therefore, it is not expected to be bioavailable to accumulate in the food chain.

Information from a 28-day bioaccumulation test conducted according to OECD 305E (Bioaccumulation: Flow-through Fish Test) on a suitable structural analogue of the isocyanate component indicates BCF values up to 200, for the isocyanate component and its hydrolysis products, concluding that the isocyanate component and its hydrolysis products are considered not bioaccumulative in aquatic environments.

Furthermore, information available on another suitable analogue also supports the conclusion that the isocyanate component in the assessed polymer is not expected to bioaccumulate due to its tendency to rapidly hydrolyse. The hydrolysis products of the aforementioned analogue are primarily polyureas, which have also been identified as polymers of low ecological concern, due to their inert characteristics, and based on the expectation that they are not bioavailable. As such, they are unlikely to accumulate in organisms and food chains in the environment.

Therefore, based on the available data on analogue chemicals, the isocyanate component that is expected to be present in excess in the assessed polymer is not bioaccumative in aquatic organisms.

Further to this, upon release from the aerosol can, the assessed polymer comes in contact with the moisture of the ambient air and the free isocyanate groups (-NCO) of the isocyanate component react immediately, forming a three-dimensional solid and high molecular weight polymer network via cross-linking. The fully cured assessed polymer is a highly stable solid polyurethane foam, where the educts are covalently bound to the polymeric network. The polymerisation and curing process is accompanied by an increase in molecular weight, which limits the polymer's bioavailability. Additionally, the assessed polymer has very low water solubility in water, further reducing its bioavailability.

In conclusion, the assessed polymer's main constituent, the isocyanate component and its hydrolysis products that may be released from the cured polymer network, are not expected to bioaccumulate. Additionally, the assessed polymer, once fully cured, is not expected to be bioavailable due to its high molecular weight, very low water solubility and high stability in water.

While there is some potential for limited amounts of the bioaccumulative tetrabromo phthalic acid to leach out of the assessed polymer, these components represent only a small percentage of the overall polymer composition and are expected to have limited potential leach into the environment. Therefore, the potential release of tetrabromo phthalic acid is not sufficient for the overall polymer to be considered bioaccumulative.

Therefore, based on a weight of evidence, the assessed polymer is considered to be not bioaccumulative in aquatic environments.

Predicted environmental concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the assessed polymer to the aquatic environment is expected to be negligible based on its assessed use pattern.

Environmental effects

Effects on aquatic Life

Acute toxicity

The following median lethal concentration (LC50), effective concentration (EC50), and no observed effect concentration (NOEC) values for model organisms were supplied for the assessed polymer.

Taxon	Endpoint	Method
Fish	96 h LC50 > 100 mg/L	*Danio Rerio* (Zebra fish) Mortality OECD TG 203 Static Nominal loading rate
Invertebrate	48 h EC50 > 100 mg/L Water accommodated fraction (WAF)	*Daphnia magna* (water flea) Immobility OECD TG 202 Static Nominal loading rate
Algae	72 h E_rC50 > 100 mg/L (WAF)	*Pseudokirchneriella subcapitata* (green algae) Growth rate OECD TG 201 Static Nominal loading rate

Chronic toxicity

The following no observed effect concentration (NOEC) values for model organisms were supplied for the assessed polymer.

Taxon	Endpoint	Method
Algae	72 h NOEC = 100 mg/L (WAF)	*Pseudokirchneriella subcapitata* (green algae) Growth rate OECD TG 201 Static Nominal loading rate

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) was not calculated as the assessed polymer is not considered harmful to aquatic organisms.

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 study, the assessed polymer is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on weight of evidence the assessed polymer is categorised as not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available ecotoxicity values above 1 mg/L the assessed polymer is categorised as Not Toxic.

Environmental risk characterisation

The assessed polymer is persistent but not toxic to aquatic organisms and does not have the potential to bioaccumulate. Therefore, the assessed polymer does not meet all three PBT criteria.

A Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as the currently available information indicates the assessed polymer is not harmful to aquatic organisms and will have limited bioavailability. Additionally, the release to the environment is expected to be minimal. Therefore, the risk from the assessed polymer can be managed.

As brominated flame retardants are subject to ongoing research and examination by international regulatory agencies, re-assessment or evaluation may be required if information becomes available that indicates the assessed polymer, or its degradants, have greater hazards than those considered in this assessment.

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