Australian Government
Department of Health, Disability and Ageing
Australian Industrial Chemicals Introduction Scheme

1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1-[2-(2-hydroxyethoxy)ethyl] 2-(2-hydroxypropyl) ester, polymer with 1,3-isobenzofurandione, 2,2′-oxybis[ethanol], polymethylenepolyphenylene isocyanate and α,α′,α″-1,2,3-propanetriyltris[ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)]]

Assessment statement (CA10150)

22 July 2026

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AICIS assessment (CA10150)

Chemical in this assessment

Name	CAS registry number
1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1-[2-(2-hydroxyethoxy)ethyl] 2-(2-hydroxypropyl) ester, polymer with 1,3-isobenzofurandione, 2,2′-oxybis[ethanol], polymethylenepolyphenylene isocyanate and α,α′,α″-1,2,3-propanetriyltris[ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)]]	3092684-80-2

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 chemical has been assessed:

- as imported into Australia at up to 50 tonnes/year
- as imported at up to 65% concentration as a component in finished end-use products intended for use in fire resistant self-expanding polyurethane foam applications
- for use only by professional workers in construction sites

Summary of assessment

Summary of introduction, use and end use

The assessed chemical is a polymer. The assessed chemical will not be manufactured, reformulated, or re-packaged in Australia. It will be imported into Australia at up to 50 tonnes/year as a component of a fire resistant self-expanding polyurethane foam at up to 65% concentration in finished end-use products. The end-use product is in 750 mL pressurised canisters with a safety valve.

The assessed chemical will only be used by professional workers at construction sites, where it is not accessible to the public.

Human health

Summary of health hazards

The submitted toxicological data on four analogue chemicals for the components of the assessed chemical (see **Supporting information**) indicate that the assessed chemical is:

- likely to be of low acute oral and dermal toxicity (oral and dermal median lethal dose (LD50) > 2,000 mg/kg bw in rats)
- not likely to be irritating to the skin
- not likely to be genotoxic

The submitted toxicological data on the analogue chemicals (see **Supporting information**) indicate that the assessed chemical is likely:

- an eye irritant
- a strong skin sensitiser
- a respiratory sensitiser
- to cause adverse health effects with repeated inhalation exposure (based on the NOAEC of 0.2 mg/m^3 established for the analogue chemical D)
- suspected of causing cancer (based on the pulmonary tumours in animals of the high-concentration group in a 2-year inhalation exposure study).

The assessed chemical 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 equal to 5,000 g/mol or greater 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 1,000 g/mol. The isocyanate functional group equivalent weight of the assessed chemical is less than 5,000 g/mol; with a relatively high proportion of low molecular weight species (over 25% of molecular weight species less than 1,000 g/mol and over 15% of molecular weight species less than 500 g/mol) present in the assessed chemical, warranting hazard classification of the assessed chemical as a respiratory sensitiser.

While two *in vitro* studies provided on the analogue chemical were inconclusive, the first study indicates that the analogue chemical could be corrosive or irritating to the eyes. Therefore, the assessed chemical is likely to be an eye irritant (Category 2, H320: Causes eye irritation), according to the GHS criteria.

No repeated dose oral or dermal toxicity data were provided for the assessed chemical.

Hazard classifications relevant for worker health and safety

Based on the data provided by the applicant, the assessed 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 for worker health and safety as adopted for industrial chemicals in Australia.

Health hazards	Hazard category	Hazard statement

Serious eye damage/eye irritation	Eye Irrit. 2	H320: Causes eye irritation
Sensitisation, skin	Skin Sens. 1A	H317: May cause an allergic skin reaction
Sensitisation, respiratory*	Resp. Sens. 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled
Carcinogenicity	Carc. 2	H351: Suspected of causing cancer
Specific target organ toxicity, repeated exposure	STOT RE 2	H373: May cause damage to organs through prolonged or repeated inhalation exposure

*Classification based on free isocyanates in the assessed chemical

Summary of health risk

Public

The assessed chemical will not be available for use by the public and is intended for 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 chemical.

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 chemical 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 from adverse health effects of the assessed chemical (possible through inhalation of vapour, skin sensitisation, and the risk of respiratory sensitisation due to the presence of free isocyanates in the assessed chemical), 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 chemical is:

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

Environmental hazard classification

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

Summary of environmental risk

The assessed chemical will be imported as a component of a fire resistant self-expanding foam that will be injected into gaps and joints in walls or floors in buildings, 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 chemical 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 chemical is not harmful to aquatic organisms and will have limited bioavailability. Additionally, the assessed chemical is not expected to be released into the environment. Therefore, on the basis of low hazard and limited exposure, the risk from the assessed chemical 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 chemical 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 chemical should be in accordance with the *Safe Work Australia Code of Practice for Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2023) 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 chemical. 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 chemical is present.

- As the assessed chemical is a skin and respiratory sensitiser, control measures may need to be supplemented with health monitoring for any worker who is at significant risk of exposure to the chemical, 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:

1. Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.
2. A person introducing this chemical should be aware of their obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

CAS number	3092684-80-2
CAS name	1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1-[2-(2-hydroxyethoxy)ethyl] 2-(2-hydroxypropyl) ester, polymer with 1,3-isobenzofurandione, 2,2′-oxybis[ethanol], polymethylenepolyphenylene isocyanate and α,α′,α″-1,2,3-propanetriyltris[ω-hydroxypoly[oxy(methyl-1,2-ethanediyl)]]
Molecular formula	$(C_{15}H_{16}Br_4O_7.C_8H_4O_3.C_4H_{10}O_3.(C_3H_6O)_n(C_3H_6O)_n(C_3H_6O)_nC_3H_8O_3.Unspecified)_x$
Number average molecular weight (NAMW, g/mol)	< 1000
Percentage of low molecular weight species (less than 1,000 g/mol)	> 25
Percentage of low molecular weight species (less than 500 g/mol)	> 15

Additional chemical identity information

The assessed chemical is a polymer which has a typical purity of 86% and contains an impurity with unreacted isocyanate groups.

Relevant physical and chemical properties

The following physical and chemical properties are tested on the Analogue chemical A.

Physical form	Brownish viscous liquid to paste
Melting point	-32.33 °C (Decomposes before melting, decomposition starts at 300 °C at 101.3 kPa)
Relative Density	1.2 ± 0.14 at 20 °C
Vapour pressure	0.001 kPa*
Water solubility	insoluble
Flash Point	> 150 °C*
Flammability	Not flammable
Viscosity, kinematic	> 20.5 mm^2/s at 40 °C*
Ionisable in the environment	No

* Provided on safety data sheet (SDS)

Human exposure

Workers

The foam containing the assessed chemical will be injected via a supplied nozzle into gaps/joints in walls or floors. The foam expands and fills the gap. The adhesive will cure and form a hard solid matrix within 20 minutes.

Dermal and or ocular exposure to the assessed chemical at up to 65% concentration may occur during application of the liquid foam into gaps in 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 chemical (0.001 kPa, as indicated on the SDS), inhalation exposure to the vapours of the assessed chemical is not expected. As the foam has a red colouring, any skin contamination will be easily visible and will be wiped off immediately.

Health hazard information

The applicant submitted toxicological data from four analogue chemicals in support of this assessment application which contain a similar functional group of concern (isocyanate) in the structural composition as the assessed chemical. These analogue chemicals were used as read-across for different toxicological endpoints.

These analogues were:

- analogue chemical A is 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 No. 2484708-66-7)
- analogue chemical B is Isocyanic acid, polymethylenepolyphenylene ester, polymer with methoxylated dehydrochlorinated brominated 2-butyne-1,4-diol-epichlorohydrin polymer (CAS No. 916652-23-8)
- analogue chemical C is 1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, mixed esters with diethylene glycol and propylene glycol, polymers with polymethylenepolyphenylene isocyanate (CAS No. 2628184-42-7)
- analogue chemical D is Isocyanic acid, polymethylenepolyphenylene ester (CAS No. 9016-87-9)

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), the analogue chemical A was administered via 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 analogue chemical A was determined to be > 2,000 mg/kg bw. Therefore, the assessed chemical is likely to be of low acute oral toxicity.

Dermal

In an acute dermal toxicity study (OECD TG 402), an analogue chemical B was applied undiluted as a single dermal dose of 2,000 mg/kg bw to the skin of two female Han:WIST rats for 24 hours. The animals were observed for 14 days after application. Signs of dermal irritation included very slight erythema between Day 1 and Day 6, and small wounds and small crusts between Day 1 and Day 10. No mortality or signs of systemic toxicity or behavioural changes were noted in the treated animals during the observation period. Mean body weight gain was within the normal range for animals of this strain and age. No abnormalities were noted at necropsy. Under the conditions of this study, the acute dermal LD50 value for the analogue chemical B was determined to be > 2,000 mg/kg bw.

In another acute dermal toxicity study (OECD TG 402), analogue chemical C was applied undiluted as a single dermal dose of 2,000 mg/kg bw to the skin of two female Han:WIST rats for 24 hours. The animals were observed for 14 days after application. No dermal irritation symptoms and deaths were observed during the study. Similarly, behavioural changes and systemic toxic signs were also not observed during the study. Mean body weight gain was within the normal range for animals of this strain and age. No abnormalities were noted at necropsy. Under the conditions of this study, the acute dermal LD50 value for the analogue chemical C was determined to be > 2,000 mg/kg bw.

Therefore, based on the above studies, the assessed chemical is likely to be of low acute dermal toxicity.

Corrosion/Irritation

Skin irritation

The analogue chemical A 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 analogue chemical A (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 test substance would be considered to be non-corrosive to skin, if the mean relative viability after 3 minutes, 1 hour and 4 hours of exposures is equal or above to 35% of the negative control. The average test item treated tissue relative viabilities were 88%, 94% and 79% after 3 minutes, 1 hour and 4 hours exposures, respectively. Based on the results and as per the test guideline, the analogue chemical A was considered non-corrosive to the skin.

In another *in vitro* skin irritation study using the EpiSkin™ reconstructed human epidermis model (OECD TG 439), the analogue chemical A 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. Based on the results and according to the test guideline, the assessed chemical was not considered to be irritating to the skin.

Two further *in vitro* skin irritation studies using the EpiSkin™ reconstructed human epidermis model (OECD TG 439) with two different analogue chemicals B and C tested separately also did not show skin irritation potential as both 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 76% and 93%, respectively (above the threshold for irritancy of ≤ 50%) after the treatment period.

Therefore, based on the above studies, the assessed chemical is not likely to be corrosive or irritating to the skin.

Eye irritation

The analogue chemical A 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 analogue chemical 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 analogue chemical, the analogue chemical is either a Category 1 corrosive or a Category 2 eye irritant according to the OECD TG 492. Therefore, the assessed chemical is either a Category 1 corrosive or a Category 2 eye irritant. Further testing is required to differentiate between GHS Categories 1 and 2.

The analogue chemical A 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 analogue chemical to cause corneal opacity, swelling and fluorescein retention in an enucleated chicken eye (three ICE classes). The observed maximum mean score for corneal opacity was 2 (ICE Class III), maximum 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) falls 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 this study.

While the two *in vitro* studies provided on the analogue chemical were inconclusive, the first study indicates that the analogue chemical could be corrosive or irritating to the eyes. Therefore, the assessed chemical is likely to be an eye irritant category (Category 2, H320: Causes eye irritation), according to the GHS criteria.

Sensitisation

Skin sensitisation

In a local lymph node assay (LLNA) (OECD TG 429), the analogue chemical A 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 were no mortalities 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) was 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 analogue chemical 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, the analogue chemical 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%.

In another LLNA (OECD TG 429), analogue chemical C at 1.0%, 2.5%, 5% and 10% (w/v) in *N*,*N*-Dimethylformamide (DMF) was applied topically on the dorsal surface of each ear of mice with 25 µL of the appropriate formulations of the test substance, the positive control substance or the vehicle control for 3 consecutive days. There were no mortalities and no other signs of systemic toxicity were observed in any test group during the study. No erythema was observed during the test. Significantly increased ear thicknesses were observed only in 10% (w/v) dose group (3/4 animals with a maximum increase of 63.2%). Significantly increased lymphocyte proliferation (indicated by a SI ≥ 3) was observed only in animals treated at 10% concentration (SI = 3.84). The SI were 1.20, 1.21, and 1.24 for 1%, 2.5%, and 5% concentrations, respectively. Based on the dose response curve, an EC3 value of 8.4% was obtained in this LLNA indicating that the analogue chemical C to be a moderate skin sensitiser.

In another LLNA (OECD TG 429), analogue chemical B at 2.5%, 5%, 10%, and 25% (w/v) in DMF was applied topically on the dorsal surface of each ear of mice (25 µL) for 3 consecutive days. No mortalities and erythema were observed in any test groups. Significantly increased ear thicknesses were observed only in the 10% and 25% dose groups. The SI values were 1.4, 1.4, 5.1 and 7.2 at concentrations of 2.5%, 5%, 10% and 25% (w/v), respectively for the test substance. The EC3 was 7.2% in this study.

Therefore, based on the analogue data above, the assessed chemical is likely to be a strong skin sensitiser (Category 1A, H317: May cause an allergic skin reaction), according to GHS criteria.

Repeat dose toxicity

Inhalation

In a combined chronic inhalation toxicity and carcinogenicity study (non-guideline) of analogue chemical D, 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 were no adverse effects on general health, survival, body weight, or haematological or clinical chemistry parameters and urinary analyses for 12 or 24 months. 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 and fibrosis surrounding macrophage accumulations were observed in both sexes at 1.0 and 6.0 mg/m³ after 12 and 24 months of exposure. At 6.0 mg/m³, both sexes also exhibited increased incidences of calcareous deposits and localised alveolar bronchiolisation. Moreover, eight pulmonary adenomas (six in males and two in females) and one pulmonary adenocarcinoma (in a male) were observed in the 6.0 mg/m^3 exposure group. The adenocarcinoma was a large (~10 mm), invasive lesion displaying both expansile and infiltrative growth patterns, indicative of malignancy. The time sequence of the

spectrum of pulmonary changes indicates that recurrent alveolar wall damage by polymeric MDI and/or polymeric MDI-containing alveolar macrophages leads to alveolar bronchiolisation and ultimately to bronchioloalveolar tumours.

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 chemical D. Therefore, based on above analogue data, the assessed chemical is likely to be classified for Specific Target Organ Toxicity (repeated exposure) (STOT-RE) (Category 2, H373: May cause damage to organs through prolonged or repeated inhalation exposure) and for carcinogenicity (Category 2, H351: Suspected of causing cancer), according to the GHS criteria.

Genotoxicity

Analogue chemical A 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, 1,600, and 5,000 µg/plate – with metabolic activation; 5, 16, 50, 160, 500, 800, and 1,200 µg/plate - without metabolic activation).

Two separate studies showed that analogue chemicals B and C were also not mutagenic in bacterial reverse mutation assays (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 with analogue chemical B (16, 50, 160, 500, 1,600, and 5,000 µg/plate) and analogue chemical C, (5, 16, 50, 160, 500, 1,600, and 5,000 µg/plate), with and without metabolic activation.

Analogue chemical D 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 (nose only) 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 chemical D did not induce any statistically significant increases in the frequency of mnPCEs in bone marrow cells of rats. 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, it was concluded that the analogue chemical D was not clastogenic.

In another study, analogue chemical D 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 D was not clastogenic in mice.

Therefore, based on the above information, the assessed chemical is not likely to be genotoxic.

Environmental exposure

The assessed chemical will be imported to Australia as a component of a fire resistant self-expanding foam in pressurised aerosol cans with safety valves. No reformulation, repackaging, dosing, or pre-mixing of the assessed chemical will occur domestically. The assessed chemical will be contained in a closed system until application. During application, the assessed chemical will be injected via a nozzle into gaps or joints in building walls and floors. Following application, the assessed chemical 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 chemical 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 chemical 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 chemical is released to water. However, there is some potential for the unreacted excess isocyanate component of the assessed chemical which is not bound to the cured polymeric network to be released into the environment.

In landfill:

In landfill the assessed chemical may degrade, resulting in the leaching of tetrabromo phthalic acid (CAS No. 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 chemical 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 chemical 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 and rapid curing, the assessed chemical 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 chemical is persistent.

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

Applicant supplied data on analogue chemical A reports an average hydrolysis half-life of 20 hours for the isocyanate component of the assessed chemical based on an experimental study. As this value is below the domestic threshold value of 60 days, the excess isocyanate component (analogue chemical D) in the assessed chemical 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 analogue chemical A.

Bioaccumulation

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

1. The main constituent of the assessed chemical which is an isocyanate component (analogue chemical D) is expected to be present in excess and may be released from the cured polymer. It is not expected to be bioaccumulative, based on read-across information provided for analogue chemical A.
2. The cured assessed chemical 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 (4,4’-methylenediphenyl diisocyanate, CAS No. 101-68-8) of the isocyanate component indicates BCF values up to 200, for the isocyanate component and its hydrolysis products, concluding that the isocyanate component (analogue chemical D) and its hydrolysis products are considered not bioaccumulative in aquatic environments.

Furthermore, information available on another suitable analogue (m-tolylidene diisocyanate, CAS No. 26471-62-5) also supports the conclusion that the isocyanate component in the assessed chemical 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 chemical is not bioaccumulative in aquatic organisms.

Further to this, upon release from the aerosol can, the assessed chemical comes into 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 chemical 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 chemical has very low solubility in water, further reducing its bioavailability.

In conclusion, the assessed chemical'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 chemical, 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 chemical, these components represent only a small percentage of the overall polymer composition and are expected to have limited potential to 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 chemical is not bioaccumulative in aquatic environments.

Predicted environmental concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the assessed chemical 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 analogue chemical A of the assessed chemical:

Taxon	Endpoint	Method
Fish	96 h LC50 > 100 mg/L	*Danio Rerio* (zebrafish) 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) value for model organisms was supplied for analogue chemical A of the assessed chemical:

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 chemical is not considered harmful to aquatic organisms.

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemical according to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW, 2022) is presented below:

Persistence

Persistent (P). Based on a measured degradation study of analogue chemical A, the assessed chemical is categorised as Persistent.

Bioaccumulation

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

Toxicity

Not Toxic (Not T). Based on available ecotoxicity values above 1 mg/L for analogue chemical A, the assessed chemical is categorised as Not Toxic.

Environmental risk characterisation

The assessed chemical is persistent but not toxic to aquatic organisms and does not have the potential to bioaccumulate. Therefore, the assessed chemical 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 chemical 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 chemical 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 chemical, or its degradants, have greater hazards than those considered in this assessment.

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