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

2-Oxepanone, polymer with 1,5-diisocyanatonaphthalene and 2,2-dimethyl-1,3-propanediol

Assessment statement (CA09625)

04 July 2023

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AICIS assessment statement (CA09625)

Chemical in this assessment

Name	CAS registry number
2-Oxepanone, polymer with 1,5-diisocyanatonaphthalene and 2,2-dimethyl-1,3-propanediol	874447-40-2

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 Health focus type.

Defined scope of assessment

The polymer has been assessed as:

- imported into Australia at up to 200 tonnes per annum
- imported at > 90% concentration for use only in industrial purposes
- used in hot-cast moulding process in the manufacturing of industrial articles/parts such as wheels and rollers coating, hydrocyclones, shock absorbers and seals.

Summary of assessment

Summary of introduction, use and end use

The assessed polymer will not be manufactured in Australia. It will be imported into Australia at up to 200 tonnes per annum at > 90% concentration in 205 L drums. These drums will, be imported and distributed directly to the site of article manufacture and stored in the end-user's warehouse until required for manufacturing.

The assessed polymer will be used only for industrial purposes and is used in hot-cast moulding process in the manufacturing of industrial articles/parts such as wheels and rollers, hydrocyclones, shock absorbers and seals.

Human health

Summary of health hazards

The assessed polymer contains isocyanate functional groups that are of concern for irritation, dermal and respiratory sensitisation, and pulmonary toxicity (Barrett, 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 5,000 g/mol

are presumed not to pose a health hazard under any conditions. In addition, concerns are generally confined to species with molecular weights less than 1,000 g/mol. The isocyanate functional group equivalent weight of the assessed polymer is less than 5,000 g/mol; however, a relatively low proportion of low molecular weight species (less than 10% of molecular weight species less than 1,000 g/mol) are present in the assessed polymer. Therefore, respiratory sensitisation cannot be ruled out.

Based on the submitted data for an analogue chemical for acute inhalation toxicity (LC50 inhalation - 4 hrs, 0.270 mg/L air) and for respiratory irritation, the assessed polymer is likely to be harmful if inhaled and may cause respiratory irritation, warranting hazard classification (see **Hazard classifications relevant for worker health and safety** section).

Based on the submitted data for an analogue for skin sensitisation, the assessed polymer is likely to be sensitising to the skin (see **Supporting information**), warranting hazard classification (see **Hazard classifications relevant for worker health and safety** section).

Based on the submitted data for an analogue chemical for repeated dose toxicity, the assessed polymer is likely to cause adverse effects with repeated inhalation exposure (see **Supporting information**), warranting hazard classification (see **Hazard classifications relevant for worker health and safety** section).

Based on the data provided, the assessed polymer:

- is likely to be of low acute oral toxicity
- is non-irritating to the skin
- is slightly irritant to eyes
- is not considered to be genotoxic.

No dermal toxicity data were provided for the assessed polymer.

Hazard classifications relevant for worker health and safety

Based on the data provided, 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
Acute toxicity	Category 4	H332 – Harmful if inhaled
Specific target organ toxicity (single exposure)	Category 3	H335 – May cause respiratory irritation
Skin Sensitisation	Skin Sens. 1	H317 – May cause an allergic skin reaction
Specific target organ toxicity (repeated exposure)	Category 2	H373 – May cause damage to organs through prolonged or repeated inhalation exposure

Summary of health risk

Public

The products containing the assessed polymer will not be available for use by the public. 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 public health that would require specific risk management measures when the assessed polymer is introduced in accordance with the terms of the assessment certificate.

Workers

Workers may experience dermal, ocular or inhalation exposure to the assessed polymer at > 90% concentration during handling, transfer, blending, testing, maintenance, and cleaning activities in industrial settings.

Given that risks of critical health effects possible through inhalation of vapour and dust and dermal contact of the assessed polymer, control measures to minimise inhalation and dermal exposure are needed to manage the risk to workers such as the use of mechanical ventilation (where required) and enclosed processes and personal protective equipment (PPE) (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

The assessed polymer satisfies the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE, 2017) as Acute Category 2 (H401) and Chronic Category 2 (H411) based on the toxicity data for green algae. In the absence of biodegradation test data and based on the assumptions of the polymer's stability, considerations were also made for the long-lasting effects of the assessed polymer.

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 2	H401: Toxic to aquatic life
Hazardous to the aquatic environment (long-term)	Aquatic Chronic 2	H411: Toxic to aquatic life with long lasting effects

Summary of environmental risk

No significant release of the assessed polymer is expected to occur as a result of its use in the manufacture of articles. The assessed polymer is expected to share the fate of the article it is incorporated into and be disposed of to landfill at the end of its useful life.

No information about the biodegradation of the assessed polymer is available. Therefore, the assessed polymer is assumed to be persistent. The polymer is expected to have low bioavailability based on a number average molecular weight exceeding 1,000 g/mol. The polymer is not expected to bioaccumulate based on its low bioavailability. The assessed polymer is toxic to aquatic organisms, but this hazard is expected to be mitigated by negligible release of the assessed polymer.

No risks to the environment have been identified that would require specific risk management measures when the assessed polymer is introduced and used in accordance with the terms of the assessment certificate.

Means for managing risk

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, could 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 manufacturing of articles:
    - Use of engineering controls such as
        - Enclosed and automated processes
        - Adequate workplace ventilation to avoid accumulation of vapours, mists, or aerosols
    - Use of safe work practices to
        - Avoid contact with skin and eye
        - Avoid inhalation of mists or 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 cannot be ruled out, 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 conclusions of this assessment are based on the information described in this statement.

Considering the means of managing risks, the Executive Director is satisfied that when the assessed polymer is introduced and used in accordance with the terms of the assessment certificate the human health and environment risks can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory, and the proposed means for managing the risks identified during this assessment are implemented.

Note: Obligations to report additional information about hazards under section 100 of the *Industrial Chemicals Act 2019* apply.

Supporting information

Chemical identity

Chemical name	2-Oxepanone, polymer with 1,5-diisocyanatonaphthalene and 2,2-dimethyl-1,3-propanediol
CAS No.	874447-40-2
Synonyms	2-Oxepanone, polymer with 1,5-diisocyanatonaphthalene and 2,2-dialkyl-1,3-alkanediol–
Molecular formula	$(C_{12}H_6N_2O_2.C_6H_{10}O_2.C_5H_{12}O_2)_x$
Molecular weight (g/mol)	Greater than 1,000
SMILES	O=C=NC1=CC=CC=2C(N=C=O)=CC=CC12.O=C1OCCCCC1.OCC(C)(C)CO
Chemical description	Polymer
Structural formula:	Unspecified

Relevant physical and chemical properties

Physical form	White paste
Pour point	0 °C
Boiling point	> 300 °C at 101.3 Pa
Vapour pressure	0.4 kPa at 20 °C
Flash point	218 °C
Ignition temperature	> 500 °C
Density	1146 kg/m³ at 20 °C
Water solubility	5.0 - 16 mg/L at 40°C, pH (2– 9)
Ionisable in the environment?	N/A
pK_a	N/A
log K_{ow}	> 11.09 (calc.)*
log K_{oc}	> 6.763 (calc.)*

* Calculated value for representative component of the polymer using KOWWIN v1.68 and KOCWIN v2.00 of EPI Suite v4.11 (US EPA, 2012)

Human exposure

Workers

There will be no widespread uses by the workers. Workers will only be involved in the production of articles at specific industrial sites and under controlled conditions.

Manufacturing of Articles

At the article manufacturing site, workers will open the 205 L drums containing the assessed polymer at > 90% concentration and connect hose and pumping equipment. The drums may be warmed to decrease viscosity. The required amount of assessed polymer will be dosed into the enclosed sealed mixing tank. Other components will also be added. When mixing is complete, the mixture will be automatically dispensed into the moulds and allowed to cure and harden. At this stage, the assessed polymer would be trapped within the cured matrix and will not be available for exposure. The completed article will be removed from the moulds, cleaned, and processed further to produce the final engineered part, such as a wheel. Dermal, ocular and inhalation exposure of workers to the assessed polymer at > 90% concentration may occur during transfer of the product containing the assessed polymer to the machine, during quality control testing and during maintenance and cleaning tasks. However, exposure is expected to be minimised by the use of local exhaust ventilation and the use of personal protective equipment (PPE) such as protective clothing, impervious gloves, eye protection and respiratory protection. In addition, processes for the manufacturing of articles are expected to be largely automated and in enclosed systems.

Public

The assessed polymer will not be available for use by the public. While the public may come in contact with the moulded products/articles containing the assessed polymer, the assessed polymer will be cured, bound within the moulded products/articles and will not be available for exposure. Therefore, direct/indirect public exposure to the assessed polymer through industrial uses are not expected.

Health hazard information

No toxicity data were submitted for the assessed polymer. The presence of the isocyanate groups in the assessed polymer is expected to give rise to similar hazards of the respective polymer. On this basis, isocyanate is expected to be a suitable read-across candidate for the hazards of the assessed polymer.

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), an analogue chemical was administered by oral gavage to two individual groups of female Wistar rats (3 rats/group) at 2,000 mg/kg bw in corn oil with 10% acetone. No signs of toxicity were observed, and 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 was determined to be > 2,000 mg/kg bw.

Inhalation

In an acute inhalation toxicity study (OECD TG403), Wistar rats (5/sex/group) were exposed to the aerosolized analogue chemical in Plexiglas exposure tubes applying a directed-flow nose-only exposure at 0,96, 189, 238, 314, 384 and 541 mg/m^3 of air for 4 hours. Animals were observed for 4 weeks following exposure. The particle size distribution revealed that 49, 46, 36, 31, 27 and 47% respirable particles in the 96, 189, 238, 314, 384 and 541 mg/m^3 groups were < 3 µm, respectively.

Exposure to concentrations of 96 mg/m^3 and higher were followed by concentration-dependent signs suggestive of irritation of the respiratory tract (e.g., bradypnoea, dyspnoea, laboured breathing pattern, rales, nose/snout area with red encrustations, serous discharge from nose, cyanosis, hypothermia) warranting hazard classification for specific target organ toxicity (Category 3). Reduced motility and body weight gain, emaciation, and flaccid muscle tone were also observed. The test substance related mortality was observed at aerosol concentrations of 238 mg/m^3 and above, induced within the first two post-exposure days. The duration of respiratory signs lasted up to day 11. Under the conditions of this study and according to the test guideline the acute LC50 inhalation (aerosol, 4 hrs) for males and females combined was determined to be 270 mg/m^3 air.

No acute dermal toxicity data were submitted for the assessed polymer.

Corrosion/Irritation

Skin irritation

The analogue chemical was tested for skin irritation potential using a reconstructed human epidermis EST-1000 (CeIiSystems, S1. Katharinen, Germany) (OECD TG 431, 2014). EST-1000 inserts were exposed to 50 µL of the test item for 3 min at room temperature and 60 min in the incubator (3 inserts/ incubation time), respectively. The viability of the EST-1000 inserts was determined by the MTT reduction assay. The test substances would be classified as " R34 corrosive, equivalent to H314 Causes severe skin burns and eye damage. H314", if the cell viability of the EST 1000 is decreased by more than 50% after 3 min of incubation to the test item, or if the cell viability was less than 15% after 60 min of exposure to the test item. The MTT reduction assay revealed that the cell viability after 3 min or 60 min of incubation was 93.08% and 108.63%, respectively. The cell viability of the negative control was 100%. Based on the results and as per the test guideline, the test substance was considered non-irritating to the skin.

Eye irritation

In an eye irritation study, the analogue chemical was instilled into the conjunctival sac of one eye of 3 female rabbits (OECD TG 405). Eye irritation was assessed (using the Draize scale) at 1, 24, 48, 72 hours following instillation. As no irritation indices were observed after 72 hours following instillation, the study was terminated at 72 hours. Slight irritant effects with mean irritation index for redness conjunctivae being 0.6 was noted which were fully reversible within 3 days following instillation. No irritation effects were seen at cornea or iris. Under the conditions of this test, the analogue chemical was determined to be a slight eye irritant in rabbits.

Sensitisation

Skin sensitisation

In a modified local lymph node assay (LLNA) (OECD TG 406, 1992; OECD TG 429, 2002), the analogue chemical in acetone/Olive Oil (4:1) was administered epicutaneously onto the dorsal part of both ears of female NMRI mice (6 animals/group) at 0%, 2%, 10% and 50% concentration (25 µL/ear) for 3 consecutive days. The body weights of the animals were not affected by any treatment.

A significant increase in ear swelling and ear weights was noted in all treatment groups. An ear swelling index of 1.00, 1.18, 1.34, and 1.32 was noted at 0, 2%, 10%, and 50% concentration, respectively. The "positive level" of ear swelling which is $2x10^{-2}$ mm increase, i.e. about 10% of the control values), has been exceeded in all dose groups. Similar significant increases were also noted with regards to ear weight with ear weight indexes of 1.00, 1.30, 1.49, 1.63 noted at 0%, 2%, 10%, and 50% concentration, respectively.

The weight of draining lymph nodes increased significantly with Stimulation index (SI) being 1.00%, 3.51%, 3.79%, and 3.47% at 0%, 2%, 10%, and 50% concentration, respectively. Similarly, the cell counts of draining lymph also increased significantly, the index being 1.00. 4.06. 4.15. and 4.42. at 0, 2%, 10%, and 50% concentration, respectively. The ‘positive level’ of index for cell counts (1.4) has been exceeded in all dose groups. As per the requirements of test guidelines, an EC3 value was not determined in the study report.

Considering the significant increases in ear swelling, ear weights, weight of draining lymph nodes, and cell counts of draining lymph nodes, the test substance is a skin sensitiser and warranting a hazard classification (Category 1).

Repeat dose toxicity

In a subacute pilot inhalation study, Wistar rats (10 male rats/dose) were exposed to the aerosolised analogue chemical in Plexiglas exposure restrainers providing a nose-only exposure for 2 weeks (6 hours/day, 5 days/week). The mean actual breathing zone concentrations (gravimetric) were 0.19, 1.1, 4.8, and 19 mg/m^3. Five rats/group were sacrificed on the day after the nineth exposure while the remaining five rats/group were sacrificed after an exposure-free recovery period of approximately 2 weeks.

Marked respiratory distress and signs suggestive of respiratory tract irritation as well as associated non-specific effects occurring at 19 mg/m^3. In this group, mortality occurred towards the end of the exposure period and body weights were significantly decreased.

Histopathology revealed epithelial lesions at all levels of the nasal cavity at 4.8 mg/m^3 and above while borderline focal inflammatory infiltrates occurred at the proximal nasal cavity at 1.1 mg/m^3. Laryngeal epithelial alterations were noticed at all levels of exposure concentration of the test substance. Animals exposed at concentrations of 1.1 mg/m^3 and above showed epithelial hypertrophy in the trachea and was associated with increased incidence of inflammatory infiltrates and hypercellularity/hypertrophy in the bronchiolo-alveolar airways. The bronchus-associated-lymphoid tissue (BALT) was more prominent at 1.1 mg^3 and above. Following a recovery period of approximately 2 weeks, the more pronounced changes were still noticeable, but all effects showed a clear tendency of recovery.

The no-observed-adverse-effect concentration (NOAEC), without consideration of the effects on larynx, was considered to be 0.19 mg/m^3. However, considering the minimal to slight

changes of the ventral aspects of the larynx, which were typical for adaptive response to irritation, the NOAEC was below 0.19 mg/m^3.

In a subchronic toxicity study, Wistar rats (10 rats/sex/dose) were exposed to the aerosolised test substance in Plexiglas exposure restrainers providing a nose-only exposure for 13 weeks (6 hours/day, 5 days/week). The mean actual breathing zone concentrations (gravimetric) were 0.065, 0.25, 1.02 and 3.96 mg/m^3. Rats exposed to air under otherwise identical test conditions served as a concurrent control group. Additional 10 male and 10 female rats were exposed in the air control and high dose exposure groups and were allowed to recover during a 4-week post-exposure period.

Clinical effects were not observed in rats exposed to the test substance up to and including 1.02 mg/m^3. At 3.96 mg/m^3, animals displayed respiratory tract irritation responses, such as bradypnea, irregular and laboured breathing patterns, dyspnoea, breathing sounds, stridor, nasal discharge (serous), red encrustations of nostrils and eye lids, reduced motility, limp, high-legged gait, cyanosis, piloerection, haircoat ungroomed, and bloated abdomen. Lung weights were significantly increased at 1.02 and 3.96 mg/m^3 and significantly increased heart weights were also noted in female rats exposed at 3.96 mg/m^3. The elevations in organ weights were not reversible with the 4-week post-exposure period.

Minimal to slight histopathological findings observed in the nasal cavities, pharynx, larynx, trachea and lungs of rats exposed at 1.02 and 3.96 mg/m^3 after 13 weeks of exposure. As there is an apparent equal susceptibility of regions with respiratory epithelium and olfactory epithelium, this lack of specificity supports a non-specific irritant mechanism. In the lungs, bronchiolo-alveolar hypercellularity, minimal septal thickening, inflammatory infiltrates and increased alveolar macrophages with foamy appearance were noted.

After 4 weeks of recovery, minimal or slight degeneration in the nasal cavities and/or atrophy of the olfactory epithelium were still apparent in all rats from the high dose group (3.96 mg/m^3). Additionally, unusual nerve-like structures were obvious in the epithelium and neuronal degeneration of nerve bundles was detected in the lamina propria. In the lungs, minimal hypercellularity of the bronchiolo-alveolar region, increased macrophages, and an increased incidence of minimal inflammatory infiltrates were still present. Histopathological findings of the pharynx, larynx, and trachea recovered completely, and respiratory tract lesions were not apparent in male and female rats at 1.02 mg/m^3.

Under the conditions of this study and according to the test guideline, a no-observed-adverse-effect-concentration (NOAEC) was determined to be 0.25 mg/m^3, based on effects related to respiratory tract irritation (supporting the classification for respiratory irritation Cat 2). In addition, significantly increased lung weights at 1.02 and 3.96 mg/m^3 and significantly increased heart weights at 3.96 mg/m^3 (female rats) were also noted. The elevations in organ weights were not reversible with the 4-week post-exposure recovery period, warranting classification for specific target organ toxicity (repeated exposure) Category 2.

Genotoxicity

The test substance used in all genotoxicity testing is the same analogue chemical.

In vitro

The analogue chemical was not mutagenic in the bacterial Reverse Mutation Assay (Ames Test) when tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, with or 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 dose (8, 40, 50, 100, 200, 400, 800, 1,000, 5,000 µg/plate), with or without metabolic activation (S9-mix).

In another bacterial Reverse Mutation Assay (Ames Test) conducted according to Japanese guidelines, the analogue chemical revealed no mutagenic activity in the absence and in the presence of a metabolic activation system with the *S. typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 as well as *E. coli* strain WP2uvrA. The analogue chemical was tested at 20, 50, 100, 200, 500, 1,000, 2,000, 5,000 µg/plate (TA 100, TA 1535, WP2uvrA) and at 10, 20, 50, 100, 200, 500, 1,000, 2,000 µg/plate (TA 98, TA 1537, TA 1538).

An *in vitro* study was performed to assess the potential of an analogue chemical for point mutagenic effects at the hypoxanthine-guanine phosphoribosyl transferase (HPRT) locus (forward mutation assay) on cultured mammalian cells (Chinese hamster V79 cells) in both the absence and presence of S9 mix (OECD TG 476) (5 hours exposure, 6 days expression time and 6 to 8 days selection time). As precipitation occurred in the medium at 48 µg/mL concentration and above and a concentration-related cytotoxicity decreases were also observed, the results were only calculated at and up to 60 µg/mL. The analogue chemical, with and without metabolic activation, induced statistically significant increases in mutant frequencies. The analogue chemical was mutagenic in the V79/HPRT Forward Mutation Assay, both with and without metabolic activation.

The clastogenic potential of the analogue chemical was assessed in Chinese hamster lung V79 cells in vitro, both in the absence and the presence of S9 mix (OECD TG 473). Three independent experiments were conducted. Concentrations of 9, 18, and 42 µg/mL were tested without S9 mix and concentrations of 6, 12, and 24 µg/mL were tested with S9 mix. Precipitation in the medium occurred in the absence of S9 mix at 36 µg/mL and above and in the presence of S9 mix at 30 µg/mL and above. Cultures treated with the analogue chemical showed biologically relevant and statistically significant increased numbers of aberrant metaphases, starting at 18 µg/mL in the absence of S9 mix and at 12 µg/mL in the presence of S9 mix. Thus, under the experimental conditions described in this study and according to the test guideline, the analogue chemical is clastogenic in vitro for mammalian cells.

In vivo

The analogue chemical 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). Male Crl: NMRI BR mice (5 animals/dose) were exposed to the aerosolized test substance in Plexiglas exposure restrainers providing a nose-only exposure for 6 hours at breathing concentrations of 5, 25, 50, and 70 mg/m^3. No mortality was observed at any dose level tested.

Under the conditions of this study, the analogue chemical did not induce any statistically significant increases in the frequency of cells with micronuclei in polychromatic erythrocytes (PCEs) in bone marrow as there was no alteration in the ratio between polychromatic and normochromatic erythrocytes, indicating that the analogue chemical was not clastogenic. Even though the presence of the analogue chemical was not demonstrated in the bone marrow, it is stated that a dose of 93 mg/m^3 is in the range of lethal threshold concentration. Therefore, based on lethality at 93 mg/m^3, it is likely that the analogue chemical would have reached the bone marrow at the maximum used concentration of 70 mg/m^3. Under the conditions of this study, it can be concluded that the analogue chemical was not clastogenic.

It is noted that the analogue chemical was negative in bacterial Reverse Mutation Assays and positive in point mutagenic effects at the HPRT locus (forward mutation assay) and also in

Chinese hamster lung V79 cells *in vitro*. The analogue chemical was negative for clastogenicity in *in vivo* assay in bone marrow of mice.

Considering the negative *in vivo* assay in mice, the analogue chemical is not considered to be genotoxic.

Environmental exposure

The assessed polymer will be imported neat into Australia for use in the manufacture of articles. The assessed polymer will not be reformulated or repackaged in Australia. Significant releases of the assessed polymer from transport or transfer are not expected. If spills or accidental releases of the assessed polymer do occur, they are expected to be collected by suitable absorbents and disposed of, in accordance with State and local government regulations.

The assessed polymer will be used in the manufacture of articles at industrial sites. The assessed polymer will be mixed with other components, automatically dispensed to moulds, and allowed to cure. Once cured into the matrix of the article, there will be limited exposure to the aquatic environment. The assessed polymer is expected to share the fate of the article it is incorporated into and be disposed of to landfill at the end of its useful life. The assessed polymer is expected to eventually degrade by biotic and abiotic processes in landfill, or by thermal decomposition, to form water and oxides of carbon and nitrogen.

Environmental fate

Partitioning

The assessed polymer is slightly to moderately soluble in water and if released into the environment, it is expected to partition to soils and sediments based on its high molecular weight (NAMW > 1,000 g/mol). This is supported by calculated partition coefficient (Log K_{ow} > 11) and adsorption/desorption values (log K_{OC} > 6) for representative components of the polymer.

Degradation

No information about the biodegradation of the assessed polymer is available. The assessed polymer is expected to be stable but will eventually degrade to simpler molecules. The assessed polymer is stable to hydrolysis, based on a screening study.

Bioaccumulation

The assessed polymer has a high molecular weight (NAMW > 1,000 g/mol) and is not expected to be bioavailable. Therefore, the assessed polymer is not expected to bioaccumulate based on its low bioavailability.

Predicted environmental concentration (PEC)

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

Environmental effects

Effects on aquatic Life

Acute toxicity

The following lethal loading (LL50), effective loading (EL50) and effective concentration (EC50) values for model organisms were supplied by the applicant for an acceptable analogue chemical:

Taxon	Endpoint	Method
Fish	96 h LL50 > 100 mg/L	*Danio rerio* (Zebra fish) Mortality OECD TG 203 Static conditions Nominal concentration
Invertebrate	48 h EL > 100 mg/L	*Daphnia magna* (Water flea) Immobility OECD TG 202 Static conditions Nominal concentration
Algae	72 h ErC50 = 8.744 mg/L	*Desmodesmus subspicatus* (Green Algae) Growth rate OECD TG 203 Static conditions Geometric mean Measured concentration

Chronic toxicity

The following measured 10th-percentile effective concentration (EC10) value for was supplied by the applicant for an acceptable analogue chemical:

Taxon	Endpoint	Method
Algae	72 h ErC10 = 0.512 mg/L	*Desmodesmus subspicatus* (Green Algae) Growth rate OECD TG 203 Static conditions Geometric mean measured concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 87.4 µg/L was calculated for the assessed polymer in the aquatic environment. This value was derived using the most conservative acute endpoint value for algae (8.744 mg/L). An assessment factor of 100 was applied to this endpoint as acute toxicity data was available for three trophic levels and chronic toxicity data was incomplete (EPHC, 2009). The acute endpoint was selected, over the algal chronic endpoint, in the absence of additional chronic endpoints to support the algal growth rate NOEC (ECHA 2008).

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). No information about the degradation of the assessed polymer was available. Based on its assumed stability, and lack of demonstrated degradation, the assessed polymer is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on its expected low bioavailability (NAMW > 1,000 g/mol), the assessed polymer is categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available acute ecotoxicity values above 1 mg/L and ErC10 greater 0.1 mg/L for algae, the assessed polymer is categorised as Not Toxic.

Environmental risk characterisation

Although the assessed polymer is persistent, it does not meet all three PBT criteria and is hence unlikely to have unpredictable long-term effects (EPHC 2009). The Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as significant release of the assessed polymer to the aquatic environment is not expected based on its assessed use pattern.

Therefore, based on the hazard profile and limited exposure from the assessed use pattern, the environmental risk from the assessed polymer can be managed within existing frameworks.

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