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

Carbamic acid, *N*,*N*′-1,6-hexanediylbis-, *C*,*C*′-bis[2-[2-(1-ethylpentyl)-3-oxazolidinyl]ethyl] ester

Assessment statement (CA09977)

1 October 2025

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AICIS assessment (CA09977)

Chemical in this assessment

Name	CAS registry number
Carbamic acid, *N*,*N*′-1,6-hexanediylbis-, *C*,*C*′-bis[2-[2-(1-ethylpentyl)-3-oxazolidinyl]ethyl] ester	140921-24-0

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 Focus type.

Defined scope of assessment

The chemical has been assessed:

- as imported into Australia at up to 200 tonnes/year in neat form or as a component of coating, adhesive and sealant end use products at 20% concentration
- for reformulation of the neat form into coating, adhesive and sealant end use products
- for end use in coating, adhesive and sealant products at concentration up to 20% by professional workers only

Summary of assessment

Summary of introduction, use and end use

The assessed chemical will not be manufactured in Australia. It will be imported into Australia at up to 200 tonnes per annum. It will be imported in neat form in containers such as 25 L plastic pails and 200 L plastic drums, and then reformulated into coating, adhesive and sealant end use products at up to 20% concentration. It will also be imported as a component in finished coating, adhesive and sealant end use products at up to 20% concentration. The end use coating, adhesive and sealant products in a variety of packages ranging from 0.025 L cartridges or cans to up to 200 L drums will be used by professional workers only.

Human health

Summary of health hazards

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

- of low acute oral toxicity (LD50 > 2,000 mg/kg bw in rats)

- of low acute dermal toxicity (LD50 > 2,000 mg/kg bw in rats)
- non-irritating to the skin
- slight irritating to the eyes
- a skin sensitiser
- unlikely to be clastogenic (see below)

In an in vitro hypoxanthine-guanine phosphoribosyl transferase (HPRT) assay using Chinese hamster ovary (CHO) cell line (OECD TG 476), the assessed chemical showed positive results in the presence of metabolic activation at concentrations ≥ 350 µg/mL, indicative of mutagenic potential. However, 3 other studies, including a bacterial reverse mutation assay (OECD TG 471), an in vivo mammalian erythrocyte micronucleus test (OECD TG 474) and an in vivo mammalian alkaline comet assay (OECD TG 489), did not reveal genotoxicity for the assessed chemical. Based on studies provided, the assessed chemical is unlikely to be clastogenic. However, its potential to cause gene mutations in mammalian cells cannot be ruled out with metabolic activation as indicated by the HPRT assay using CHO cell line.

In a repeated dose oral toxicity study (OECD TG 407), the assessed chemical was tested in rats by oral gavage for 29 days at dose levels of 0, 40, 200 and 1,000 mg/kg bw/day. The study authors reported the NOAEL as 200 mg/kg bw/day. However, increased mean kidney weights were reported in females treated at all dose levels (statistically significant only at high dose) and reduced urine volumes and increased urine density at 200 mg/kg bw/day (see **Supporting Information**). There were no histopathological changes related to treatment.

In a one-generation reproductive toxicity study via oral route in rats, the assessed chemical was tested at 0, 100, 300 and 1,000 mg/kg bw/day. A NOAEL of 1,000 mg/kg bw/day was established for reproductive and developmental toxicity.

No acute or repeated dose inhalation toxicity data were provided.

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.

Hazards	Hazard category	Hazard statement
Flammable liquids*	Cat. 4	H227: Combustible liquid
Skin sensitisation	Skin Sens. 1B	H317: May cause an allergic skin reaction

* Based on measured flash point of the chemical (see **Supporting information**)

Summary of health risk

Public

End use coating, adhesive and sealant products containing the assessed chemical will not be available for use by the public. As the end use products will be cured following professional applications, the assessed chemical will be bound within the dried matrix and is not expected to be available for exposure by the public. Therefore, 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 require specific risk management measures.

Workers

Potential exposure of workers to the assessed chemical at up to 100% concentration may occur during reformulation operations and at up to 20% concentration during professional end use applications of coating, adhesive and sealant products. The end use products may be applied by spray, roller, trowel, caulking gun or other applicable methods. The principal route of exposure to the chemical will be dermal, while ocular and inhalation exposures are also possible especially when the products are applied by spray.

Given the skin sensitisation risk of the assessed chemical for workers, control measures to minimise dermal exposure are needed to manage the risk to workers during reformulation and end use applications (see **Means for managing risk**). Control measures to minimise ocular and inhalation exposure may be also needed if aerosols or mists are formed during reformulation or spray application of the end use products containing the assessed chemical.

Environment

Summary of environmental hazard characteristics

According to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022) and based on the available data the chemical is:

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

Environmental hazard classification

The chemical satisfies the criteria for classification according to the GHS (UNECE 2017) as Acute Category 3 (H402) and Chronic Category 3 (H412) based on the toxicity data for aquatic organisms. Considerations were also made for the degradation and bioaccumulation potential of the assessed chemical.

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 3	H402: Harmful to aquatic life
Hazardous to the aquatic environment (long-term)	Aquatic Chronic 3	H412: Harmful to aquatic life with long lasting effects

Summary of environmental risk

The assessed chemical will be introduced as a neat liquid form for reformulation into finished coatings, adhesives and sealants at up to 20% concentration for use in the industrial settings. The assessed chemical will also be imported as a component of the finished coatings, adhesives and sealants up to 20% concentration.

No significant release of the assessed chemical is expected to occur as a result of its use in industrial coatings, adhesives and sealants. The assessed chemical is expected to share the

fate of the articles it is incorporated into and be disposed of to landfill at the end of its useful life.

The assessed chemical is not readily biodegradable and is considered to be persistent. The assessed chemical has no potential for bioaccumulation and is not toxic to aquatic organisms based on data supplied for three trophic levels.

According to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022), the assessed chemical is persistent, but it does not meet all three PBT criteria. It is unlikely to have unpredictable long-term effects in the environment. Based on the low hazard and low exposure, the environmental risk from the introduction of 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:

- Use of engineering controls such as
  - Enclosed and automated systems where possible during reformulation
  - Adequate workplace ventilation to avoid accumulation of mists or aerosols
- Use of safe work practices to
  - Avoid contact with skin and eyes
  - Avoid inhalation of mists or aerosols
- Use of personal protective equipment (PPE)
  - Impervious gloves
  - Protective clothing
  - Respiratory protection where formation of mists or aerosols is possible
- Spray coating applications should be carried out in accordance with the *Safe Work Australia Code of Practice for Spray Painting and Powder Coating* (SWA 2020) or relevant State or Territory Code of Practice.
- 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.
- As the assessed chemical is a skin sensitiser, the 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:

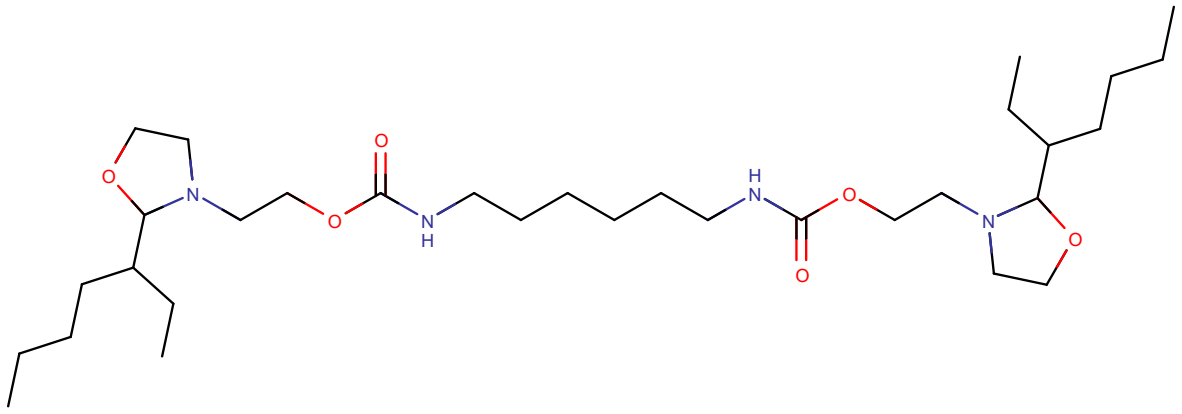
1. Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.
2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

CAS number	140921-24-0
CAS name	Carbamic acid, *N*,*N*′-1,6-hexanediylbis-, *C*,*C*′-bis[2-[2-(1-ethylpentyl)-3-oxazolidinyl]ethyl] ester
Molecular formula	$C_{32}H_{62}N_4O_6$
Associated names	*C*,*C*′-Bis[2-[2-(1-ethylpentyl)-3-oxazolidinyl]ethyl] *N*,*N*′-1,6-hexanediylbis[carbamate]
Molecular weight (g/mol)	598.86
SMILES (canonical)	O=C(OCCN1CCOC1C(CC)CCCC)NCCCCCCNC(=O)OCCN2CCOC2C(CC)CCCC

Representative structure



Additional chemical identity information

The assessed chemical is a mixture of diastereomers with a combined purity above 94.5%.

Relevant physical and chemical properties

Physical form	Amber liquid
Melting point	Becoming glassy when cooled down to -25°C
Boiling point	207.6°C at 101.3 kPa
Density	1,029.3 kg/m^3 at 20 °C
Vapour pressure	< 10^{-6} kPa at 20 and 25 °C

Water solubility	1.6795 mg/L at 25 °C
Flash Point	70 °C at between 100.6 and 102 kPa
Autoignition Temperature	330 °C
Ionisable in the environment	No
pK_a	Not applicable
log K_{ow}	-1.03

Health hazard information

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 401), a single dose of the assessed chemical was administered via oral gavage to Wistar rats (n = 5/sex) at 2,000 mg/kg bw. All test animals survived during the 14-day observation period. All males and 1 female exhibited rough coat as a sign of intoxication after the treatment. Two males also showed increased salivation and apathy. The signs appeared approximately half an hour after the treatment, were of slight to moderate intensity, and persisted up to 24 hours. There were no noticeable gross pathological findings. Growth of the animals was not affected by the treatment.

The acute oral median lethal dose (LD50) value for the assessed chemical was determined to be greater than 2,000 mg/kg bw in rats. Therefore, the assessed chemical is of low acute oral toxicity.

Dermal

In an acute dermal toxicity study (similar to OECD TG 402), the assessed chemical was applied under semi-occlusive conditions to the skin of Wistar rats (n = 5/sex) at 2,000 mg/kg bw for 24 hours. The animals were observed for 14 days after the application. All animals survived during the observation period. No local skin effects were observed and no clinical signs related to treatment were noted. All animals sacrificed at the end of the test were pathologically and anatomically unremarkable. Growth of males was not impacted. Some females showed a temporary decrease or stagnation in body weight gain.

The acute dermal LD50 of the assessed chemical was determined to be greater than 2,000 mg/kg bw in rats. The assessed chemical is of low acute dermal toxicity.

Corrosion/Irritation

Skin irritation

In a skin irritation study (OECD TG 404), 500 µL of the undiluted assessed chemical was applied under semi-occlusive conditions to the shaved skin of 3 New Zealand White female rabbits for 4 hours. The animals were observed for 7 days after the patch removal. There was

no irritation observed on the skin during the test. Under the conditions of this study, the assessed chemical was non-irritating to the skin.

Eye irritation

In an eye irritation study (OECD TG 405), 100 µL of the undiluted assessed chemical was instilled into the conjunctival sac of one eye of each of the 3 female New Zealand White rabbits and the animals were observed for 7 days. One hour after the treatment all 3 animals showed conjunctiva discharge, with 2 having slight moistening of periorbital areas and 1 having considerable moistening of periorbital areas. The effects were reversible within 24 hours. There was no other irritation effect on the eyes during the test. Under the conditions of this study, the assessed chemical was considered as slightly irritating to the eyes but does not meet the GHS criteria for classification.

Sensitisation

Skin sensitisation

In a skin sensitisation study conducted on the assessed chemical (OECD TG 406 - Guinea pig maximisation test), a group of 20 male guinea pigs (Bor:DHPW) were induced with the chemical at 5% concentration in propylene glycol by intradermal injection, with or without Freund's Complete Adjuvant (FCA). Three weeks after the injection, the animals were topically induced with the chemical at 100% concentration. One week after the topical induction, the animals were first challenged with the chemical at 100% concentration followed by a second challenge at 5% and 50% concentrations.

One animal in the test group was found dead on day 5 during the induction period. Skin lesions in some of the animals after the topical induction, including open wounds and scabbing, in both test and control groups were observed and most likely were caused by mechanical irritation when the patches were removed from the skin. However, these observations were not considered to have significant impact on the validity of the test results.

Reduced bodyweight in some test animals during the study indicated that the assessed chemical might have a mild systemic toxic effect. The first challenge at 100% concentration caused very mild skin reddening in 12 of 19 test animals (63% positive ratio). The second challenge caused very mild to clearly visible skin reddening and scaling in 12 animals (63% positive ratio) at 50% concentration and in 2 animals (11% positive ratio) at 5% concentration.

Based on the results, the assessed chemical is a skin sensitiser and requires classification according to the GHS criteria (Skin Sens. Cat. 1B).

Repeat dose toxicity

Oral

In a repeated dose oral toxicity study (OECD TG 407), the assessed chemical was administered to Wistar-Bor:WISW(SPF Cpb) rats (5/sex/dose) by oral gavage for 29 days at dose levels of 0, 40, 200 and 1,000 mg/kg bw/day using 1,2-propandiol as the vehicle. No animal died during the study.

No treatment related changes were observed in general behaviour and growth. The animals in the low and mid dose groups did not exhibit treatment related clinical signs. Administration of high dose caused scruffy fur. No changes were found in feed and water intake at up to 200

mg/kg bw/day. At high dose, feed intake was increased by an average of 18% in females and water intake was increased by an average of 15% in males and 22% in females. No statistically significant changes in bodyweight gain were observed in both sexes during the study period.

The results of haematological and histological investigations indicated treatment related effects in the blood or bone marrow in mid dose group males and low dose group females.

Statistically significant decrease (3%) in mean corpuscular volume erythrocytes was observed in mid and high dose group males. Statistically significant decreases in haemoglobin (6%), haematocrit (7%) and reticulocyte counts (29%), and statistically significant increase in thrombocytes (28%) were also noted in high dose group males. Statistically significant reduction (3%) in mean corpuscular haemoglobin concentration was also reported in high dose group females. Low and high dose group females had statistically significant increased aspartate aminotransferase (ASAT) (22% and 28% respectively). Increase (6%, not statistically significant) in ASAT was also observed in mid dose group females when compared to control group. Further, increased plasma protein (9%) and albumin (7%) and reduced creatine concentrations (10%) were observed in high dose group females. High dose group males showed reduced alanine aminotransferase (ALAT) (21%) and increased albumin (7%) concentrations. These findings in conjunction with the increased absolute and relative liver weights in high dose males (21%) and females (52%) were indicative of liver effects related to the treatment. However, there were no correlated histopathological findings in the liver.

High dose group had statistically significant changes in various clinical chemistry parameters. Increased phosphorus (17%) and calcium (6%), and decreased creatine (10%) levels were observed in females. Decreased levels of protein (68%) and protein volume (74%) were observed in males. Mid dose group also showed certain statistically significant changes in clinical chemistry parameters. Increased blood chlorine (2%) and decreased phosphorus (18%) levels were observed in males. Reduced urine volume (50%) and increased urine density were observed in females. As there was no dose response with the changes, the study authors reported them to have no toxicological significance.

Statistically significant reduction (12%) in mean absolute kidney weight was observed in low dose group males. High dose group females also showed statistically significant increase in mean absolute kidney weights (24%).

Males and females in high dose group showed statistically significant increase in mean absolute liver weights (21% and 52% respectively). Males in high dose group also showed increases in mean absolute adrenal gland weights (27%). However, haematological, clinical-chemical, organgravimetric, pathological-anatomical and histopathological investigations showed no evidence of associated damage to correlated organs and tissues.

The NOAEL was reported as 200 mg/kg bw/day in rats by the study authors as the observed changes in clinical chemistry parameters did not show a dose response and there were no histopathological changes related to the treatment. However, there were mean kidney weight increases observed in females in all treatment groups (statistically significant only at the high dose), with low urine volumes and increased density reported in mid dose females. Therefore, the NOAEL cannot be confirmed as 200 mg/kg bw/day in rats.

Genotoxicity

The assessed chemical was found to be non-mutagenic in a bacterial reverse mutation assay using *Escherichia coli* strain WP2uvrA with or without metabolic activation (S9-mix) (OECD TG 471). The assessed chemical was tested up to 5,000 µg/plate using plate incorporation and pre-incubation methods. The test results showed that inhibitory effect of the assessed chemical

on bacterial growth was observed at concentrations ranging from 1,600 to 5,000 µg/plate, indicative of potential cytotoxicity. No statistically significant increases in revertant colony numbers were noted following the treatment either in the presence or absence of S9-mix. However, sporadic increases in revertant colony numbers were observed in independently performed experiments. The study authors reported that there was no dose response associated with biological significance.

The assessed chemical tested positive in a HPRT assay using Chinese hamster ovary (CHO) cell line (OECD TG 476) in the presence of metabolic activation (S9-mix). However, no statistically significant increases of mutation frequency were observed in the absence of S9-mix. In an initial test, at the concentrations of 350, 400, 450 and 500 µg/mL, the assessed chemical caused statistically and biologically significant increases of the mutant frequency with dose response in the presence of S9-mix. Again, positive dose-response results were observed in a second test at concentrations of 400, 450 and 500 µg/mL with S9-mix. The assessed chemical was determined by the study authors to be mutagenic in this in vitro mammalian cell gene mutation test performed with CHO-K1 cells.

In a mammalian erythrocyte micronucleus test using mice/Bor:NMRI (SPF Han) (OECD TG 474), the assessed chemical was intraperitoneally administered at a single dose of 15 mg/kg bw. The test animals showed symptoms of toxicity after the administration of the chemical and 1/40 animals died during the study. No statistically significant increase of micronucleated polychromatic erythrocytes were noted after the treatment. Weak but relevant variations to the ratio of polychromatic to normochromatic erythrocytes were observed without statistically significant differences. The assessed chemical was found to be non-clastogenic.

In a mammalian alkaline comet assay (OECD TG 489), the assessed chemical was orally administered to rats at 500, 1,000 and 2,000 mg/kg bw /day for 2 days. The assessed chemical did not induce statistically significant increases in DNA strand breaks at any of the tested dose levels in liver or in stomach cells. A statistically significant decrease of DNA strand breaks was noticed at the 2,000 mg/kg bw/day, however, this was not considered by the study authors as biologically relevant. The assessed chemical was found to be non-genotoxic in the study.

Based on the above genotoxicity studies provided, the assessed chemical is unlikely to be clastogenic. However, its potential to cause gene mutations in mammalian cells cannot be ruled out with metabolic activation as indicated by the HPRT assay using CHO cell line.

Reproductive and development toxicity

In a reproduction/developmental toxicity screening study (OECD TG 421), female and male rats (Hsd.Brl.Han:Wistar) (n = 12/sex/dose) were administered the assessed chemical by oral gavage at 0, 100, 300 and 1,000 mg/kg bw/day. The test animals were dosed once daily for 14 days prior to mating. Then the males were dosed up to the day before the necropsy (a total of 41 days) and the females were dosed through the gestation period and up to lactation days 3 or 4 before the necropsy (a total of 41 to 44 days).

For parental animals, there was no treatment related mortality at any dose level.

Adverse signs of systemic toxicity related to treatment were not noted, and the behavioural and physical conditions of the animals were not impaired at any dose level during the study.

The mean body weight gain of male animals in high dose group was lower during the treatment period with reduced food consumption. However, this change was not associated with significant changes in the mean body weight. Mean body weight gain of pregnant females in

high dose group between gestation day 0 and 7 was statistically significantly reduced ($p < 0.01$). It was considered as biological variation by the study authors.

Number of fertile males was statistically significantly reduced in low and high dose groups, hence the reduction of male fertility index. Similar results were observed in females where non-pregnant females were statistically significantly increased in low and high dose groups, hence the reduction of female pregnancy index. However, no such reproductive index reductions were observed in the mid dose group. There was no associated dose response, and the fertility indices were within the historical control ranges of both sexes.

In 1 male of the low dose group (1/2), decreased intensity of spermatogenesis in the testes and lack of spermatozoa in the ductuli of epididymides (both sides) were observed. The study authors indicated that these findings were common in rats of this strain with similar age and not considered as toxicologically relevant as similar changes were not detected at the higher doses where 12 males were tested.

There were no treatment related differences between the control and treatment groups in delivery data of dams, and in the reproductive performance of males and females. There were no specific macroscopic alterations related to the treatment at necropsy. No treatment related changes in brain, testes and epididymides weights in males were observed. Histopathological examinations of male and female genital organs, including ovaries, testes and epididymides, did not reveal treatment related changes.

Litter weight gain in mid and high dose groups was statistically significantly reduced. The study authors indicated that the changes were well within the historical control ranges. No treatment related adverse findings on offspring development, mortality, sex distribution, clinical signs and body weight at necropsy, were noted at termination.

The NOAEL for F0 systemic toxicity, F0 reproductive performance, and F1 offspring is considered to be 1,000 mg/kg bw/day, based on no treatment related adverse effects observed at the highest dose tested.

Environmental exposure

The assessed chemical will be imported into Australia as a neat liquid for reformulation into finished coatings and adhesives/sealants or as a component of finished products up to 20% concentrations. Reformulated and imported finished products will be used in industrial settings only. During reformulation, the assessed chemical will be transferred into a mixing vessel for blending with other additives and/or solvents. The reformulation processes will be enclosed and automated. Release of the assessed chemical is only expected to occur from accidental spills during the transport, storage and product transfer stages. Accidental spills and wastes generated during the reformulation process are expected to be collected and disposed of in accordance with local government regulations.

Coatings, adhesives and sealants containing the assessed chemical will be used by professional workers in industrial settings only and not by do-it-yourself (DIY) users. The coatings, adhesives and sealants may be applied to the surface or cavities by spray gun, brush or roller. After application, the assessed chemical is not expected to be released to the environment once it cured into a solid matrix. The assessed chemical is expected to share the fate of the product it is incorporated into and be disposed of to landfill at the end of its useful life.

During professional use, release of the chemical may occur through overspray and accidental spills. Incidental releases are expected to be collected for appropriate disposal. Wastes and residues in empty containers are expected to be collected and disposed of by incineration by the approved agent or disposed of to landfill according to local government regulations.

Environmental fate

Partitioning

Based on measured hydrolysis data, the assessed chemical is expected to hydrolyse rapidly.

A preliminary hydrolysis study on the assessed chemical (OECD TG 111) showed immediate, rapid hydrolysis, forming insoluble products. Therefore, if the assessed chemical is released to water, it is expected to stay in water only transiently, resulting in the formation of products which will partition to soils and sediment and become immobile.

Degradation

Based on the measured biodegradation in water, the assessed chemical is not readily biodegradable and is expected to form persistent degradants.

A supplied biodegradation study for the assessed chemical conducted according to EC Directive 79/831 EEC Annex V demonstrated 43% degradation of the assessed chemical over 28 days with an observed plateau. Therefore, as the chemical is hydrolytically unstable, the major hydrolysis products are expected to be stable in water.

Bioaccumulation

Based on its log K_{ow} value, the assessed chemical does not have the potential to bioaccumulate.

No bioaccumulation information was provided for the assessed chemical. The experimental partition coefficient of the assessed chemical (log K_{ow} = -1.036) is below the domestic bioaccumulation threshold of log K_{ow} = 4.2 (DCCEEW 2022).

Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) has not been calculated as the assessed chemical is not released into environmental waters under the assessed use.

Environmental effects

Effects on Aquatic Life

Acute toxicity

The following nominal lethal concentration (LC50) and median effective concentration (EC50) values for model organisms were supplied for the assessed chemical:

Taxon	Endpoint	Method
Fish	96 h LC50 = 316 mg/L	*Brachydanio rerio* (Zebrafish) Federal Environment Agency, Berlin, ISO SOP 4.002 Static conditions Nominal concentration
Invertebrate	48 h EC50 = 193 mg/L	*Daphnia magna* (Water flea) Immobility/other effect EEC 67/548 draft 1992 C.2 Method (SOP 4.004) Static conditions Nominal concentration
Algae	72 h ErC50 = 43 mg/L	*Desmodesmus subspicatus* (Freshwater algae) Growth rate/other effect EEC Part C, Method 3 Static conditions Nominal concentration
Microorganisms	EC50 = 1,770 mg/L	Activated sludge, Respiration inhibition, ISO 8192 -1986, Nominal concentration

Chronic toxicity

The following no-observed-effect concentration (NOEC) value of the assessed chemical for the model organism was provided by the applicant:

Taxon	Endpoint	Method
Algae	NOErC = 12.5 mg/L	*Desmodesmus subspicatus* (Freshwater algae) Growth rate/other effect EEC Part C, Method 3 Static conditions Nominal concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 430 µg/L was calculated for the assessed chemical in the aquatic environment. This value was derived using the most conservative endpoint value for algae (43 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 chemical according to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022) is presented below:

Persistence

Persistent (P). Based on the measured biodegradation study, the assessed chemical is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on low measured log K_{ow} value, the assessed chemical is categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available ecotoxicity values above 1 mg/L and evidence of low chronic toxicity, the assessed chemical is categorised as Not Toxic.

Environmental risk characterisation

The assessed chemical 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 release of the assessed chemical to the aquatic environment is not expected based on its assessed use pattern.

Therefore, based on the low toxicity, expected low bioavailability and limited environmental exposure from the assessed use pattern, the risk from the assessed chemical can be managed.

References

DCCEEW (2022), Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals, DCCEEW, accessed 20 February 2025.

ECHA (European Chemicals Agency) (2008), Guidance on information requirements and chemical safety assessment, Chapter R.10: Characterisation of dose [concentration]-response for environment, accessed 24 March 2022

EPHC (2009), Environment Protection and Heritage Council, Environmental Risk Assessment Guidance Manual for industrial chemicals, Prepared by: Chris Lee-Steere Australian Environment Agency Pty Ltd, February 2009. ISBN 978-1-921173-41-7

SWA (Safe Work Australia) (2020), Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, Accessed 12 March 2025

SWA (Safe Work Australia) (2023), Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, Accessed 12 March 2025

UNECE (United Nations Economic Commission for Europe) (2017), Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition. Accessed 20 February 2025