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

# Morpholine, 4-$C_{x-y}$-alkyl derivs.

## Assessment statement (CA10135)

**23 April 2026**

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# AICIS assessment (CA10135)

## Chemical in this assessment

| AICIS Approved Chemical Name (AACN) |
| --- |
| Morpholine, 4-$C_{x-y}$-alkyl derivs. |

## 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 225 tonnes/year
- as imported at up to 100% concentration for industrial use only as an extraction agent in mining
- with no direct release to natural waterways, municipal water supplies, or municipal sewerage systems.

## Summary of assessment

### Summary of introduction, use and end use

The assessed chemical will not be manufactured or repackaged in Australia. It will be imported into Australia as a liquid at up to 100% concentration in 200 L drums or 1,000 L intermediate bulk containers for industrial use only. The containers of the assessed chemical will be directly transported from the port to the end-use industrial mining facilities by road. At the end use sites, the assessed chemical will be blended with other reagents as part of the extraction process.

The assessed chemical will only be used as an extraction agent in industrial mining facilities. There will be no consumer use of the assessed chemical.

### 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 dermal toxicity (median lethal dose (LD50) > 2,000 mg/kg bw in rats)
- a slight eye irritant
- not a skin sensitiser
- not likely to be genotoxic

The toxicological information also indicates that the assessed chemical is:

- harmful if swallowed (200 mg/kg bw < LD50 < 2,000 mg/kg bw in rats)
- a skin irritant

The assessed chemical was negative for skin corrosion and skin irritation in two in vitro assays according to the criteria specified in the test guidelines (OECD TG 431 and OECD TG 439). However, in an in vivo study in rabbits, well-defined erythema and slight to very slight oedema was observed. Other skin reactions noted were moderate desquamation, loss of skin elasticity, glossy skin, and superficial cracking of the epidermis. Based on the in vivo results, the assessed chemical is classified as a skin irritant according to the GHS criteria (Category 2; H315: Causes skin irritation). Irritant effects of the assessed chemical were also observed in the acute dermal toxicity study and repeat dose toxicity study, further supporting classification of the assessed chemical as a skin irritant.

In a 90-day repeat dose oral toxicity study in rats, the no observed adverse effect level (NOAEL) was determined as 300 mg/kg bw/day. AICIS notes that local, adverse changes observed in these animals were mainly due to the local irritant properties of the assessed chemical rather than the systemic toxicity.

In a prenatal developmental toxicity study, the NOAEL for maternal toxicity and developmental toxicity was established to be the highest tested dose (100 mg/kg bw/day). AICIS notes that adverse irritation effects were observed in 4/22 females and one female was sacrificed due to ill health at 100 mg/kg bw/day. These effects were mostly limited to forestomach, stomach or gastrointestinal tract and were due to local irritation related effects and not due to systemic toxicity of the assessed chemical.

No acute or repeated dose inhalation 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 |
|---|---|---|
| Acute toxicity - oral | Acute Tox. 4 | H302: Harmful if swallowed |
| Skin irritation | Skin Irrit. 2 | H315: Causes skin irritation |

### Summary of health risk

**Public**

The assessed chemical is for industrial use only and 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 chemical.

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

**Workers**

Potential exposure of workers to the assessed chemical in liquid form at up to 100% concentration may occur during transfer processes at end-use industrial mining sites (see **Supporting information**). The principal route of exposure will be dermal, while ocular and inhalation exposures are also possible. According to the applicant, worker exposure will be minimised using automated transfer systems via metering pumps and automated enclosed systems contained within a bunded area for extraction processes. The applicant has also indicated that in addition to engineering controls, it is mandatory for workers to wear personal protective equipment (PPE) such as protective clothing and footwear, impervious gloves, and goggles.

Given the risk of critical health effects (acute oral toxicity and skin irritation) of the assessed chemical, control measures to minimise oral and dermal exposure are needed to manage the risk to workers (see **Means for managing risk**).

## 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 assessed chemical is:

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

### Environmental hazard classification

The assessed chemical satisfies the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) as Acute Category 1 (H400) and Chronic Category 1 (H410) based on the toxicity data for aquatic organisms. Considerations were also made for the degradation and bioaccumulation of the assessed chemical.

| Environmental Hazard | Hazard Category | Hazard Statement |
|---|---|---|
| Hazardous to the aquatic environment (acute / short-term) | Aquatic Acute 1 | H400: Very toxic to aquatic life |
| Hazardous to the aquatic environment (long-term) | Aquatic Chronic 1 | H410: Very toxic to aquatic life with long lasting effects |

### Summary of environmental risk

The assessed chemical will be introduced as an extraction agent in mining. This use will not result in release of the assessed chemical into the environment as the assessed chemical is expected to be stored, used and disposed of in on-site bunded areas and managed in accordance with relevant Local, State, Territory and Federal regulations.

The assessed chemical is readily degradable and is not persistent. The assessed chemical has the potential to bioaccumulate and is toxic to aquatic organisms.

No significant release of the assessed chemical to the environment is expected from the assessed use. Therefore, when the assessed chemical is used and disposed of in accordance with the defined scope of the assessment, and relevant state, territory and federal regulations as well as recommendations on the environmentally safe storage, handling and containment, use and disposal of industrial chemicals, it is expected that the environmental risk from the introduction of the assessed chemical can be managed.

# Means for managing risk

## Workers

### 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 blending and end use:

- Use of engineering controls such as
  - Enclosed and automated systems where possible
- 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 local ventilation may be inadequate or where aerosol or mist exposure is possible
- 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.
- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

## Transport

The information in this statement should be considered in the context of the ADG Code in conjunction with relevant state or territory legislation when transporting the assessed chemical by road or rail at concentrations that are hazardous to the environment according to the classification criteria of the ADG Code.

# 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

| | |
|---|---|
| **AACN** | Morpholine, 4-$C_{x-y}$-alkyl derivs. |

**Additional chemical identity information**

The assessed chemical is a chemical of unknown or variable composition, complex reaction product or biological material (UVCB).

## Relevant physical and chemical properties

| | | |
|---|---|---|
| **Physical form** | liquid | |
| **Melting point** | -8 | °C |
| **Density** | 870 | kg/m$^3$ at 20 °C |
| **Vapour pressure** | 0.00018 | kPa at 20 °C |
| **Water solubility** | 0.0015 | g/L at 20 °C, pH 8 |
| **Flash point** | 100 | °C |
| **Auto-ignition point** | 245 | °C |
| **Ionisable in the environment** | No | |
| **Surface tension** | 69 | mN/m at 25°C, pH 7 |
| **p$K_a$** | 7.8-8.02 (calculated) | |
| **log $K_{ow}$** | 3.9-4.3 | |
| **log $K_{oc}$** | 4.2-5.0 (major component 1)<br>4.7-5.8 (major component 2) | |

## Human exposure

### Workers

Prior to blending with other reagents at the end use sites, the assessed chemical is metered via metering pumps into a fixed location at the extraction cells. Workers will open the imported containers, connect hoses and pumping equipment, then pump the assessed chemical into an onsite blending tank. Dosing of the solutions into the process feed will be automated via fixed pipes minimising the potential for exposure. The blending system is fully enclosed, and the assessed chemical is contained within suitable and appropriately designed tanks, pumps and

pipework. Blending is contained within a bunded area. The required extraction product is partitioned into froth in the extraction cells and carried by a conveyor to an outdoor stockpile.

Workers are not expected to be exposed to the assessed chemical except in the case of an accident involving spillage. According to the applicant, in addition to the engineering controls, all workers wear mandatory personal protective equipment (PPE) such as protective clothing and footwear, impervious gloves, and goggles which will reduce worker exposure during the operation process.

# Health hazard information

## Acute toxicity

### Oral

In a non-guideline acute oral toxicity study, the assessed chemical was administered in olive oil via oral gavage to two separate groups of Wistar rats (n = 3/sex/group) at 200 mg/kg bw and to one group of female Wistar rats (n = 3/group) at 2,000 mg/kg bw. The animals were observed for 14 days after administration.

At the 200 mg/kg bw, there were no deaths and no clinical signs of toxicity. All animals showed expected gains in body weight. At the 2,000 mg/kg bw, all three females were found dead within 2 days following administration. Clinical signs indicative of systemic toxicity consisted of dyspnoea, piloerection, apathy, ataxia, tremor, twitching, exsiccosis, shaking, and chromodacryorrhea were observed prior to death. No macroscopic findings were recorded at necropsy. The acute oral median lethal dose (LD50) value for the assessed chemical was determined to be between 200 and 2,000 mg/kg bw. Therefore, the assessed chemical is classified as harmful if swallowed (Category 4, H302: Harmful if swallowed) according to GHS criteria.

### Dermal

In an acute dermal toxicity study (OECD TG 402), a group of ten Wistar rats (n = 5/sex/group) received a single dermal dose of the assessed chemical (24-hour, semi-occluded) at 2,000 mg/kg bw. The animals were observed for 14 days after application. Signs of dermal irritation included well-defined erythema, very slight oedema, crust formation, small superficial scattered scabs, and scab lifting at edges to reveal bleeding or dried blood. No mortality or signs of systemic toxicity were noted in the treated animals during the observation period. No abnormalities were noted at necropsy. Under the conditions of this study, the acute dermal LD50 value for the assessed chemical was determined to be > 2,000 mg/kg bw. Therefore, the assessed chemical is of low acute dermal toxicity.

## Corrosion/Irritation

### Skin irritation

The assessed chemical was tested for skin irritation potential in three New Zealand White rabbits (OECD TG 404). In this study, as part of preliminary testing, undiluted test substance (0.5 mL) was applied to three areas of clipped skin at the back of one rabbit, covered with a semi-occlusive dressing. One patch was removed in this rabbit at each of three time points: 3 minutes, 1 hour and 4 hours after application. In two additional rabbits, the undiluted test substance (0.5 mL) was applied to an area at the back and allowed to remain in contact with

the skin for a period of 4 hours. Reactions at the test sites were recorded at 1, 24, 48 and 72 hours after patch removal. A 3-minute and 1-hour semi-occluded applications of the test substance to the intact skin of one rabbit produced no skin effects.

A single 4-hour semi occluded application of the assessed chemical to the intact skin of three rabbits produced well-defined erythema and very slight to slight oedema (primary irritation index for erythema and oedema = 2.8, moderate skin irritant). Other skin reactions noted were moderate desquamation, loss of skin elasticity, glossy skin, and superficial cracking of the epidermis. Corrosive effects were not noted and the score at the end of the 14-day observation period was 0 for all three animals. Therefore, under the conditions of this study, the assessed chemical is classified as Category 2 skin irritant (H315: Causes skin irritation), according to GHS criteria.

The assessed chemical was also tested for skin irritation potential in an in vitro skin irritation test using the human epidermis skin model test (EpiDerm™ kits) (OECD TG 439). The relative mean viability of the assessed chemical treated tissues was 95.5% after the 60-minute exposure period. The relative mean viability value of negative control was 100% and that of positive control was 5.5%. The relative mean viability value threshold for irritancy was ≤ 50%. Therefore, the assessed chemical is not classifiable as a skin irritant according to the TG 439.

The assessed chemical was determined not to be corrosive to the skin in an in vitro skin corrosion test using the human epidermis tissue model test (EpiDerm™ kits) (OECD TG 431). The relative mean viability of the test chemical-treated tissues was 74.8% after a 3-minute exposure period and 87.8% after 60 minutes exposure period. These values did not exceed the threshold for corrosivity which is defined to be 50% after the 3 minutes exposure and 15% after the 60-minute exposure. Therefore, under the conditions of this study, the assessed chemical is not corrosive to the skin.

Although the in vitro assays were negative for skin irritation and corrosion for hazard classification, considering the results of the rabbit study, the assessed chemical is classified as a skin irritant (Category 2; H315: Causes skin irritation) according to the GHS criteria. Skin irritation observed in the acute dermal toxicity study following application of the assessed chemical at 2,000 mg/kg bw in rats supports the classification of the assessed chemical as a skin irritant.

### Eye irritation

In an eye irritation study (OECD TG 405), 0.1 mL of the undiluted test substance was instilled into the conjunctival sac of one eye of each of two New Zealand White rabbits. The other eye remained untreated and served as control. The ocular reactions were assessed approximately at 1, 24, 48 and 72 hours after application. Corneal or iridial effects were not noted during the study. Minimal to moderate conjunctival irritation was noted in both the treated eyes at 1 and 24 hours after treatment. Minimal conjunctival irritation was still noted in both treated eyes at the 48 hours observation. Both treated eyes appeared normal at the 72 hours observation. Normal body weight gain was noted in both animals during the study. Therefore, under the conditions of this study, the assessed chemical is slightly irritating to the eyes.

The eye irritation potential of the assessed chemical was tested using Bovine Corneal Opacity and Permeability (BCOP) test method by application of 0.75 mL of the assessed chemical (undiluted) into the anterior part of each holder containing isolated bovine cornea for 10 minutes (OECD TG 437). After incubation, all the tissues were rinsed and further incubated in the complete medium and opacity was measured. Based on corneal opacity and permeability, an In vitro Irritancy Score (IVIS) was calculated. An IVIS greater than 55 being indicative of risk of serious damage to eyes according to the TG. The assessed chemical, relative to the

negative control, did not induce an increase of the corneal opacity or permeability and the calculated mean in vitro IVIS score was 0.00. Therefore, under the conditions of the study, the assessed chemical is not likely to be corrosive/severe irritant to the eyes.

## Sensitisation

### Skin sensitisation

The skin sensitisation potential of the assessed chemical was tested using a guinea pig maximisation test (GPMT) in 15 female Dunkin Hartley albino guinea pigs (10 test and 5 control animals) (OECD TG 406). An intradermal induction was conducted with the assessed chemical at 25% concentration in Freund's Complete Adjuvant. This was followed by a topical induction after one week with 10% concentration of the assessed chemical for 48 hours under occlusion. Two weeks after the topical induction, all animals were challenged with epidermal application of 1% concentration of the assessed chemical. Skin reactions were evaluated at 24 and 48 hours after removal of the dressing.

Discrete or patchy erythema were observed in 1 of 10 (10%) test group animals only at 24 and 48 hours after challenge with 1% concentration of the assessed chemical, which was below the threshold of 30% for classification as skin sensitiser. Therefore, under the conditions of this study, the assessed chemical is not a skin sensitiser.

## Repeat dose toxicity

### Oral

In a repeated dose oral toxicity study (OECD TG 408), the assessed chemical was administered to Wistar rats (n = 10/sex/dose) by oral gavage for 90 consecutive days at dose levels of 30, 100, and 300 mg/kg bw/day. A control group (n = 5/sex/dose) was dosed with the vehicle alone (corn oil).

No mortality was observed in any of the dose groups. There were no treatment-related adverse effects observed on survival, ophthalmology findings, clinical biochemistry, functional observation battery, haematological coagulation parameters and organ weights.

Body weight gain was reduced in males at 300 mg/kg bw/day. The mean body weight of these males was significantly lower compared to controls (16%). This effect on body weight was not accompanied by a decrease in food consumption. All animals treated at 300 mg/kg bw/day showed clinical signs of toxicity consisting of hunched posture and slight piloerection which occurred consistently from week 8 onwards.

A dose-related increase in salivation was noted in all treated groups. The study authors considered the observation to be a physiological response related to the irritant properties of the assessed chemical. Focal erythema, scabs and/or scales were observed at the mouth of several animals dosed with 300 mg/kg bw/day and were considered to be signs of irritation.

Females in the 300 mg/kg bw/day treatment group had statistically significant higher relative liver weights than controls (17%). Neither corroborative changes in clinical biochemistry parameters nor histopathological hepatic changes were noted. The study authors considered the increase in liver weight as not adverse. Statistically significant higher relative kidney weights when compared to control were observed in males (19%) and females (16%) in the 300 mg/kg bw/day group. As no histopathological changes in the kidneys or clinical

biochemistry changes were observed the change in kidney weight was considered as non-adverse by the study authors.

Forestomach lesions (inflammation, epithelial hyperplasia/hyperkeratosis, and erosion/ulceration) were observed in a single female at 30 mg/kg bw/day and in animals treated at ≥ 100 mg/kg bw/day, increasing in severity and extent at higher doses. These findings were considered local adverse effects due to local irritant properties of the assessed chemical rather than the systemic toxicity. The observed forestomach lesions are considered species-specific to rats and not relevant to humans, as humans do not possess a forestomach.

Hyaline droplet accumulation was noted at increased incidence and severity in males treated at 100 or 300 mg/kg bw/day. This finding is known to represent alpha 2u-globulin, a male rat-specific protein which is not present in female rats or in humans. Therefore, this effect is not relevant for humans. The mesenteric lymph node showed increased macrophage foci in all rats at 300 mg/kg bw/day. These foci were without necrosis or additional inflammatory response. As the mesenteric lymph node is directly draining the gastro-intestinal tract, the increase in macrophage foci is regarded to be related to the forestomach changes in rats.

Based on the above results, the no observed adverse effect level (NOAEL) for the assessed chemical was established as 300 mg/kg bw/day (the highest tested dose).

## Genotoxicity

The assessed chemical was not mutagenic in the bacterial Reverse Mutation Assay (Ames Test) when tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* strain WP2uvrA, 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 concentration (0.625 - 5,000 µg/plate) with metabolic activation (S9-mix) or without metabolic activation (without S9-mix).

The clastogenic potential of the assessed chemical was tested in cultures of human lymphocytes in vitro, both in the absence and the presence of S9 mix (OECD TG 473). In this study, three independent experiments were performed. The concentrations used in the first experiment were 10, 17.5, 30.7, 53.7, 94, 164.5, 287.9, 503.8, 881.6, 1,542.9 and 2,700 µg/mL (with and without S9 mix) with an expression period of 4 hours. The concentrations used in the second experiment were: 0.3, 0.6, 1, 1.7, 3.0, 5.2, 9.1, 16, 28, 49, 85.7 and 150 µg/mL (without S9 mix) and 12.5, 25, 50, 75, 100, 125, 150, 175, 200, 225, 250 and 500 µg/mL (with S9 mix) with an expression period of 22 hours (without S9 mix) and 4 hours (with S9 mix). The concentrations used in the third experiment were: 2.5, 5, 10, 15, 20, 25, 30, 35, 40, 50, 75 and 150 µg/mL (without S9 mix) with an expression period of 4 hours. The assessed chemical did not induce a statistically significant increase in the numbers of polyploid cells at any concentration in any of the exposure groups. Under the conditions of this study, the assessed chemical is not clastogenic to human lymphocytes in vitro.

The assessed chemical was tested for its potential to induce mutations at the mouse lymphoma thymidine kinase (TK) locus in mouse lymphoma L5178Y cells (OECD TG 476). Two independent experiments were performed based on data from a pre-experiment. The concentrations used in the first main experiment were: 2.5, 5, 10, 20, 40, and 60 µg/mL (without S9 mix) and 2.5, 5, 10, 20, 40, and 80 µg/mL (with S9 mix) for a treatment period of 4 hours. The concentrations used in the second main experiment were: 1.3, 2.5, 5, 10, 20, and 30 µg/mL (without S9 mix) and 2.5, 5, 10, 20, 30, and 40 µg/mL (with S9 mix) for a treatment period of 24 hours (without S9 mix) and 4 hours (with S9 mix). No biologically relevant increase in the mutation frequency at the TK locus was found after treatment with the assessed chemical (with or without metabolic activation). The numbers of small and large colonies in the treated

cultures were comparable to the numbers of small and large colonies of the solvent controls. Under the conditions of this study and according to the test guideline, the assessed chemical was not mutagenic in the TK mutation test system.

Overall, the assessed chemical is not likely to be genotoxic.

### Reproductive and development toxicity

In a prenatal developmental toxicity study (OECD TG 414), the assessed chemical was administered to mated female Wistar Han rats by oral gavage at dose levels of 10, 30 and 100 mg/kg bw/day (n = 22/group) once daily during Gestation Days (GD) 6–20. All surviving animals were sacrificed on the respective GD 21.

While no maternal toxicity was observed in the 10 and 30 mg/kg bw/day groups, one animal of the 100 mg/kg bw/day group was sacrificed on day 20 post coitum after rapid decline of the animal's health. This female showed black-brown foci on the glandular stomach with irregular surface of the forestomach as signs of severe irritation. In addition, enlarged and dark-red discoloured adrenal glands, and a reduced size of the thymus were also noted. Four more females in this group also showed signs of severe irritation or adverse effects to the forestomach or the gastro-intestinal tract.

No clinical signs were noted among surviving animals of all treatment groups. Body weight gain (with and without correction for uterus weight) appeared slightly lower but not statistically significant in rats treated at 100 mg/kg bw/day, compared to controls (35% vs 41% body weight gain in controls). Relative food consumption (corrected for body weight) was reduced on day 21 post coitum for rats dosed at 100 mg/kg bw/day, which was merely caused by the three rats that suffered weight loss.

There were no effects on the number of pregnant females, corpora lutea, implantation sites, or pre- or post-implantation loss at up to 100 mg/kg bw/day. Examination of cage debris of pregnant females revealed no signs of abortion or premature births. There were no treatment-related effects on litter size for any group, male:female sex ratio, and foetal body weight at up to the highest tested dose of 100 mg/kg bw/day. Furthermore, there were no treatment-related effects on foetal morphological examinations, external malformations and variations, visceral malformations and variations, and skeletal malformations and variations at up to the highest tested dose.

The NOAEL for maternal toxicity and developmental toxicity was noted to be the highest tested dose (100 mg/kg bw/day). AICIS notes that adverse irritation effects were observed in 4/22 females and one female was sacrificed due to ill health at 100 mg/kg bw/day. These effects were mostly limited to forestomach, stomach or gastrointestinal tract and were due to local irritation related effects and not due to systemic toxicity of the assessed chemical.

## Environmental exposure

The assessed chemical will be imported into Australia and is not expected to be directly released into the environment during its transport, use, storage or disposal.

Spills and wastes from transport are expected to be collected with suitable absorbent materials and disposed of according to state, territory and federal regulations.

During use, liquid containing the assessed chemical will be transferred using enclosed pipes, pumps and valves to minimise the release of the liquid into the environment during the mining process.

Wastes containing the assessed chemical generated from the mining process will be dewatered and the assessed chemical will form part of the produced salts. The waste salts will then be transported to a stockpile with appropriate containment measures including an earthen containment bund.

Very small quantities of the assessed chemical may disperse into environmental compartments through soil erosion, runoff, seepage, or wind-borne particulates. However, these exposures are expected to be negligible given the controls in place and adherence to relevant local regulatory practices.

## Environmental fate

### Partitioning

Based on the high measured log $K_{oc}$ value (log Koc ≥ 4.2) and low water solubility (water solubility = 1.5 mg/L at 20 °C), if released into the environment, the assessed chemical is expected to partition to soils, sediments or sludge where it will become immobile.

### Degradation

The assessed chemical is considered Not persistent based on the measured biodegradation in fresh water.

A ready biodegradation screening test, conducted according to OECD TG 301D, showed 64% degradation of the test substance in 28 days. Because the test substance is an UVCB, the 14-days window criterion is not applicable. Based on these results, the assessed chemical is considered readily biodegradable.

### Bioaccumulation

The assessed chemical is categorised as bioaccumulative based on the measured log $K_{OW}$ value of a major UVCB component.

An in-vitro biotransformation study conducted according to OECD TG 319 was provided for the assessed chemical. However, results from this test method, on their own, are insufficient to support a bioaccumulation determination (OECD 2018). Measured partition coefficient values were log Kow = 3.9 for the constituent representing > 60% of the UVCB substance and log Kow = 4.3 for the constituent representing > 20% of the UVCB substance. As > 20% of the assessed substance is above the domestic bioaccumulation threshold of log $K_{OW}$ ≥ 4.2 (DCCEEW, 2022), the substance is considered bioaccumulative (UNECE 2017).

## Predicted environmental concentration (PEC)

A predicted environmental concentration was not calculated as the assessed chemical is not expected to be released into the aquatic environment under the assessed use.

# Environmental effects

## Effects on aquatic life

### Acute toxicity

The following measured median 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 > 0.0258 mg/L | *Danio rerio* (Zebrafish)<br>OECD TG 203<br>Semi-static conditions<br>Measured concentration |
| **Invertebrate** | 48 h EC50 = 0.106 mg/L | *Daphnia magna*<br>(Water flea)<br>Immobility<br>OECD TG 202<br>Static conditions<br>Measured concentration |
| **Algae** | 72 h $E_rC50$ = 0.025 mg/L | *Pseudokirchneriella subcapitata*<br>(Green algae)<br>Growth inhibition<br>OECD TG 201<br>Static conditions<br>Measured concentration |

### Chronic toxicity

The following measured 10th percentile effective concentration (EC10) and 10th percentile effective loading rate (EL10) values for model organisms were supplied for the assessed chemical:

| Taxon | Endpoint | Method |
|---|---|---|
| **Fish** | 34 d $EC10_{(growth)}$ = 0.0027 mg/L | *Danio rerio* (Zebrafish)<br>OECD TG 210<br>Flow-through conditions<br>Measured concentration |
| **Invertebrates** | 21 d $EL10_{(reproduction)}$ = 0.00583 mg/L | *Daphnia magna* (Water flea)<br>Effect on reproduction<br>OECD TG 211<br>Semi-static conditions<br>Measured concentration |
| **Algae** | 72 h ErC10 = 0.006 mg/L | *Pseudokirchneriella subcapitata* (Green algae)<br>Growth inhibition<br>OECD TG 201<br>Static conditions<br>Measured concentration |

### Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 0.27 µg/L was calculated for the assessed chemical in the aquatic environment. This value was derived using the endpoint value for fish (34 d EC10 = 2.70 µg/L). An assessment factor of 10 was applied to this endpoint as acute and chronic toxicity data were available for three trophic levels (EPHC 2009).

## 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

Not Persistent (Not P). Based on measured biodegradation study, the assessed chemical is categorised as Not Persistent.

### Bioaccumulation

Bioaccumulative (B). Based on a major component of the UVCB substance (> 20%) with a measured log $K_{ow}$ value > 4.2, the assessed chemical is categorised as Bioaccumulative.

### Toxicity

Toxic (T). Based on measured acute endpoints below 1 mg/L and chronic endpoints < 0.1 mg/L, the assessed chemical is categorised as Toxic.

# Environmental risk characterisation

Although the assessed chemical is toxic and bioaccumulative, it does not meet all three PBT criteria and therefore is unlikely to have unpredictable long-term effects (EPHC 2009).

A Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as no release of the assessed chemical into aquatic environment is expected based on its use as an extraction agent in mining. Therefore, based on its low environmental exposure, the risk from the assessed chemical can be managed.

# References

DCCEEW (2022) Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals, DCCEEW, Accessed 18 February 2026.

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.

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