Australian Government



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

# Acetonitrile, 2-(2,4,4trimethylcyclopentylidene)-

**Assessment statement (CA09883)** 

13 December 2024



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# AICIS assessment (CA09883)

# Chemical in this assessment

Name	CAS registry number

Acetonitrile, 2-(2,4,4-trimethylcyclopentylidene)- 1392276-61-7

# Reason for the assessment

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

### Certificate application type

AICIS received the application in a Very Low to Low Risk type.

# Defined scope of assessment

The chemical has been assessed:

- as imported into Australia at up to 1 tonne/year.
- as imported in fragrance formulations at up to 1% concentration for local reformulation into continuous action air fresheners at up to 0.8% concentration, instant action air fresheners at up to 0.1% concentration, fine fragrances at up to 0.5% concentration, and other cosmetic and household products at up to 0.02% concentration.
- as imported in continuous action air fresheners at up to 0.8% concentration, in instant action air fresheners at up to 0.1% concentration, in fine fragrances at up to 0.5% and in other cosmetic and household products at up to 0.02% concentration.

# Summary of assessment

### Summary of introduction, use and end use

The assessed chemical will not be manufactured in Australia. It will be imported either in fragrance formulations at up to 1% concentration for local reformulation into end use cosmetics and household products or in finished end use cosmetic and household products at various concentrations, including in air fresheners (up to 0.8% in continuous action air fresheners and up to 0.1% in instant action air fresheners), fine fragrances at up to 0.5% and other cosmetic and household products at up to 0.02% concentrations.

The cosmetic and household end use products containing the assessed chemical are proposed to be used by professional workers and members of the general public.

# Human health

### Summary of health hazards

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

- is harmful if swallowed (acute oral LD50 between 300 and 2,000 mg/kg bw in rats)
- is a skin sensitiser
- is slightly irritating to skin and eyes
- is not expected to be genotoxic based on a bacterial reverse mutation assay and in an in vitro micronucleus assay with human lymphocytes

In an in vitro micronucleus assays using human lymphocytes the assessed chemical at the lowest test concentration (0.09 mM) induced an increase in the number of binucleated cells with micronuclei in a 24-hour continuous treatment without metabolic activation. Higher test concentrations (0.20 and 0.44 mM) under same test conditions did not induce such increases and no dose response relationship was observed. Although the increase was statistically significant, it was within the historic vehicle control range.

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

The assessed chemical contains a nitrile functional group. Nitrile compounds may be able to release cyanide on metabolism and produce typical cyanide toxicity. In rodents, aliphatic nitriles have been shown to cause malformations, foetal death and intrauterine growth retardation (IUGR) when given orally at doses ranging from 30 – 2,000 mg/kg/day during the organogenesis period (days 6-15 of gestation). Malformations vary but tend to be cleft palate or relate to disruptions to the developing neural tube/central nervous system and may also include limb/tail abnormalities. Embryo-foetal toxicity has also been generally observed (Dereck Nexus Version 6.0.1). However, not all nitriles are capable of liberating significant amounts of cyanide. Alkyl substituents of more than 4 carbons may less likely release cyanide on metabolism (Dereck Nexus Version 6.0.1).

Hazard classifications relevant for worker health and safety

Based on the data provided, the assessed chemical 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 Hazard	Hazard Category	Hazard Statement
Acute toxicity	Acute Tox. 4	H302: Harmful if swallowed
Skin sensitisation	Skin Sens. 1	H317: May cause an allergic skin reaction

### Summary of health risk

#### Public

There will be widespread and repeated exposure of the public to the assessed chemical at up to 0.8% using a wide range of cosmetic and household products. The principal route of exposure will be dermal and inhalation, while incidental oral or ocular exposure is also possible. Inhalation exposure occurs particularly from the use of air care products and other products applied by spray.

The assessed chemical is slightly irritating to skin and eyes. However, skin and eye irritation effects are not expected to occur from use of the assessed chemical at the proposed low end use concentrations (up to 0.8%) in cosmetic and household products.

Based on results of a local lymph node assay (LLNA) provided, the assessed chemical is a weak skin sensitiser with an EC1.4 value of 48.21%. The LLNA study allowed the derivation of an Acceptable Exposure Level (AEL) of 35.8  $\mu$ g/cm<sup>2</sup>/day for consumers using an overall safety factor of 300. Based on the quantitative risk assessment (QRA) calculations, this AEL was considered to be greater than each of the individual consumer exposure levels (CELs) for various household and cosmetic products with intended maximum use concentrations as proposed in the application. Since the AEL is greater than CELs, induction of skin sensitisation associated with the use of the assessed chemical in a single consumer product is unlikely to occur. However, it is acknowledged that consumers may be exposed to multiple products containing the assessed chemical, and a QRA based on aggregate exposure has not been conducted.

No inhalation toxicity data are provided for the assessed chemical. Taking hairspray as a worstcase scenario example for inhalation exposure assessment, the systemic exposure is estimated to be up to 1  $\mu$ g/kg bw/day (see **Supporting information** section). Inhalation exposure to the assessed chemical from use of other cosmetic and household products, especially air fresheners, may also occur. However, due to low concentrations of the assessed chemical in the end use products, it is not expected to pose a health risk through inhalation.

Due to lack of repeated dose toxicity data, no QRA was possible to determine the margin of exposure (MOE). Based on the worst-case exposure scenario, consumers simultaneously using multiple cosmetic and household products may be systemically exposed to the assessed chemical at approximately 110 µg/kg bw/day through repeated or prolonged dermal and inhalation exposure (see **Supporting information** section). Considering this very low systemic exposure level to the assessed chemical in the worst-case exposure scenario, health risks from repeated exposure to the public are not expected.

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

#### Workers

Reformulation workers may be incidentally exposed to the assessed chemical at up to 1% concentration during reformulation processes mainly via the dermal route, while ocular and inhalation exposures are also possible. To mitigate potential repeated dose exposure risks to reformulation workers, control measures would be required (see **Means for managing risk**) to minimise the exposure. It is anticipated by the applicant that engineering controls such as enclosed and automated processes and local ventilation will be implemented where possible. Use of appropriate personal protective equipment (PPE) such as safety glasses, impervious chemical resistant gloves, protective clothing and respiratory protection will reduce worker exposure.

Professional workers in cleaning or cosmetic businesses may experience exposure via dermal, inhalation and accidental ocular exposure to the assessed chemical during the use of cleaning or cosmetic products containing the assessed chemical at up to 0.8% concentration. The professional workers may wear some PPE (including gloves, coveralls and face masks or safety glasses). If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using the same end use products containing the assessed chemical, requiring no specific risk management measures for these workers.

# 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 2 (H401) and Chronic Category 2 (H411) 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 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

The assessed chemical will be introduced as a fragrance ingredient for use in a variety of cosmetic and household products. These uses may result in the release of the assessed chemical to sewers and to air.

The assessed chemical is not readily degradable and is persistent. The assessed chemical does not have potential for bioaccumulation and is not expected to cause toxic effects in aquatic organisms according to domestic threshold values.

Although the assessed chemical is persistent according to the Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals (DCCEEW 2022), it does not meet all three PBT criteria. It is hence unlikely to have unpredictable long-term effects and its risk may be estimated by the risk quotient method ( $RQ = PEC \div PNEC$ ). Based on the estimated RQ values < 1 for the river and ocean compartments, it is expected that 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 during reformulation:

- Use of engineering controls such as
  - Enclosed and automated systems where possible
  - Adequate workplace ventilation to avoid accumulation of dusts, 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 local ventilation may be inadequate
- As the assessed chemical is a skin sensitiser, control measures may need to be supplemented with health monitoring for any worker who is at significant risk of exposure to the chemical, if valid techniques are available to monitor the effect on the worker's health.
- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

# Conclusions

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

Note:

- 1. Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.
- 2. 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	1392276-61-7
CAS name	Acetonitrile, 2-(2,4,4-trimethylcyclopentylidene)-
Molecular formula	$C_{10}H_{15}N$
Associated names	-
Molecular weight (g/mol)	149.23
SMILES (canonical/isomeric)	N#CC=C1CC(C)(C)CC1C
Representative structure	N

#### Additional chemical identity information

The assessed chemical contains all possible stereoisomers with a combined purity greater than 90%.

# Relevant physical and chemical properties

Physical form	Liquid
Melting point	-101.3 °C
Boiling point	227.8°C at 101.3 kPa
Density	891.8 kg/m³ at 20 °C
Vapour pressure	0.0117 kPa at 20 °C (Calc.)
Water solubility	174 mg/L at 20 °C
Flash Point	89°C (closed cup)
Auto-ignition temperature	398 °C
Ionisable in the environment	No
log K <sub>ow</sub>	3.12 at 20°C

# Human exposure

### Public

There will be widespread and repeated exposure of the public to the assessed chemical at up to 0.8% concentration through the use of a range of cosmetic and household products. The principal route of exposure will be dermal, while ocular and inhalation exposures are also possible, particularly if the products are applied by spray.

#### Dermal exposure

Data on typical use patterns of cosmetic products (SCCS 2012; Cadby et al. 2002; ACI 2010; Loretz et al. 2006) in which the assessed chemical may be used are shown in the following table. A dermal absorption (DA) rate of 100% was used as a worst-case scenario along with a combined average body weight (BW) for males and females of 60 kg for calculation purposes.

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (µg/kg bw/day)
Body lotion	7,820	0.02	1	26
Face cream	1,540	0.02	1	5
Hand cream	2,160	0.02	1	7
Fine fragrances	750	0.5	1	62
Deodorant (non-spray)	1,500	0.02	1	5
Shampoo	10,460	0.02	0.01	0
Conditioner	3,920	0.02	0.01	0
Shower gel	18,670	0.02	0.01	1
Hand wash soap	20,000	0.02	0.01	1
Hair styling products	4,000	0.02	0.1	0
Hair dye products	11,600	0.02	0.1	1
Total				108

C = maximum intended concentration of assessed chemical; RF = retention factor Daily systemic exposure = (Amount × C × RF × DA)/BW

Dermal exposure from using household cleaning products containing the assessed chemical and wearing clothes washed with products containing the assessed chemical will result in approximately additional 1  $\mu$ g/kg bw/day systemic exposure, considering low concentrations and retention factors for these products.

#### Inhalation exposure

Hairspray was taken as a worst-case scenario example for the inhalation exposure assessment. A 2-zone approach was used (Steiling et al. 2014; Rothe et al. 2011; Earnest Jr. 2009) with an adult inhalation rate of 20 m<sup>3</sup>/day (enHealth 2012). It was conservatively assumed that the fraction of the assessed chemical inhaled is 50%.

Amount of hairspray applied	9.89	g/day
Maximum intended concentration of the chemical	0.02	%
Inhalation rate of the user	20	m <sup>3</sup> /day
Exposure duration zone 1	1	minutes
Exposure duration zone 2	20	minutes
Fraction inhaled by the user	50	%
Volume zone 1	1	m <sup>3</sup>
Volume zone 2	10	m <sup>3</sup>
Daily systemic exposure	1	µg/kg bw/day

C = maximum intended concentration of assessed chemical

Total daily systemic exposure = daily systemic exposure zone 1 + daily systemic exposure zone 2

- Daily systemic exposure zone 1 = (amount × C × inhalation rate × exposure duration zone 1 × fraction inhaled)/volume zone 1/body weight
- Daily systemic exposure zone 2 = (amount × C × inhalation rate × exposure duration zone 2 × fraction inhaled)/volume zone 2/body weight

It is acknowledged that inhalation exposure to the assessed chemical from use of other cosmetic and household products, especially air fresheners, may also occur.

The worst-case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above tables that contain the assessed chemical at the maximum intended concentrations specified in various product types. This would result in a combined internal dose of 110  $\mu$ g/kg bw/day (0.11 mg/kg bw/day) for the assessed chemical. It is considered that the combination of the conservative hair spray inhalation exposure assessment parameters, and the aggregate exposure from use of the dermally applied products, which assumes a conservative 100% dermal absorption rate, is sufficiently protective to cover additional inhalation exposure to the assessed chemical from use of other spray cosmetic and household products with lower exposure factors (e.g. air fresheners).

The estimated low level of worst-case systemic exposure is unlikely to pose a health risk to the public with the use of cosmetic and household products containing the assessed chemical.

# Health hazard information

## Acute toxicity

### Oral

In an acute oral toxicity study (OECD TG 423), the assessed chemical was administered by oral gavage to 3 female Sprague Dawley rats at a single dose of 2,000 mg/kg bw and then 6 female Sprague Dawley rats at a single dose of 300 mg/kg bw.

At 2,000 mg/kg bw, all 3 test animals were found dead within 24 hours (1 test animal died 7 hours after administration and other 2 animals died 23 hours after the treatment). Treatment related clinical signs, including decrease in spontaneous activity (1/3 animal) and dilated pupils (3/3 animals) were observed prior to death. Postmortem stiffening of muscles and salvation were observed in all 3 animals prior to necropsy. Thinning of the forestomach (3/3) and thinning of the corpus (3/3) associated with a white coloration (3/3) and red spots (1/3) were observed at the macroscopical examination at necropsy.

At 300 mg/kg bw, no mortality was noted in treated animals. Decrease in spontaneous activity (5/6), piloerection (1/6) and salivation (1/6) were observed at the 30 minutes and 1-hour observations. No clinical signs were observed 3 hours after the treatment. Normal body weight gains were observed throughout the study. Thinning of forestomach (2/6) was noted at the macroscopical examination at necroscopy.

The acute median lethal oral dose (LD50) value for the assessed chemical was established to be between 300 and 2,000 mg/kg bw. Therefore, the assessed chemical warrants hazard classification "Harmful if swallowed" (Category 4) according to the GHS criteria.

### Corrosion/Irritation

### Skin irritation

Skin irritation potential of the assessed chemical was tested in rabbits following the OECD TG 404. Skin of 3 New Zealand White male rabbits were exposed to 0.5 mL of the undiluted assessed chemical for 4 hours under semi-occlusive conditions. Slight erythema (maximum score of 1) was noted in all 3 test animals at the 1-hour and 24-hour observations after the patch removal. Symptom persisted in 2 animals at the 48-hour and in 1 animal at the 72-hour observations which was reversible in 7 days. Slight oedema (maximum score of 2) was observed in 2 test animals and very slight oedema (maximum score of 1) in 1 animal 1 hour after the exposure. A very slight oedema was observed in 1 animal at the 48-and 72-hour observations which was reversible in 7 days. Dryness of skin at application area was noted in 1 test animal at the 24-hour observation, in another animal at the 48-hour observation and in the third animal at the 72-hour observation. The affected skin recovered to normal between day 7 and day 14.

Based on the results, the assessed chemical is considered as slightly irritating to the skin but does not meet the GHS criteria for classification as adopted by Australia for industrial chemicals.

### Eye irritation

Eye irritation potential of the assessed chemical was tested in rabbits following the OECD TG 405. The undiluted chemical (0.1 mL) was instilled in one eye of each 3 female New Zealand white rabbits. The untreated eyes served as controls. Moderate conjunctivae reactions including redness (score 1), discharge (score 3) and chemosis (score 1) were observed 1 hour after the exposure in all 3 animals. Two test animals showed mild conjunctival redness at the 24-hour observation and the symptom recovered by day 7. The effects were fully reversed by day 14. All 3 test animals showed slight chemosis (score 1) at the 1-hour observation and the symptom was fully reversed in 48 hours. No iris and cornea effects were observed during the test.

Based on the results, the assessed chemical is considered as slightly irritating to the eyes but does not meet the GHS criteria for classification as adopted by Australia for industrial chemicals.

### Sensitisation

#### Skin sensitisation

In a local lymph node assay (LLNA) (OECD TG 429), the assessed chemical in acetone/olive oil (4:1) was applied topically on the dorsal part of both ears of CBA/J female mice (4 animals/group) at 0%, 25%, 50% and 100% (v/v) concentrations at a dose of 25  $\mu$ L/ear for 3 consecutive days. One mouse from 100% concentration treatment group was found dead on day 2. The macroscopical examination of this mouse did not reveal any treatment related changes. Slight reduction in bodyweight gain was observed in 2 test animals treated with 50% and 100% concentrations. No signs of systemic toxicity and no signs of erythema were noted in all animals. No significant increase in ear thickness or ear weight was reported for all treated animals.

On day 6, test animals were euthanised with sodium pentobarbital and the draining auricular lymph nodes from the mice were excised and pooled for each experimental group. The proliferation of lymphocytes in the lymph nodes was determined by cell counting. Stimulation Index (SI), calculated by comparing to the control group, were 1.14, 1.42 and 1.96 at the test concentrations of 25%, 50% and 100% respectively. SI calculated for the positive control ( $\alpha$ -hexylcinnamaldehyde at 5%, 10% and 25% concentrations were 0.99, 1.54 and 1.6 respectively. The concentration of the assessed chemical expected to result in a 1.4 SI (EC1.4, equivalent to EC3 based on <sup>3</sup>H-thymidine incorporation method) was calculated to be 48.21% using linear interpolation. Under the conditions of the study and according to the GHS criteria the assessed chemical is a Category 1 skin sensitiser.

### Genotoxicity

The assessed chemical was not mutagenic in a bacterial reverse mutation assay (Ames Test), when tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* strain WP2 (pKM101), with and without metabolic activation (OECD TG 471). No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any test concentration (5, 1.67, 0.56, 0.19 and 0.06  $\mu$ g/plate, with and without metabolic activation).

A screening in vitro mammalian cell micronucleus assay was conducted using a method similar to OECD TG 487 in cultured lymphocytes from human blood. The assessed chemical was tested in the absence and presence of metabolic activation at 0.38 to 1.5 mM and 0.38 to 2.0

mM respectively for 4 hours with a 24-hour recovery period. The chemical was also tested in the absence of metabolic activation for 24 hours at 0.09 to 1.5 mM without a recovery period. In the latter test, statistically significant increase in the number of binucleated cells with micronuclei at the lowest concentration (0.09 mM) was observed (16 out of 2,000 cells compared to 4 out of 2,000 cells in DMSO). The increase of the micronucleated cells was within the historical data range for solvents (6 to 28 out of 2,000 cells in 20 tests with aqueous solvent and DMSO). No statistically significant increases of number of the micronucleated cells were recorded in other tested concentrations and exposures in the absence and presence of metabolic activation. In the absence of dose response and within the historical control data, the study authors considered the above statistically significant increase as not treatment related.

Based on the results of these studies, the assessed chemical is not mutagenic and unlikely to be clastogenic.

# Environmental exposure

The assessed chemical will be imported into Australia for use as a fragrance in end-use products, or as a component of fragrance formulations for reformulation into end-use products. Reformulation and repackaging will occur in both closed and open processes. Significant releases of the assessed chemical to the environment are not expected during reformulation, transport or storage.

The assessed chemical will be included in a wide range of products, resulting in a variety of potential exposure scenarios.

Consumer and professional end-use of the assessed chemical in cosmetic and household products is expected to result in the release of the assessed chemical "down the drain" and into the sewers. Consequently, the assessed chemical will be treated at sewage treatment plants (STPs) before release to surface waters.

Use of the assessed chemical in air-care products will result in direct release of the assessed chemical into the air compartment.

### Environmental fate

#### Partitioning

The partitioning of the assessed chemical was not determined. The chemical is treated as if it is mobile in the environment as a worst-case scenario.

#### Degradation

Based on its measured degradation in water, the assessed chemical is considered persistent.

Degradation studies in water indicate that the assessed chemical is not readily biodegradable. A supplied OECD 301D biodegradation study for the assessed chemical demonstrated 0% degradation of the assessed chemical over 28 days and 1% degradation at 60 days.

#### Bioaccumulation

Based on its log  $K_{\text{OW}}$  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  $K_{OW} = 3.12$ ) is below the domestic bioaccumulation threshold of log  $K_{OW} = 4.2$  (DCCEEW 2022).

### Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) for Australian waters was calculated assuming the maximum allowable introduction volume for environmental exposure band 2 (1,000 kg/annum) with a release reduction factor of 1 for down-the-drain style end use scenarios. Correspondingly, 100% of the introduction volume is released into sewage treatment plants (STP) over 365 days per annum. The extent to which the assessed chemical is removed from the effluent in STP processes was not calculated as a worst-case scenario.

This calculated value is conservative as not all uses of the assessed chemical are expected to result in release to STP.

Total Annual Import Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release	2.74	kg/day
Water use	200	L/person/day
Population of Australia	25.423	Million
Removal within STP	0%	Mitigation
Daily effluent production	5,085	ML/day
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River	0.54	µg/L
PEC - Ocean	0.05	µg/L

The calculation of the PEC is detailed in the table below:

# Environmental effects

# Effects on aquatic Life

### Acute toxicity

The following measured and modelled median effective concentration (EC50) values for model organisms across three trophic levels were provided by the applicant:

Taxon	Endpoint	Method
Fish	96 h LC50 = 3.1 mg/L	Brachidanio rerio (Zebrafish) OECD TG 203 Semi-static conditions Mean measured concentration
Invertebrate	48 h EC50 = 7.62 mg/L (Calc.)	Daphnia magna (Water Flea) Immobility/other effect iSafeRate, HA - QSAR v1.9 Ecotox module, Calculated concentration
Algae	72 h ErC50 = 11.82 mg/L	Pseudokirchneriella subcapitata (Green algae) Growth rate OECD TG 201 Static conditions Geometric mean measured concentration

**Chronic toxicity** 

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

Taxon	Endpoint	Method
Algae	72 h NOErC = 3.51 mg/L	Pseudokirchneriella subcapitata (Green Algae) Growth rate OECD TG 201 Static conditions Geometric means measured concentration

### Predicted no-effect concentration (PNEC)

The predicted no-effect concentration is expected to be greater than 0.54 µg/L.

The available standard acute ecotoxicity endpoints for this chemical are greater than 0.54 mg/L. With a conservative assessment factor of 1,000, the lowest calculable PNEC is greater than 0.54  $\mu$ g/L.

# 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 measured degradation 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

Although the assessed chemical is persistent, it does not meet all three PBT criteria. It is hence unlikely to have unpredictable long-term effects (EPHC 2009). An estimate of risk may therefore be determined using the risk quotient method.

Compartment	PEC	PNEC	RQ
River	< 0.54 µg/L	> 0.541 µg/L	< 1
Ocean	< 0.05 µg/L	> 0.541 µg/L	< 0.1

The risk quotient for the aquatic compartment is expected to be less than 1. This is based on a conservative PEC, assuming 100% release of 1 tonne/annum to STPs and no removal from the aqueous stream during STP processes, and a conservative PNEC based on an assessment factor of 1,000 and acute aquatic toxicity endpoints for the chemical that each exceed 0.54 mg/L.

Therefore, based on the expected RQ less than 1 the assessed chemical is not expected to pose a risk to the environment. As such, the environmental risks associated with the assessed chemical can be managed.

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