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

# Butanal, 4-(3,3,4-trimethylcyclopentylidene)-, (4*E*)-

## Assessment statement (CA10011)

**16 June 2025**

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# AICIS assessment (CA10011)

## Chemical in this assessment

| Name | CAS registry number |
|---|---|
| Butanal, 4-(3,3,4-trimethylcyclopentylidene)-, (4*E*)- | 2411191-47-2 |

## Reason for the assessment

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

### Certificate application type

AICIS received the application in a 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
- as imported or reformulated into finished end use products for end use in:
    - Personal care products (cosmetics) except oral care products - at up to 0.1% concentration
    - Fine fragrances - at up to 0.28% concentration
    - Cleaning and furniture care products - at up to 0.1% concentration
    - Laundry and dishwashing products - at up to 0.1% concentration
    - Apparel and footwear care products - at up to 0.1% concentration
    - Air care products - at up to 1% in continuous action air fresheners and up to 0.1% in instant action air fresheners

## Summary of assessment

### Summary of introduction, use and end use

The assessed chemical has functional use as a fragrance. The assessed chemical will not be manufactured in Australia. It will be imported in liquid fragrance formulations at up to 1% concentration for local reformulation or as a component of finished end use products. The assessed chemical has end use in the following products:

- Personal care products (cosmetics) except oral care products
- Fine fragrances
- Cleaning and furniture care products
- Laundry and dishwashing products
- Apparel and footwear care products

- Air care products

The proposed maximum use concentration in these products is up to 0.1% except for in fine fragrances at up to 0.28% and air fresheners (continuous action) at up to 1%.

The end use products containing the assessed chemical are proposed to be used by professional workers and members of the 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:

- not irritating to eyes
- not genotoxic

The toxicological information also indicate that the assessed chemical is:

- harmful if swallowed (median lethal dose (LD50) between 300 and 2,000 mg/kg bw in rats)

Although limited data are available, *in silico* prediction data suggest that the assessed chemical has the potential to cause skin irritation and skin sensitisation. However, the available data does not support classification of the assessed chemical for skin irritation and skin sensitisation according to *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (Rev. 7, UNECE 2017) adopted in Australia for industrial chemicals.

No inhalation or repeated dose 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 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 | H301: Harmful if swallowed |

### Summary of health risk

**Public**

There will be widespread and repeated exposure of the public to the assessed chemical at up to 1% concentration when using a wide range of cosmetic and domestic products containing the assessed chemical. 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 could be irritating and sensitising to the skin. However, skin irritation and skin sensitisation effects are not expected to occur from use of the assessed chemical at the proposed low end use concentrations in cosmetics (up to 0.1% in cosmetics, except 0.28% in fine fragrances) and domestic products (up to 0.1%, except in continuous action air fresheners up to 1%). The continuous action air fresheners are not expected to come into direct contact with skin due to designed nature of the products.

No inhalation toxicity data are provided for the assessed chemical. Taking hairspray as a worst-case scenario example for inhalation exposure assessment, the systemic exposure is estimated to be up to 34 µg/kg bw/day (see **Supporting information** section). Inhalation exposure to the assessed chemical from use of other cosmetic and domestic products, especially and air fresheners may also occur. However, due to low concentrations of the assessed chemical in the end use products and the assessed chemical is not persistent in the environment, it is not expected to pose a health risk through inhalation.

Due to lack of repeated dose toxicity data, no quantitative risk assessment (QRA) was possible to determine the margin of exposure (MOE). Based on the worst-case exposure scenario, consumers simultaneously using multiple cosmetic and domestic products may be systemically exposed to the assessed chemical at approximately 310 µg/kg bw/day through repeated or prolonged dermal and inhalation exposure (see **Supporting information** section). Considering the low systemic exposure level to the assessed chemical in the worst-case exposure scenario (< 0.5 mg/kg bw/day), 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. Although the chemical may be irritating to skin and a weak sensitiser, the risk to workers is expected to be low due to the low concentration of the chemical as introduced and used (up to 1%). 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 using end use products including those in cleaning, shoe repair or cosmetic businesses may experience exposure via dermal, inhalation and accidental ocular exposure to the assessed chemical up to a concentration of 1%. 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 assessed chemical is:

- Not Persistent (Not P)
- Bioaccumulative (B)
- Not toxic (Not T)

### Environmental hazard classification

The assessed 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 rapid degradation 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 products. These uses may result in the release of the assessed chemical to sewers and to air.

The assessed chemical is ultimately degradable and is not persistent. The assessed chemical has potential for bioaccumulation and is not toxic to aquatic organisms.

Although the assessed chemical is bioaccumulative, 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 ÷ PNEC). Based on the expected 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 mists or aerosols

- Use of safe work practices to
  - Avoid contact with skin
  - Avoid inhalation of mists or aerosols

- Use of personal protective equipment (PPE)
  - Impervious gloves
  - Protective clothing
  - Respiratory protection where local ventilation may be inadequate

- The storage of the assessed chemical should be in accordance with the Safe Work Australia *Code of Practice for Managing Risks of Hazardous Chemicals in the Workplace* (SWA 2023) or relevant State or Territory Code of Practice.

- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

## Conclusions

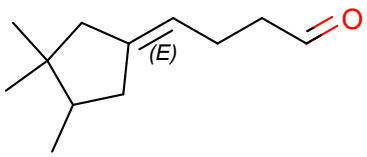
The Executive Director is satisfied that the risks to human health or the environment associated with the introduction and use of the industrial chemical can be managed.

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** | 2411191-47-2 |
| **CAS name** | Butanal, 4-(3,3,4-trimethylcyclopentylidene)-, (4*E*)- |
| **Molecular formula** | $C_{12}H_{20}O$ |
| **Molecular weight (g/mol)** | 180.29 |
| **SMILES (isomeric)** | C(\CCC=O)=C\1/CC(C)(C)C(C)C1 |
| **Representative structure** |  |



**Additional chemical identity information**

The assessed chemical is a racemate and has a purity of greater than or equal to 87%.

## Relevant physical and chemical properties

| | |
|---|---|
| **Physical form** | Pale yellow translucent liquid |
| **Melting point** | < -20 °C |
| **Boiling point** | 250.3 ± 0.1 °C at 101.3 kPa |
| **Density** | 902.7 kg/m$^3$ at 20 °C |
| **Vapour pressure** | 0.005 kPa at 20 °C<br>0.009 kPa at 25 °C |
| **Water solubility** | 50.3 mg/L at 20 °C, pH = 5.3 |
| **Flash Point** | 101 °C at 101.3 kPa |
| **Auto ignition temperature** | 205 °C at 97.7 kPa |
| **Ionisable in the environment** | No |
| **log $K_{ow}$** | 4.3 at 25 °C, pH = 5 |
| **log $K_{oc}$** | 2.15 (MCI method) |

# Human exposure

## Public

Dermal exposure of the public to the assessed chemical at a maximum concentration of 0.28% will be wide-spread and frequent across the use of a variety of cosmetic and domestic products. Incidental oral, ocular or respiratory exposure to the chemical at a maximum concentration of 1% may also be possible.

### Dermal exposure

Data on typical use patterns of product categories in which the assessed chemical may be used on a daily basis are shown in the following tables and these are based on information provided in various literatures (SCCS 2012; Cadby et al. 2002; ACI 2010; Loretz et al. 2006). For the purposes of exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. A dermal absorption (DA) rate of 100% is assumed for the assessed chemical and an average body weight (BW) of 60 kg is used for male and female adults for calculation purposes.

*Cosmetic products*

| Product type | Amount (mg/day) | C (%) | RF | Daily systemic exposure (mg/kg bw/day) |
|---|---|---|---|---|
| Body lotion | 7820 | 0.10 | 1 | 0.130 |
| Face cream | 1540 | 0.10 | 1 | 0.026 |
| Hand cream | 2160 | 0.10 | 1 | 0.036 |
| Fine fragrances | 750 | 0.28 | 1 | 0.035 |
| Deodorant (non-spray) | 1500 | 0.10 | 1 | 0.025 |
| Shampoo | 10460 | 0.10 | 0.01 | 0.002 |
| Conditioner | 3920 | 0.10 | 0.01 | 0.001 |
| Shower gel | 18670 | 0.10 | 0.01 | 0.003 |
| Hand soap | 20000 | 0.10 | 0.01 | 0.003 |
| Hair styling products | 4000 | 0.10 | 0.1 | 0.007 |
| **Total** | | | | **0.268** |

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

*Domestic products*

| Product type | Frequency (use/day) | C (%) | Contact area ($cm^2$) | Product use C ($g/cm^3$) | Film thickness (cm) | Time scale factor | Daily systemic exposure (mg/kg bw/day) |
|---|---|---|---|---|---|---|---|
| Laundry liquid | 1.43 | 0.1 | 1980 | 0.01 | 0.01 | 0.007 | 0 |
| Dishwashing liquid | 3 | 0.1 | 1980 | 0.009 | 0.01 | 0.03 | 0.001 |
| All-purpose cleaner | 1 | 0.1 | 1980 | 1 | 0.01 | 0.007 | 0.002 |
| **Total** | | | | | | | **0.003** |

C = maximum intended concentration of assessed chemical
Daily systemic exposure = (Frequency × C × Contact area × Product Use Concentration × Film Thickness on skin × Time Scale Factor × DA)/BW

*Domestic products (from wearing clothes)*

| Product type | Amount (g/use) | C (%) | Product Retained (PR) (%) | Percent Transfer (PT) (%) | Daily systemic exposure (mg/kg bw/day) |
|---|---|---|---|---|---|
| Laundry liquid | 230 | 0.1 | 0.95 | 10 | 0.004 |
| Fabric softener | 90 | 0.1 | 0.95 | 10 | 0.001 |
| **Total** | | | | | **0.005** |

C = maximum intended concentration of assessed chemical
Daily systemic exposure = (Amount × C × PR × PT × DA)/BW

## Inhalation exposure

Hairspray is taken as a worst-case scenario example for the inhalation exposure assessment. A 2-zone approach (Steiling et al. 2014; Rothe et al. 2011; Earnest Jr. 2009) and an adult inhalation rate of 20 $m^3$/day (enHealth 2012) are used in the calculation. It is 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 | 1 | % |
| Inhalation rate of the user | 20 | $m^3$/day |
| Exposure duration in zone 1 | 1 | minutes |
| Exposure duration in zone 2 | 20 | minutes |
| Fraction inhaled by the user | 50 | % |
| Volume of zone 1 | 1 | $m^3$ |

| | | |
|---|---|---|
| Volume of zone 2 | 10 | $m^3$ |
| Daily systemic exposure | 0.034 | mg/kg bw/day |

C = maximum intended concentration of assessed chemical
Total daily systemic exposure = Daily systemic exposure in zone 1 [(amount × C × inhalation rate × exposure duration (zone 1) × fraction inhaled)/(volume (zone 1) × body weight)] + Daily systemic exposure in 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 domestic products may also occur.

### Overall systemic exposure

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 for various product types. This would result in a combined internal dose of 0.310 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 domestic products with lower exposure factors (e.g. air fresheners, polishes and waxes).

# Health hazard information

The applicant has provided test data on the chemical for most health endpoints. *In silico* predictions have also been provided for some endpoints. When the test data provided are based on studies conducted using the OECD TGs (test guidelines), these results were considered as adequate and conclusive to fulfil the data requirements for this assessment, unless any limitations were recorded in the TG studies.

## Acute toxicity

### Oral

A screening test was conducted with two female Wistar rats administered the assessed chemical once orally at 300 mg/kg bw or 2,000 mg/kg bw in corn oil. The high dose rat showed loose faeces at 1-2 h observation. Both rats appeared normal at 4-h observation.

In the main test (OECD TG 420), Wistar rats (n = 4 females/dose) were administered the assessed chemical via oral gavage (in corn oil) at 2,000 mg/kg bw and 300 mg/kg bw. In the 2,000 mg/kg bw group, all 4 rats were euthanised on Day 2 due to clinical signs of toxicity including piloerection (4/4), hunched posture (4/4), elevated gait (4/4), unsteady gait (4/4), irregular breathing (2/4), partially closed eyelids (2/4) and decreased activity (2/4) observed at the 2-hour observation.

Macroscopic examinations of the euthanised animals revealed:

- congestion in the subcutaneous tissue (4/4), heart (4/4), brain (4/4), lungs and bronchi (4/4), liver (2/4), kidneys (2/4) and spleen (1/4)

- pallor of liver (3/4), spleen (3/4) and kidneys (2/4)
- atrophy of the spleen (4/4) and cecum (4/4)
- gaseous distension of stomach (4/4)
- yellow fluid in the duodenum (4/4), small intestines (4/4) and large intestines (4/4)

According to the applicant, the adverse macroscopic effects are likely due to the local irritative effects of the assessed chemical caused by the metabolism of the aldehyde group into carboxylic acid after administration through the oral route. There were no mortalities, clinical signs of toxicity or abnormalities at necropsy in rats administered the assessed chemical at 300 mg/kg bw. Expected body weight gains were noted during the observation period.

The median lethal dose (LD50) of the assessed chemical was determined to be greater than 300 and less than 2,000 mg/kg bw, warranting hazard classification for Acute Oral Toxicity Category 4 (H302: Harmful if swallowed) according to GHS criteria as adopted in Australia for industrial chemicals.

## Irritation

### Skin irritation

The endpoint specific profiling functionality of the OECD Quantitative Structure Activity Relationship (QSAR) Toolbox v4.5 (OECD 2023) was used to determine the presence of potential structural alerts for skin irritation/corrosion. The assessed chemical has a positive structural alert for aldehydes.

QSAR modelling using OASIS TIMES (optimized approach based on structural indices set–tissue metabolism simulator) predicted that the assessed chemical was irritating to skin based on the structural alert for aromatic/aliphatic aldehydes. However, there is insufficient data to support the skin irritation classification of the assessed chemical.

### Eye irritation

In an *in vitro* eye irritation study (OECD TG 492 - EpiOcular™ model) conducted on the assessed chemical, the relative mean viability of the test substance-treated tissues was 73.2% after 30 minutes of exposure. As the tissue viability was > 60%, the test substance is identified as not requiring classification for eye irritation. The assessed chemical is not expected to be an eye irritant.

## Sensitisation

### Skin sensitisation

The endpoint specific profiling functionality of the OECD QSAR Toolbox v4.5 (OECD 2023) was used to determine the presence of potential structural alerts for skin sensitisation. The assessed chemical has a positive structural alert for protein binding for aldehydes.

QSAR modelling using OASIS TIMES predicted that the assessed chemical was a skin sensitiser based on the structural alert for aldehydes.

The knowledge based expert system Deductive Estimation of Risk from Existing Knowledge (DEREK) Nexus version 6.0.1 was utilised to estimate the skin sensitisation potential of the assessed chemical. The chemical is predicted as positive with an alert for skin sensitisation

due to the presence of an aldehyde group. Aldehydes have the ability to undergo Schiff base formation with nucleophilic groups present in skin protein. Therefore, they are likely to interact with skin proteins by such a mechanism. The predicted effective concentration for a 3-fold increase (EC3) in lymphocyte proliferation in local lymph node assay (LLNA) for the assessed chemical is 12%, indicating weak skin sensitisation potential.

Based on the available information, there is insufficient data to support the skin sensitisation classification of the assessed chemical according to GHS (Rev. 7, UNECE 2017) adopted in Australia for industrial chemicals.

### Genotoxicity

The assessed chemical was not mutagenic in a bacterial reverse mutation assay (OECD TG 471). The assessed chemical was also found not to be clastogenic in an *in vitro* mammalian micronucleus test using cultured human lymphocytes (OECD TG 487).

## 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 apparel and footwear care products, personal care products (cosmetics) except oral care products, cleaning and furniture care products and laundry and dishwashing 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 and fine fragrances 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 categorised as not persistent.

The result of a supplied prolonged biodegradation study conducted using the OECD TG 301D (oxygen consumption) demonstrated 74% degradation of the assessed chemical in 60 days. Therefore, the assessed chemical is categorised as not persistent in water.

### Bioaccumulation

Based on its log $K_{OW}$ value, the assessed chemical has the potential to bioaccumulate.

No bioaccumulation information was provided for the assessed chemical. The experimental partition coefficient of the assessed chemical (log $K_{OW}$ = 4.3) is above 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.

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

| | | |
|---|---|---|
| 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 |

# Environmental effects

## Effects on aquatic Life

### Acute toxicity

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

| Taxon | Endpoint | Method |
|---|---|---|
| **Fish** | 96 h LC50 = 2.2 mg/L | *Danio rerio*<br>(zebra fish)<br>Mortality<br>iSafeRat HA-QSAR v1.9<br>Ecotox module<br>Calculated concentration |
| **Invertebrate** | 48 h EC50 = 1.083 mg/L | *Daphnia magna*<br>(water flea)<br>Immobility<br>OECD TG 202<br>Semi-static conditions<br>Geometric mean<br>Measured concentration |
| **Algae** | 72 h ErC50 = 3.919 mg/L | *Pseudokirchneriella subcapitata*<br>(green algae)<br>Growth rate<br>OECD TG 201<br>Static conditions<br>Geometric mean<br>Measured concentration |
| **Microorganisms** | 3 h EC50 > 1,000 mg/L | Activated sludge from a STP<br>Respiration inhibition<br>OECD TG 209<br>Static conditions<br>Nominal concentration |

### Chronic toxicity

The following measured 10th percentile effect concentration (EC10) value for model organisms was supplied for the assessed chemical:

| Taxon | Endpoint | Method |
|---|---|---|
| **Algae** | 72 h ErC10 = 1.963 mg/L | *Pseudokirchneriella subcapitata* (green algae)<br>Growth rate<br>OECD TG 201<br>Static conditions<br>Geometric mean 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 > 0.54 µg/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

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

## Bioaccumulation

Bioaccumulative (B). Based on high measured log $K_{ow}$ value, the assessed chemical is categorised as Bioaccumulative.

## Toxicity

Not toxic (Not T). Based on available acute ecotoxicity values above 1 mg/L and a chronic ecotoxicity value above 0.1 mg/L, the assessed chemical is categorised as Not Toxic.

# Environmental risk characterisation

Although the assessed chemical is bioaccumulative, 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 < 1 the assessed chemical is not expected to pose a significant risk to the environment. As such, the environmental risks associated with the assessed chemical can be managed.

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