



Australian Government

Department of Health and Aged Care

Australian Industrial Chemicals Introduction Scheme

2*H*-2,4a-Methanonaphthalen-1(5*H*)-one, hexahydro-5,5-dimethyl-2-propyl-, (2*R*,4a*R*,8a*S*)-rel-

Assessment statement (CA10025)

23 June 2025



Table of contents

AICIS assessment (CA10025).....	3
Chemical in this assessment.....	3
Reason for the assessment	3
Defined scope of assessment.....	3
Summary of assessment	3
Means for managing risk.....	6
Conclusions	7
Supporting information	8
Chemical identity	8
Relevant physical and chemical properties	8
Human exposure	9
Health hazard information	11
Environmental exposure	13
Environmental effects	15
Categorisation of environmental hazard.....	16
Environmental risk characterisation	17
References	18

AICIS assessment (CA10025)

Chemical in this assessment

Name	CAS registry number
2H-2,4a-Methanonaphthalen-1(5H)-one, hexahydro-5,5-dimethyl-2-propyl-, (2R,4aR,8aS)-rel-	1441045-54-0

Reason for the assessment

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

Certificate application type

AICIS received the application in a 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
- imported in fragrance formulations at up to 1% concentration for local reformulation
- imported or reformulated into finished end use products for consumers end use in:
 - Personal care products (cosmetics) except oral care products - at up to 0.1% concentration
 - Fine fragrances - at up to 0.46% concentration
 - Laundry, dishwashing, cleaning, disinfecting and fabric softener products - at up to 0.1% concentration
 - Air care products - at < 1% in continuous action air fresheners and up to 0.2% in instant action air fresheners
- imported or reformulated as a component of finished domestic products for professional use - at up to 0.1% in domestic products such as washing, cleaning, detergent products and in polishes and wax blends.

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 either in 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 cosmetic and domestic products:

- Personal care products (cosmetics) except oral care products
- Fine fragrances

- Cleaning, disinfecting and furniture care products
- Laundry and dishwashing products
- Air care products

The proposed maximum use concentration of the assessed chemical in these products is up to 0.1% except for in fine fragrances at up to 0.46% and air fresheners at up to 0.2% (instant action) or < 1% (continuous action).

The finished domestic products at up to 0.1% concentrations are also proposed for professional use such as in washing, cleaning, detergent products and in polishes and wax blends.

Human health

Summary of health hazards

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

- of low acute oral and dermal toxicity (LD50 > 2,000 mg/kg bw in rats)
- not genotoxic

The toxicological information also indicate that the assessed chemical is:

- slightly irritating to skin
- causes serious eye irritation
- a skin sensitiser (LLNA EC1.4 = 19.40%)

No repeated dose oral toxicity data and no acute inhalation 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
Eye irritation	Category 2A	H319: Causes serious eye irritation
Skin sensitisation	Category 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 less than 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 is slightly irritating to skin, serious irritant to eyes, and a skin sensitiser. However, these effects are not expected to occur from use of the assessed chemical at the proposed low end use concentrations in cosmetics (at up to 0.1% in cosmetics, except 0.46% in fine fragrances) and domestic products (up to 0.1%, except in air fresheners at up to 0.2% (instant action) or < 1% (continuous action)). The air fresheners are not expected to come into direct contact with skin or eyes due to designed nature of the products.

Repeated dose toxicity data were not provided for the assessed chemical, although it will be used in consumer products that will be used repeatedly. However, based on the quantitative risk assessment (QRA) for the worst case scenario, consumers simultaneously using multiple cosmetics and domestic products could be systemically exposed to the assessed chemical at approximately < 0.5 mg/kg bw/day (301.1 µg/kg bw/day) through repeated or prolonged exposure. Considering the low systemic exposure level to the assessed chemical, health risks from repeated exposure to the public are not expected.

No inhalation toxicity data were provided for the assessed chemical. Due to low concentrations and low vapour pressure of the assessed chemical in the end use products, it is not expected to pose a health risk through inhalation when the assessed chemical is used according to the assessed use scenarios.

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

Workers

Reformulation workers may experience exposure to the assessed chemical at up to 1% concentration during reformulation processes such as weighing and transfer, blending, quality control analysis, filling and repackaging, and cleaning and maintenance of equipment. While exposure is expected to be mainly via the dermal route, ocular and inhalation exposures are also possible. It is anticipated by the applicant that engineering controls such as enclosed and automated processes and local ventilation will be implemented where possible. To mitigate the risks to formulation workers from any potential skin sensitisation and eye irritation effects and from repeated exposure, control measures would be required (see **Means for managing risk**) to minimise the exposure. Use of appropriate personal protective equipment (PPE) such as safety glasses, impervious chemical resistant gloves, protective clothing and respiratory protection will reduce worker exposure. Therefore, considering the use of engineering controls and PPE, minimal exposure is expected to workers during reformulation.

Professional workers in cleaning businesses and workers using polishes and wax blends may experience dermal and inhalation exposure and accidental ocular exposure to the assessed chemical at up to 0.1% concentration. The professional workers may wear some PPE (including impervious chemical resistant gloves, safety glasses, protective clothing). 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.

Overall, this assessment does not identify any risks to end use workers that require specific risk management measures.

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:

- Persistent (P)
- Not bioaccumulative (Not B)
- Toxic (T)

Environmental hazard classification

The chemical satisfies the criteria for classification according to the 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 potential 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 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 not readily degradable and is persistent and toxic to aquatic organisms. However, the assessed chemical does not have a potential for bioaccumulation.

Although the assessed chemical is persistent and toxic 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 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 dusts, mists or aerosols
- Use of safe work practices to
 - Avoid contact with skin and eyes
 - Avoid inhalation of vapours, mists or aerosols
- Use of personal protective equipment (PPE)
 - Impervious gloves
 - Protective clothing
 - Safety glasses
 - 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.
- As the assessed chemical is a skin sensitiser, the control measures may need to be supplemented with health monitoring for any worker who is at significant risk of exposure to the chemical, if valid techniques are available to monitor the effect on the worker's health.
- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

Conclusions

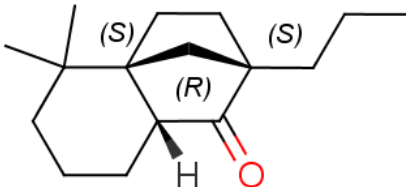
The Executive Director is satisfied that the risks to human health or the environment associated with the introduction and use of the industrial chemical can be managed.

Note:

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

Supporting information

Chemical identity

CAS number	1441045-54-0
CAS name	2 <i>H</i> -2,4a-Methanonaphthalen-1(5 <i>H</i>)-one, hexahydro-5,5-dimethyl-2-propyl-, (2 <i>R</i> ,4a <i>R</i> ,8a <i>S</i>)- <i>rel</i> -
Molecular formula	C ₁₆ H ₂₆ O
Molecular weight (g/mol)	234.38
SMILES (isomeric)	<chem>CC1(C)[C@]23[C@](C(=O)[C@](CCC)(C2)CC3)(C CC1)[H]</chem>
Representative structure	

Additional chemical identity information

The assessed chemical has a purity of greater than 98%.

Relevant physical and chemical properties

Physical form	White crystalline powder
Melting point	46.1 ± 0.2 °C
Boiling point	317.3 ± 0.4 °C at 101.3 kPa
Density	1080.7 kg/m ³ at 20 °C 9.49 x 10 ⁻⁵ kPa at 20 °C
Vapour pressure	1.93 x 10 ⁻⁴ kPa at 25 °C
Water solubility	5.4 mg/L
Flash Point	151 ± 2 °C at 101.3 kPa
Particle Size	L10: 279.93 µm L50: 534.04 µm (Median diameter) L90: 922.69 µm
Flammability	Not highly flammable

Ionisable in the environment	No
log K_{ow}	4.72
log K_{ow}	3.63

Human exposure

Public

There will be widespread and repeated exposure of the public to the assessed chemical at up to 0.1% concentration through the use of cosmetics and domestic products and at less than 1% concentration when using continuous action air fresheners. The main routes of exposure will be dermal and inhalation, while incidental oral or ocular exposures are also possible.

Dermal exposure

Data on typical use patterns of product categories in which the assessed chemical may be used 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	0.1	1	0.1303
Face cream	1540	0.1	1	0.0257
Hand cream	2160	0.1	1	0.0360
Fine fragrances	750	0.46	1	0.0575
Deodorant (non-spray)	1500	0.1	1	0.0250
Shampoo	10460	0.1	0.01	0.0017
Conditioner	3920	0.1	0.01	0.0007
Shower gel	18670	0.1	0.01	0.0031
Hand soap	20000	0.1	0.01	0.0033
Hair styling products	4000	0.1	0.1	0.0067

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (mg/kg bw/day)
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Total

0.2900

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	0.0000
Dishwashing liquid	3	0.1	1980	0.009	0.01	0.03	0.0003
All-purpose cleaner	1	0.1	1980	1	0.01	0.007	0.0023
Total							0.0026

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	0.0036
Fabric softener	90	0.1	0.95	10	0.0014
Total					0.0051

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 m³/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

0.1 %

Inhalation rate of the user

20 m³/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	0.0034 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 in various product types. This would result in a combined internal dose of 0.3011 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).

Health hazard information

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), the assessed chemical was administered via oral gavage to 6 female Sprague Dawley (SD) rats at a single dose of 2,000 mg/kg bw. Animals were observed for mortality, clinical signs and bodyweights for 14 days. No mortality occurred during the study. While piloerection was observed in 3/6 animals at 4 hours following administration, the animals recovered to a normal behaviour at 24 hours. No other clinical signs related to the treatment were recorded. The body weight in both treated and control animals remained in the normal range with no statistical significance during the study. There were no gross abnormalities noted for the animals when necropsied at the conclusion of the 14-day observation period. The acute oral LD50 value of assessed chemical was determined to be > 2,000 mg/kg bw. Therefore, the assessed chemical is considered to be of low acute oral toxicity.

Dermal

In an acute dermal toxicity study (OECD TG 402), the assessed chemical was applied at a single dermal dose of 2,000 mg/kg bw on the intact skin at the back and flank area of Sprague Dawley rats (n = 5 rats/group/sex) for 24 hours. All animals survived until the end of the study period of 14 days. Neither cutaneous reactions nor systemic clinical signs related to the administration of the test item were noted. All animals showed gains in body weight over the observation period. The macroscopical examination of the animals at the end of the study did not show treatment-related changes. The acute dermal LD50 value of 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

In a skin irritation study (OECD TG 404), 0.5 g of undiluted assessed chemical was applied on an undamaged skin area of the flank of 3 female New Zealand White rabbits for 4 hours under semi-occlusive conditions. The mean scores for each animal within 3 scoring times (24, 48 and 72 hours) were 1.7 / 0.0 / 1.3 for erythema and 2.0 / 0.0 / 0.3 for oedema, respectively. These effects were reversible at day 7 in all three animals. Dryness was noted on day 3 in all animals and was totally reversible between days 7 and 14. Under the conditions of this study, the assessed chemical was considered to be slightly irritating to the skin.

Eye irritation

In an eye irritation study (OECD TG 405), 0.1 g of undiluted assessed chemical was instilled into the conjunctival sac of one eye of each of 3 New Zealand White male rabbits. The other eye remained untreated serving as a control. The eyes were examined for any changes at 1, 24, 48 and 72 hours and on days 7 and 14 following treatments. Mean individual scores at 24, 48 and 72 hours after exposure for the 3 animals were 1.7, 1.0, 0.7 for cornea opacity, 0.3, 0.0, 0.0 for iris, 1.7, 1.7, 1.0 for conjunctivae redness, and 1.3, 1.0, 1.3 for conjunctivae chemosis, respectively. While iris and corneal changes were reversed to normal by day 7, slight conjunctival redness and opacity changes were still present in one animal only on day 7.

Under the conditions of the study and based on moderate corneal opacity observed in two animals (corneal opacity ≥ 1), the assessed chemical is classified as an eye irritant Category 2 (H319: Causes serious eye irritation Category 2A) according to the GHS criteria.

Sensitisation

Skin sensitisation

The skin sensitisation potential of the assessed chemical was tested using a local lymph node assay (LLNA) in mice (OECD TG 429). Three groups of four female mice (CBA/J) received topical application of 50 μ L of the assessed chemical at concentrations of 10%, 25% or 50% (in acetone:olive, oil 4:1) to the dorsal surface of each ear (25 μ L/ear) for 3 consecutive days. A control group of four female mice was treated with the vehicle (acetone:olive oil 4:1) only. At day 6, the draining auricular lymph nodes from the four mice were excised and pooled for each

experimental group and the proliferation of lymphocytes in the draining lymph nodes was determined by cell counting.

No mortality and no signs of systemic toxicity were noted during the study. As no significant increase in ear thickness and in ear weight was noted in all treated animals, the assessed chemical was considered by the study authors as not excessively irritating at the three tested concentrations. The Stimulation Index (SI) calculated by pooled approach was 0.93, 1.68 and 1.52 for the treated groups at 10%, 25%, and 50%, respectively. A stimulation index of more than 1.4 was recorded for two concentrations of the test item (25% and 50% (v/v) in acetone/olive oil). The EC1.4 value determined by linear regression was 19.40%.

AICIS notes that the positive control (α -Hexylcinnamaldehyde) used in the study achieved SI of 0.99, 1.54, and 1.60 at concentrations of 5%, 10% and 25%, respectively, with an EC 1.4 value of 8.73%. Therefore, under the conditions of the study and as stimulation index of more than 1.4 was recorded for two concentrations of the assessed chemical (25% and 50%), the assessed chemical is classified as skin sensitizer Category 1 (H317: May cause an allergic skin reaction) according to the GHS criteria.

Repeat dose toxicity

No data on repeated dose toxicity on the assessed chemical or on an analogue chemical were provided.

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 (pKM101), with or without metabolic activation (S9-mix) (OECD TG 471). The lowest cytotoxic concentration was 6.9 $\mu\text{g}/\text{plate}$; used as the highest concentration for this test. Five doses ranging from 0.1 and 6.9 $\mu\text{g}/\text{plate}$ were tested. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any tested dose (0.0001, 0.0003, 0.0008, 0.0023, 0.0069 mg/plate), with or without metabolic activation (S9-mix).

An *in vitro* chromosome aberration test, using cultured human lymphocytes, was conducted to assess clastogenic potential of the assessed chemical (OECD TG 473). The assessed chemical was tested at up to 64 $\mu\text{g}/\text{mL}$ in the absence or presence of metabolic activation system (S9 mix). Three exposure groups were tested: 4 hours exposure without S9 at 0, 4, 8, 16, 32, 48, 64 $\mu\text{g}/\text{mL}$ with cell harvest after a 20-hour expression period; 4 hours exposure with S9 at 0, 4, 8, 16, 32, 48, 64 $\mu\text{g}/\text{mL}$ with cell harvest after a 20-hour exposure period; and 24-hour exposure without S9 at 0, 4, 8, 16, 32, 40, 48, 56, 64 $\mu\text{g}/\text{mL}$. The assessed chemical did not induce any statistically significant increases in the frequency of cells with chromosome aberrations to human lymphocytes. Therefore, under the conditions of this study, the assessed chemical was not clastogenic to human lymphocytes *in vitro*.

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

Environmental exposure

The assessed chemical will be imported into Australia 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 products, washing, cleaning and disinfection 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 the biodegradation results in water, the assessed chemical is considered not readily biodegradable and is persistent.

Degradation studies in water indicate that the assessed chemical is not readily biodegradable. Biodegradation studies based on OECD 301D for the assessed chemical demonstrated 8.60% and < 20% degradation of the assessed chemical over 28 days.

Bioaccumulation

Based on the available weight of evidence, the assessed chemical does not have the potential to bioaccumulate.

A bioaccumulation study was conducted according to a modified OECD TG 305 study on a suitable analogue chemical (2*H*-2,4a-Methanonaphthalen-8(5*H*)-one, 1,3,4,6,7,8a-hexahydro-1,1,5,5-tetramethyl-) which showed a kinetic bioconcentration factor value (BCF_k) of 381 L/kg. Additionally, the bioconcentration factors were calculated using Episuite and Catalogic software models resulting in BCF values of 689.2 and 955 respectively. The available weight of evidence indicates that the BCF value of the assessed chemical is below 2,000 and therefore, the assessed chemical is categorised as Not Bioaccumulative.

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 key measured median lethal concentration (LC50) and effective concentration (EC50) values for model organisms were supplied for the assessed chemical:

Taxon	Endpoint	Method
Fish	96 h LC50 = 2.1 mg/L	<i>Danio rerio</i> (Zebrafish), Mortality OECD TG 203 Semi-static conditions Measured concentration
Invertebrate	48 h EL50 = 0.98 mg/L	<i>Daphnia magna</i> (Water Flea) Immobility <i>iSafeRat</i> , HA - QSAR v1.8 Ecotox module Calculated concentration
Algae	72 h ErC50 = 2.6 mg/L	<i>Raphidocelis subcapitata</i> (green algae) Growth rate <i>iSafeRat</i> , HA - QSAR v1.8 Ecotox module Calculated 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

Persistent (P). Based on measured degradation studies, the assessed chemical is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on the available weight of evidence that the assessed chemical has a low bioconcentration factor (BCF < 2,000 L/kg), the assessed chemical is categorised as Not Bioaccumulative.

Toxicity

Toxic (T). Based on the calculated ecotoxicity value below 1 mg/L, the assessed chemical is categorised as Toxic.

Environmental risk characterisation

Although the assessed chemical is persistent and toxic, 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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