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

1,3-Dioxane, 2-(3,3-dimethyl-1-cyclohexen-1-yl)-2,5,5-trimethyl-

Assessment statement (CA09714)

25 September 2023

Final

Table of contents

Contents

AICIS assessment statement (CA09714)

Chemical in this assessment

Name	CAS registry number
1,3-Dioxane, 2-(3,3-dimethyl-1-cyclohexen-1-yl)-2,5,5-trimethyl-	1853175-99-1

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 a fragrance component imported into Australia at up to 1 tonne/year
- as imported in fragrance formulations at up to 1% concentration for reformulation of end use cosmetics and household products
- as imported or reformulated in continuous action air fresheners at up to 1% concentration, in fine fragrances at up to 0.5% concentration, in instant action air fresheners at up to 0.25% concentration, in other cosmetic products at up to 0.05% concentration and in other 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 or in end use cosmetic and household products at various concentrations as shown below:

Product type	Proposed end use concentration (%)
Continuous action air fresheners	1.0
Fine fragrance	0.5
Instant action air fresheners	0.25
Other leave-on and rinse-off cosmetic products	0.05

Product type	Proposed end use concentration (%)
Other household products	0.02

The cosmetic and household end use products containing the chemical are proposed to be used by professional workers under industrial or non-industrial settings and by 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:

- of low acute oral and dermal toxicity
- slightly irritating to skin and eyes
- expected to be a weak skin sensitiser
- not expected to be genotoxic
- not expected to cause systemic toxicity following repeated oral exposure

The submitted data warrant hazard classification for skin sensitisation Cat. 1B for the assessed chemical (see section below).

No inhalation toxicity data on the chemical was provided by the applicant.

Hazard classifications relevant for worker health and safety

The 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 as follows:

Health hazards	Hazard category	Hazard statement
Skin sensitisation	Skin Sens. 1B	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 concentrations from 0.02% to 1% through the use of 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 in neat form is expected to be a weak skin sensitiser and is slightly irritating to skin and eyes. However, these effects are not expected to occur from use of the assessed chemical at the proposed low end use concentrations in cosmetic and household products (up to 0.5%), except for continuous action air fresheners. The continuous action air

fresheners are not expected to come into direct contact with skin or eyes due to designed nature of the products.

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

Based on the quantitative risk assessment (QRA) for the worst case scenario, consumers simultaneously using multiple cosmetics and household products could be systemically exposed to the assessed chemical at approximately 156 µg/kg bw/day through repeated or prolonged exposure (see **Supporting information** section). Considering the low systemic exposure level to the assessed chemical, health risks from repeated exposure to the public are not expected.

Overall, this assessment does not identify any risks to public health that would require specific risk management measures if the assessed chemical is introduced and used in accordance with the terms of the assessment certificate.

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 the risks to formulation workers from any skin sensitisation effects and repeated exposure, 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 0.5% concentration. The professional workers may wear some PPE (including gloves, safety glasses, coveralls and face masks). 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 domestic environmental hazard thresholds and based on the available data the chemical is:

- Not Persistent (not P)
- Bioaccumulative (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 readily biodegradation 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 end uses may result in the release of the assessed chemical to sewers and to air.

The assessed chemical is not readily biodegradable but it is not persistent based on > 60% degradation in 60 days. The assessed chemical has a potential for bioaccumulation and is not toxic to aquatic organisms, according to the domestic toxicity criteria.

As the assessed chemical does not meet all three PBT criteria it is 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

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.

Recommendation to Safe Work Australia

- It is recommended that Safe Work Australia (SWA) update the *Hazardous Chemical Information System* (HCIS) to include the classification relevant to work health and safety (see **Hazard classifications relevant for worker health and safety**).

Information relating to safe introduction and use

- The following control measures should be implemented to manage the risk arising from exposure to the assessed chemical during reformulation:
    - Use of engineering controls such as
        - automated and enclosed systems where possible
        - adequate workplace ventilation to avoid accumulation of vapours, mists or aerosols
    - Use of safe work practices to

        - avoid contact with skin and eyes
        - avoid inhalation of vapours, mists or aerosols

    - Workers should wear the following personal protective equipment (PPE)
        - overalls
        - gloves
        - respiratory protection if required

- These 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 employees.

Conclusions

The conclusions of this assessment are based on the information described in this statement.

Considering the means for managing risks, the Executive Director is satisfied that when the assessed chemical is introduced and used in accordance with the terms of the assessment certificate the human health and environment risks can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory and the means of managing the risks identified during this assessment are implemented.

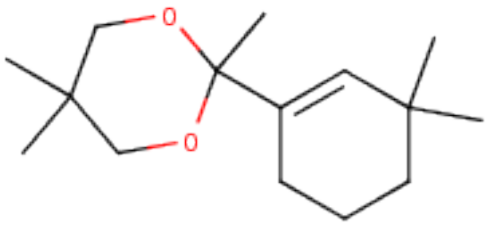
Note: Obligations to report additional information about hazards under section 100 of the *Industrial Chemicals Act 2019* apply.

Supporting information

Chemical identity

Chemical name	1,3-Dioxane, 2-(3,3-dimethyl-1-cyclohexen-1-yl)-2,5,5-trimethyl-
CAS No.	1853175-99-1
Synonyms	2-(3,3-Dimethyl-1-cyclohexen-1-yl)-2,5,5-trimethyl-1,3-dioxane
Molecular formula	$C_{15}H_{26}O_2$
Molecular weight (g/mol)	238.37
SMILES (Canonical)	O1CC(C)(C)COC1(C2=CC(C)(C)CCC2)C
Purity	> 90 - < 100% (w/w)

Representative Structure:



Relevant physical and chemical properties

Physical form	Colourless liquid
Melting point	-75 °C
Boiling point	254.6 °C
Density	940 kg/m^3 at 20 °C
Vapour pressure	2.40 Pa at 20 °C 3.76 at 25 °C
Water solubility	7.1 mg/L at 20 °C 15.4 mg/L at 25 °C
Ionisable in the environment?	No
pK_a	N/A
log K_{ow}	4.37 at 20 °C (pH = 7.1)

Log K_{oc}	2.88 – 3.29 (Calc.)
Flash point	110 °C
Autoignition temperature	240 °C

Human exposure

Public

There will be widespread and repeated exposure of the public to the assessed chemical at up to 0.5% concentration through the use of cosmetic and household products and up to 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 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 70 kg (enHealth 2012) for calculation purposes.

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (µg/kg bw/day)
Body lotion	7,820	0.05	1	56
Face cream	1,540	0.05	1	11
Hand cream	2,160	0.05	1	15
Fine fragrances	750	0.5	1	54
Deodorant (non-spray)	1,500	0.05	1	11
Shampoo	10,460	0.05	0.01	1
Conditioner	3,920	0.05	0.01	0
Shower gel	18,670	0.05	0.01	1
Hand wash soap	20,000	0.05	0.01	1
Hair styling products	4,000	0.05	0.1	3
Total				**153**

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 and wearing clothes will result in additional 1 µg/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). An adult inhalation rate of 20 m^3/day (enHealth 2012) was used and 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	0.05	%
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	**2**	µg/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 household products may also occur.

Overall, the worst-case scenario estimation 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 156 µg/kg bw/day (= 0.156 mg/kg bw/day) for the assessed chemical. This low level of worst-case systemic exposure is unlikely to pose health risk to the public with repeated use of products containing the assessed chemical.

Health hazard information

The results from toxicological investigations conducted on the assessed chemical provided by the applicant are summarised in the following table.

Endpoint	Test guideline	Results and Conclusion
Rat, acute oral toxicity	OECD TG 423	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	OECD TG 402	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation, EpiDerm™ reconstructed human epidermis tissue model	OECD TG 439	Does not require classification for skin irritation
Rabbit, skin irritation	OECD TG 404	Slightly irritating
Rabbit, eye irritation	OECD TG 405	Slightly irritating
Skin sensitisation – direct peptide reactivity assay (DPRA)	OECD TG 442C	Positive
Skin sensitisation – LLNA	OECD TG 442B	Evidence of sensitisation
Combined repeated dose oral (diet) toxicity study with reproduction/developmental toxicity screening test	OECD TG 422	NOAEL was reported as 10,000 ppm by the study authors (equivalent to 551-625 mg/kg bw/day, the highest doses tested); however, there were statistically significant decreases in food consumption and bodyweight gain in rats at this dose level and changes in the oestrus cycle of females at all dose levels.
Mutagenicity – bacterial reverse mutation	OECD TG 471	Non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	OECD TG 473	Non clastogenic

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), 6 female Sprague Dawley (SD) rats were administered a single dose of the assessed chemical at 2,000 mg/kg bw. No mortalities, test substance-related clinical signs or macroscopic findings were observed in any treated animals. Body weight gain appeared normal. The median lethal dose (LD50) was determined to be greater than 2,000 mg/kg bw indicating the assessed chemical is of low acute oral toxicity.

Dermal

In an acute dermal toxicity study (OECD TG 402), a single dose of the assessed chemical at 2,000 mg/kg bw was applied (semi-occlusive for 24 hours) on the intact skin of 10 SD rats (n = 5/sex). No mortalities were observed. Slight erythema was observed in treated females at the 48-hour observation. Treated skin sites appeared normal on the 5-Day observation and no other skin reactions were observed. There were no treatment-related macroscopic findings.

Body weight gain was normal. The LD50 was determined to be greater than 2,000 mg/kg bw, indicating the assessed chemical is of low acute dermal toxicity.

Corrosion/Irritation

Skin irritation

The assessed chemical is not classified as a skin irritant, according to the results of an in vitro skin irritation test using the EpiDerm™ reconstructed human epidermis tissue model (OECD TG 439). The relative mean viability of the test substance-treated tissues was 100.9% (above the threshold of ≤ 50% for classification according to GHS criteria) after the 1-hour exposure period (followed by a 42-hour post-exposure incubation period).

The assessed chemical was also tested in rabbits (OECD TG 404). A single 4-hour, semi-occluded application of the test substance to the intact skin of 3 rabbits produced slight to well-defined erythema (maximum score of 2) and very slight to slight oedema (maximum score of 2) in all animals at the 1-hour observation and the reactions persisted until the 72-hour observation. Loss of litheness was noted in 1 animal at the 72-hour observation and dryness of the skin was observed in all animals at the 7-day observation. At the 14-day observation, only dryness of the skin was observed in 1 animal. Under the conditions of this study, the assessed chemical was slightly irritating to skin but does not meet the GHS criteria for classification.

Eye irritation

The assessed chemical was tested for eye irritation using 3 female rabbits (OECD TG 405). After a single application of the test substance, slight to moderate conjunctival irritation (maximum score of 2) and corneal opacity (maximum score of 2) were observed in the treated eye of all animals 1 hour after treatment. Slight conjunctival irritation (maximum score of 1) remained in the treated eye of one animal at the 72-hour observation. Iridial congestion was noted in 1 animal at the 1-hour observation. Treated eyes appeared normal at the 48-hour or 7-day observations. Under the conditions of this study, the assessed chemical was slightly irritating to the eyes but does not meet the GHS criteria for classification.

Sensitisation

Skin sensitisation

One *in chemico* assay was conducted to evaluate the skin sensitisation potential of the assessed chemical. This assay is part of Integrated Approach to Testing and Assessment (IATA) which address specific events of the Adverse Outcome Pathway (AOP) leading to development of skin sensitisation (OECD, 2016). The direct peptide reactivity assay (DPRA) is an i*n chemico* method and aims to address the first key event (KE) (molecular initiation) of the AOP by measuring the interaction of the assessed chemical with cysteine and lysine, small synthetic peptides representing the nucleophilic centres in skin proteins (OECD TG 442C). The assessed chemical was positive in the DPRA assay (cysteine depletion was 93.4%, and lysine depletion was 0.3%; mean depletion was 46.9%).

The other two KE assays of the AOP were not available for the assessed chemical.

A Local Lymph Node Assay (LLNA): BrdU-ELISA in mice (OECD TG 442B) was conducted using the assessed chemical. In this study, the mice (4 per group) were treated by daily application of 25 µL of the test substance at concentrations of 25%, 50% or 100%

(acetone/olive oil 4:1 as vehicle for 25% or 50%) to the dorsal surface of each ear for 3 consecutive days. There were no mortalities or signs of systemic toxicity. Body weight gain was comparable to controls. The stimulation index (SI) values at 25%, 50% and 100% concentrations were 1.33, 1.46 and 1.61, respectively. The concentration of test substance expected to result in a 1.6-fold increase in BrdU incorporation (EC1.6 value) was calculated (by linear interpolation) to be 96.67%.

Based on the results of the studies, the assessed chemical is a weak skin sensitiser, warranting classification for Skin Sensitisation (Cat 1B: H317: May cause an allergic skin reaction) according to the GHS criteria.

Repeat dose toxicity/Reproductive and development toxicity

Oral

In a combined repeated dose oral (diet) toxicity study with reproduction/developmental toxicity screening test (OECD TG 422), the assessed chemical was administered to SD rats at dose levels of 0, 1,000, 3,000 and 10,000 ppm for up to 6 weeks. Rats were tested for general systemic toxicity (10 males and 5 females per group), reproductive toxicity (10 females per group) and 28-day recovery after treatment (5 per sex for control and high-dose groups). The dose selection of this study was based on the results of a previous 14-day dose range finding study.

Effect on parental animals

There were no deaths of animals during the course of the study. There were no test substance-related effects on general appearance, behavioural parameters, functional performance, and sensory reactivity.

There were statistically significant reductions in the mean body weight of high-dose males and females, and some mid-dose males due to a statistically significant reduction in food intake during the study. At the end of the recovery period, there was a slight reduction in the mean body weight of females (-10%), but males were fully recovered. The study authors stated the effects were due to palatability of the test substance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis, Thyroid Hormone

No test substance-related effects were observed in urinalysis and thyroid hormone levels.

There were statistically significant increases in plasma urea, plasma cholesterol, total protein and globulin in high-dose males as well as decreases in sodium, potassium and chloride concentrations in the mid- or high-dose males. In the high-dose group females, there were statistically significant decreases in phosphorus concentration, aspartate transferase activity and increased prothrombin time. Decreases in haemoglobin (-3%), activated partial thromboplastin time (APTT) (-22%) and increased globulin (4%) were also observed in high-dose females. While males recovered, there were still decreases in haemoglobin (-6%), APTT levels (-12%) phosphorus concentrations (-24%) as well as increased globulin (6%) in the high-dose females. The study authors reported these effects as not toxicologically relevant, due to no dose response.

In the reproductive screening group females, statistically significant increases in triglyceride, sodium and chloride concentrations as well as decreases in red cell distribution width and alkaline phosphatase activity were observed in the mid or high-dose groups. All treated

reproductive females also had reduced alanine transferase activity; however, full recovery from all effects was observed by the end of the study.

Effects on Organs

At the end of the treatment period, absolute and relative mean liver weights increased in both sexes of the mid- and high-dose groups in comparison to controls. A slight increase in thyroid and parathyroid weight as well as a slight reduction in heart weight were also observed in both sexes of the high-dose group. After recovery, there was a slight increase in the mean liver weight of both sexes of the high-dose group (6%) and thyroid and parathyroid mean weights decreased by14% in males and 33% in females, in comparison to controls. At Day 13 of lactation, the absolute and relative uterus, cervix and oviducts weights were decreased in all treated females with a dose-response reported for the relative weights (13-15%). These changes were considered by the study authors to be spontaneous and not treatment related.

No test substance-related abnormalities were observed at macroscopic examinations of organs.

Microscopic analysis revealed hypertrophy of centrilobular hepatocytes in the liver, follicular cell hypertrophy/hyperplasia in the thyroid and diffuse hypertrophy of the zona glomerulosa in the adrenals in majority of the high-dose males and females. Basophilia of cortical tubules were also observed in the kidneys of high-dose males. These effects were no longer observed or comparable to controls by the end of the recovery period.

Based on these findings, the No Observed Adverse Effect Level (NOAEL) for systemic toxicity was reported by the study authors as 10,000 ppm (equivalent to 551 and 625 mg/kg bw/day for males and females, respectively).

Reproductive Effects

There were no test substance-related effects on male reproductive parameters (including male mating and fertility indices) and female reproduction and delivery data (including female mating and fertility indices, gestation index, birth indices and post-implantation loss).

Abnormal oestrous cycles were observed in 6 females of the low dose group, 2 females of the mid-dose group, and 3 females of the high-dose group, which was characterised by irregular dioestrus cycles of 4 to 5 days and acyclicity throughout the treatment period. Slightly extended lengths of pre-coital interval were also observed during treatment. Normal oestrous cycles were observed in all reproductive females at the end of the study. The increase in acyclicity and irregular cycles in treated females did not affect mating performance and fertility, as all females displayed a 100% conception rate.

The NOAEL for reproductive toxicity was reported by the study authors as 10,000 ppm (equivalent to 609 mg/kg bw/day during gestation and 1,332 mg/kg bw/day lactation).

Effects on pups

Reduced body weight gain (19%) in comparison to control were reported for the offspring of the high-dose females. The study authors considered the findings to be due to decreased food intake of the mothers but noted that their relation to the test substance could not be excluded with certainty.

There were no test substance-related effects on sex ratio, mean body weight values of the pups per dam, litter weight per dam, anogenital distance, and T4 hormone level. No

abnormalities were noted during macroscopic external examination at necropsy and microscopic examination of the thyroid grands.

Based on these findings, the NOAEL for developmental toxicity was reported by the study authors as 10,000 ppm (equivalent 1,332 mg/kg bw/day during lactation).

Although the NOAELs for systemic, reproductive and developmental toxicity was reported by the study authors to be the highest dose tested (10,000 ppm), there are concerns with the reported decreased body weight gain in high-dose females and their offspring. Irregular or acyclic oestrous cycles were observed in females at all doses. While these effects could be due to decreased food intake caused by palatability issues or secondary to the reduced food intake, their relation to the test substance cannot be ruled out. Therefore, the NOAELs reported in the study cannot be confirmed without further data, such as from an oral gavage study.

Genotoxicity

The assessed chemical was found to be non mutagenic in a bacterial reverse mutation assay (OECD TG 471). The assessed chemical was also found to be non clastogenic in an in vitro mammalian chromosome aberration test using human peripheral blood lymphocytes (OECD TG 473).

Environmental exposure

The assessed chemical will be imported into Australia for use as a fragrance in end use cosmetic and household 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 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

Degradation studies in water indicate that the assessed chemical is not readily biodegradable but will not be persistent. A supplied OECD 301D biodegradation study for the assessed chemical demonstrated 45% and 72% degradation of the assessed chemical over 28 days and

60 days, respectively. Therefore, the assessed chemical is categorised as not persistent based on > 60% degradation in 60 days.

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} = 4.37) is above the domestic bioaccumulation threshold of log K_{OW} = 4.2 (EPHC, 2009).

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 in this worst-case exposure 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 measured median lethal concentration (LC50) and median effective concentration (EC50) values for model organisms were supplied by the applicant:

Taxon	Endpoint	Method
Fish	96 h LC50 > 5.4 mg/L	*Danio rerio* (Zebra fish) OECD TG 203 Semi-static conditions Geometric means of measured concentration
Invertebrate	48 h EC50 = 2.2 mg/L	*Daphnia magna* (Water flea) Immobility/other effect OECD TG 202 Static conditions Nominal concentration
Algae	72 h E_rC50 > 3.5 mg/L	*Desmodesmus subspicatus* (Green algae) Growth rate OECD TG 203 Semi-static conditions Geometric means of 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 µg/L.

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemical according to domestic environmental hazard thresholds 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 a high measured log K_{ow} value (4.37), the assessed chemical is categorised as Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available ecotoxicity values above 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	> 0.54 µg/L	< 1
Ocean	< 0.05 µg/L	> 0.54 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.

References

ACI (2010) Consumer Product Ingredient Safety, Exposure and risk screening methods for consumer product ingredients, 2nd Edition, American Cleaning Institute, Washington DC

Cadby PA, Troy WR, Vey MG (2002) Consumer Exposure to Fragrance Ingredients: Providing Estimates for Safety Evaluation. Regulatory Toxicology and Pharmacology, 36:246-252

Earnest CW Jr. (2009) A Two-Zone Model to Predict Inhalation Exposure to Toxic Chemicals in Cleaning Products, MScEng thesis, The University of Texas at Austin.

enHealth (2012) Australian Exposure Factor Guide, companion document to: Environmental Health Risk Assessment: Guidelines for assessing human health risks from environmental hazards, EnHealth, Commonwealth of Australia.

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

Loretz L, Api AM, Barraj L, Burdick J, Davis DA, Dressler W, Gilberti E, Jarrett G, Mann S, Pan YHL, Re T, Renskers K, Scrafford C, Vater S (2006) Exposure data for personal care products: Hairspray, spray perfume, liquid foundation, shampoo, body wash, and solid antiperspirant. Food and Chemcial Toxicology, 44:2008-2018.

Rothe H, Fautz R, Gerber E, Neumann L, Rettinger K, Schuh W, Gronewold C (2011) Special aspects of cosmetic spray evaluations: Principles on inhalation risk assessment. Toxicology Letters, 205:97-104.

SCCS (2012) The SCCS's notes of guidance for the testing of cosmetic substances and their safety evaluation (8th revision), European Commission - Scientific Committee on Consumer Safety

Steiling W, Bascompta M, Carthew P, Catalano G, Corea N, D'Haese A, Jackson P, Kromidas L, Meurice P, Rothe H, Singal M (2014) Principle considerations for the risk assessment of sprayed consumer products. Toxicology Letters, 227:41-49.

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