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

Tetrapleura tetraptera, ext.

Assessment Statement (CA10095)

12 May 2026

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AICIS assessment statement (CA10095)

Chemical in this assessment

Name	CAS registry number
Tetrapleura tetraptera, ext.	2131091-72-8

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 an extract of *Tetrapleura tetraptera* obtained from the fruit by ethanol extraction
- as imported into Australia at up to 25 kg/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 0.5% 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% concentration in continuous action air fresheners and up to 0.1% concentration 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 at up to 25 kg/year 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 concentration of the assessed chemical in end use products is up to 0.1%, except for fine fragrances at up to 0.5% and continuous action air fresheners 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**) indicate that the assessed chemical is:

- of low acute oral toxicity
- not a skin sensitiser at up to 25% concentration
- not mutagenic in a bacterial reverse mutation assay
- a skin irritant (see below)

The assessed chemical is a skin irritant based on an in vitro skin irritation study (OECD TG 439). Therefore, the assessed chemical is classified as a Category 2 skin irritant (H315: Causes skin irritation).

No eye irritation, inhalation toxicity 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 *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
Skin irritation/corrosion	Skin Irrit. 2	H315: Causes skin irritation

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 is a skin irritant and no eye irritation data were provided. However, skin and eye irritation 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 0.5% 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 and eyes due to designed nature of the products.

No inhalation toxicity data were provided for the assessed chemical. Taking hairspray as a worst-case scenario for inhalation exposure assessment, the systemic exposure is estimated to be up to 0.034 mg/kg bw/day (see **Supporting information**). Inhalation exposure to the assessed chemical from use of other cosmetic and domestic products including air fresheners may also occur. However, given the low end use concentrations of the assessed chemical and its lack of environmental persistence, risks from inhalation are not expected under normal use.

No repeated dose toxicity data were provided for the assessed chemical. Therefore, quantitative risk assessment (QRA) could not be performed to determine the margin of exposure (MOE). Under a worst-case scenario, consumers simultaneously using multiple cosmetic and domestic products may experience systemic exposure of approximately 0.338 mg/kg bw/day through repeated or prolonged dermal and inhalation routes (see **Supporting information**). Considering the low systemic exposure level to the assessed chemical in the worst-case exposure scenario, health risks from repeated exposure to the public are not expected.

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

Workers

Reformulation workers may be incidentally exposed to the assessed chemical at up to 1% concentration during reformulation processes primarily via the dermal route, with ocular and inhalation exposures also possible. To mitigate any 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, and 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 be exposed to the assessed chemical at up to 1% via dermal, inhalation and incidental ocular exposure. These 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. Therefore, no additional risk management measures are required 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 low hazard of its components (in the absence of ecotoxicity data for the assessed chemical), the assessed chemical is:

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

Environmental hazard classification

The assessed chemical is not harmful to aquatic life based on endpoints available for individual constituents representing the majority of the assessed chemical. Therefore, the assessed chemical does not satisfy the criteria for classification under the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) for acute and chronic aquatic toxicities (UNECE, 2017).

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

According to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022), the assessed chemical does not meet any of the PBT criteria. It is hence unlikely to have unpredictable long-term effects.

Based on the low introduction volume, and expected low hazard of the assessed chemical, 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 and eyes
  - Avoid inhalation of mists or aerosols
- Use of personal protective equipment (PPE)
  - Impervious gloves
  - Safety glasses
  - Protective clothing
  - Respiratory protection where local ventilation may be inadequate
- 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. A person introducing this chemical should be aware of their obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

CAS number	2131091-72-8
CAS name	Tetrapleura tetraptera, ext.

Additional chemical identity information

The assessed chemical is an extract of Tetrapleura tetraptera obtained from the fruit by ethanol extraction.

Relevant physical and chemical properties

Physical form	Pasty dark brown liquid
Melting point	< - 20 °C at 98.3 kPa
Boiling point	Degrades prior to boiling
Density	1,311.5 kg/m^3 at 20 °C
Water solubility	Not determined. The assessed chemical contains approximately > 95% of constituents with water solubility ≥ 500 mg/L.
Ionisable in the environment	No
log *K*ow	Not determined. The assessed chemical contains approximately 95% of constituents with log Kow < 0, 5% with log Kow > 7.

Human exposure

Public

Dermal exposure of the public to the assessed chemical at a maximum concentration of 0.5% will be wide-spread and frequent across the use of a variety of household and cosmetic 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 literature (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	7,820	0.100	1	0.130
Face cream	1,540	0.100	1	0.026
Hand cream	2,160	0.100	1	0.036
Fine fragrances	750	0.500	1	0.063
Deodorant (non-spray)	1,500	0.100	1	0.025
Shampoo	10,460	0.100	0.01	0.002
Conditioner	3,920	0.100	0.01	0.001
Shower gel	18,670	0.100	0.01	0.003
Hand wash soap	20,000	0.100	0.01	0.003
Hair styling products	4,000	0.100	0.1	0.007
Total				**0.296**

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	1,980	0.01	0.01	0.007	0.000
Dishwashing liquid	3	0.1	1,980	0.009	0.01	0.03	0.000
All-purpose cleaner	1	0.1	1,980	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 household 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 0.338 mg/kg bw/day for the assessed chemical. It is considered that the combination of the conservative hair spray inhalation exposure assessment parameters, and the aggregate exposure from use of the dermally applied products, which assumes a conservative 100% dermal absorption rate, is sufficiently protective to cover additional inhalation exposure to the assessed chemical from use of other spray cosmetic and household products with lower exposure factors (e.g. air fresheners).

Health hazard information

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), 6 female Sprague Dawley rats were administered a single dose of the assessed chemical via oral gavage at 2,000 mg/kg bw. Increased salivation was observed at 30 minutes post-dose in 5/6 animals. This resolved at 1-hour post-dose. No other signs of systemic toxicity were observed, and body weight gain appeared normal during the study. No mortalities or treatment related macroscopic changes were observed in any treated animal.

The median lethal dose (LD_{50}) was determined to be greater than 2,000 mg/kg bw. The assessed chemical is of low acute oral toxicity.

Corrosion/Irritation

Skin irritation

In an *in vitro* skin irritation study (OECD TG 439), 0.5 cm^2 reconstructed human epidermis (SkinEthic RHE model) was treated with approximately 16 mg of the assessed chemical applied on a nylon mesh for 42 minutes (n = 3). The mean percentage viability of the treated tissues was 41%. According to the TG, tissue viability < 50% warrants skin irritation Cat 2 classification.

However, this test method (TG 439) should be used for chemicals proven to be non-corrosive using other OECD TGs such as 430, 431 or 435. No data were provided to rule out corrosivity of the assessed chemical. However, the major components of the assessed UVCB chemical are carbohydrates, which have no known corrosive properties. Therefore, the assessed chemical is not likely to be corrosive and is classified as a Category 2 skin irritant (H315: Causes skin irritation).

Eye irritation

No data were provided for the assessed chemical. Considering the low concentrations in end use products, eye irritation effects are not likely to occur.

Sensitisation

Skin sensitisation

The assessed chemical was investigated for skin sensitisation with three groups of 4 CBA/J strain mice using a mouse local lymph node assay (LLNA:BrdU-ELISA) (OECD TG 442B).

Preliminary investigation showed 50% of the assessed chemical caused alopecia and slight dryness in the animals on day 6. The main test was conducted with 5%, 10% and 25% concentration of the assessed chemical and 1/4, 4/4 and 4/4 animals, respectively, showed

skin dryness on day 6. The Stimulation Indices (SI) of groups treated with 5%, 10% and 25% were 1.20, 1.20 and 1.27 respectively. No significant increase in ear thickness and ear weight was observed between 5 - 25%. Under the conditions of this study, the assessed chemical is not sensitising to the skin at up to 25% concentration.

Repeat dose toxicity

No data were provided for the assessed chemical. Considering the low concentrations in end use products, repeated dose toxicity effects are not likely to occur.

Genotoxicity

The assessed chemical was found to be not mutagenic in an *in vitro* bacterial reverse mutation assay (Ames test) using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* strain WP_2uvrA with or without metabolic activation (S9-mix) (OECD TG 471).

Two independent assays were conducted with doses 5,000, 1,500, 500, 150 and 50 µg/plate. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at up to 5,000 µg/plate of the assessed chemical, either with or without metabolic activation.

Environmental exposure

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 use of the assessed chemical in cosmetic products, washing, cleaning and disinfection products will result in the release of the assessed chemical “down the drain” and into the sewers. Consequently, the assessed chemical will be treated at sewage treatment plants (STPs) before release to surface waters.

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

Environmental fate

Partitioning

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

Degradation

Based on its measured degradation in water, the assessed chemical is considered readily biodegradable and not persistent.

Degradation studies in water indicate that the assessed chemical is readily biodegradable. Biodegradation studies based on OECD 301D for the assessed chemical demonstrated 63% degradation of the assessed chemical over 28 days.

Bioaccumulation

No bioaccumulation study was provided.

The assessed chemical is a UVCB substance with approximately 95% of the constituents having measured log Kow < 0, 5% of the constituents having a measured log Kow > 7 but are expected to be rapidly metabolised.

Based on the low log Kow values of the major constituents, the assessed chemical is concluded to be not bioaccumulative.

Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) for Australian waters was calculated assuming 100% of the introduction volume is released into sewage treatment plants (STP) over 365 days per annum. Concentration of the assessed chemical after STP primary and secondary treatments were calculated based on the worst-case scenario of no removal of the assessed chemical during STP processes, modelled by SimpleTreat 4.1 (Struijs 2014) which has been adjusted to suite Australian STP conditions.

In Australia, about 20% of sewage is treated to primary levels which then discharged to ocean, and 80% of Australian sewage is treated to at least secondary levels which then discharged to both ocean and rivers (Blue Environment 2020). A dilution factor of 1 was applied to river discharge and a dilution factor of 10 was applied to ocean discharge (EPHC 2009). PEC values for river and ocean discharges are summarised in the table below:

Total Annual Import Volume	25	kg/year
Proportion expected to be released to sewer	100 %	
Days per year where release occurs	365	days/year
Daily chemical release	0.07	kg/day
Water use	200	L/person/day
Population of Australia	25.423	Million
Removal from primary treatment	0 %	Mitigation
Removal from secondary treatment	0 %	Mitigation
Daily effluent production	5,085	ML/day

PEC - River	0.01	µg/L
PEC - Ocean	0.001	µg/L

Environmental effects

Effects on aquatic life

No ecotoxicity information was provided for the assessed chemical.

The assessed chemical is not expected to be toxic to aquatic life based on the previous assessments on individual sugar and carbohydrate constituents representing the majority of the assessed chemical (NICNAS, 2020 and NICNAS, 2021), and the remaining components are also expected to have low aquatic toxicity.

Predicted no-effect concentration (PNEC)

The predicted no-effect concentration was not calculated as no ecotoxicological data were provided.

Categorisation of environmental hazard

According to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022) and based on the low hazard of its majority components, the chemical is categorised as:

Persistence

Not Persistent (Not P).

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

Bioaccumulation

Not Bioaccumulative (Not B).

The assessed chemical is a UVCB substance with approximately 95% of the constituents having measured log Kow < 0. Of the remaining 5% of the constituents having a measured log Kow > 7 are expected to be rapidly metabolised.

Toxicity

Not Toxic (Not T).

The assessed chemical is not expected to be toxic to aquatic life based on the previous assessments on individual constituents representing the majority of the assessed chemical

(NICNAS, 2020 and NICNAS, 2021), and the remaining components are expected to have low aquatic toxicity too.

Environmental risk characterisation

The assessed chemical is not a PBT chemical and hence is unlikely to have unpredictable long-term effects (EPHC 2009).

No ecotoxicity data were provided for the assessed chemical. Therefore, the Risk Quotients (RQ = PEC ÷ PNEC) was not calculated. However, the assessed chemical is not expected to be released to the environment in quantities that would pose a significant risk to aquatic life. The assessed chemical is expected to be rapidly biodegradable and does not have the potential to bioaccumulate. On the basis of low introduction volume, lack of persistence and bioaccumulation potential, and assumed low toxicity, the assessed chemical is not expected to pose significant risk to the aquatic environment. As such, the risk from the introduction of the assessed chemical can be managed.

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