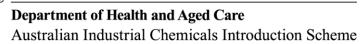
Australian Government



# Phenol, 2-ethoxy-4-(ethoxymethyl)-

# **Assessment statement (CA09856)**

13 May 2024



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# AICIS assessment (CA09856)

## Chemical in this assessment

Name	CAS registry number
Phenol, 2-ethoxy-4-(ethoxymethyl)-	71119-07-8

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

# Summary of assessment

### Summary of introduction, use and end use

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

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

### Human health

### Summary of health hazards

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

- is of low acute oral toxicity
- may cause drowsiness or dizziness
- is slightly irritating to skin
- is irritating to eyes
- is not mutagenic in a bacteria reverse mutation assay

The results of the submitted acute oral toxicity study warrant classification of the assessed chemical for specific target organ toxicity - single exposure (STOT SE) via oral route (Category 3, H336) based on the transient clinical effects reported in rats (see below and **Supporting Information** section).

The results of the submitted eye irritation study warrant classification of the assessed chemical for eye irritation Category 2B (see **Supporting Information** section).

The results of the submitted guinea pig maximisation test (GPMT) for skin sensitisation showed skin reactions in test animals (2 of 10 in each challenge) in the first and second challenges at 100% concentration of the assessed chemical (see **Supporting information** section). However, the evidence was insufficient for hazard classification under GHS. Computer modelling (Derek Nexus v6.0.1) indicates that the assessed chemical contains dihydroxybenzene which is a structural alert for skin sensitisation. Hence skin sensitisation potential for the assessed chemical at high concentration cannot be ruled out.

No inhalation or repeated dose toxicity data were submitted on 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
Specific target organ toxicity (single exposure - oral)	STOT SE (oral) 3	H336: May cause drowsiness or dizziness
Eye irritation	Eye Irri 2B	H320: Causes eye irritation

#### Summary of health risk

#### Public

There will be widespread and repeated exposure of the public to the assessed chemical at up to 0.5% concentration using a wide range of cosmetic and household products. The principal route of exposure will be dermal and inhalation, while incidental oral or ocular exposure is also

possible. Inhalation exposure occurs particularly from the use of air-care products and other products applied by spray.

The assessed chemical in neat form is slightly irritating to skin and irritating to eyes. However, irritation risks are not expected to occur from use of the assessed chemical at the low proposed end use concentrations of maximum 0.5% in cosmetic and household products.

The assessed chemical may cause drowsiness or dizziness on single oral exposure to high doses. The assessed chemical will only be imported at a maximum concentration of 1% and used at up to 0.5% concentration in consumer products and single exposure of the chemical at such low concentrations in the products are unlikely to cause adverse health effects.

Although the potential for skin sensitisation of the assessed chemical cannot be completely ruled out, when used at up to 0.02% concentration in cosmetic and household products (except in fine fragrances and air fresheners at up to 0.5% concentration, and instant action air fresheners at up to 0.1% concentration), skin sensitisation risk is not expected.

No acute or repeated dose inhalation toxicity data are provided for the assessed chemical. Due to low concentrations of the assessed chemical proposed in the end use products, inhalation toxicity risk is not expected.

No repeated dose toxicity data were provided on the assessed chemical. Based on the quantitative risk assessment (QRA) for the worst-case exposure scenario, consumers simultaneously using multiple cosmetic and household products may be systemically exposed to the assessed chemical at approximately 115 µg/kg bw/day through repeated or prolonged exposure (see **Supporting information** section). Considering the low systemic exposure level calculated for the worst-case exposure scenario, health risks from repeated exposure to the chemical for the public are not expected.

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

#### Workers

Reformulation workers may be incidentally exposed to the assessed chemical at up to 1% concentration during reformulation processes mainly via the dermal route, while ocular and inhalation exposures are also possible. To mitigate potential exposure to the chemical for reformulation workers, control measures are required (see **Means for managing risk**). 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, coveralls, and face masks or safety glasses). If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using the same end use products containing the assessed chemical, requiring no specific risk management measures for these workers.

### Environment

#### Summary of environmental hazard characteristics

According to domestic environmental hazard thresholds and based on the available data the chemical is:

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

#### Environmental hazard classification

The assessed chemical satisfies the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE, 2017) as Acute Category 3 (H402) and Chronic Category 3 (H412) 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 3	H402: Harmful to aquatic life
Hazardous to the aquatic environment (long-term)	Aquatic Chronic 3	H412: Harmful to aquatic life with long lasting effects

#### Summary of environmental risk

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

The assessed chemical is not readily degradable and is not persistent. The assessed chemical does not have the 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 is not a PBT chemical, hence it is unlikely to have unpredictable longterm 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
  - 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 eyes and skin
  - avoid inhalation of vapours, mists or aerosols
- Use of personal protective equipment (PPE)
  - coveralls
  - goggles
  - gloves
  - respiratory protection if exposure to vapours, mists or aerosols is possible
- 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

Chemical name	Phenol, 2-ethoxy-4-(ethoxymethyl)-	
CAS No.	71119-07-8	
Synonyms	2-Ethoxy-4-(ethoxymethyl)phenol	
	4-Hydroxy-3-ethoxybenzyl ethyl ether	
Molecular formula	$C_{11}H_{16}O_3$	
Molecular weight (g/mol)	196.24	
SMILES (canonical)	OC1=CC=C(C=C1OCC)COCC	
Structural formula		

H<sub>3</sub>C CH<sub>3</sub>

### **Chemical description**

The assessed chemical has a purity greater than or equal to 97%.

# Relevant physical and chemical properties

Physical form	Liquid
Melting point	- 62.4 °C ± 0.1 °C
Boiling point	281.9 °C at 101.3 kPa
Relative density (D20/4)	1.077
Vapour pressure	3.77 × 10 <sup>-4</sup> kPa at 25 °C (QSAR prediction)
Water solubility	83 mg/L
Ionisable in the environment?	No

log K <sub>ow</sub>	1.81
Auto-ignition temperature	283 °C at 97.2 kPa
Flashpoint	100.7 °C ± 0.3 °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 a range of cosmetic and household products. The principal route of exposure will be dermal, while ocular and/or inhalation exposures are also possible, particularly if the products are applied by spray or when used in air fresheners.

#### Dermal exposure

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

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (µg/kg bw/day)
Body lotion	7,820	0.02	1	26
Face cream	1,540	0.02	1	5
Hand cream	2,160	0.02	1	7
Fine fragrances	750	0.5	1	63
Deodorant (non-spray)	1,500	0.02	1	5
Shampoo	10,460	0.02	0.01	0
Conditioner	3,920	0.02	0.01	0
Shower gel	18,670	0.02	0.01	1
Hand wash soap	20,000	0.02	0.01	1
Hair styling products	4,000	0.02	0.1	1
Hair dye products	11,600	0.02	0.1	4
Total				113

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

#### Inhalation exposure

Hairspray was taken as a worst-case scenario example for the inhalation exposure assessment. A 2-zone approach was used (Steiling et al. 2014; Rothe et al. 2011; Earnest Jr. 2009). 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	0.02	%
Inhalation rate of the user	20	m <sup>3</sup> /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 <sup>3</sup>
Volume of zone 2	10	m <sup>3</sup>
Daily systemic exposure	1	µg/kg bw/day

C = maximum intended concentration of assessed chemical

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

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

It is acknowledged that inhalation exposure to the assessed chemical from use of other cosmetic and household products 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 115  $\mu$ g/kg bw/day (= 0.115 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

### Acute toxicity

### Oral

Acute toxicity potential of the assessed chemical was tested following the OECD TG 423. The assessed chemical was administered by oral gavage to 6 female Sprague Dawley rats at the single dose of 2,000 mg/kg bw. One rat died 3 hours after the administration and macroscopic examinations revealed thickening and red colouration of the fundus stomachal mucous. Clinical signs such as reduced spontaneous activity, decreased muscle tone, piloerection and bradypnea (slow breathing) were observed in all treated animals to varied degree at 30-minute,1-hour and 4-hour readings after the exposure. All these effects were resolved in 24 hours. Decreased body weight gain (-67%) was observed in all surviving rats 48 hours after the exposure. Then the body weight gain remained normal and was similar between treated and control animals. The macroscopical examination of the 5 animals that survived the test, did not reveal treatment related changes at the end of the study. Based on the results of this study, the median lethal dose (LD50) of the chemical was determined to be greater than 2,000 mg/kg bw in female rats. The assessed chemical is of low acute oral toxicity.

However, the transient clinical signs observed in the treated animals up to 4 hours, including reduced spontaneous activity, slow breathing and decreased muscle tone warrants the classification of the assessed chemical with STOT SE Category 3 (may cause drowsiness or dizziness) under GHS.

### Corrosion/Irritation

#### Skin irritation

Skin irritation potential of the assessed chemical was tested in rabbits following the OECD TG 404. Skin of 3 New Zealand white male rabbits were exposed to 0.5 mL of the undiluted assessed chemical for 4 hours under semi-occlusive conditions. Slight erythema (maximum score of 1) was observed in 2 test animals 24 hours after the exposure which were reversed in 48 hours. Based on the results, the assessed chemical is considered as slightly irritating to the skin but does not meet the GHS criteria for classification.

#### Eye irritation

Eye irritation potential of the assessed chemical was tested in rabbits following the OECD TG 405. The undiluted chemical (0.1 mL) was instilled in one eye of each of 3 male New Zealand white rabbits. The untreated eyes of the animals served as controls. Mild to moderate conjunctival redness, chemosis and discharge (maximum score of 2) was observed in all test animals 1 hour after the exposure. The conjunctival effects were fully reversed by day 3 in one test animal, day 6 in the second and day 7 in the third test animal. Corneal opacity (maximum score 2 in 2 animals and score 1 in the other animal) was also observed 24 hours after exposure which was fully reversed by day 4. Based on the results, the assessed chemical is considered as irritating to eyes and meets eye irritation Category 2B GHS classification criteria.

### Sensitisation

#### **Skin sensitisation**

A guinea pig maximisation test (GPMT) following Magnusson and Kligman maximisation method (OECD TG 406) was conducted to assess skin sensitisation potential of the assessed chemical. Ten test animals were induced with the assessed chemical (intradermal injection at 6.25% concentration on day 0 and topical application at 100% concentration on day 7). After 16 days of rest, the test animals were challenged with 100% and 50% (in paraffin oil) concentrations of the assessed chemical, and skin reactions were recorded 24, 48 and 72 hours after the challenge. Slight erythema (maximum score of 1) was noted in 2 test animals exposed to 100% concentration and 1 test animal exposed to 50% concentration. The skin reactions were reversed by day 3 of the challenge in the 2 test animals exposed to 100% concentration and by 48 hours in the test animal exposed to 50% concentration. Six days after the first challenge, a second challenge was conducted with same concentrations. Skin reactions were recorded 24 and 48 hours after the re-challenge. Slight erythema (maximum score of 1) was noted in 2 different test animals exposed to 100% concentration which was reversed 48 hours after the re-challenge. No skin reactions were observed in test animals exposed to 50% concentration during the second challenge. Skin dryness was observed in 3 animals at 24-hour observation and in 6 animals at 48- and 72-hour observations after the first challenge at 100% concentration, and in 2 animals at 24- and 48-hour observations after the second challenge at 100% concentration. One control animal was found dead on day 27 observation and this mortality was not attributed to the treatment.

The applicant considered that the skin reactions observed in the challenge phase were due to irritation rather than sensitisation and provided a review article (Kligman and Basketter 1995) to support their opinion. Based on the review article, allergic reactions should persist on rechallenge weeks later, while nonspecific irritant reactions generally fade and are irreproducible in the same animals. Given the skin reactions in the first challenge were not reproduced in the same animals in the second challenge, the effects seen in the test were likely due to skin irritation. Therefore, the results of this GPMT does not provide conclusive evidence for classification of the assessed chemical as a skin sensitiser according to the GHS criteria, considering the findings of the review article.

The potential for the assessed chemical to cause skin sensitisation cannot be fully ruled out. The assessed chemical contains dihydroxybenzene group which is an identified structural alert for skin sensitisation based on in silico modelling. With a few exceptions, compounds containing the structural alert have been reported as weak to moderate skin sensitisers in the GPMT and in the murine local lymph node assay (LLNA) (DEREK version 6.0.1).

### Genotoxicity

The mutagenic potential of the assessed chemical was tested in a bacterial reverse mutation assay following the OECD TG 471 using the plate incorporation and pre-incubation methods. *Salmonella typhimurium* strains TA 1535, TA 1537, TA 102, TA 98 and TA 100 were used for the test. The assessed chemical was tested at up to 5  $\mu$ L/plate in the absence or presence of metabolic activation. No test substance mediated increase in the number of revertant colonies (with or without metabolic activation) was observed under the test conditions and the assessed chemical was not considered as mutagenic.

# 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 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

Degradation studies in water indicate that the assessed chemical is not readily biodegradable. A supplied OECD TG 301D biodegradation study for the assessed chemical demonstrated 52% degradation of the assessed chemical over 28 days and 65% degradation at 60 days (according to oxygen consumption). Therefore, the assessed chemical is not readily biodegradable but is not persistent.

#### Bioaccumulation

Based on its log  $K_{\text{OW}}$  value, the assessed chemical does not have the potential to bioaccumulate.

No bioaccumulation information was provided for the assessed chemical. The experimental partition coefficient of the assessed chemical (log  $K_{OW} = 1.81$ ) is below 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 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 measured and modelled median effective concentration (EC50) values for model organisms across two trophic levels were provided by the applicant:

Taxon	Endpoint	Method
Invertebrate	48 h EC50 = 19 mg/L	Daphnia magna (Water Flea) Immobility/other effect iSafeRate, HA - QSAR v1.9 Ecotox module Calculated concentration
Algae	72 h ErC50 = 268.2 mg/L 72 h ErC50 = 110 mg/L (Calc.)	Desmodesmus subspicatus (Green algae) Growth rate OECD TG 201 Static conditions Nominal concentration

#### Chronic toxicity

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

Taxon	Endpoint	Method
Algae	72 h NOErC = 1.9 mg/L	Desmodesmus subspicatus (Green Algae) Growth rate OECD TG 201 Static conditions Nominal concentration

### Predicted no-effect concentration (PNEC)

The predicted no-effect concentration is expected to be greater than  $0.54 \mu g/L$ .

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  $\mu$ g/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

Not Bioaccumulative (Not B). Based on low measured log  $K_{OW}$  value, the assessed chemical is categorised as Not Bioaccumulative.

### Toxicity

Not Toxic (Not T). Based on available ecotoxicity values above 1 mg/L, the assessed chemical is categorised as Not Toxic.

# Environmental risk characterisation

The assessed chemical is not a PBT chemical. 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.

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