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

Ethanone, 1-(2-hydroxy-5-nonylphenyl)-, oxime, branched

Assessment statement (CA09615)

22 November 2022

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AICIS assessment statement

Chemical in this assessment

Name	CAS registry number
Ethanone, 1-(2-hydroxy-5-nonylphenyl)-, oxime, branched	244235-47-0

Reason for the assessment

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

Certificate Application type

Health and environment focus

Based on introduction, use and end use information described in the application, the exposure band of the introduction is 4 for human health (clause 1, table item 6 of Schedule 1) and 4 for the environment (clause 3, table item 5 of Schedule 1) of the *Industrial Chemicals (General) Rules 2019* (the Rules).

The assessed chemical has hazard characteristics in human health hazard band C (clause 2, table item 2 of Schedule 1) and environment hazard band D (clause 4, table item 4 of Schedule 1).

In accordance with table item 5, section 28 and table item 8, section 29 of the Rules, the indicative human health risk for the proposed introduction is medium to high and the indicative environment risk for the proposed introduction is medium to high.

Defined scope of assessment

The chemical has been assessed for use as a component of metal extraction fluid in industrial or commercial mining settings by professional workers:

- as imported at 60 tonnes per year or less at a concentration of 70% or less;
- to be used in metal extraction at 10% concentration or less;
- with no direct release to natural water ways, municipal water supplies, or municipal sewerage systems.

Summary of assessment

Summary of introduction, use and end use

The assessed chemical will be imported into Australia at up to 70% concentration and will be used as a component of metal extraction fluid in the mining industry. The imported product containing the assessed chemical will be blended into a solution with other ingredients. The final extraction fluid will contain the assessed chemical at up to 10% concentration.

The metal extraction fluid containing the assessed chemical will be recycled in a closed loop process to collect metals from a leaching solution obtained through mining. There will be no consumer use of products containing the assessed chemical.

Human health

Summary of health hazards

Based on the available data on the assessed chemical and an analogue chemical, the assessed chemical is likely to be irritating to the skin and eyes and sensitising to the skin, may damage fertility, may damage the unborn child, and may cause damage to organs through prolonged or repeated exposure (see **Supporting information**), warranting hazard classification (see **Hazard classifications** section).

The available toxicity data indicate that the assessed chemical:

- is likely to be of low acute oral and dermal toxicity; and
- is not considered to be genotoxic.

No inhalation toxicity data were provided on the assessed chemical or analogues.

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 follows. This does not consider classification of physical and environmental hazards.

Health hazards	Hazard category	Hazard statement
Skin irritant (Category 2)	Skin Irrit. 2	H315: Causes skin irritation
Skin sensitisation (Category 1A)	Skin Sens. 1A	H317: May cause an allergic skin reaction
Eye irritant (Category 2)	Eye Irrit. 2	H319: Causes serious eye irritation
Specific target organ toxicity – repeated exposure (Category 2)	STOT Rep. Exp. 2	H373: May cause damage to organs through prolonged or repeated exposure

In addition, the applicant has classified the assessed chemical for reproductive toxicity based on analogue data (see **Supporting information**):

Health hazards	Hazard category	Hazard statement
Reproductive toxicity (Category 1B)	Repr. 1B	H360FD: May damage fertility. May damage the unborn child.

Summary of health risk

Public

When introduced and used in the proposed manner, it is unlikely that the public will be exposed to the assessed chemical. No risks are identified for public health during this assessment that require specific risk management measures if the assessed chemical is introduced and used in accordance with the terms of the assessment certificate.

Workers

Potential exposure of workers to the assessed chemical at up to 70% concentration may occur during transfer, mixing, dilution and equipment maintenance activities. Given that the assessed chemical is likely to be irritating to the skin and eyes, sensitising to the skin, may cause reproductive and developmental toxicity, and systemic toxicity through repeated exposure, control measures to minimise dermal and ocular exposure are needed to manage the risk to workers (see **Means for managing risk** section). As the inhalation toxicity of the chemical is unknown, control measures are also needed if there is potential for mists or aerosols to be generated during handling of the chemical.

Environment

Summary of environmental hazard characteristics

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

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

Environmental hazard classification

The chemical satisfies the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) as Acute Category 1 (H400) and Chronic Category 1 (H410) based on toxicity to fish. The chemical is not considered to be rapidly degradable in aquatic ecosystems for the purposes of this aquatic hazard classification.

Environmental Hazard	Hazard Category	Hazard Statement
Acute Aquatic	Acute aq. – Cat. 1	H400: Very toxic to aquatic life
Chronic Aquatic	Chronic aq. – Cat. 1	H410: Very toxic to aquatic life with long lasting effects

Summary of environmental risk

The assessed chemical will be used as a complexing agent in industrial mining. No significant release of the assessed chemical to the environment is expected from the assessed use, as the chemical is either consumed in the industrial process or it is only to be disposed of in tailings dams, according to licenses administered by state and territory environment protection agencies.

The assessed chemical is not readily degradable and is persistent. The assessed chemical is not bioaccumulative and is toxic to aquatic organisms, according to domestic environmental hazard thresholds.

Although the assessed chemical is persistent and toxic, it does not meet all three PBT criteria. No significant release of the assessed chemical to the environment is expected from the assessed use. Therefore, when the assessed chemical is used and disposed of in accordance with the assessment certificate and relevant state, territory and federal regulations, and recommendations on the environmentally safe storage, handling and containment, use and disposal of industrial chemicals, 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 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 information in this statement including recommended hazard classifications, should be used by a person conducting a business or undertaking (PCBU) 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 handling of the chemical:
    - Use of engineering controls such as
        - Enclosed and automated processes 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
    - Workers should wear the following personal protective equipment (PPE)
        - Impervious gloves
        - Protective clothing
        - Chemical resistant footwear
        - Safety glasses/goggles or face mask
        - Respiratory protection where local ventilation may be inadequate

- As the assessed chemical is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.
- 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, 2020) or relevant State or Territory Code of Practice.
- A copy of the Safety Data Sheet (SDS) should be easily accessible to employees.

Environment

Information relating to safe introduction and use

- The chemical is to be captured on-site, treated and/or disposed of through appropriate tailings disposal facilities in accordance with the relevant State, Territory and Federal regulations and current leading practice tailings management.

Conclusions

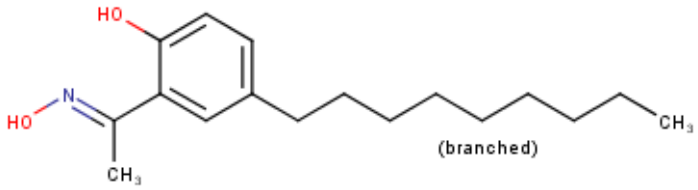
The conclusions of this assessment are based on the information described in this statement.

Considering the means for managing risks, the Executive Director is satisfied that when the 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 proposed 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

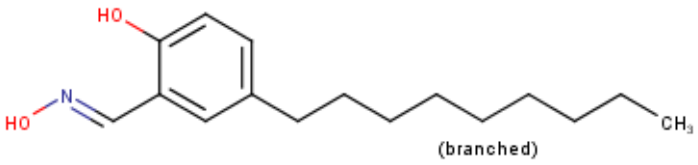
Chemical identity

Chemical name	Ethanone, 1-(2-hydroxy-5-nonylphenyl)-, oxime, branched
CAS No.	244235-47-0
Synonyms	1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime
Structural formula	
Molecular formula	$C_{17}H_{27}NO_2$
Molecular weight (g/mol)	277.4 g/mol
Chemical description	The assessed chemical typically has a degree of purity of greater than 77%.

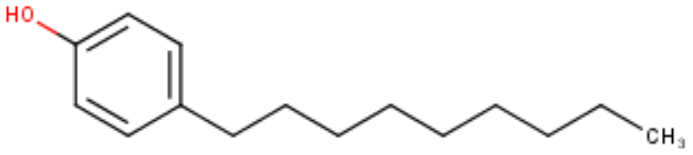
Relevant physical and chemical properties

Physical form	Light brown viscous liquid
Glass transition temperature	-27 °C
Boiling point	No boiling temperatures up to 234 °C
Density	1008.8 kg/m^3 at 20 °C
Dynamic viscosity	114,000 mPa*s at 20 °C
Vapour pressure	≤ 1.5 × 10^{-3} kPa at 20 °C
Water solubility	< 0.1 mg/L at 20°C
Ionisable in the environment?	Not applicable
log K_{ow}	4.8 and ≥ 5.7
Log K_{oc}	3.9
Flash point	135 °C at 101.3 kPa
Auto-ignition temperature	345 °C

Chemical identity of Analogue 1

Chemical name	Benzaldehyde, 2-hydroxy-5-nonyl-, oxime, branched
CAS No.	174333-80-3
Synonyms	C9-Aldoxime
Structural formula	
Molecular formula	$C_{16}H_{25}NO_2$
Molecular weight (g/mol)	263.37 g/mol

Chemical identity of Analogue 2

Chemical name	Phenol, 4-nonyl-
CAS No.	104-40-5
Synonyms	4-NP *p*-nonylphenol
Structural formula	
Molecular formula	$C_{15}H_{24}O$
Molecular weight (g/mol)	220.35 g/mol

Introduction and use

Up to 60 tonnes/year of the assessed chemical will be imported into Australia at up to 70% concentration. It will be transported by trucks to use sites in intermediate bulk containers (IBCs) or drums. The assessed chemical will be used as a complexing agent for metal extraction, specifically from primary aqueous leaching liquid. Mixing and dilution of the assessed chemical is conducted in a solvent extraction plant comprised of a series of mixing/settling units interlaced with a common organic stream. The organic and aqueous phases are recycled in a closed continuous process in a contained manner. Processing plants usually drain the assessed chemical into a buffered organic tank, which then gets distributed through the system with the flow. Normal practice is to add fresh reagents containing the assessed chemical into the loaded organic tank. Some plants may add the reagent straight into one of the stage-mixer boxes to facilitate faster dissolution. After repeated use, the assessed chemical will be

gradually absorbed by residual ore, cake, and clay, which will then eventually collected and disposed of.

Human exposure

Workers

Transport, storage and warehouse workers are not expected to be exposed to the assessed chemical, except in the unlikely event of an accidental rupture of containers.

During transfer, mixing, dilution and equipment maintenance activities, there is potential for worker exposure to the assessed chemical at up to 70% concentration. The extraction plant is expected to use automated, closed systems where possible, limiting the potential exposure of workers. According to the applicant, workers are expected to wear appropriate PPE to reduce potential dermal, ocular and respiratory exposure.

Mine workers may experience dermal or ocular exposure to extraction fluid containing the assessed chemical at up to 10% concentration during addition of extraction fluid and equipment maintenance activities, especially if using manual processes. However, according to the applicant, workers are expected to wear appropriate PPE to reduce potential dermal and ocular exposure.

Public

There will be no public exposure to the assessed chemical as the assessed chemical will only be used by professional workers in industrial and commercial settings, where mining extraction processes are carried out.

Health hazard information

Acute toxicity

Oral

An acute oral toxicity study was conducted on the assessed chemical following OECD TG 420 (fixed dose procedure). An initial limit dose of 2,000 mg/kg bw was administered to one female rat (Wistar) by oral gavage. In the absence of mortality, another 5 male and 5 female rats received a single dose of the test substance at 2,000 mg/kg bw simultaneously. All animals survived and showed slight clinical signs of toxicity, including decreased motor activity and piloerection. The gross necropsy showed no pathological abnormalities. The assessed chemical is likely to be of low acute toxicity to rats via the oral route with an LD50 > 2,000 mg/kg bw.

Dermal

An acute dermal toxicity study was conducted on Analogue 1 following procedures similar to OECD TG 402. Five male and 5 female New Zealand White rabbits had the test substance applied at 2,000 mg/kg bw for a 24-hour contact period. One animal died on day 4 (reasons for death not indicated in the study report), but all surviving animals showed no abnormalities. The analogue chemical was found to be of low acute dermal toxicity in rabbits (LD50 > 2,000

mg/kg bw). Based on the results of the analogue, the assessed chemical is likely to be of low acute toxicity to rabbits via the dermal route.

Corrosion/Irritation

Skin irritation

A skin irritation study was conducted on the assessed chemical following OECD TG 404. The test was conducted in 3 female albino rabbits using a semi-occlusive patch (2.5 cm × 2.5 cm) with 0.5 mL of the chemical applied to each of the treated site for 4 hours. The site was evaluated for irritation upon the patch removal at 60 minutes followed by 24, 48 and 72 hours, as well as 7, 14 and 21 days. After application of the test substance, all rabbits showed very slight oedema. After 24 h, well-defined to severe erythema and slight to moderate oedema were observed in all treated areas. All treated sites were completely covered in scales by day 7, which recovered by Day 21. The mean individual erythema scores from gradings at 24, 48 and 72 hours were 2.67, 3.00, 3.00, respectively. The mean individual oedema scores from gradings at 24, 48 and 72 hours were 2.67, 3.00, 3.17, respectively. Based on the results, the assessed chemical is considered to be irritating to the skin, warranting a hazard classification for skin irritation (Category 2, H315: Causes skin irritation) according to GHS criteria.

Eye irritation

An eye irritation study was conducted on the assessed chemical following OECD TG 405. The test was conducted in 3 female albino rabbits. A volume of 0.1 mL of the test substance was instilled into one eye of each rabbit and ocular irritation was evaluated after exposure at 1, 24, 48 and 72 hours, as well as 7, 14 and 21 days. All animals showed a variety of treatment-related effects, including opacity of the cornea, iris with markedly deepened rugae, hyperaemic conjunctival blood vessels, congestion, swelling, tear flow, and reaction to light. These treatment-related effects persisted with different degrees of severity up to 72 h. All treatment-related effects had recovered by Day 7, though scabs caused by contact with the test substance had formed around the eyes, which gradually recovered by Day 21. The mean individual corneal opacity scores (after instillation of fluorescein) at 24, 48 and 72 hours were 1.33, 1.00, 0.67, respectively. The mean individual iritis scores at 24, 48 and 72 hours were 0.67, 0.67, 0.33, respectively. The mean individual conjunctival redness scores at 24, 48 and 72 hours were 2.33, 1.67, 1.67, respectively. The mean individual chemosis scores at 24, 48 and 72 hours were 2.00, 1.33, 1.67, respectively. Based on the results, the assessed chemical is considered to be irritating to the eyes, warranting a hazard classification for eye irritation (Category 2, H319: Causes serious eye irritation) according to GHS criteria.

Sensitisation

Skin sensitisation

A local lymph node assay (LLNA) was conducted on Analogue 1 following OECD TG 429. Female CBA/JHsd mice (4 animals/group) were treated at 10%, 25% or 50% concentration on both ears for 3 consecutive days. All treated animals survived, and no signs of local irritation or systemic toxicity were observed. A statistically significant increase in ear thickness was observed in the low and mid dose groups but not observed in the high dose group. The Stimulation Indices (SI) were calculated to be 12.80, 16.10 and 15.74 for 10%, 25% and 50% concentration, respectively. The EC3 value of the test substance was calculated to be 0.7%. Based on the results of the analogue, the assessed chemical is considered to be a skin sensitiser, warranting a hazard classification for skin sensitisation (Category 1A, H317: May cause an allergic skin reaction) according to GHS criteria.

Repeat dose toxicity and reproductive and development toxicity

Oral

In a preliminary repeated dose toxicity study, the assessed chemical was administered by oral gavage to Wistar rats (5/sex/dose) for 14 days at 150, 450 and 750 mg/kg bw/day. The high dose was reduced to 600 mg/kg bw/day from day 3 onwards due to clinical signs of toxicity and body weight loss. The study authors reported a systemic no observed adverse effect level (NOAEL) of 150 mg/kg bw/day for female rats based on anaemia, centrilobular hypertrophy in liver cells and changes of the interstitial glands in the ovaries at 450 mg/kg bw/day and above. The study authors also reported a systemic NOAEL of lower than 150 mg/kg bw/day for male rats based on a dose-dependent decrease in absolute organ weights of the seminal vesicles at all doses tested, findings in the male reproductive organs, anaemia and centrilobular hypertrophy in liver cells at 450 mg/kg bw/d and above.

In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422), Analogue 1 was administered to Wistar rats (10/sex/group) by oral gavage at 8, 25 and 100 mg/kg bw/day for up to 59 days.

Clinical examinations
There were no primary signs of systemic toxicity in male animals of any dose group and in female animals of the low and mid dose groups.

In female animals of the high dose group, food consumption was significantly decreased during the first week of application and the gestational period. Dam mean body weights were statistically significantly lower on GDs 14 (-13%) and 20 (-28%) and body weight change values were decreased between GDs 7-14, 14-20 and 0-20. The reduced food consumption and body weights during the gestational period were both considered to affect the missing pregnancies. During the gestation period, 2 animals showed red vaginal discharge and 2 animals showed piloerection. One animal had a complete litter loss at term. Eighty percent of the sperm-positive dams did not have any implantation sites and did not deliver pups, and these findings also had secondary effects on clinical and reproductive parameters.

Fertility indices and live birth indices
In the high dose group, male and female fertility indices were only 20%. One female had 3 implantation sites and 3 liveborn pups, and another female had 2 implantations sites and a single liveborn pup. The rest of the animals did not deliver any pups and did not show any implants at necropsy. A high post-implantation loss of 25% was calculated based on the very low number of implants and pups. The live birth index was 100% in this group. The viability index of this group indicating pup mortality between PND 0 and 4 was reduced to 50% since the animal that gave birth to a single pup had cannibalised it on PND 1.

Litter data were not affected by the test substance in other groups (the mean number of delivered F1 pups per dam was 11.6 in the control group, 12.4 in the low dose group and 11.9 in the mid dose group). The live birth index was 93.1% in the control group and 100% in the low and mid dose groups.

Pathology
The organ weights of prostate, seminal vesicle and epididymides of male animals of the high dose group were below historical control data and the finding was considered to be treatment-related and adverse. The study authors also reported that it could not be excluded that these weight changes in the male reproductive tract could be related to the observed reduction in pregnancies in female animals of this group.

Although still within historical control values, the reduced terminal body weight in female animals of the high dose group was considered by the study authors to be treatment-related, secondary to the reduced pregnancy and adverse, and may have led to the reduced pregnancy. The ovary weights of all treated groups were reduced, but were still within historical control data and no histopathologic finding was observed. However, the study authors considered that the reduced ovary weight could have been treatment-related, given that only two female animals in the high dose group were pregnant, and the functionality of the ovaries may have been affected. The adversity of any effects on the ovaries seemed unlikely but could not be ruled out completely.

The kidneys of 6 out of 10 male animals of the high dose group showed degeneration/regeneration of the tubules. Centrilobular hypertrophy in the liver was observed in 4 female animals of the high dose group but the liver weight was not statistically significantly changed and there were no changes in clinical parameters of the liver.

The study authors considered the systemic and reproductive NOAEL to be 25 mg/kg bw/day for both sexes. The study authors also reported a developmental NOAEL of 25 mg/kg bw/day.

Based on the results of the analogue, the assessed chemical is considered to be toxic to specific target organs following repeated exposure, warranting a hazard classification for specific target organ toxicity – repeated exposure (Category 2, H373: May cause damage to organs through prolonged or repeated exposure) according to GHS criteria.

There is limited information available to classify the analogue chemical as toxic to reproduction/development, as the reproductive/developmental findings may be secondary to the systemic toxicity. Based on the results of the analogue, the potential for the assessed chemical to cause reproductive and developmental toxicity cannot be ruled out.

Genotoxicity

Analogue 1 was found negative in a bacterial reverse mutation assay (OECD TG 471) using TA1535, TA1537, TA98, TA100 and TA102 strains of *Salmonella typhimurium* tested at up to 5,000 µg/plate.

The assessed chemical was found negative in an *in vitro* mammalian cell gene mutation test (OECD TG 476) when tested at up to 25 µg/mL and 10 µg/mL (limited by cytotoxicity of the assessed chemical) with and without metabolic activation, respectively.

The assessed chemical was found negative in an *in vitro* mammalian chromosome aberration test (OECD TG 473) when tested at up to 1,000 µg/mL and 500 µg/mL with and without metabolic activation, respectively. A statistically significant increase in the number of aberrant cells was observed in a series of samples tested at 1.6, 6.3, 9.4, 12.5 and 18.8 µg/mL with 4 hours of exposure and with metabolic activation. This positive result could not be reproduced in subsequent experiments and was considered by the study authors to be biologically irrelevant.

Based on the above results, the assessed chemical is considered to be non-genotoxic.

Environmental exposure

The assessed chemical will be imported into Australia and is not expected to be directly released into the environment during its transport, use or storage. Spills and wastes are

expected to be collected with suitable absorbent materials and disposed of according to state, territory and federal regulations.

The assessed chemical will be used as a complexing agent for metal extraction, specifically from primary aqueous leaching liquid. Mixing and dilution of the assessed chemical is conducted in a solvent extraction plant comprised of a series of mixing/settling units interlaced with a common organic stream. The organic and aqueous phases are recycled in a closed continuous process in a contained manner. Processing plants usually drain the assessed chemical into a buffered organic tank, which then gets distributed through the system with the flow. Normal practice is to add fresh reagents containing the assessed chemical into the loaded organic tank. Some plants may add the reagent straight into one of the stage-mixer boxes to facilitate faster dissolution. The assessed chemical can be consumed during the process by 1) entrainment to the leaching stage with raffinate, where it gets decomposed in the process, and absorbed by ore, or cake, and eventually disposed of with tailings; 2) entrainment to the electrowinning stage with electrolyte, where it rapidly degrades in the electrowinning cells, collected, and disposed of, usually with clay treatment products; and 3) clay treatment, where it gets absorbed by clay, which is then disposed of in accordance with company protocols and state, territory and federal regulations.

Based on the assessed end use as an extraction agent in industrial mining, the chemical is expected to be disposed of in on-site tailings dams. Very small quantities of the assessed chemical are expected to be dispersed to environmental compartments by soil erosion, runoff and through seepage and wind-borne particulates. These exposure pathways are not expected to be significant given the industry adheres to the current leading practices for tailings management.

Environmental fate

Partitioning

The assessed chemical has a high log K_{OC} value (log K_{OC} = 3.9). Therefore, the chemical is expected to partition to and become immobile in soils and sediments.

The assessed chemical is very slightly water soluble (water solubility < 0.1 mg/L at 20°C). If the assessed chemical is released to surface water, a proportion of the assessed chemical is expected to remain in water compartment and a proportion of the chemical is expected to partition to sediments based on its very slightly water solubility and high log Koc value.

The assessed chemical may be volatile (vapour pressure ≤ 1.5 Pa at 20°C). If the assessed chemical is treated by STPs, a large proportion of the assessed chemical may be expected to partition to air during STP treatment based on SimpleTreat 3.0 model outputs (Struijs, 1996). Additionally, when the assessed chemical is directly released to air it may not expected to partition to other compartments.

Degradation

Based on its measured degradation in water, the assessed chemical is considered to be persistent.

In a supplied OECD 301D ready biodegradation screening test conducted in water, the assessed chemical showed 1% degradation after 28 days, indicating that it is not readily biodegradable.

In a supplied OECD 302C inherent biodegradation screening test conducted in water, Analogue 1 of the assessed chemical showed no degradation after 28 days, indicating that it is not inherently biodegradable.

Hydrolysis is not considered to be a relevant degradation pathway in the environment, based on the assessed chemical's very low water solubility (water solubility < 0.1 mg/L at 20°C).

The half-life of Analogue 2 of the assessed chemical in rice paddy soil under oxic conditions was determined to be less than 6 months (Shan et al., 2011). Therefore, the assessed chemical is not expected to persist in the soil compartment.

Bioaccumulation

The assessed chemical is considered to be not bioaccumulative, based on an experimental result of an acceptable analogue.

The bioaccumulation of Analogue 1 of the assessed chemical was investigated in an OECD 305 aqueous exposure fish test employing rainbow trout (*Oncorhynchus mykiss*). The steady state BCF values were 138-159 L/kg and the depuration time was 4-8 days. As the experimental BCF values are below the domestic threshold value of 2000 L/kg, the assessed chemical is considered to be not bioaccumulative.

The assessed chemical is reported to contain 4-nonylphenol (13% w/w). The bioaccumulation potential of this constituent has been previously assessed (NICNAS, 2016).

Predicted environmental concentration (PEC)

A predicted environmental concentration has not been calculated as the assessed chemical is not expected to be released into the environment under the assessed use.

Environmental effects

In addition to the specific toxicity information outlined below for the assessed chemical and acceptable analogues, the toxicity of 4-nonyphenols has been assessed and reported previously (NICNAS, 2016).

Effects on Aquatic Life

Acute toxicity

The following measured median lethal concentration (LC50), median effective loading rate (EL50) and inhibition concentration (IC50) values for model organisms were supplied for the assessed chemical:

Taxon	Endpoint	Method
Fish	96 h LC50 = 0.46 mg/L	*Brachydanio rerio* (zebrafish) Mortality EU Directive 92/69/EEC Semi-static conditions Measured concentration
Invertebrates	48 h EL50 = 9.55 mg/L WAF[1]	*Daphnia magna* (water flea) Immobility OECD TG 202 Static conditions Nominal concentration
Algae	72 h EL50 nd[2], expected to be > 100 mg/L[3] WAF[1]	*Desmodesmus subspicatus* (green algae) Growth rate OECD TG 201 Static conditions Nominal concentration
Microorganisms	3 h IC50 > 1000 mg/L[3]	Activated sludge from a STP Respiration inhibition OECD TG 209 Static conditions Nominal concentration

[1]WAF: water accommodated fraction.

[2]nd: not determined due to mathematical reasons or inappropriate data.

[3]The endpoint value is beyond the test concentrations.

Chronic toxicity

The following measured no-observed-effect concentration (NOEC) and no-observed-effect loading rate (NOEL) values for model organisms were supplied for the assessed chemical and an acceptable analogue:

Taxon	Endpoint	Method
Fish	Analogue 1: 34 d NOEC = 4.27 µg/L	*Danio rerio* (zebrafish) Hatching success OECD 210 Flow through conditions Measured concentration
Invertebrates	21 d NOEL = 2.8 mg/L WAF[1]	*Daphnia magna* (water flea) Reproduction OECD TG 211 Semi-static conditions Nominal concentration
Algae	72 h NOEL ≥ 100 mg/L[3] WAF[1]	*Desmodesmus subspicatus* (green algae) Growth rate OECD TG 201 Static conditions Nominal concentration

Effects on terrestrial Life

The following measured no-observed-effect concentration (NOEC) and effective inhibition concentration (ICx) values for model organisms were supplied for acceptable analogues of the assessed chemical:

Taxon	Endpoint	Method
Earthworms	Analogue 1: 28 d NOEC= 125 mg/kg soil dw	*Eisenia fetida* (earthworm) Reproduction OECD TG 222 Laboratory/artificial soil conditions Nominal concentration
Plants	Analogue 2: 15 d IC10 = 574 mg/kg 15 d IC50 = 1449 mg/kg	*Brassica rapa* (dicots) Fresh weight OECD TG 208 Laboratory/artificial soil conditions Nominal concentration
Microorganisms	Analogue 2: 40 d NOEC = 100 mg/kg soil dw 40 d IC64 = 1000 mg/kg soil dw	*Soil microorganisms from a mixture of manure sewage sludge compost and sandstone* Respiration inhibition Similar to OECD TG 217 Intermittent aeration conditions Nominal concentration

Effects on sediment dwelling life

The following measured no-observed-effect concentration (NOEC) values for model organisms were supplied for an acceptable analogue of the assessed chemical:

Taxon	Endpoint	Method
Worms	Analogue 1: 28d NOEC = 32 mg/kg sediment dw	*Lumbriculus variegatus* (sediment-water Lumbriculus) Reproduction OECD TG 225 Freshwater/artificial sediment conditions Nominal concentration

Endocrine effects

No data on the endocrine effects of the assessed chemical were supplied. However, the assessed chemical is expected to have endocrine activity like 4-nonylphenol, based on the justification for acceptable analogues and composition indicating 13% w/w nonylphenol. Various studies have detailed the endocrine disrupting effects of 4-nonylphenol in aquatic organisms at concentrations higher than 1 µg/L (ECHA, 2013, NICNAS, 2016).

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 0.427 µg/L was calculated for the assessed chemical in the aquatic environment. This value was derived using the most conservative chronic endpoint value for fish (4.27 µg/L), which is further supported by evidence indicating endocrine effects for the assessed chemical. An assessment factor of 10 was applied to this endpoint as chronic toxicity data was available for three trophic levels (EPHC, 2009).

The assessed chemical is considered to be slightly toxic to earthworms and soil microorganisms based on the provided terrestrial ecotoxicity information (Mensink et al., 1995). The assessed chemical is considered to be not toxic to plants according to the provided plant ecotoxicity information (Domene et al., 2009). A PNEC of 10 mg/kg soil dw was calculated for the assessed chemical in the terrestrial environment. This value was derived using the most conservative chronic endpoint value for soil microorganisms (100 mg/kg soil dw). An assessment factor of 10 was applied to this endpoint as toxicity data was available for three trophic levels (EPHC, 2009).

A PNEC of 0.32 mg/kg sediment dw was calculated for the assessed chemical in the sediment environment. This value was derived using the chronic endpoint value for sediment worms (32 mg/kg sediment dw). An assessment factor of 100 was applied to this endpoint as chronic toxicity data was only available for one trophic level (EPHC, 2009).

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemical according to domestic environmental hazard thresholds is presented below:

Persistence

Persistent (P). Based on measured degradation in water under ready and inherent biodegradability test conditions, the assessed chemical is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (not B). Based on measured bioconcentration factors (BCF) = 138-159 L/kg in fish for an acceptable analogue, the assessed chemical is categorised as not Bioaccumulative.

Toxicity

Toxic (T). Based on available the acute ecotoxicity value below 1 mg/L and chronic ecotoxicity value below 0.1 mg/L, the assessed chemical is categorised as Toxic.

Environmental risk characterisation

The assessed chemical will be imported into Australia for uses as a complexing agent in industrial mining. No significant release of the assessed chemical to the environment is expected from the assessed use, as the chemical is either consumed in the industrial process or it is only to be disposed of in tailings dams, according to licenses administered by state and territory environment protection agencies.

Although the assessed chemical is persistent in water, very toxic to fish, slightly toxic to terrestrial organisms and expected to have endocrine effects, it does not meet all three PBT criteria. When disposed of in tailings dams there is some potential for exposure to terrestrial organisms (birds and mammals) in the tailings dam systems; however, no ecotoxicological information is available for these species.

While the assessed chemical demonstrates the potential for persistence, toxic effects and endocrine effects, as no significant release of the assessed chemical to the environment is expected from the assessed use, it is expected that the environmental risk from the introduction of the assessed chemical can be managed within existing risk management frameworks.

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