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

# Alkanedioic acid compd. with $N^1$-(9*Z*)-9-octadecen-1-yl-1,3-propanediamine (1:?)

## Assessment statement (CA09657)

**17 May 2024**

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# AICIS assessment (CA09657)

## Chemical in this assessment

| AICIS Approved Chemical Name (AACN) |
| --- |
| Alkanedioic acid compd. with $N^1$-(9*Z*)-9-octadecen-1-yl-1,3-propanediamine (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 Health and Environment Focus type.

## Defined scope of assessment

The chemical has been assessed:

- as imported into Australia at up to 8.7 tonnes per annum
- as imported at up to 5% concentration in fully finished end use products for use by professional workers only
- for use as a corrosion inhibitor for the protection of boiler/steam system components at a concentration of up to 0.005%.

## Summary of assessment

### Summary of introduction, use and end use

The assessed chemical will not be manufactured in Australia. The assessed chemical will be imported into Australia in 1,000 L intermediate bulk containers or 200 L drums as an aqueous solution at a concentration of up to 5%. These containers will be either stored at the applicant's warehouse facilities or transported directly to the industrial facilities of customers.

The assessed chemical will be used at industrial sites as a corrosion inhibitor for the protection of boiler/steam system components. The assessed chemical will be fed directly from the container into the boiler feedwater line or deaerator using an automated dosing system. The final concentration of assessed chemical in boiler/steam systems will be up to 0.005%. There will be no consumer use of products containing the assessed chemical.

The assessed chemical functions by forming a hydrophobic barrier between the metal and the water/moisture throughout the boiler/steam system to protect the metal surface from reactions with oxygen or corrosive material.

## Human health

The assessed chemical consists of the amine, *N*[1]-(9*Z*)-9-octadecen-1-yl-1,3-propanediamine (chemical A), compounded with an alkanedioic acid (chemical B). The submitted toxicological data on chemicals A and B, or analogues of these chemicals (see **Supporting information**), indicate that the assessed chemical is:

- of moderate acute oral toxicity (median lethal dose (LD50) = 300 – 2,000 mg/kg bw in rats)
- of low acute dermal and inhalation toxicity
- irritating to the skin
- expected to cause serious eye damage
- not a skin sensitiser
- expected to cause serious systemic health effects following repeated oral exposure (statistically significant reduction in body weight gain of rats reported at 12.5 mg/kg bw/day in a 28-day study of an analogue chemical; the No Observable Adverse Effect Level (NOAEL) = 3.25 mg/kg bw/day)
- not expected to cause serious systemic health effects following repeated dermal exposure (only local effects were observed following repeated dermal application)
- not genotoxic

### 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 |
|---|---|---|
| Acute toxicity (oral) | Acute Tox. 4 | H301: Harmful if swallowed |
| Skin irritation | Skin Irrit. 2 | H315: Causes skin irritation |
| Eye damage | Eye Damage 1 | H318: Causes serious eye damage |
| Specific target organ toxicity (repeated exposure) | STOT Rep. Exp. 1 | H372: Causes damage to organs through prolonged or repeated exposure |

### Summary of health risk

**Public**

The assessed chemical will not be available for use by the public. When introduced and used in the proposed manner, it is unlikely that the public will be exposed to the chemical.

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

**Workers**

As there will be no manual handling of the assessed chemical during end use applications due to the use of engineering/enclosed systems, limited operational exposure to the assessed chemical is expected. According to the applicant, workers will be wearing personal protective equipment (PPE) such as protective clothing, eye protection, impervious gloves, and appropriate respiratory protection where general ventilation is insufficient.

Considering the critical health effects possible through exposure to the assessed chemical, control measures to minimise dermal, ocular and inhalation exposure are required to manage the risks to workers (see **Means for managing risk** section).

## 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)
- Toxic (T)

### Environmental hazard classification

The assessed chemical satisfies the criteria for classification according to the GHS (UNECE 2017) as Acute Category 1 (H400) and Chronic Category 3 (H412) based on the toxicity data for algae of chemical A (see **Supporting information**). Considerations were also made for the degradation of the assessed chemical.

| Environmental Hazard | Hazard Category | Hazard Statement |
|---|---|---|
| Hazardous to the aquatic environment (acute / short-term) | Aquatic Acute 1 | H400: Very toxic to aquatic life |
| Hazardous to the aquatic environment (long-term) | Aquatic Chronic 3 | H412: Harmful to aquatic life with long lasting effects |

### Summary of environmental risk

The product containing the assessed chemical will be imported into Australia and used at industrial sites as a corrosion inhibitor for protection of boiler/steam system components. The assessed chemical will be recycled through condensate return and about 5% of the introduction volume will be released to sewers.

The assessed chemical is readily biodegradable and is not persistent. The assessed chemical is categorised as bioaccumulative and is toxic to aquatic organisms.

Although the assessed chemical is bioaccumulative and toxic, it does not meet all three PBT criteria. It is hence unlikely to have unpredictable long-term effects and its risk may be estimated by the risk quotient method (RQ = PEC ÷ PNEC). Based on calculated RQ values < 1 for the river and ocean compartments, it is expected that the environmental risk from the introduction of the assessed chemical can be managed.

# Means for managing risk

## Workers

### Recommendation to Safe Work Australia

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

### Information relating to safe introduction and use

The information in this statement, including recommended hazard classifications, should be used by a person conducting a business or undertaking at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

The following control measures could be implemented to manage the risk arising from exposure to the assessed chemical during reformulation:

- Use of engineering controls such as
  - Enclosed and automated systems where possible
  - Adequate workplace ventilation to avoid accumulation of 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
  - Protective clothing
  - Safety glasses/goggles or face mask
  - Respiratory protection where local ventilation may be inadequate

- The storage of the assessed chemical should be in accordance with the Safe Work Australia *Code of Practice for Managing Risks of Hazardous Chemicals in the Workplace* (SWA 2023) or relevant State or Territory Code of Practice.

- 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

| | |
|---|---|
| **AACN** | Alkanedioic acid compd. with $N^1$-(9*Z*)-9-octadecen-1-yl-1,3-propanediamine (1:?) |

## Relevant physical and chemical properties

The assessed chemical consists of the amine, $N^1$-(9*Z*)-9-octadecen-1-yl-1,3-propanediamine (chemical A), compounded with an alkanedioic acid (chemical B). When data on the assessed chemical were not available, data on chemical A and chemical B were provided.

| | | |
|---|---|---|
| **Physical form** | Colourless to light yellow liquid | |
| **Water solubility** | Miscible in water | |
| **Ionisable in the environment** | Yes | |
| **p$K_a$** | chemical A: 8.64 and 10.62<br>chemical B: 4.5 – 5.5 | |
| **log $K_{ow}$** | chemical A: no reliable data[1]<br>chemical B: 1.57 | |
| **log $K_{oc}$/log $K_p$** | chemical A: log $K_p$[2] = 2.318 – 3.017<br>chemical B: log $K_{oc}$ = 2.17 (MCI method, KOCWIN V2.00) | |
| **Dynamic viscosity** | 14.5 | mPa.s at 25 °C |

[1]Chemical A is surface active, and the method used for measuring its log $K_{ow}$ is not applicable for surface active chemicals, therefore the log $K_{ow}$ value provided is not reliable

[2]$K_p$ is solids-water adsorption coefficient

# Health hazard information

The assessed chemical consists of chemical A compounded with chemical B at an approximate ratio of 70:30 (w/w). While data on the assessed chemical were not available, data on chemical A and chemical B, or suitable analogues of these chemicals, were provided for this assessment statement.

## Toxicokinetics

No toxicokinetic data were available for the assessed chemical. In aqueous conditions the assessed chemical can form a microemulsion comprised of chemical A and chemical B. As such, exposure to chemical A and chemical B may occur during use of the assessed chemical. The low volatility of the assessed chemical is expected to minimise inhalation exposure.

## Acute toxicity

### Oral

In an acute oral toxicity study (OECD TG 423), 3 female HsdRccHan:WIST rats were administered a single dose of chemical A via oral gavage at 2,000 mg/kg bw in cotton seed oil (REACH n.d.). Severe toxicity indicated by salivation, apathy, piloerection and partial eyelid closure were observed in this group after the application. Two animals died within 24 hours following administration of chemical A and one animal was euthanised at 25 hours after administration for animal welfare reasons. In a second study (OECD TG 423), chemical A was administered once to 6 additional rats via oral gavage at 300 mg/kg bw. Two animals showed slight signs of toxicity indicated by piloerection and reduced spontaneous activity until up to 48 h following administration. One animal showed severe signs of toxicity indicated by reduced spontaneous activity, partial eyelid closure, piloerection, weight loss and laboured breathing and was found dead after 10 days. The other 5 animals survived to 14 days after administration. The acute oral LD50 was not reported but the study authors recommended that chemical A be classified for acute oral toxicity (Cat. 4; LD50 = 300 – 2,000 mg/kg bw) (REACH n.d.).

In a non-guideline acute oral toxicity study, the minimum lethal dose of chemical B was reported to be 3,750 mg/kg bw in male mice and 5,000 mg/kg bw in female mice and male rats.

Based on the results described above, the assessed chemical is of moderate acute oral toxicity, warranting hazard classification (Acute Tox. Cat. 4).

### Dermal

In an acute dermal toxicity study (similar to OECD TG 402), an analogue of chemical A was dermally applied under occlusion to Sprague-Dawley (SD) rats (n = 2/sex/dose) at 500 or 2,000 mg/kg bw. No clinical signs were observed at 500 mg/kg bw. At 2,000 mg/kg bw, hunched posture, abnormal gait, lethargy and decreased respiratory rate were noted. No mortalities were reported. The acute dermal LD50 for the analogue of chemical A was determined to be > 2,000 mg/kg bw (ECHA RAC 2011).

An analogue of chemical B has a reported acute dermal LD50 in rabbits of > 7,940 mg/kg bw.

Based on the above studies, the assessed chemical is of low acute dermal toxicity.

### Inhalation

In a non-guideline study, SD rats (n = 10 males/dose) were exposed to the vapour of an analogue of chemical A at mean analytical concentrations of 0.063 and 0.099 mg/L for 1 hour by whole-body exposure. No mortalities were recorded during the exposure or recovery periods. Several animals in the lower dose group (0.063 mg/L) exhibited a slight irritation around the muzzle and all animals were hypoactive at the end of the exposure. All rats in the high dose group (0.099 mg/L) showed mild to severe irritation around the muzzle and reddish areas on the fur at the end of exposure. All rats in both groups exhibited normal appearance and behaviour throughout the 14-day post-exposure observation period. There were no mortalities. No necropsy findings were noted in any rat from either dose group (ECHA RAC 2011). The median lethal concentration (LC50) of the analogue of chemical A was determined to be > 0.099 mg/L. The 4-hour LC50 was calculated by dividing the 1-hour LC50 by a factor of 2 (GHS 2017). The 4-hour LC50 for the analogue chemical is > 0.0495 mg/L.

The reported 4-hour LC50 for dusts and mists of an analogue of chemical B is > 7.7 mg/L.

Based on the above studies, the assessed chemical is of low acute inhalation toxicity.

## Corrosion/Irritation

### Skin irritation

The applicant provided a public report summarising several studies that demonstrate the skin irritation potential of analogues of chemical A. In the most detailed study (OECD TG 404), a single 4-hour topical semi-occlusive application of 0.5 g of an analogue chemical to the intact skin of 3 New Zealand White rabbits produced pronounced erythema and slight to moderate oedema. The mean erythema score was 3.0 at all time points, and the mean oedema scores were 2.7, 1.3 and 1.3, at the 24, 48 and 72-hour time-points, respectively. Desquamation and dried, brittle, crusty, and cracked skin was observed. Effects were reversible in one rabbit by 14 days and in the remaining 2 rabbits by 28 days. The analogue of chemical A, as per the above information, is classified as a skin irritant (Skin Irrit. Cat. 2) (ECHA RAC 2011).

Data submitted by the applicant from non-guideline studies on humans and rabbits indicate that chemical B is a Category 2 skin irritant.

Based on the available data, the assessed chemical is a skin irritant, warranting hazard classification (Skin Irrit. Cat. 2).

### Eye irritation

The applicant provided a public report summarising multiple studies demonstrating that analogues of chemical A have the potential to cause severe eye damage. In an eye irritation study using 3 New Zealand White rabbits (OECD TG 405), 100 mg of an analogue of chemical A caused irreversible eye damage. The average scores were reported as 1.0 (iris), 3.3 (cornea density), 3.0 (conjunctival redness) and 3.1 (conjunctival chemosis). There was pronounced redness of the conjunctivae and chemosis, corneal opacity and moderate iris lesions observed throughout the observation period. The effects on the iris were reversible between days 14 and 21. The other effects were not reversed within 21 days (ECHA RAC 2011).

Data provided by the applicant from non-guideline studies on humans and rabbits indicate that chemical B is an eye irritant. In addition, the applicant has stated that chemical B is expected

to present a hazard concern for irreversible effects on the eye, based on the acidity of the substance.

Based on the available data, the assessed chemical is damaging to the eye, warranting hazard classification (Eye Damage Cat. 1).

## Sensitisation

### Skin sensitisation

In a guinea pig maximisation test (similar to OECD TG 406), intradermal induction was performed on 10 female Dunkin Hartley guinea pigs using a 1% (w/w) dilution of an analogue of chemical A and topical induction with 5% of the analogue chemical. The animals were challenged with 2% of the analogue chemical. No positive skin reactions were observed in test animals (ECHA RAC 2011). However, the validity of this result is questionable, as an unsuitable vehicle was used and the reported nominal concentrations of test chemical were not technically achievable (NICNAS 2014).

Based on the data submitted by the applicant, chemical B is not considered to be a skin sensitiser.

Based on the limited information available on analogue chemicals, the assessed chemical is not a skin sensitiser.

## Repeat dose toxicity

### Oral

In a subchronic repeated dose toxicity study (OECD TG 407), an analogue of chemical A was administered to groups of SD rats (n = 5/sex/dose) by oral gavage for 28 days, at doses of 0 (control), 3.25, 12.5, or 50 mg/kg bw/day. On day 29, the animals were necropsied. In the control and high dose groups, an additional treatment cohort (n = 5/sex/dose) were examined and necropsied after a recovery period of 14 days (ECHA RAC 2011).

There were no treatment-related deaths in the main study and no clinical signs were observed in the 3.25 and 12.5 mg/kg bw/day groups. Impairment of motility (stilted and/or uncoordinated gait) was noted in some animals (2 males and 5 females) of the 50 mg/kg bw/day group from the 2nd and 3rd week onwards and lasted until the end of treatment, with subsequent recovery. No abnormal neurobehaviour was observed in any group. As no other symptom of altered neurobehaviour or neurotoxicity was observed, the impaired motility was considered by the authors to be non-specific.

Mean body weight was significantly lower for mid dose (-7.5%) and high dose males (-10%) and for high dose females (-10.4%) at the end of the treatment period when compared to control groups. At the end of the recovery period, body weight in high dose males remained significantly lower (-9.8%), while in high dose females a tendency to recover was seen at the end of the recovery period (-5.9%; not statistically significant).

Compared to control animals, mean body weight gain was significantly lower at the end of treatment for high dose males (-19%), high dose females (-20%) and mid dose males (-15%). Weight gain was normalised at the end of the recovery period for high dose males and was even higher in the high dose female group, indicating a tendency for recovery. Food consumption remained unaffected throughout the study in all dose groups.

Haematology findings in high dose group animals included significantly increased haematocrit and decreased reticulocyte counts (males only) and slightly increased white blood cell counts with a shift towards neutrophils (males and females). These changes were reversible. Clinical chemistry changes comprised significantly increased total bilirubin for the high dose group, slightly increased urea nitrogen for mid and high dose females and slightly increased liver enzyme activity in high dose males. No organ weight, macroscopic or microscopic changes of toxicological significance were reported.

Based on the significantly reduced body weight gain at 12.5 mg/kg bw/day, the NOAEL was established at 3.25 mg/kg bw/day in this study (ECHA 2011). The applicants provided a 90-day NOAEL for this analogue of chemical A of 1.08 mg/kg bw/day by applying a duration extrapolation factor of 3 to the 28-day NOAEL (ECHA 2012).

Based on information available to AICIS from 3 non-guideline studies, chemical B is not expected to cause serious systemic health effects following repeated oral exposure up to 800 mg/kg bw/day.

Based on the data on an analogue of chemical A, the assessed chemical is expected to cause serious systemic health effects following repeated oral exposure (Specific target organ toxicity (repeated exposure) Cat. 1).

### Dermal

In a non-guideline study, an analogue of chemical A was applied dermally to SD rats (n = 4/sex/dose) at dosages of 0,12.5, 62.5 or 125 mg/kg bw/day for approximately 6 hours/day for 14 days (applied in two five-day dosing periods with an intermediate two-day non-dosing period). Due to excessive tissue destruction in the 62.5 and 125 mg/kg groups, dosing of those groups was discontinued on day 9 and the animals humanely sacrificed. All rats in the low dose group (12.5 mg/kg bw/day) survived until scheduled sacrifice. Moderate to severe erythema was observed in the animals in the 62.5 and 125 mg/kg bw/day groups, which progressed to hardening and sloughing of the skin in some instances. Females were more sensitive to the irritant effects of the chemical than males. In the 12.5 mg/kg bw/day group, erythema scores of 1 to 2, indicating mild to moderate irritation, and flaking of the outer layers of the epidermis were observed. No other treatment related irritant effects or clinical signs were observed. Necropsy data were not available for this study. As effects were observed at the lowest dose (12.5 mg/kg bw/day), a NOAEL could not be determined. The Lowest Observable Adverse Effect Level (LOAEL) for local dermal effects was reported as 12.5 mg/kg bw/day (ECHA RAC 2011). Even though the reported LOAEL is low, as only local effects were observed, the analogue of chemical A is not expected to cause serious systemic health effects following repeated dermal exposure.

Several non-guideline studies reviewed by AICIS found that chemical B is not expected to cause serious systemic health effects following repeated dermal exposure, with NOAELs reported to be 300 – 450 mg/kg bw/day.

Based on the above studies, the assessed chemical is not expected to cause serious systemic health effects following repeated dermal exposure.

## Genotoxicity

The applicant provided a report summarising multiple studies demonstrating that analogues of chemical A are not mutagenic.

According to the available information, 4 analogues of chemical A were not mutagenic in bacterial reverse mutation assays with *Salmonella typhimurium* strains TA97, TA98, TA100, TA1535, TA1537, TA1538 and/or *Escherichia coli* strain WP2uvrA, with or without S9 metabolic activation (OECD TG471) (ECHA RAC 2011).

An analogue of chemical A was found to be negative for mutagenic effects in an in vitro L5178Y *tk*+/- mouse lymphoma assay (OECD TG 490) and at the *Hprt* locus in Chinese hamster ovary cells (OECD TG 476), in both the absence and presence of S9 metabolic activation (ECHA RAC 2011).

An analogue of chemical A did not induce in vivo chromosomal damage in SD rat bone marrow cells after a single oral dose of 2,000 mg/kg bw. The tested dose level induced clinical signs of toxicity (piloerection, hunched posture, hypoactivity and shallow breathing) in all animals and was lethal to one male rat from the 48-hour sampling time group. Another analogue of chemical A also did not induce in vivo chromosomal damage in mouse bone marrow cells after an acute oral dose of up to 5,000 mg/kg bw. Clinical signs of toxicity were observed in treated animals in both studies, indicating that the analogue chemicals were systemically available after oral application (ECHA RAC 2011).

In an in vitro bacterial reverse mutation assay (similar to OECD TG 471), chemical B was not mutagenic in *Salmonella typhimurium* strains TA1535, TA1537, TA98 and TA100 at up to 10 mg/plate in either the presence or absence of S9 metabolic activation.

Chemical B also yielded negative results in mutagenicity assays in Chinese hamster lung cells and human lymphocytes, in both the presence and absence of S9 metabolic activation. Similarly, Chemical B was non-mutagenic at up to 2,000 mg/kg bw in a mouse micronucleus assay and dominant lethal assay in mice. It is not known if these studies were carried out in accordance with OECD test guidelines.

Based on the available data, the assessed chemical is not genotoxic.

# Environmental exposure

The assessed chemical will be imported into Australia as a component of an aqueous product. Significant release of the product containing the assessed chemical to the environment is not expected during transport and storage. The product containing the assessed chemical will be used at industrial sites as a corrosion inhibitor for protection of boiler/steam system components. The product is directly injected by a pump from the shipping container into water piping at industrial sites. These activities take place in rigorously contained systems with strict control. Release of the product containing the assessed chemical to the environment due to accidental spills is expected to be absorbed on suitable materials, and disposed of in accordance with relevant Local, State, Territory and Federal regulations.

According to the applicant, the assessed chemical will be recycled back into the boiler/ steam system through condensate return. Any of the assessed chemical which cannot be recycled will be disposed of to sewers, which is estimated to account for 5% of the introduction volume of the assessed chemical.

## Environmental fate

### Partitioning

The assessed chemical is miscible in water. If the assessed chemical is released to surface water, a large proportion of the assessed chemical is expected to remain in the water compartment and a small proportion of the chemical is expected to partition to sediments based on its miscibility in water, log $K_{oc}$ of 2.17 and log $K_p$ of 2.318 – 3.017.

### Degradation

Based on measured degradation in water of chemical A and chemical B, the assessed chemical is considered not persistent.

In a supplied OECD 301D ready biodegradation screening test conducted in water, chemical A showed 66% degradation after 28 days, the 10-day window is waived as the test substance is a microemulsion. Therefore, chemical A is considered readily biodegradable.

Chemical B is also considered readily biodegradable in water as it achieved > 79% degradation in 28 days in BODIS (modified OECD 301D) and OECD 301 E tests (OECD 2014).

### Bioaccumulation

The assessed chemical is categorised as bioaccumulative based on currently available information on long chain aliphatic amines.

Log $K_{ow}$ values were provided for chemical A and chemical B. However, as chemical A is surface active, and the method used for measuring its log $K_{ow}$ is not applicable for surface active chemicals, the log $K_{ow}$ value provided is not a reliable indicator of bioaccumulation.

No other bioaccumulation information was provided for the assessed chemical. However, Kierkegaard et al. (2021) have measured bioconcentration factors (BCFs) of C9 to C16 long chain aliphatic amines. At pH 7.6, the BCF exceeded 2,000 L/kg for 4 amines with chains ≥ C13, showing that bioconcentration can be considerable for some longer chained aliphatic amines. The bioaccumulation potential of aliphatic amines with alkyl chains longer than C16 is unknown, but as BCFs increased with increasing alkyl-chain length (Kierkegaard et al. 2021), it is expected that they will also have the potential to bioaccumulate.

## Predicted environmental concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a conservative scenario with 5% release of the assessed chemical to a small sewage treatment plant (STP) over 260 working days per year. A small plant is defined as a plant connected to 10,000 – 20,000 properties (BoM 2020) and average number of persons per property in Australia is 2.6 (ABS 2022). Therefore, as a worst-case scenario, 26,000 people may be served by the STP the assessed chemical is released to. The extent to which the assessed chemical is removed from the effluent in STP processes is based on results of an OECD TG 303 simulation test with aerobic sewage treatment on an analogue of chemical A.

The calculation of the PEC is detailed in the table below:

| | | |
|---|---|---|
| Total Annual Import Volume | 8,700 | kg/year |
| Proportion expected to be released to sewer | 5 % | |
| Annual quantity of chemical released to sewer | 435 | kg/year |
| Days per year where release occurs | 260 | days/year |
| Daily chemical release | 1.13 | kg/day |
| Water use | 200 | L/person/day |
| Population served by a small STP | 26 | Thousand |
| Removal within STP | 99 % | Mitigation |
| Daily effluent production | 5 | ML/day |
| Dilution Factor - River | 1.0 | |
| Dilution Factor - Ocean | 10.0 | |
| PEC - River | 3.22 | µg/L |
| PEC - Ocean | 0.32 | 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 for the product containing the assessed chemical:

| Taxon | Endpoint | Method |
|---|---|---|
| **Fish study 1** | 96 h LC50 = 5.6 mg/L | *Pimephales promelas* (Fathead minnow)<br>AAT, Inc Standard SOP GENCHR001.1<br>Semi-static conditions<br>Nominal concentration |
| **Fish study 2** | 96 h LC50 = 7.1 mg/L | *Oncorhynchus mykiss* (Rainbow trout)<br>AAT, Inc Standard SOP GENCHR001.1<br>Semi-static conditions<br>Nominal concentration |
| **Invertebrate** | 48 h EC50 = 2.5 mg/L | *Daphnia magna* (Water flea)<br>AAT, Inc Standard SOP GENCHR001.1<br>Semi-static conditions<br>Nominal concentration |

The following measured median effective concentration (EC50) value for algae was supplied for chemical A, and modelled median effective concentration was supplied for chemical B.

| Taxon | Endpoint | Method |
|---|---|---|
| **Algae** | Chemical A<br>72 h EC50 = 507 µg/L | *Desmodesmus subspicatus* (Green algae)<br>Growth rate inhibition<br>OECD TG 201<br>Static conditions<br>Nominal concentration |
| | Chemical B<br>96 h ErC50 = 1,053 mg/L | Predicted by ECOSAR V1.11, EPISUITE 4.1 |

### Chronic toxicity

The following measured 10th-percentile effective concentration (EC10) value for model organisms was supplied for chemical A.

| Taxon | Endpoint | Method |
|---|---|---|
| **Algae** | Chemical A 72 h ErC10 = 188 µg/L | *Desmodesmus subspicatus* (Green algae)<br>Growth rate inhibition<br>OECD TG 201<br>Static<br>Nominal concentration |

### Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 5.07 µg/L was calculated for the assessed chemical in the aquatic environment. This value was derived using the most sensitive acute endpoint value, which is for algae (72 h ErC50 = 507 µg/L). An assessment factor of 100 was applied to this endpoint as acute toxicity data are available for three trophic levels and chronic toxicity data are available for one trophic level (EPHC 2009). The acute endpoint was selected, over the algal chronic endpoint, in the absence of additional chronic endpoints to support the algal growth rate ErC10 (ECHA 2008).

## 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 measured degradation data on chemical A and chemical B, the assessed chemical is categorised as Not Persistent.

### Bioaccumulation

Bioaccumulative (B). The assessed chemical is categorised as bioaccumulative based on currently available information on long chain aliphatic amines.

### Toxicity

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

## Environmental risk characterisation

Although the assessed chemical is bioaccumulative and toxic, it does not meet all three PBT criteria. It is hence unlikely to have unpredictable long-term effects (EPHC 2009). An estimate of risk may therefore be determined using the risk quotient method.

Based on the PEC and PNEC values determined above, Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for release of the assessed chemical to water:

| Compartment | PEC | PNEC | RQ |
|---|---|---|---|
| **River** | 3.22 µg/L | 5.07 µg/L | 0.635 |
| **Ocean** | 0.32 µg/L | 5.07 µg/L | 0.063 |

For the river and ocean compartments, an RQ less than 1 indicates that introduction of the assessed chemical, in line with the terms outlined in this assessment statement, is not expected to pose a significant risk to the environment. As such, the risk from the assessed chemical can be managed, based on consideration of the environmental hazard characteristics and estimated releases.

# References


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