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

Methanaminium, 1-carboxy-*N*,*N*,*N*-trimethyl-, 2-hydroxybenzoate (1:1)

Assessment statement (CA09996)

12 December 2025

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AICIS assessment (CA09996)

Chemical in this assessment

Name	CAS registry number
Methanaminium, 1-carboxy-*N*,*N*,*N*-trimethyl-, 2-hydroxybenzoate (1:1)	17671-53-3

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 Focus type.

Defined scope of assessment

The chemical has been assessed:

- as imported into Australia at up to 1 tonne/year
- as imported in finished end use products at up to 2% concentration
- for end use:
  - in non-spray skin applied personal care products (cosmetics) intended for use on face and neck only
  - by persons aged 13 years and above

Summary of assessment

Summary of introduction, use and end use

The assessed chemical will not be manufactured or reformulated in Australia. It will be imported as a component at up to 2% concentration in an end-use skin toner product in retail pack sizes for cosmetic use only to persons aged 13 years and above.

The applicant expects that the toner product containing the chemical will be used mainly by consumers and occasionally applied by professional workers to customers under commercial settings.

Human health

Summary of health hazards

No toxicology study reports on the assessed chemical were submitted by the applicant. The assessed chemical is a salt of methanaminium, 1-carboxy-*N*,*N*,*N*-trimethyl-, hydroxide, inner salt (betaine, CAS No. 107-43-7) and salicylic acid (CAS No. 69-72-7) in a 1:1 ratio. It is

expected that the assessed chemical will be dissociated into betaine cation and salicylic acid anion in physiological conditions. Toxicology information on salicylic acid was submitted by the applicant as a source of read across. Other available data on salicylic acid and its salts, and betaine and its salts were also used in this assessment to infer the toxicity of the assessed chemical.

The available toxicological information on betaine and salicylic acid as well as their salts (see **Supporting information**) indicate that the assessed chemical is:

- of low acute dermal toxicity (LD50 > 2,000 mg/kg bw in rats)
- not a skin irritant
- not expected to be a skin sensitiser
- unlikely to cause serious systemic health effects (other than developmental toxicity) following repeated exposure (up to 237 mg/kg bw/day for salicylic acid as tested in rats)
- not expected to be genotoxic

Based on available information from salicylic acid and its salts, the assessed chemical is expected to have moderate acute oral toxicity (LD50 > 891 mg/kg bw in rats for salicylic acid, harmful if swallowed).

Based on available information, the assessed chemical is expected to be irritating to eyes. Although salicylic acid can cause irreversible eye damage, based on the available data from sodium salicylate, salts of salicylic acid are only irritating to eyes. For sodium salicylate, reversible eye irritation (mean conjunctival redness score of 2 in all 3 animals) was observed in an eye irritation study in rabbits (OECD TG 405). A range of severity of effects was also observed in non-guideline in vivo studies and in vitro predictions for salts of salicylic acid.

Based on the available data, the assessed chemical may cause adverse effects on development. Salicylic acid and other salicylates caused adverse effects on foetus development in studies in 2 animal species (rat and monkey). The main effects observed in rats were increased incidences of neural tube defects (craniorachischisis), increased incidences of skeletal variations, decreased pup body weight, foetal growth retardation and increased foetal mortality in pups born from parental rats that were exposed to salicylic acid, sodium salicylate, methyl salicylate or acetylsalicylic acid (aspirin) during gestation. The lowest no observed adverse effect level (NOAEL) for developmental toxicity was considered to be 75 mg/kg bw/day based on a non-guideline pre-natal developmental toxicity study similar to OECD TG 414 in Wistar rats. In monkeys, neural tube defects and kidney cysts were observed at 150 mg/kg bw/day. There was no evidence of adverse developmental effects in rabbit. Epidemiology studies from human medicinal use of aspirin, a metabolic precursor of salicylic acid, did not indicate an increased risk of birth defects.

Hazard classifications relevant for worker health and safety

Based on the available information, 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	H302: Harmful if swallowed
Eye irritation	Eye irritation 2	H319: Causes serious eye irritation

Health hazards	Hazard category	Hazard statement
Reproductive toxicity	Repr. 2	H361d: Suspected of damaging the unborn child

Summary of health risk

Public

Members of the public may apply the skin toner product containing the assessed chemical on face and neck twice daily. There will be widespread repeated and prolonged exposure of the public to the assessed chemical at up to 2% concentration. The principal route of exposure will be dermal, while incidental oral or ocular exposure is also possible.

High concentration of the assessed chemical may cause eye irritation (see **Supporting information**). However, eye irritation effects are not expected from the skin toner product containing the assessed chemical at up to 2% concentration, which is below the GHS cut-off concentration (≥ 10%) for hazard classification for mixtures containing a Cat 2 eye irritant (UNECE 2017).

The assessed chemical is not considered to be a skin irritant.

Based on a typical use pattern of the skin toner product, the total daily systemic exposure of an adult user to the assessed chemical is estimated to be < 0.5 mg/kg bw/day considering 60% dermal absorption. The systemic toxicity risk of the assessed chemical upon daily use can be estimated by calculating the margin of exposure (MOE). Using a NOAEL of 75 mg/kg bw/day derived from the rat developmental toxicity study on salicylic acid (see **Supporting information** section), an MOE of greater than 100 can be estimated. MOE greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences. Therefore, no risk of adverse systemic or developmental effects is expected upon daily normal use of the toner product containing the assessed chemical at up to 2% concentration.

The Scientific Committee on Consumer Safety (SCCS 2025) assessed the safety of salicylic acid in children of 3 to 10 years old and concluded that salicylic acid is not safe for this age group when used at 0.5%, due to concerns regarding aggregate exposure. According to the applicant, imported skin toner products containing the assessed chemical at up to 2% concentration will not be used in children aged below 13 years of age.

Workers

Professional workers in cosmetic businesses may experience exposure to the assessed chemical at up to 2% concentration mainly via dermal route during applications of the toner product containing the assessed chemical to customers. The professional workers may wear person protective equipment (PPE, including gloves, safety glasses, face masks and coveralls). 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 product containing the assessed chemical.

Environment

Summary of environmental hazard characteristics

According to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022) and based on the available data the assessed chemical is:

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

Environmental hazard classification

No aquatic toxicity information was available for the assessed chemical. However, based on the ecotoxicological information available for the dissociation products of the assessed chemical, it is not expected to be harmful to aquatic life. Therefore, the assessed chemical does not satisfy the criteria for classification under the GHS for acute and chronic aquatic toxicities (UNECE 2017).

Summary of environmental risk

The assessed chemical is a cosmetic ingredient of a finished skin care product. Use of the product 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.

The assessed introduction does not meet any of *the Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022). It is unlikely to have unpredictable long-term effects, and its risk may be estimated by the risk quotient method (RQ = PEC ÷ PNEC). Based on calculated RQ values < 1 for the river and ocean compartments, 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**).

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:

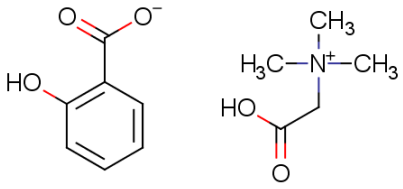
1. Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.
2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

CAS number	17671-53-3
CAS name	Methanaminium, 1-carboxy-*N*,*N*,*N*-trimethyl-, 2-hydroxybenzoate (1:1)
Molecular formula	$C_7H_5O_3.C_5H_{12}NO_2$
Associated names	Benzoic acid, 2-hydroxy-, ion(1-), 1-carboxy-*N*,*N*,*N*-trimethylmethanaminiumCobalt(2+) sulfide Methanaminium, 1-carboxy-*N*,*N*,*N*-trimethyl-, salt with 2-hydroxybenzoic acid (1:1) Betaine, salicylate
Molecular weight (g/mol)	255.27
SMILES (canonical)	O=C([O-])C=1C=CC=CC1O.O=C(O)C[N+](C)(C)C

Representative structure



Additional chemical identity information

This chemical has been represented according to CAS nomenclature/identity conventions. Typical purity is greater than 98%.

Relevant physical and chemical properties

Following properties are for the neat form of the assessed chemical that is not introduced into Australia. The assessed chemical will only be imported at up to 2% concentration in a liquid skin tonner product.

Physical form	Powder
Melting point	113.1°C
Boiling point	160 - 300°C

Density	1,347.2 to 1,348.7 kg/m3
Water solubility	4.08 g/L at 24.1°C
Flash Point	185.5°C
Autoignition temperature	145°C
Particle Size	Inhalable fraction (< 100 µm): 10% Respirable fraction (< 10 µm): 0%
Ionisable in the environment	Yes
pK_a	3.04
log K_{ow}	< 0.3
log K_{oc}	< 0.1

Regulatory status of salicylic acid

Canada

Salicylic acid is listed in the *List of Ingredients that are Restricted for Use in Cosmetic Products* as permitted to be used at a maximum concentration of 2% (Canada 2025).

European Union

Cosmetics Directive Annex III *List of Restricted Substances* restricts salicylic acid to:

- 3.0% for rinse off hair products
- 2.0% for cosmetic products other than rinse off hair products, except body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant
- 0.5% for body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant.

Cosmetics Directive Annex VI *List of Preservatives Allowed* restricts salicylic acid and its salts to 0.5 % maximum for use as preservatives. Salicylic acid is:

- not to be used in preparations for children under 3 years of age
- not to be used in applications that may lead to exposure of the end-user's lungs by inhalation
- not to be used in oral products.

The SCCS (SCCS 2025) assessed the safety of exposure to salicylic acid for children of the age group between 3 and 10 years old and concluded that salicylic acid is not considered safe for this age group when used at 0.5%, due to concerns regarding aggregate exposure.

Australia

Salicylic acid in preparations for dermal use except in preparations containing 40% or less is listed in the Poisons Standard (SUSMP) as Schedule 3 and sodium salicylate in preparations for internal use for the treatment of animals is listed in SUSMP as Schedule 4.

Schedule 3 chemicals are labelled with “pharmacist only medicine” and are described as “substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.”

Schedule 4 chemicals are labelled with “prescription only medicine or prescription animal remedy” and are described as “substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.”

Salicylic acid is listed in *Hazardous Chemical Information System* (HCIS) as Acute toxicity (category 4) and Eye damage (category 1).

Human exposure

Public

From using the toner product containing the assessed chemical, repeated and prolonged dermal exposure of the public to the assessed chemical at up to 2% concentration will be widespread. Incidental oral or ocular exposure to the chemical may also be possible.

Based on information provided by the applicant, the skin toner product with the assessed chemical at up to 2% concentration is intended for cosmetic use on the face and neck. The estimated amount applied per use is approximately 800 mg, either by hands or with a cotton pad. The frequency of use is typically twice daily, in the morning and evening after facial cleansing. Using a dermal absorption (DA) rate of 60% (see section below) for the assessed chemical and a default body weight (BW) of 60 kg, daily systemic exposure by an average adult is estimated as below:

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (mg/kg bw/day)
Skin toner	800 × 2	2	1	0.32

C = maximum intended concentration of assessed chemical; RF = retention factor
Daily systemic exposure = (Amount × C × RF × DA)/BW; DA = 60%; BW = 60 kg

The calculation indicates that typical daily use of the toner product would result in a combined internal dose < 0.5 mg/kg bw/day for the assessed chemical.

Health hazard information

No toxicology study reports on the assessed chemical were submitted by the applicant. An SCCS opinion on salicylic acid (SCCS 2023) was provided. The assessed chemical is a salt of betaine and salicylic acid. Therefore, data on betaine (and its salts) and salicylic acid (and its salts) have been used for read-across purposes.

Toxicokinetics

The assessed chemical is expected to dissociate into betaine (anion) and salicylic acid (cation) in body fluids. In a percutaneous absorption/permeation study (similar to OECD TG 428), betaine was tested for dermal absorption using Franz chambers. The results showed an extremely low percutaneous permeation capability (0.1% of the initial dose regardless of formulation) (REACH n.d.-a). Once absorbed, betaine is anticipated to be completely metabolised in liver and kidney by methylation to dimethylglycine and ultimately to serine.

Salicylic acid is readily absorbed when applied to the skin. Dermal absorption depends on many factors including product formulation, pH, application site and application conditions. Human studies gave dermal absorption values of salicylic acid ranging between 8% and 71% (AICIS 2024). SCCS in their opinion on salicylic acid (SCCS 2023) concluded that a dermal absorption rate of 60% should be used in safety assessment in view of the high variability with vehicle and formulation. Orally administered salicylic acid is readily and extensively absorbed into the blood (AICIS 2024, SCCS 2023).

Metabolism of salicylic acid in rats and humans follows a similar route. It is metabolised mainly to salicyluric acid, and conjugated salicylic acid compounds, with a small proportion of oxidative metabolites. The majority of salicylic acid is excreted in the urine. The elimination half-life increases with dose as elimination pathways switch from first order to zero order kinetics (AICIS 2024).

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 401), the LD50 of betaine was reported to be 11,178 mg/kg bw in rats (REACH n.d.-a). Betaine is of low acute oral toxicity.

In an acute oral toxicity study (similar to OECD TG 401), LD50 of salicylic acid was determined as 891 mg/kg bw (REACH n.d.-b). SCCS in their opinion on salicylic acid stated that it is included in ECHA annex VI of CLP (EU Regulation 2018/1480) and is classified as Acute Toxicity Category 4 (H302: Harmful if swallowed) (SCCS 2023). Safe Work Australia also listed salicylic acid in the HCIS as acute toxicity – category 4.

The LD50 of sodium salicylate in rats was < 2,000 mg/kg bw. Various signs of toxicity, including hyperactivity and muscle weakness or muscle spasticity, were observed (NICNAS 2013).

The assessed chemical is considered harmful via oral route, warranting hazard classification (Acute Toxicity Category 4).

Dermal

The LD50 of salicylic acid and its salts in rats and rabbits was determined to be > 2,000 mg/kg bw (NICNAS 2013). The assessed chemical is considered to be of low acute dermal toxicity.

Corrosion/Irritation

Skin irritation

Betaine hydrochloride (CAS No 590-46-5) was considered to be not irritating to skin in an in vitro reconstructed human epidermis (RhE) test (OECD TG 439) (REACH n.d.-c).

SCCS in their opinion on salicylic acid concluded that neat form of salicylic acid is not irritating to skin (SCCS 2023). In humans, salicylic acid is considered a mild transient irritant based on repeated application under occlusive or semi-occlusive conditions at 3% concentration with a pH 2.5 - 3.8 (NICNAS 2013).

The assessed chemical is unlikely to be a skin irritant.

Eye irritation

In an eye irritation study (OECD TG 405), 10% water solution of betaine did not show ocular irritation in rabbits and therefore was not considered to be an eye irritant (REACH n.d.-a). The eye irritation potential of betaine hydrochloride could not be concluded based on the results from an in vitro Isolated Chicken Eye (ICE) test (OECD TG 438) (REACH n.d.-c).

Although salicylic acid can cause irreversible eye damage, based on the available data from sodium salicylate, salts of salicylic acid may only be irritating to eyes. For sodium salicylate, reversible eye irritation (mean conjunctival redness score of 2 in all 3 animals) was observed in an eye irritation study in rabbits (OECD TG 405). A range of severity of effects were also observed in non-guideline in vivo and in vitro studies.

The assessed chemical is considered to be irritating to the eyes, warranting hazard classification under GHS (Eye Irritation Category 2, H319: Causes serious eye irritation).

Sensitisation

Skin sensitisation

In a guinea pig maximisation test (OECD TG 406), betaine at 50% concentration was not considered to be skin sensitiser (REACH n.d.-a). In a local lymph node assay (LLNA - BrdU-ELISA, OECD TG 429) betaine hydrochloride at up to 50% concentration was not considered to be a sensitiser with a simulation index values < 1.6.

Available animal data on salicylic acid indicate that it is unlikely to be a skin sensitiser. QSAR predictions and animal studies, including mouse LLNA and modified guinea pig Buehler tests, did not reveal any evidence of skin sensitisation. Human test of salicylic acid, induced at 20% and challenged at 10% concentrations, resulted in no evidence of sensitisation in 25 healthy adult subjects (NICNAS 2013). SCCS (2023) also considered that salicylic acid has no skin sensitising potential based on the studies provided.

The assessed chemical is unlikely to be a skin sensitiser.

Repeat dose toxicity

Oral

Betaine is found in microorganisms, plants and animals, and is a significant component in many foods, including wheat and spinach (Arumugam et al 2021). It is a zwitterionic quaternary ammonium compound, a methyl derivative of the amino acid glycine (Stuart 2004). It is listed in the US FDA's *Substances Added to Food* (formerly EAFUS, US FDA 2025) and has been generally recognized as a safe flavouring ingredient (FEMA 2005). The European Food Safety Authority (EFSA) concluded that betaine as a novel food is safe to be used at a maximum intake level of 6 mg/kg bw/day in addition to the intake from the background diet (EFSA 2017).

In a repeated dose toxicity study (OECD TG 407), betaine was administered to female SD rats (n = 20/dose) orally via diet at concentrations of 1% (~1,147 mg/kg bw/day), 2% (~2,298 mg/kg bw/day) and 5% (~5,771 mg/kg bw/day). No mortality or treatment related adverse effects were observed in the test animals. The NOAEL was determined by the study authors as 5,771 mg/kg bw/day, the highest dose tested (REACH n.d.-a).

A 28-day dietary study in rat on salicylic acid reported a No Observed Effect Level (NOEL) of 237 mg/kg bw/day, the highest dose tested. A chronic oral toxicity study performed in rat on aspirin, a metabolic precursor of salicylic acid, at a dose of 200 mg/kg bw/day for 200 days showed no significant toxic effects compared to the control group (NICNAS 2013).

Dermal

Several dermal repeated dose toxicity studies of salicylic acid in rabbits reported no systemic toxicity at doses up to 120 mg/kg bw/day. Local irritation was the main observation recorded (NICNAS 2013).

Observation in humans

Human data showed that oral doses of aspirin at 100 mg/kg bw or higher can induce salicylism or salicylic acid intoxication with symptoms occurring at plasma level of 35 mg/100 mL or higher (NICNAS 2013). Toxic effects have also been reported after topical application of salicylic acid to extensive areas of the body with diseased skin. Children are more sensitive than adults to develop salicylism after the treatment (SCCS 2023).

Genotoxicity

Betaine is not considered to be a genotoxic (REACH n.d.-a). Negative results were reported in:

- an in vitro chromosome aberration study in mammalian cells;
- a bacterial reverse mutation (Ames) test;
- an in vitro gene mutation study in mammalian cells.

Available data do not support mutagenic or genotoxic potential for salicylic acid. Data on salicylic acid, sodium salicylate and methyl salicylate showed negative results in bacterial reverse mutation (Ames) tests and in vivo genotoxicity tests including chromosome aberrations and sister chromatid exchange assays (NICNAS 2013). SCCS was also of the opinion that salicylic acid could be considered to pose no genotoxic hazard (SCCS 2023).

The assessed chemical is not expected to be genotoxic.

Reproductive and development toxicity

In a developmental toxicity study, similar to OECD TG 414, salicylic acid showed 26% and 100% foetal mortality at 150 and 300 mg/kg bw/day respectively in rats. Various other teratogenic effects, including external, internal and skeletal anomalies in offspring were observed. Based on the above evidence, the study authors established a NOAEL of 150 mg/kg bw/day for maternal toxicity and 75 mg/kg bw/day for developmental toxicity (AICIS 2024).

In several non-guideline developmental toxicity studies conducted in rats and monkeys, various adverse developmental effects including skeletal malformation, neural tube defects (craniorachischisis), growth retardation and foetal mortalities, were observed. The adverse effects on development caused by salicylic acid are supported by data on chemicals that metabolise to salicylic acid including methyl salicylate and aspirin. However, there were no developmental effects observed in rabbits for salicylic acid. Extensive human data on aspirin did not reveal evidence to support an increased risk of birth defects (AICIS 2024).

Overall, the assessed chemical is considered to be a developmental toxicant, warranting classification under GHS (Reproductive Toxicity Category 2, H361d: suspected of damaging the unborn child).

Carcinogenicity

Salicylic acid is not expected to be carcinogenic (NICNAS 2013).

Endocrine effects

There are indications from the literature that salicylic acid may have endocrine modulating properties, however, there are no in vivo or in vitro studies available that have explicitly examined the potential endocrine mode of action. The current available data does not provide evidence of an adverse effect from an endocrine mode of action (AICIS 2024).

Environmental exposure

The assessed chemical will be imported into Australia as a component in a formulated skin care product. Significant releases of the assessed chemical to the environment are not expected during transport or storage. 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. Any unused product containing the assessed chemical is expected to be disposed of in accordance with relevant Local, State, Territory and Federal regulations.

Consumer end-use of the assessed chemical in the skin care product 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 STPs before release to surface waters.

Environmental fate

Partitioning

The assessed chemical is readily water soluble (water solubility = 4.08 g/L at 24.1°C) and have low log Pow values (Log Kow < 0.3). Therefore, when the assessed chemical is released to surface water, it is expected to mainly remain in the water compartment. If released to soil or sediments, the assessed chemical is expected to be mobile based on the low log Koc value (log Koc < 1.0).

Degradation

No information on the degradation of the assessed chemical was provided. Based upon the degradation and natural occurrence of dissociation products of the assessed chemical, the assessed chemical is considered Not Persistent.

The assessed chemical is expected to dissociate into betaine and salicylic acid under environmental conditions. A previous evaluation of salicylic acid conducted by AICIS found that salicylic acid was readily biodegradable (> 88% degradation after 28 days) (AICIS 2024). Betaine is a naturally occurring compound found in various plants used in foods and is therefore expected to degrade in the environment.

Bioaccumulation

Based on its log K_{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} < 0.3 is below the domestic bioaccumulation threshold of log K_{OW} = 4.2 (EPHC 2009).

Predicted environmental concentration

A predicted environmental concentration (PEC) for Australian waters was calculated assuming 100% of the introduction volume is released into STPs over 365 days per annum. The extent to which the assessed chemical is removed from the effluent in STP processes is based on its physicochemical properties, modelled by SimpleTreat 3.0 (Struijs 1996). Based on the partitioning and biodegradability of the assessed chemical, total removal during STP treatment is estimated to be 95%. Therefore, 5% of the total introduction volume is estimated to be released to the aquatic environment.

The calculation of the PEC (Struijs 1996; EPHC 2009) 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	200.0	L/person/day
Population of Australia	25.423	Million
Removal within STP	95%	Mitigation
Daily effluent production	5,085	ML/day
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River	0.03	µg/L
PEC – Ocean	0.003	µg/L

Environmental effects

Acute toxicity

No ecotoxicity data was provided for the assessed chemical. The assessed chemical is expected to dissociate into betaine and salicylic acid. It is expected that the salicylic component of the assessed chemical will be the primary contributor to any potential environmental toxicity. A previous evaluation of salicylic acid conducted by AICIS found the following LC50 and EC50 endpoints for salicylic acid and its salts (AICIS 2024):

Taxon	Endpoint	Method
Fish	Sodium salicylate: 96h LC50 = 1,370 mg/L	*Pimephales promelas* (fathead minnow) Flow-through Measured concentrations Equivalent to OECD TG 203
Invertebrate	Salicylic acid: 48h EC50 = 870 mg/L	*Daphnia magna* (water flea) Immobilisation Static conditions, pH neutralised Nominal concentrations Equivalent to OECD TG 202
Algae	Salicylic acid: 72h EC50 > 100 mg/L	Desmodesmus subspicatus (green algae) Cell density Static conditions Nominal concentrations OECD TG 201

Predicted no-effect concentration

No ecotoxicity data was provided for the assessed chemical. The predicted no-effect concentration (PNEC) was calculated based on the available toxicity data on analogue chemical, salicylic acid.

A PNEC of 1,000 µg/L was calculated for the assessed chemical in the aquatic environment. This value was derived using the most conservative endpoint, 72 h EC50 for algae (> 100 mg/L) for salicylic acid. An assessment factor of 100 was applied to this endpoint as acute

toxicity data were available for three trophic levels and chronic toxicity data were incomplete (EPHC 2009). The lowest acute endpoint was selected as the basis of PNEC calculation in the absence of comparable chronic endpoints to support the algal growth rate NOEC (ECHA 2008).

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemical according to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022) is presented below:

Persistence

Not Persistent (Not P). Based upon the degradation and natural occurrence of the assessed chemicals dissociation products, the assessed chemical is considered 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 read-across information for an acceptable analogue chemical, the assessed chemical is categorised as Not Toxic.

Environmental risk characterisation

The assessed chemical is not PBT and 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, soil and sediment:

Compartment	PEC (µg/L)	PNEC (µg/L)	RQ
River	0.03	1,000	0.00003
Ocean	0.003	1,000	0.000003

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 certificate, 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.

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