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

Amines, *N*-(C_{18}-unsatd. alkyl)trimethylenedi-, ethoxylated

Assessment statement (CA09752)

08 November 2023

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AICIS assessment (CA09752)

Chemical in this assessment

Name	CAS registry number
Amines, *N*-(C_{18}-unsatd. alkyl)trimethylenedi-, ethoxylated	1268344-02-0

Reason for the assessment

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

Certificate Application type

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 100 tonnes per year
- imported at 100% concentration for local reformulation into finished asphalt (bitumen) emulsion at up to 2% concentration
- use only by industrial and professional workers for surfacing of roads, potholes and cracks

Summary of assessment

Summary of introduction, use and end use

The assessed chemical will not be manufactured in Australia. It will be imported into Australia at 100% concentration in tight head drums of 180 kg or in one-way totes (IBCs) of 900 kg. The assessed chemical will be transported from the dock to the reformulation site by road.

The assessed chemical in neat form or at up to 2% concentration in bitumen will not be available to public and will only be used by industrial and professional workers for surfacing of roads, potholes, and cracks.

Human health

Summary of health hazards

Based on the submitted data for an analogue chemical for acute oral toxicity, the assessed chemical is likely to be harmful if swallowed (see **Supporting information**), warranting hazard classification (see **Hazard classifications relevant for worker health and safety** section).

Based on the submitted data for a number of analogue chemicals for skin corrosion/irritation, the assessed chemical is likely to be corrosive to the skin and eyes (see **Supporting information**), warranting hazard classification (see **Hazard classifications relevant for worker health and safety** section).

Based on the submitted data for the assessed chemical for repeated dose oral toxicity, the assessed chemical is likely to cause adverse effects (due to its corrosive nature) with repeated exposure (see **Supporting information**), warranting hazard classification (see **Hazard classifications relevant for worker health and safety** section).

Based on the data provided, the assessed chemical is:

- not a skin sensitiser
- not considered to be mutagenic, however, an aneugenic or clastogenic potential of the assessed chemical cannot be ruled out. Two different analogue chemicals tested separately in *in vitro* micronucleus assays using cultured peripheral human lymphocytes induced a statistically significant increase in the number of binucleated cells with micronuclei in the absence of S9-mix (without dose response relationship).
- The no observed adverse effect level (NOAEL) for systemic toxicity from repeated exposure is established as 1 mg/kg bw/day, due to the effects observed in gastrointestinal tract from corrosive nature of the assessed chemical.

No dermal or inhalation toxicity data were provided for the assessed chemical.

Hazard classifications relevant for worker health and safety

Based on the data provided, the assessed chemical satisfies the criteria for classification for human health according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017), as adopted for industrial chemicals in Australia.

Health hazards	Hazard category	Hazard statement
Acute toxicity	Category 4	H302: Harmful if swallowed
Skin and eye corrosion/irritation	Category 1	H314: Causes severe skin burns and eye damage
Specific target organ toxicity (repeated exposure)	Category 1	H372: Causes damage to organs (gastrointestinal tract) 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 assessed chemical. Following application, the finished road surface coatings containing the assessed chemical at up to a concentration of 2% will cure under ambient conditions. The assessed chemical will be bound within the dried bitumen and is not expected to be available for exposure.

This assessment does not identify any risks to public health that would require specific risk management measures when the assessed chemical is introduced in accordance with the terms of the assessment certificate.

Workers

Workers may experience exposure to the assessed chemical at various concentrations including in its neat form, during various formulation operations and during professional end use applications.

Considering the risks of critical health effects (corrosive to skin, harmful if swallowed) of the assessed chemical, control measures to minimise dermal and ocular exposure are needed to manage the risk to workers (see **Means for managing risk section**). Control measures to minimise inhalation exposure may be also needed if aerosols or mists are formed during the blending processes.

Environment

Summary of environmental hazard characteristics

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

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

Environmental hazard classification

The assessed chemical satisfies the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE, 2017) as Acute Category 1 (H400) and Chronic Category 1 (H410) based on the toxicity data for algae and invertebrates. Considerations were also made for the ready biodegradability and potential to bioaccumulate 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 1	H410: Very toxic to aquatic life with long lasting effects

Summary of environmental risk

The assessed chemical will be introduced as a neat chemical for use as a cationic emulsifier that will be reformulated into bitumen mixtures used in road paving.

Based on its end use as a cationic emulsifier, greater than 99% of the assessed chemical is expected to remain in asphalt once it is cured. A large portion of the amount that may be released to the environment is expected to be adsorbed onto soil and remain close to roadside. Correspondingly, no direct release to the surface waters or sewers is expected from the use of the assessed chemical. Therefore, a PEC for the assessed chemical has not been

calculated. Any residue or waste containing the assessed chemical is expected to be disposed of according to federal, state and territory regulations.

Although the assessed chemical is toxic to aquatic organisms, it is not harmful to soil macroorganisms. It is not persistent and does not have the potential to bioaccumulate. Therefore, the assessed chemical does not meet all three PBT criteria.

When the assessed chemical is used and disposed of in accordance with existing federal, state or territory legislations, the amounts released to the environment are expected to be minimal based on its use patterns. Any release will adsorb to soil where it will eventually degrade. Hence, 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, could 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 operations:
    - Use of engineering controls such as
        - Enclosed and in-line processes
        - Adequate workplace ventilation to avoid accumulation of vapours, mists, or aerosols
    - Use of safe work practices to
        - Avoid contact with skin and eye
        - Avoid inhalation of mists or aerosols or vapours
    - Use of personal protective equipment (PPE)
        - Impervious gloves
        - Protective clothing and footwear
        - Eye protection
        - Foot protection
        - 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, 2012) or relevant State or Territory Code of Practice.

- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

Conclusions

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

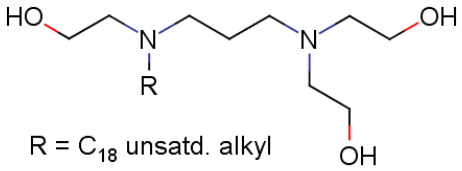
Considering the proposed means of managing risks, the Executive Director is satisfied that when the assessed chemical is introduced and used in accordance with the terms of the assessment certificate the human health and environment risks can be managed within existing risk management frameworks. This is provided that:

- all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.
- the means for 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	Amines, *N*-(C_{18}-unsatd. alkyl)trimethylenedi-, ethoxylated
CAS No.	1268344-02-0
Molecular formula	Unspecified
Representative structure	

Chemical Description

The chemical is an unknown or variable composition, complex reaction product or biological material (UVCB) and has a purity of greater than 60% and less than or equal to 100%.

Relevant physical and chemical properties

Physical form	Amber colour liquid at 23 ºC
Melting point	-3 ºC
Boiling point	> 300 ºC
Vapour pressure	1.5 × 10^{-6} kPa at 20 °C*
Density	944 kg/m³ at 20 ºC
Flash point	> 200 ºC
Flammability	Not expected to be flammable
Water solubility	19 mg/L (CMC)[1] at 25 °C, pH = 7
Ionisable in the environment?	Yes
pK_a	7.76 (Ho et al. 1994)
log K_{ow}	2.8 at 25 °C, pH = 5-6
log K_{oc}	5.4 - 6.7

*Based on an analogue chemical

[1] CMC: Critical micelle concentration

Human exposure

Workers

Reformulation

At the reformulation site, the assessed chemical will be transferred from the import containers into a blending tank using hoses and pumping equipment. The assessed chemical will be mixed with other ingredients/additives through an in-line dosing system and dispersed in warm acidic water. The formulated asphalt emulsion at up to 2% concentration of the assessed chemical will either be stored in a tank and filled to drums or filled into a tank truck via closed transfer systems and transported to road construction sites.

Dermal, ocular and inhalation exposure (if aerosols or mists are formed) of workers to the assessed chemical in its neat form is possible during reformulation and to the final formulation containing the assessed chemical at up to 2% concentration during transfer activities. However, the exposure is expected to be minimised through the use of hoses and pumping equipment, closed transfer systems, mechanical ventilation and through the use of PPE, which includes goggles, gloves, boots and coveralls.

Professional End Use

End-user exposure to the bitumen containing the assessed chemical at up to 2% concentration may occur to tanker driver, operator and supervisor during application from a purpose designed tanker with spray nozzle held close to the road surface. Since the bitumen is applied at high temperature (90 °C or above), workers will take precautions to stay at a suitable distance from the tanker. This will reduce the likelihood of exposure to any spray mist. Exposure is also expected to be further minimised through the use of PPE which includes goggles, gloves, boots, and coveralls. As the attraction between the bitumen and the aggregate is strong for a rapid curing of applied bitumen, the surface can be trafficked in 1-4 hours.

End-user exposure to the bitumen containing the assessed chemical at up to 2% concentration may also occur during the small-scale use of bitumen for slurry seal and microsurfacing. In these situations, workers will apply mix as a thin layers of emulsion cold mixed bitumen to the potholes and cracks in the road surface using a manual dispensing from a can and leveling with a shovel. Workers will wear overalls, leather gloves, safety glasses, hard hat, and safety boots during this operation to minimise exposure to the assessed chemical.

Health hazard information

The assessed chemical and two different analogue chemicals were used in the following studies. The assessed chemical was used for the skin sensitisation study, combined repeated dose toxicity study with the reproduction/developmental toxicity screening test and bacterial reverse mutation study. Same analogue chemical was used for both acute oral toxicity studies, skin irritation study, and *in vitro* micronucleus study. A different analogue chemical was used for the bacterial reverse mutation study, *in vitro* gene mutation study, and for another *in vitro* micronucleus study.

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), an analogue chemical was administered in corn oil via oral gavage to two individual groups of Wistar rats (n = 3/sex/group) at 200 mg/kg bw and to one group of male Wistar rats (n = 3/group) at 2,000 mg/kg bw. The animals were observed for 14 days after administration. At the 200 mg/kg bw, while no mortality was noted in female rats, one male rat was found dead on day 14. Hypoactivity, piloerection and hypersalivation were observed in this animal on days 1 and 2, however, no clinical signs were observed from day 3.

At the 2,000 mg/kg bw, all three males were found dead on day 2. Hypoactivity, piloerection and dyspnea were observed prior to death. At necropsy, no apparent abnormalities were observed.

The acute oral LD50 value for the analogue chemical was established to be between 200 and 2,000 mg/kg bw. Therefore, the assessed chemical is considered to be "Harmful if swallowed", warranting hazard classification (Category 4).

In a non GLP and non-guideline acute oral toxicity study conducted in 1964, the same analogue chemical as above, was administered undiluted orally to groups of male Sprague-Dawley albino rats (n = 5/group) at dose levels of 0.313, 0.625, 1.25, 2.5, and 5.00 mL/kg bw. At the higher dosage levels of 2.5 and 5.0 mL/kg bw, all the animals died within 72 hours following administration of the analogue chemical. Mortality at 0.625 mL/kg bw was 2/5 animals and at 1.25 mL/kg bw, the mortality was 4/5 animals. At 0.313 mL/kg bw, all five animals survived.

At autopsy, all animals dosed at levels above 0.313 mL/kg bw showed signs of gastric irritation, probably due to the corrosive nature of the analogue chemical. At microscopic examination congestion of renal tubules was noted. The acute oral LD50 value for the analogue chemical was established to be 770 (497-1200) mg/kg bw. Therefore, the assessed chemical is considered to be "Harmful if swallowed", warranting hazard classification (Category 4).

No acute dermal or inhalation toxicity data were submitted for the assessed chemical.

Corrosion/Irritation

Skin irritation

An analogue chemical was tested for skin irritation potential in New Zealand white rabbits (OECD TG 404). In this study, as part of preliminary testings, the test substance (0.5 mL) was applied undiluted to an area of clipped skin of one flank of rabbits, covered with a semi-occlusive dressing for 3 minutes and 4 hrs. Reactions at the test site were recorded at 1, 24, 48 and 72 hours after patch removal. After a 3-minute and 4-hours exposure (one animal for each exposure), a severe erythema and a severe oedema, together with cutaneous necrosis, were noted on days 2 and 3. Based on the results and as per the test guideline, the test substance was considered to be corrosive and no further skin irritation testing was performed.

Based on the above information, the assessed chemical is considered to be corrosive to skin, warranting hazard classification as a corrosive (H314: Category 1).

Eye irritation

The applicant has not submitted any data for eye irritation as the assessed chemical is considered to be corrosive to skin. Therefore, based on skin corrosive hazard classification, the assessed chemical is considered to cause serious eye damage, warranting hazard classification (Category 1).

Sensitisation

Skin sensitisation

The assessed chemical's potential of skin sensitisation was tested using a guinea pig maximisation test (GPMT) (OECD TG 406). Following preliminary tests, an intradermal induction concentration of 0.1% v/v in arachis oil BP, topical induction concentration of 5% v/v in arachis oil BP and topical challenge concentrations of 2% v/v in arachis oil BP and 1% v/v in arachis oil BP were selected. Ten animals (Dunkin-Hartley guinea pigs) for the test group and 5 animals for the negative control group were used.

No skin reactions were observed at the challenge sites of the test or negative control group animals at the 24 or 48-hour observations at 2% and 1% challenge concentrations. Under the conditions of this study and according to the test guideline, the assessed chemical is not a skin sensitiser.

Repeat dose toxicity

Oral

A Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD TG 422) was provided for the assessed chemical (**see** below). Under the conditions of the study, the NOAEL for repeated dose toxicity was determined to be 1 mg/kg bw/day for rats, based on no adverse effects noted at this highest tested dose (1 mg/kg bw/day). At 1 mg/kg bw/day, histopathological findings were confined to foamy macrophage foci in the mesenteric lymph node of 2/5 males and 2/5 females (up to slight degree).

The above lesions in the small intestines were observed only in parental animals and the resulting low NOAEL is likely to be due to the corrosive nature of the test item rather than from systemic toxicity.

No repeated dose dermal or inhalation toxicity data on the assessed chemical were submitted.

Genotoxicity

The assessed chemical was not mutagenic in the bacterial Reverse Mutation Assay (Ames Test) when tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* strain WP2uvrA (pKM101), with or without metabolic activation (OECD TG 471). No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any tested doses (0.5, 1.5, 5, 15, 50, and 150 µg/plate) with metabolic activation (S9-mix) and (0.15,0.5, 1.5, 5, 15 and 50 µg/plate) without metabolic activation (S9-mix).

The analogue chemical was not mutagenic in a bacterial reverse mutation assay using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, and *Escherichia coli* strain WP2uvrA, with or without metabolic activation (OECD TG 471). The concentration used for the first, second and third experiments were up to 100 µg/plate, 5,000 µg/plate, and 333 µg/plate, respectively, with or without metabolic activation (S9-mix). No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains in three separate experiments.

The analogue chemical was tested for its potential to induce mutations at the mouse lymphoma thymidine kinase (TK) locus in mouse lymphoma L5178Y cells (OECD TG 490). The concentrations used in the main experiment were: 0.01, 0.03, 0.1, 0.3, 0.6, 1, 1.5 and 2 µg/mL (without S9 mix) and 0.1, 10, 15, 17.5, 25, 27.5, 32.5 and 35 µg/mL (with S9 mix), based on data from a pre-experiment. No biologically relevant increase in the mutation frequency at the TK locus was found after treatment with the test item (with or without metabolic activation). The numbers of small and large colonies in the test item treated cultures were comparable to the numbers of small and large colonies of the solvent controls. Under the conditions of this study and according to the test guideline, the assessed chemical was not mutagenic in the TK mutation test system.

In an *in vitro* micronucleus assay, an analogue chemical was tested for its clastogenic and aneugenic potential using cultured peripheral human lymphocytes, in the presence and absence of a metabolic activation system (OECD TG 487). Two independent experiments were conducted: 3-hour exposure at up to 30 and 40 µg/mL with a 27 hours harvest time, with and without S9-mix, respectively (experiment 1); 24-hours exposure at up to 15 µg/mL with a 24 hours harvest time, in the absence of S9-mix (experiment 2).

In the first cytogenetic assay, the test substance did not induce a statistically significant or biologically relevant increase in the number of mono and binucleated cells with micronuclei in the presence of S9-mix. In the absence of S9-mix, the test substance induced a statistically significant increase in the number of binucleated cells with micronuclei at an intermediate concentration of 25 µg/ml. Although this increase is not dose dependent, the number of binucleated cells with micronuclei is above the historical control data range. In the second cytogenetic assay, the test substance did not induce a statistically significant or biologically relevant increase in the number of mono- and binucleated cells with micronuclei.

As the test substance induced a statistically significant increase in the number of binucleated cells with micronuclei in the absence of S9-mix only (first experiment), the possibility of the test substance might be an aneugenic or clastogenic compound cannot be ruled out.

The above *in vitro* micronucleus assay was repeated with a different analogue chemical in cultured peripheral human lymphocytes (OECD TG 487). Same testing conditions, as above, were applied however, the first cytogenetic assay was tested at up to 20 µg/mL and the second cytogenetic assay was tested at up to 22 µg/mL.

In the first cytogenetic assay with a 3 hours continuous exposure time with a 27 hours harvest time in the absence and presence of S9-fraction, the test substance did not induce a statistically significant or biologically relevant increase in the number of mono and binucleated cells with micronuclei in the absence and presence of S9-mix. In the second cytogenetic assay with a 24 hours continuous exposure and with a 24 hours harvest time in the absence of S9-mix, the test substance induced a statistically significant increase in the number of binucleated cells with micronuclei at an intermediate concentration of 10 µg/mL. Although this increase was not dose dependent, the number of binucleated cells with micronuclei was just above the historical control data range.

The test substance was not clastogenic or aneugenic in human lymphocytes after 3 hours of exposure both in the absence and presence of S9-mix. However, as the test substance induced a statistically significant increase in the number of binucleated cells with micronuclei in the absence of S9-mix at a prolonged exposure period only (experiment 2), the possibility that the test substance might be considered an aneugenic or clastogenic compound cannot be ruled out.

The results demonstrated that both analogue chemicals induced a statistically significant increase in the number of binucleated cells with micronuclei in the absence of S9-mix. It is also noted that, while this increase was above historical control data, the increase was not dose dependent.

Based on the results of *in vitro* analogue data, the assessed chemical is not mutagenic but aneugenic or clastogenic potential of the assessed chemical cannot be ruled out.

Reproductive and development toxicity

In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test, the assessed chemical was administered to Wistar Han rats (n = 10/sex/group) in propylene glycol via oral gavage at dose levels of 0, 1, 5 and 25 mg/kg bw/day, once daily, 7 days a week (OECD TG 422). The dose levels were selected based on the maximum tolerable dose from a range finding study. Males were exposed for 29 days, 2 weeks prior to mating, during mating, and up to the day prior to scheduled necropsy. Females were exposed for 43-52 days, 2 weeks prior to mating, during mating, during post-coitum, and during at least 4 days of lactation (up to the day prior to scheduled necropsy).

No treatment-related changes in clinical signs, body weights, body weight gain, food consumption, functional observations, haematology, clinical biochemistry and macroscopic findings were observed up to 25 mg/kg bw/day. No mortality occurred during the study period.

In parental animals, treatment resulted in histopathological findings at 25 mg/kg bw/day: foamy macrophage foci in the lamina propria of the duodenum (all males up to moderate degree, 2/6 females up to slight degree), jejunum (all males, 5/6 females up to moderate degree) and ileum (4/5 males at slight degree, all females up to moderate degree), foamy macrophage foci in the mesenteric lymph node in all males and females (up to marked degree).

At 5 mg/kg bw/day, these histopathological findings consisted of foamy macrophage foci in the lamina propria of the jejunum (3/5 males, up to slight degree, one female at minimal degree) and ileum (4/5 males, all females up to slight degree), foamy macrophage foci in the mesenteric lymph node in all males and females (up to moderate degree), granuloma in the mesenteric lymph node of one male (minimal degree) and one female (marked degree), and a slightly higher severity of macrophage foci in the mesenteric lymph node of females.

The above lesions in the small intestines only in parental animals and the resulting low NOAEL are likely to be due to the corrosive nature of the test item rather than the systemic toxicity.

No treatment related changes were observed in any of the reproductive parameters investigated in this study such as mating, fertility and conception indices, precoital time, numbers of corpora lutea and implantations sites up to the highest dose level tested (25 mg/kg bw/day).

No treatment-related changes were noted in any of the developmental parameters investigated in this study: gestation index and duration, parturition, maternal care and early postnatal pup development consisting of mortality, clinical signs, body weight and macroscopic observations up to the highest dose level tested (25 mg/kg bw/day).

The NOAEL for reproductive and developmental toxicity was determined to be > 25 mg/kg bw/day, based on no adverse developmental and reproductive effects noted up to the highest dose tested (25 mg/kg bw/day).

Environmental exposure

The assessed chemical will be imported into Australia at a 100% concentration in tight head drums or intermediate bulk container (IBC) totes. Reformulation of the assessed chemical into bitumen will occur domestically. At reformulation sites, the assessed chemical will be transferred from import containers into blending tanks using hoses and pumping equipment. There are no emissions to surface water during the reformulation as any surplus water (breaking water), which is released from the emulsion during mixing, will be collected and recycled into the next batch of emulsion. The resulting bitumen will contain the assessed chemical at up to 2% concentration.

Bitumen containing the assessed chemical will be used by professional workers in industrial settings. The bitumen mixture will be sprayed onto road aggregates at high temperatures (90˚C or above) from a purpose designed boom with spray nozzles which are situated close to the road surface. Therefore, the amounts of the assessed chemical that may enter the air compartment due to any overspray occurring during the spray application process, is expected to be minimal. When used in small scale applications, such as filling potholes and cracks on the road surface, applications will be done by manually dispensing the bitumen mixture from cans. After application the bitumen will set and completely cure within 1-4 hrs and the assessed chemical is expected to be bound to and remain in asphalt.

The indicative road distance covered by annual use of 100 tonnes of the assessed chemical to produce asphalt emulsion depends on the treatment method. Chip sealing and slurry surfacing are expected to be spread over 2,381 km and 317 km of roads (of approximate 7 m width, 2 lane), respectively. As such, use of the assessed chemical is expected to be widely dispersed.

The majority of the environmental exposure of the assessed chemical will be due to run-off caused by precipitation immediately after road surfacing. This results in exposure of the assessed chemical to soil and surface waters (Campbell et al. 2000; Ball et al. 2008). Until the emulsion has fully cured, residual water from the emulsion will be present, containing the assessed chemical. During this period, precipitation may wash the residual water off the road surface into the surrounding soil or, in urban areas, into the stormwater system (Ball et al. 2008). However, simulated studies done on structurally similar cationic emulsifiers suggest that a large portion of the assessed chemical (> 99.98%) will remain in asphalt after curing and only very small amounts of the assessed chemical (< 0.02%) will be leached out into run-off waters (Campbell et al. 2000). These studies also demonstrate that > 99.99% of the assessed chemical that is leached out of asphalt into run-off waters, will adsorb strongly to soil and sediment and not desorb on washing (Campbell et al. 2000; Ball et al. 2008). Therefore, based on supplied data and literature studies on suitable analogues, only very small amounts of the assessed chemical are expected to be released from the cured asphalt to the environment due to rain run-off.

Vapours from the assessed chemical can enter the air compartment during bitumen applications, as this process occurs via spray applications at temperatures above 90 °C. Based on data provided for a suitable analogue, the assessed chemical is expected to be slightly volatile (vapour pressure = 0.0015 Pa at 20 °C). As spray applications of bitumen mixtures will be done onto aggregates close to the road surface, exposures of spray mist to air are expected to be minimal. Reported studies on emissions of cationic emulsifiers with similar structures have indicated that no emulsifiers were detected in air samples collected after chip sealing and slurry surfacing processes, where chip sealing occurred at temperatures as high as 50-60 °C (Campbell et al. 2000; Ball et al. 2008).

Environmental release that may occur via wastes and residues containing the assessed chemical during reformulation and application, are expected to be minimal. Wastes and used containers are expected to be collected and disposed of to landfill according to local government regulations. Any spills or accidents that occur while loading, reformulating or application, are also expected to be contained, collected, and disposed of according to local government regulations.

Environmental fate

Partitioning

The assessed chemical is moderately soluble, with a critical micelle concentration (CMC) of 19 mg/L. Based on data provided on suitable read across analogues, the assessed chemical is expected to be slightly volatile (vapour pressure = 0.0015 Pa) and have a very high log K_{oc} (log K_{oc} = 5.4 – 6.7). If the assessed chemical is released to the environment during application, a large portion is expected to partition to and strongly adsorb to negatively charged mineral surfaces and soil/sediment. As such, it will become immobile close to the roadside application site.

Based on its very slight volatility, the assessed chemical is not expected to evaporate and partition to air. Studies on emission analysis of air samples around chip sealing and slurry surfacing operations have shown that no emulsifiers were detected in the analysed air samples (Campbell et al. 2000).

The assessed chemical is positively charged and is expected to have a pK_a value of 7.76 based on literature reported pK_a values of suitable analogues. (Ho et al. 1994). Greater than 90% of the assessed chemical will be in the cationic form in the pH range 4-9. Due to its charged nature, the assessed chemical is expected to adsorb strongly to negatively charged surfaces and partition to soil and sediment.

Degradation

Results of a supplied degradation study on a suitable analogue demonstrate that the assessed chemical is not readily biodegradable. However, it is not persistent in aquatic environments. A study showed 61% degradation in 28 days, without fulfilling the 10-day window criteria (OECD 301F).

The assessed chemical is a UVCB substance, and this result indicates that the major portion of the assessed chemical is expected to be susceptible to biodegradation. However, this study result does not preclude recalcitrant components forming part of this UVCB substance. The components in the assessed UVCB chemical that are present at levels > 0.1% (w/w) have similar structural scaffolding and functional groups to the major portion of the assessed chemical and as such are expected to have similar biodegradability to the assessed chemical.

Additionally, the degradation percentage of the assessed chemical did not reach a plateau after 28 days, indicating the assessed UVCB chemical will eventually degrade overtime.

Although the assessed chemical is not readily biodegradable, it is not considered to be persistent in aquatic compartment.

Bioaccumulation

No experimental data on bioaccumulation was provided for the assessed chemical. Due to the positively charged nature of the assessed chemical, it is likely to either strongly adsorb and bind to the surface of negatively charged cellular membranes, limiting the ability for the whole molecule to pass through biological membranes, or disrupt the cell membrane and result in cytotoxicity at site of exposure, limiting the assessed chemical's potential to bioaccumulate (McWilliams et al. 2000). Additionally, studies on bioaccumulation of ethoxylated alkyl surfactants have shown that increasing the length of the hydrophilic ethoxylate moiety of the surfactant molecule resulted in an overall decrease in bioconcentration (McWilliams et al. 2000). This is attributed to the fact that surfactant molecules containing long ethoxylated chains have difficulty passing through cell membranes due to steric crowding, thereby decreasing the chemical uptake and inhibiting overall bioaccumulation potential (McWilliams et al. 2000). As the assessed chemical is a triethoxylated long chain alkyl molecule, it is expected to have a low uptake due to steric factors, resulting in a lower potential for bioaccumulation.

A supplied OECD TG 123 test of a suitable analogue of the assessed chemical showed a partition coefficient of log K_{ow} = 2.8. This value can be attributed to the main component of the assessed UVCB chemical and is below the domestic threshold of log K_{ow} = 4.2 for bioaccumulation in aquatic organisms. While a single K_{ow} value obtained by testing the UVCB chemical as a whole substance, may not account for partition coefficients of all the components of the assessed UVCB chemical (Salvito et al. 2020), it supports the overall weight of evidence that the assessed chemical is unlikely to bioaccumulate.

Further, the supplied soil adsorption coefficient of a suitable analogue of the assessed chemical was log K_{oc} = 5.4 – 6.7. Thus, the assessed chemical is expected to adsorb strongly to soil and sediment, thereby greatly reducing long-term exposure and the bioavailability of the assessed chemical in the aquatic environment.

Therefore, based on the weight-of-evidence, the assessed chemical is not expected to bioaccumulate.

Predicted environmental concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the assessed chemical to the aquatic environment is expected to be negligible based on its assessed use patterns.

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 suitable analogues of the assessed chemical:

Taxon	Endpoint	Method
Fish	96 h LC50 = 0.17 mg/L	*Oncorhynchus mykiss* (Rainbow trout) Mortality OECD TG 203 Static conditions Nominal concentration
Invertebrate	48 h EC50 = 0.31 mg/L	*Daphnia magna* (water flea) Immobility OECD TG 202 Static conditions Nominal concentration
Algae	72 h EC50 = 0.256 mg/L	*Pseudokirchneriella subcapitata* (green algae) Growth rate OECD TG 201 Static Nominal concentration

Chronic toxicity

The following measured 10th percentile effective concentration (EC10) and no-effect concentration (NOEC) values for model organisms were supplied for suitable analogues of the assessed chemical:

Taxon	Endpoint	Method
Algae	72 h EC10 = 0.086 mg/L	*Pseudokirchneriella subcapitata* (green algae) Growth rate OECD TG 201 Static Nominal concentration
Invertebrate	21 d NOEC = 0.27 mg/L	*Daphnia magna* (water flea) Reproduction OECD TG 211 Semi-static conditions Nominal concentration

In the above reported chronic toxicity study on invertebrates, the observed effect was increased reproduction. The parental daphnids showed immobilisation within 48 hours without any reproduction, at a concentration of 0.81 mg/L. However, at the next test concentration level of 0.27 mg/L, there was no immobilisation or any detrimental effect on reproduction till day 20, compared to the control, demonstrating a low acute-chronic toxicity ratio. This observation is indicative of a non-specific mode of action and is often associated with non-systemic effects that are known occur in cationic surfactants on aquatic organisms. As such, the assessed chemical's toxicity is expected to be associated with physical binding to respiratory membranes, rather than causing toxic effects via crossing the biological membrane (McWilliams et al. 2000).

Effects on terrestrial Life

The following measured no effect concentration (NOEC) values for model organisms were supplied for suitable analogues of the assessed chemical:

Taxon	Endpoint	Method
Macroorganisms except arthropods	28 d NOEC = 500 mg/kg soil dw	*Eisenia fetida* (earthworm) Reproduction OECD TG 222 Static conditions Nominal concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 1.7 µg/L was calculated for the assessed chemical in the aquatic environment. This value was derived using the most conservative endpoint value for fish (0.17 mg/L). An assessment factor of 100 was applied based on data available for acute endpoints for three trophic levels and chronic endpoints for two 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

Not Persistent (Not P). Based on degradation studies for a suitable analogue, the assessed chemical is categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on the weight of evidence available, the assessed chemical is categorised as Not Bioaccumulative.

Toxicity

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

Environmental risk characterisation

The assessed chemical is toxic to aquatic organisms but not harmful to terrestrial macroorganisms. It is not persistent and does not have the potential to bioaccumulate. Therefore, the assessed chemical does not meet all three PBT criteria.

Based on its end use as a cationic emulsifier, > 99% of the assessed chemical is expected to remain in asphalt once it is cured. A large portion of the amount that may be released to the environment is expected to partition to and adsorb onto soil where it will remain close to roadside. As such, no direct release to the surface waters or sewers is expected. Therefore, a PEC or a risk quotient for the assessed chemical has not been calculated. When the assessed chemical is used and disposed of in accordance with existing state or territory legislations, the amounts release to the environment is expected to be minimal based on the assessed use patterns.

As the assessed chemical will biodegrade and is not bioaccumulative and the assessed use pattern results in minimal environmental exposure, the environmental risk from the introduction of the assessed chemical can be managed.

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