Australian Government
Department of Health
Australian Industrial Chemicals Introduction Scheme

1,3-Propanediamine, *N*-[3-(C_{11-14}-isoalkyloxy)propyl] derivs., C_{13}-rich, acetates

Assessment Statement (CA09351)

26 May 2021

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AICIS assessment statement

Chemical in this assessment

Name	CAS registry number
1,3-Propanediamine, *N*-[3-(C_{11-14}-isoalkyloxy)propyl] derivs., C_{13}-rich, acetates	151789-08-1

Reason for the assessment

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

Certificate Application Type

Human health and environment focus

Based on the introduction, use and end use information described in the application, the human health and environment exposure bands of the introduction are both 4 [Clause 1, table item 6 and Clause 3, table item 5 of Schedule 1, *Industrial Chemicals (General) Rules 2019* (the Rules)]. The assessed chemical has hazard characteristics in human health hazard band B [Clause 2, table items 10, 11, 13 and 14 of Schedule 1 of the Rules], and environment hazard band C [Clause 4, table item 6 of Schedule 1 of the Rules]. In accordance with Section 28, table item 5 of the Rules, the indicative human health risk for the proposed introduction is medium to high. In accordance with Section 29, table item 8 of the Rules, the indicative environment risk for the proposed introduction is medium to high.

Defined scope of assessment

The chemical has been assessed:

- as imported at less than or equal to 200 tonnes/annum with no reformulation or repackaging occurring in Australia;
- for use only by workers in industrial mining facilities as a flotation agent at less than or equal to 5% concentration.

Summary of assessment

Summary of introduction, use and end use

The chemical will be imported into Australia in neat form and will be directly transported in original containers from the port to the end use mining site. No reformulation or repackaging process will occur in Australia.

The assessed chemical will be diluted with water and will only be used in industrial mining facilities as an amine flotation agent. The end use concentration will be up to 5%.

Human health

Summary of health hazards

Based on the available information, health hazards identified for the assessed chemical include the following:

- toxic if swallowed;
- causes severe skin burns and eye damage;
- causes damage to organs through prolonged or repeated exposure.

Health hazard classification

Based on the available data, the assessed chemical warrants hazard classification for human health according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS, United Nations 2017), as adopted for industrial chemicals in Australia.

Health hazard	Hazard category	Hazard statement
Acute Toxicity (Oral)	Category 3	H301 - Toxic if swallowed
Skin Corrosion	Category 1B	H314 - Causes severe skin burns and eye damage
Specific Target Organ Toxicity (Repeated Exposure)	Category 1	H372 - Causes damage to organs through prolonged or repeated exposure

For classification of the assessed chemical in mixtures or solutions during end-use, refer to the **Recommendations** section.

Summary of health risk

Public

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

Workers

Workers may experience severe health effects including acute toxicity, skin corrosion, serious eye damage, chronic organ damage and possible developmental toxicity, if exposed to the assessed chemical during its use in mining facilities. Specific risk management measures (see **Recommendations** section) are required to manage the risk to workers.

Environment

Summary of environmental hazards

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

- Not persistent (not P)
- Not bioaccumulative (not B)
- Toxic (T)

Environmental hazard classification

The assessed chemical is formally classified under the GHS for acute and chronic toxicities based on the ecotoxicological endpoint data and biodegradability data.

Environmental Hazard	Hazard Category	Hazard Statement
Acute Aquatic	Category 1	H400 - Very toxic to aquatic life
Chronic Aquatic	Category 1	H410 - Very toxic to aquatic life with long lasting effects

Summary of environmental risk

Based on the end use as an industrial flotation agent in mining facilities, the assessed chemical is not expected to be directly released into the environment as the chemical is only to be disposed of in on-site tailings dams according to licenses administered by state and territory environment protection agencies.

Therefore, assuming the assessed chemical is used and disposed of in accordance with the relevant federal, state and territory regulations, policies and recommendations on the environmentally safe storage, handling and containment, use and disposal of industrial chemicals, the assessed chemical is unlikely to cause environmental risks.

Conclusions

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. 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 proposed means for managing the risks identified during this assessment are set out in the **Recommendations** section.

Recommendations

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 **Health hazard classification**)

Advice to industry

- The following control measures should be implemented to manage the risks arising from exposure to the assessed chemical:

- Use of engineering controls such as
  - Enclosed and automated processes
  - Adequate workplace ventilation to avoid accumulation of vapours, mists or aerosols

- Use of safe work practices to
  - Avoid contact with skin and eyes
  - Avoid inhalation of vapours, mists or aerosols
  - Avoid spills

- Workers should wear the following personal protective equipment (PPE)
  - Impervious gloves
  - Safety glasses or goggles
  - Face mask
  - Respiratory protection where local ventilation may be inadequate
  - Protective clothing
  - Chemical resistant boots

- Mixtures or solutions containing the assessed chemical should be classified as hazardous to health in accordance with the GHS as adopted for industrial chemicals in Australia. According to the GHS criteria, the generic cut-off values/concentration limits should apply. However, if the hazard of the chemical will be evident below the generic cut-off values/concentration limits, the mixture containing the chemical should be classified accordingly (see GHS Section 1.3.3.2.2). Workplace labelling requirements for hazardous mixtures should also apply (see GHS Section 1.4.10.5.5.1).
- Workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.
- Due to the acute and chronic health hazards expected from exposure to the assessed chemical, introducers of the chemical should consider their obligations under the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (ADG code) (NTC, 2018).
- 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.

Environment

Recommendation to Department of Agriculture, Water and the Environment

- Schedule the chemical under the *Industrial Chemicals Environmental Management (Register) Act 2021* once the *Industrial Chemicals Environmental Management Standard* (IChEMS) is operational.

Advice to industry

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

Supporting information

Chemical identity

Synonyms	Lilaflot 817M (trade name)
Structural formula	Unspecified
Molecular formula	Unspecified
Molecular weight (g/mol)	> 500
Chemical description	Unknown variable composition or biological (UVCB) substance

The assessed chemical is a UVCB substance with the following composition:

Chemical Name	CAS No.	Typical Conc. (%)	Conc. Range (%)
1,3-Propanediamine, *N*-[3-(tridecyloxy)propyl]-, branched, monoacetate	102047-27-8	32	24-60
N-[3-(undecyloxy)propyl]propane-1,3-diamine, branched acetate (1:1)	-	0.8	0-3.5
N-[3-(dodecyloxy)propyl]propane-1,3-diamine, branched acetate (1:1)	-	11	0-21
N-[3-(tetradecyloxy)propyl]propane-1,3-diamine, branched acetate (1:1)	-	3.7	0-10
1,3-Propanediamine, N^1-[3-(tridecyloxy)propyl]-, branched	68479-04-9	27	18-51
N-[3-(undecyloxy)propyl]propane-1,3-diamine, branched	-	0.7	0-3
N-[3-(dodecyloxy)propyl]propane-1,3-diamine, branched	-	9	0-18
N-[3-(tetradecyloxy)propyl]propane-1,3-diamine, branched	-	3	0-9
3-(tridecyloxy)propan-1-amine, branched acetate (1:1)	-	2.8	0-5
3-(dodecyloxy)propan-1-amine, branched acetate (1:1)	-	0.9	0-2
3-(dodecyloxy)propan-1-amine, branched	-	0.7	0-2
1-Propanamine, 3-(isotridecyloxy)-	50977-10-1	2.1	0-5
Isotridecanol	27458-92-0	1.6	0-5
Isododecanol	25428-98-2	0.6	0-2
N-(3-{[3-(tridecyloxy)propyl]amino}propyl), branched acetamide	-	1.1	0-5

Chemical Name	CAS No.	Typical Conc. (%)	Conc. Range (%)
N-(3-{[3-(dodecyloxy)propyl]amino}propyl), branched acetamide	-	0.4	0-2
N-(3-aminopropyl)-*N*-[3-(tridecyloxy)propyl]propane-1,3-diamine, branched	-	0.7	0-5
N-(3-aminopropyl)-*N*-[3-(dodecyloxy)propyl]propane-1,3-diamine, branched	-	0.3	0-5
N-(3-aminopropyl)-*N*-[3-(tridecyloxy)propyl]propane-1,3-diamine, branched acetate (1:1)	-	0.7	0-5
N-(3-aminopropyl)-*N*-[3-(dodecyloxy)propyl]propane-1,3-diamine, branched acetate (1:1)	-	0.3	0-2

Relevant physical and chemical properties

Physical form	Clear light yellow liquid
Water solubility	> 1,300 mg/L*
Ionisable in the environment?	Yes
pKa	7.6
log K_{ow}	-0.4
Log K_{oc}	4.5 - 14

*Based on the critical micelle concentration

Introduction and use

The chemical will be imported into Australia in neat form in 205 L drums, 1,000 L intermediate bulk containers (IBCs) or 18,000 L shipping containers (Isotainers). The containers containing the assessed chemical will be directly transported from the port to the industrial mining facilities by road. No reformulation or repackaging processes will occur in Australia before the end use.

Operations at the end use sites will occur within a bunded area. Workers will open the imported containers, connect hoses and pumping equipment, then pump the contents into an onsite blending tank (with a capacity of approximately 1,000 L) that will automatically dilute the chemical to 5% concentration with water. The solutions containing the assessed chemical will be used as a flotation agent in flotation tanks. Dosing of the solutions into the process feed will be automated via fixed pipes. The assessed chemical will be automatically dosed at approximately 400 g per tonne of mineral solids with a final use concentration of assessed chemical at approximately 50 mg/L in the floatation tanks. The floatation tanks will be enclosed and the process will occur within large, well ventilated sheds to reduce any formation of vapour, mist or aerosol. According to the applicant, workers will be required to wear PPE during these operations to minimise exposure.

Human exposure

Workers

End Use

Dermal and ocular exposure of workers to the assessed chemical at neat form is possible when opening the containers and connecting pipes to imported containers. Exposure to the diluted chemical at up to 5% concentration is also possible due to leaks, spills or maintenance of equipment. Solutions containing the assessed chemical may be heated during the mining processes, hence vapour, mist or aerosol may form if the processes are not enclosed and local ventilation is inadequate. Therefore, inhalation exposure to small amount of the chemical may potentially occur inside sheds with flotation tanks.

Health hazard information

Acute toxicity

Oral

In an acute toxicity study conducted in rats (OECD TG 401), an analogue chemical structurally similar to the assessed chemical was found to be toxic via the oral route. In the range-finding study, all animals (2 males and 2 females) died on Day 1 of observation at 2,000 mg/kg bw and 1 of 2 males died on Day 4 at the 200 mg/kg bw. No deaths occurred in the main study when 5 males and 5 females were treated with the analogue chemical at 200 mg/kg bw. Signs of morbidity included hunched posture and pilo-erection, observed in all treated animals up to 4 hours after dosing.

The median lethal dose (LD50) of the chemical was determined to be greater than 200 and less than 2,000 mg/kg bw, warranting hazard classification for Acute Oral Toxicity Category 3 (H301: Toxic if swallowed) according to GHS criteria as adopted in Australia for industrial chemicals.

Corrosion/Irritation

Skin irritation

In a skin irritation study (OECD TG 404), the assessed chemical was found to be corrosive to the skin of 2 rabbits. Irreversible skin necrosis was seen in the female rabbit after 4 hours of exposure and in the male rabbit after 3 minutes of exposure, warranting hazard classification for Skin Corrosion Category 1B (H314: Causes severe skin burns and eye damage) according to GHS criteria as adopted in Australia for industrial chemicals.

Eye irritation

No data were provided for the assessed chemical on eye irritation. As the chemical is corrosive to the skin, and based on GHS (Figure 3.3.1, Step 1b) as adopted in Australia for industrial chemicals, it is deemed to cause serious eye damage.

Sensitisation

Skin sensitisation

No data on skin sensitisation potential of the assessed chemical were provided. As the chemical is corrosive to the skin, no skin sensitisation study was conducted.

Repeat dose toxicity

Oral

In a 90-day repeated dose oral (gavage) toxicity study conducted in rats (OECD TG 408), the assessed chemical was administered to rats at 0, 0.5, 2 and 8 mg/kg bw/day. Clinical signs of toxicity and mortality were observed in all treated groups.

A dose-related trend in the incidence and onset of mortality was apparent. At 8 mg/kg bw/day, 1/10 males was found dead on Day 42. In the same group, 4/10 males and 7/10 females were sacrificed in extremis between Days 42 and 64, and Days 36 and 64 respectively. All remaining animals in the group were sacrificed on Day 65. Additionally, 2/20 animals at 0.5 mg/kg bw/day and 5/20 animals at 2 mg/kg bw/day were sacrificed in extremis.

Clinical signs of morbidity included abnormal gait/hypotonia/swelling of the hindlegs and/or tail at 0.5 mg/kg bw/day and above, which was supported by histopathological findings of arthritis of the tail vertebrae, and tarsal and knee joints. Massive granulomas with and without central necrosis were observed in the mesenteric lymph nodes in the animals.

In addition to the above observations, treatment-related adverse effects on clinical chemistry, haematology, urinalysis, behaviour, and gross pathology were also recorded in all treated groups during the study.

Based on the results, a No Observed Adverse Effect Level (NOAEL) could not be established. Considering the deaths of treated animals and adverse effects observed from the lowest dose tested, the assessed chemical warrants hazard classification of Specific Target Organ Toxicity (Repeated Exposure) Category 1 (H370: Causes damage to organs) according to GHS criteria as adopted in Australia for industrial chemicals.

Genetic toxicity

In a bacterial reverse mutation assay (OECD TG 471) and an *in vitro* mammalian cell gene mutation test in Chinese hamster lung cells (OECD TG 476), the chemical was found to be non-mutagenic. The chemical was also determined to be non-clastrogenic in an *in vitro* mammalian chromosome aberration test in human lymphocytes (OECD TG 473).

Reproductive toxicity

In a prenatal development toxicity study conducted in rats (OECD TG 414), the assessed chemical was administered to the animals by oral gavage from Days 6 to 20 post-coitum, inclusive, at 0, 3, 7 and 15 mg/kg bw/day. Clinical signs of toxicity, and gross pathological findings were observed in all treated groups.

A higher incidence of unossified metatarsals was observed for all treatment groups, which showed an apparent dose-related trend. In the 3, 7 and 15 mg/kg bw/day groups, the mean

litter proportion of unossified metatarsals was 8.6%, 10.2% and 18.9% respectively, as compared to 2.9% in the control group. A trend towards a higher incidence of unossified sternebae in the 7 and 15 mg/kg bw/day groups was also observed with 4.5% and 4.6% mean litter proportion respectively, as compared to 2.4% in the control group.

Treatment at 15 mg/kg bw/day resulted in a 9.8% reduction in foetal body weights in both sexes. Litter sizes, sex ratio, external and visceral malformations and variations were unaffected by treatment.

Based on the results, a NOAEL could not be established for reproductive or developmental toxicity. The evidence present in the study was not adequate to determine whether the unossified metatarsals in the foetuses were due to reversible variations or malformations. There is an uncertainty that requires further information to clarify on whether the assessed chemical has any potential to cause developmental effects on the unborn child.

Environmental exposure

The assessed chemical is not expected to be directly released into the environment during its transport, use or storage. Spills are expected to be collected with suitable absorbent materials and disposed of according to State and Territory regulations.

The flotation circuit is enclosed, and process water will be recycled. Based on the assessed end use as a flotation agent, the chemical is expected to be disposed of in on-site tailings dams, with no further release. When disposed of in tailings dams there is some potential for exposure to birds in the tailings dam systems; however, no ecotoxicological information is available for these species. Very small quantities of the assessed chemical are expected to be dispersed to environmental compartments by soil erosion, runoff and through seepage and wind-borne particulates. These exposure pathways are not significant given the industry adheres to the current leading practices for tailings management.

Environmental fate

The assessed chemical exhibits surfactant properties, with a critical micelle concentration (CMC) of > 1,300 mg/L and is expected to strongly sorb to soils based on measured log K_{OC} values from studies conducted on analogue chemicals according to OECD test guidelines.

The assessed chemical is not readily biodegradable and does not contain functional groups susceptible to hydrolysis under environmental pH range (pH 4-9); however, it is not considered persistent (63% degradation over 60 days in a modified OECD TG 301 D study). As the assessed chemical is a surfactant with cationic charge under environmental conditions, it is likely to bind to the epithelial surface rather than cross the lipid barrier, and therefore has a low potential for bioaccumulation. This is supported by experimental data available for cationic surfactants (McWilliams, 2001).

The assessed chemical will be used in industrial settings only, ultimately being disposed of in on-site tailings dams with no release into the environment.

Predicted environmental concentration (PEC)

A predicted environmental concentration has not been calculated as the assessed chemical is not released into environmental waters under the assessed use.

Environmental effects

Effects on Aquatic Life

Acute toxicity

Based on the measured acute ecotoxicological endpoints for aquatic invertebrates and algae, and the read across data for acute fish toxicity provided by the applicant, the assessed chemical is considered acutely very toxic to fish, aquatic invertebrates and algal growth.

Taxon	Endpoint	Method
Fish	96 h LC50 = 0.1 mg/L	OECD TG 203
Invertebrates	48 h EC50 = 0.151 mg/L	OECD TG 202
Algae	72 h ErC50 = 0.42 mg/L	OECD TG 201
Microbial Activity	3 h IC50 = 43 mg/L	OECD TG 209

Chronic toxicity

Based on the chronic ecotoxicological endpoints provided by the applicant the assessed chemical is chronically very toxic to aquatic invertebrates and algal growth:

Taxon	Endpoint	Method
Invertebrates	21 d NOEC = 0.09 mg/L	OECD TG 211
Algae	72 h ErC10 = 0.19 mg/L	OECD TG 201

Effects on sediment dwelling life

The results from the supplied read across data for sediment toxicity are summarised in the table below:

Taxon	Endpoint	Method
Nematode (Acute)	96 h NOEC = 1,000 mg/kg sediment dw	ISO 10872 (2008)
Worm (Chronic)	28 d LOEC (reproduction) = 68 mg/kg sediment dw	OECD TG 225

Predicted No-Effect Concentration (PNEC)

A Predicted No-Effect Concentration (PNEC) was calculated based on the above chronic endpoint for aquatic invertebrates using an assessment factor of 10 as three acute trophic endpoints and two chronic trophic endpoints are available. The resulting PNEC is 9 µg/L.

Environmental hazard information

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

Persistence

Not Persistent (Not P). Based on a modified ready biodegradability study (half-life < 60 days in environmental water) the assessed chemical is categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). The assessed chemical has a low potential for bioaccumulation based on structural considerations.

Toxicity

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

References

McWilliams, P., Payne, G. (2001) *Bioaccumulation Potential of Surfactants: A Review*. Royal Society of Chemistry & EOSCA, Manchester, United Kingdom.

National Transport Commission (2020) *Australia Code for the Transport of Dangerous Goods by Road & Rail, Edition 7.7*. Commonwealth of Australia.

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