β-Alanine, *N*-(2-hydroxyethyl)-*N*-[2-[(1-oxooctyl)amino]ethyl]-

Assessment statement (CA09508)

29 March 2022

Table of contents

Contents

AICIS assessment statement

Chemical in this assessment

Name	CAS registry number
β-Alanine, *N*-(2-hydroxyethyl)-*N*-[2-[(1-oxooctyl)amino]ethyl]-	64265-45-8

Reason for the assessment

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

Certificate Application Type

Environment focus

Based on introduction, use and end use described in the application, the exposure bands of the introduction are 3 for human health and 4 for the environment [table item 4 clause 1 and table item 4 clause 3 of Schedule 1, Industrial Chemicals (General) Rules 2019 (the Rules)]. Categorisation volumes for human health and the environment are calculated based on Industrial Chemicals Categorisation Guidelines and are used to determine the exposure bands.

The assessed chemical has hazard characteristics in human health hazard band B (clause 2 Schedule 1 of the Rules) and environment hazard band B (clause 4 Schedule 1 of the Rules). In accordance with table item 10 section 28 and table item 8 section 29 of the Rules, the indicative human health risk for the proposed introduction is low and the indicative environment risk for the proposed introduction is medium to high.

Defined scope of assessment

The chemical has been assessed:

- as imported into Australia at up to 0.5 tonne per annum;
- in imported products at up to 2% concentration for reformulation of end use products;
- for firefighting use at diluted concentration of 0.12% or less at industrial and mining sites only.

Summary of assessment

Summary of introduction, use and end use

The chemical will not be manufactured in Australia. It will be imported into Australia as a component of products at up to 2% concentration for further reformulation to ≤ 0.12% concentration prior to its end use of fighting fires.

The reformulated end use products containing the assessed chemical at ≤ 0.12% concentration will be used at mining sites, and industrial fire services, in industrial fire extinguishers and in mining vehicles for the fire suppression system. Firefighting products containing the assessed chemical at ≤ 0.12% concentration will not be used against domestic fires or available to the public, for instance fire extinguishers sold in retail shops.

Human health

Summary of health hazards

Based on the available data the assessed chemical is likely to be irritating to the eyes and sensitising to the skin (see **supporting information**), warranting hazard classification (see below).

The available toxicity data indicate that the assessed chemical:

- is likely to be of low acute oral and dermal toxicity;
- is non-irritating to the skin;
- is unlikely to cause systemic toxicity following repeated exposure; and
- is not considered to be genotoxic.

No inhalation toxicity data were provided on the assessed chemical.

Health hazard classification

Based on the available data, the assessed chemical satisfies the criteria for 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 hazards	Hazard category	Hazard statement
Serious eye damage – Eye irritation	Category 2	H319: Causes serious eye irritation
Skin sensitisation	Category 1B	H317: May cause an allergic skin reaction

Summary of health risk

Public

The firefighting products containing the assessed chemical will not be available for use in the public or domestic areas. When introduced and used in the proposed manner, it is unlikely that the public will be exposed to the assessed chemical. Therefore, there are no identified risk to the public that require management, if the assessed chemical is introduced and used by workers only, in accordance with the terms of the assessment certificate.

Workers

Workers are expected to experience dermal and ocular exposure to the assessed chemical at a maximum of 2% concentration during handling, reformulation and application of the firefighting products containing the chemical. Given that the chemical is a skin sensitiser, control measures to minimise dermal exposure are needed to manage the risk to workers (see **means for managing risk** section). As the inhalation toxicity of the chemical is unknown

control measures are also needed if there is potential for mists or aerosols to be generated during reformulation and application of the firefighting products containing the chemical. The risk of eye irritation is minimised by the low concentration of the chemical as introduced and used.

Environment

Summary of environmental hazard characteristics

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

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

Environmental hazard classification

The chemical satisfies the criteria for classification for environment according to *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS, United Nations 2017). Data on three acute endpoints were available. The aquatic acute classification was determined from the lowest acute endpoint for algae (ErC50 = 65 mg ac/L) and to be Acute Category 3. One chronic endpoint was available for algae (NOEC = 4.6 mg ac/L). The most stringent outcome was based on the chronic data taking into account that the substance is not readily biodegradable but inherently biodegradable. Therefore, the overall long-term classification is Chronic Category 3 (United Nations, 2017).

Environmental Hazard	Hazard Category	Hazard Statement
Chronic Aquatic	Category 3	H412: Harmful to aquatic life with long lasting effects

Summary of environmental risk

Based on the end use in firefighting foam products, the majority of the assessed chemical is expected to be released directly during firefighting events. As the assessed chemical is for emergency firefighting use at industrial and mining sites only, where guidance has been provided by relevant authorities to site managers that bunding is to be erected to capture the release of firewater, no significant release of the assessed chemical to the environment is expected (see **means for managing risk** section).

The assessed chemical is inherently degradable and, therefore, not persistent. The assessed chemical has a low potential for bioaccumulation based on its log Kow and is harmful, but not toxic, to aquatic organisms.

Based on its low hazards and assessed use pattern, the assessed chemical is unlikely to cause environmental risk.

Means for managing risk

Workers

Recommendation to Safe Work Australia

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

Information relating to safe introduction and use

- The information in this statement including recommended hazard classifications, should be used by a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.
- The following control measures could be implemented to manage the risk arising from exposure to the assessed chemical during handling or reformulation activities:
    - Use of engineering controls such as
        - Adequate workplace ventilation to avoid accumulation of mists or aerosols
    - Use of safe work practices to
        - Avoid contact with skin
        - Avoid inhalation of mists or aerosols
    - Workers should wear the following personal protective equipment (PPE)
        - Impervious gloves
        - Protective clothing

- The following control measures could be implemented to manage the risk arising from exposure to the assessed chemical during applying activities:
    - Use of engineering controls such as
        - Adequate workplace ventilation to avoid accumulation of mists or aerosols
    - Use of safe work practices to
        - Avoid inhalation of mists or aerosols
    - Workers should wear the following personal protective equipment (PPE)
        - Respiratory protection

- As the assessed chemical is a skin sensitiser, these control measures may need to be supplemented with conducting health monitoring for any worker who is at significant risk of exposure to the chemical, if valid techniques are available to monitor the effect on the worker's health.
- Model codes of practice, available from the Safe Work Australia website, provide information on how to manage the risks of hazardous chemicals in the workplace, prepare an SDS and label containers of hazardous chemicals. Your Work Health and Safety regulator should be contacted for information on Work Health and Safety laws and relevant Codes of Practice in your jurisdiction.

Environment

Information relating to safe introduction and use:

- The risks associated with the assessed chemical can be managed provided that when the chemical is used for testing or training purposes the end-users have in place containment measures to control firewater run-off and prevent release of firewater to sewers, surface waters or soil.

- Emergency response plans and resources should also be established by end-users to mitigate the release of firewater run-off to sewers and surface waters during firefighting at mining and industrial sites.

Conclusions

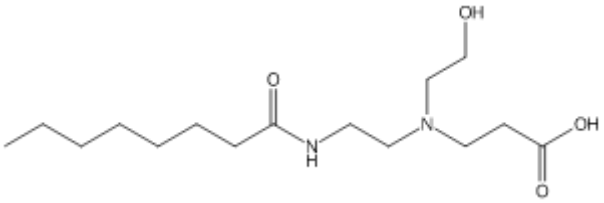
The conclusions of this assessment are based on the information described in this statement.

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, and the proposed 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	β-Alanine, *N*-(2-hydroxyethyl)-*N*-[2-[(1-oxooctyl)amino]ethyl]-
CAS No.	64265-45-8
Synonyms	*N*-(2-Hydroxyethyl)-*N*-[2-[(1-oxooctyl)amino]ethyl]-β-alanine
Structural formula	
Molecular formula	$C_{15}H_{30}N_2O_4$
Molecular weight (g/mol)	302.41
SMILES	O=C(O)CCN(CCO)CCNC(=O)CCCCCCC

Relevant physical and chemical properties

All measured values are based on the studies provided on the assessed chemical and conducted according to OECD test guidelines.

Physical form	Appearance at 20 ºC and 101.3 kPa at 50% concentration is clear yellow liquid.
Melting point	Has no melting point
Boiling point	Has no boiling point
Vapour pressure	< 1.47×10^{-6} kPa at 20 °C
Density	1.13×10^{3} kg/m^3 at 20 °C
Flammability	Not highly flammable
Autoignition Temperature	375 °C
Explosive Properties	Not explosive
Oxidising Properties	Not oxidising

Surface tension	38.2 mN/m
Water solubility	> 1000 g/L at 21 ºC
Hydrolysis as a function of pH	Stable to hydrolysis (t1/2 > 1 year) at pH = 4, 7 and 9
Acid dissociation constant (pKa)	-1.49, 4.75, 8.00, 15.0 (calc.)
Octanol-water partition coefficient (log Kow)	0.3-4.1 at 22 ºC and pH = 7 (weighted mean = 1.1)
Adsorption coefficient (log Koc)	< 1.32 - > 5.63 at pH = 7

Introduction and use

The assessed chemical will not be manufactured in Australia. It will be imported as products at ≤ 2% concentration for further reformulation to ≤ 0.12% concentration for end uses.

The reformulated products containing the assessed chemical at ≤ 0.12% concentration will be used at mining sites, industrial fire services, and industrial fire extinguishers and on mining vehicles for fire suppression systems. The reformulated products containing the assessed chemical at ≤ 0.12% concentration will be for industrial uses only and will not be used against domestic fires. The products containing the assessed chemical at ≤ 0.12% concentration will not be available to the public, for instance fire extinguishers sold in retail shops.

Human exposure

Workers

Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport from dock to applicant's site for reformulation (unloading/loading trucks)	2	6 hours / year	6 hours / year
Handling and storage operators	20	0.5 hours / day	2.3 days / year
Fire brigade fire fighters	20	0.1 hours / month	1.2 days / year
Industrial fire service personnel	60	0.125 / day	9.56 days / year
Equipment maintenance and cleaning	20	0.5 hours / day	2.3 days / year

Exposure Details

Transport and storage

Transportation and warehouse workers are not expected to have contact with the assessed chemical, except in the case of accidental rupture of the product containers.

Reformulation

Reformulation of the firefighting end use product using the imported product containing the assessed chemical at ≤ 2% will be a simple mix with water and pressurised with carbon dioxide gas. These are performed by qualified fire extinguisher manufacturers, using PPE such as face shields, chemical resistant gloves, overalls, protective footwear suitable for pressurised containers.

Foam application

The chemical will be used or further diluted at ≤ 0.12% concentration during firefighting. A hose and nozzle will be connected to the tank where it is mixed with water, and the product pumped through the hose and directed towards the fire via the nozzle. Incidental dermal and ocular exposure to the foam containing the assessed chemical at ≤ 0.12% concentration may occur when workers apply the product foam. However, firefighting personnel are usually equipped with appropriate PPE such as self-contained breathing apparatus and full protective clothing. Inhalation exposure is not expected during these processes as the foam is intended to be used outdoors. Given fire fighters wear self-contained breathing apparatus and full protective clothing, exposure of the chemical to workers will be reduced.

Public

Products containing the assessed chemical are intended for industrial uses only and will not be sold to or used by the public. Firefighting foam containing the assessed chemical is not used to fight domestic fires.

Health hazard information

Toxicokinetics

Given the relatively low molecular weight (302.41 g/mol) and the partition coefficient (log Pow = 0.3-4.1 at 22 ºC) of the assessed chemical, absorption across biological membranes is possible.

Acute toxicity

Oral

Based on an acute oral toxicity study of the assessed chemical (OECD TG 423), the assessed chemical was found to be of low acute oral toxicity in rats (LD50 > 2000 mg/kg bw).

Dermal

Based on an acute dermal toxicity study of the assessed chemical (OECD TG 402), the assessed chemical was found to be of low acute dermal toxicity in rats (LD50 > 2000 mg/kg bw).

Inhalation

No acute inhalation toxicity data are provided for the assessed chemical.

Corrosion/Irritation

Skin irritation

The assessed chemical was determined not to be irritating to the skin in an *in vivo* skin irritation test in rabbits (OECD TG 404). The assessed chemical does not require classification for skin irritation according to the GHS criteria.

Eye irritation

In an *in vivo* eye irritation study (OECD TG 405), irritation of the conjunctivae consisted of redness (mean scores in 3 rabbits: 2.7, 3.0, and 2.7), chemosis (mean scores: 1.7, 1.3, and 1.7), and discharge (mean scores: 1.7, 1.0, and 1.3) were observed in the rabbits, but completely resolved within 14 days. Opacity (mean scores of 1.0 in all rabbits), and epithelial damage were also observed. No evidence of eye corrosion was noted and no symptoms of systemic toxicity in the animals or mortality were observed. The assessed chemical was considered as irritating to the eye, requiring classification for eye irritation (Category 2: H319: Causes serious eye irritation).

Sensitisation

Skin sensitisation

The skin sensitisation potential of the assessed chemical was assessed using a local lymph node assay (LLNA) in mice (OECD TG 429). The assessed chemical was tested at concentrations of 25%, 50% and 100%. The assessed chemical was found to be a skin sensitiser with an EC3 value of 30.6%. The assessed chemical is a skin sensitiser, requiring classification for Skin Sensitisation (Category 1B: H317: May cause an allergic skin reaction).

Repeat dose toxicity

Oral

A repeated dose oral (gavage) toxicity study (OECD TG 407) on the assessed chemical was conducted in rats, in which the test substance was administered at 0, 50, 150 and 1000 mg/kg bw/day for 28 consecutive days. The No Observed Adverse Effect Level NOAEL was established at 1000 mg/kg bw/day in this study, based on no toxicologically relevant adverse effects at the highest dose level were observed.

Genotoxicity

The assessed chemical was found to be non-mutagenic in a bacterial reverse mutation assay (OECD TG 471) and in an *in vitro* mammalian chromosome aberration test (OECD TG 473).

Environmental exposure

Significant releases of the assessed chemical to the environment are not expected during transport, reformulation or storage. The assessed chemical will have end-uses in the mining industry, industrial fire services, fire extinguishers and on mining vehicle fire suppression systems for extinguishing hydrocarbon fires. The assessed chemical will only be used at mining and industrial sites. The assessed chemical will not be available to the public.

During firefighting, it is expected the assessed chemical will be further diluted. A hose and nozzle will be connected to the tank where it is mixed with water, and the product pumped through the hose and directed towards the fire via the nozzle. Releases to the environment through spills, drips and leaks are expected to be controlled through capture equipment and bunding.

Based on the assessed use as a component of firefighting foam products, the majority of the assessed chemical is expected to be released directly to the localised terrestrial environment as firewater, during its use at firefighting events. Most of the immediate environmental release is expected to be to the soil compartment (HEPA, 2018). The applicant has provided information stating that the relevant authorities will take measures such as erecting bunding to prevent direct releases of firewater to sewer or surface water. However, the relevant authorities have provided guidance to site managers of the users of firefighting foams to take additional measures of their own to control firewater run-off to prevent direct releases of firewater to sewer or surface water (EPAV, 2018, FRV, 2018, Queensland Government 2016, 2021).

Environmental fate

Dissolution, speciation and partitioning

The assessed chemical is measured to be highly water soluble (> 1000 g/L). However, based on the assessed end-uses the assessed chemical is expected to be released to the terrestrial environment. The assessed chemical has a measured log Koc range from less than 1.32 through to greater than 5.63 at pH = 7 according to OECD Test No. 121. However, greater than 73 % of components in the screening test displayed log Koc greater than 5.63, indicating the assessed chemical is largely immobile in soil.

Degradation

The assessed chemical is not persistent, based on experimental degradation results.

The assessed chemical underwent 38 to 45% degradation after 28 days in OECD 301F ready biodegradation tests. Therefore, the substance is not considered readily biodegradable. However, the assessed chemical can be considered to demonstrate inherent degradation according to OECD guidance (OECD, 2006).

Bioaccumulation

The assessed chemical is not expected to bioaccumulate in the environment based on its measured octanol-water partition coefficient range of log Kow = 0.3 – 4.1 at pH = 7, with a weighted mean log Kow = 1.1.

Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) has not been calculated as release of the assessed chemical to the aquatic environment is not expected. The assessed chemical will only be used at mining and industrial sites and will not be made available to the public. At these sites, containment measures, such as bunding, will be erected to mitigate aquatic release of the assessed chemical. These measures are based on guidance provided by the relevant authorities to the site managers of the users of firefighting foams to take additional measures to prevent the release of firewater to sewers and surface waters.

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 by the applicant:

Taxon	Endpoint	Method
Fish	96 h LC 50 > 100 mg ac/L	*Cyprinus carpio* (Carp) Mortality OECD TG 203 Static conditions Measured concentration
Invertebrate	48 h EC50 > 100 mg ac/L	*Daphnia magna* (water flea) Immobility OECD TG 202 Static conditions Measured concentration
Algae	72 h ErC50 = 65 mg ac/L NOEC = 4.6 mg ac/L	*Pseudokirchneriella subcapitata* (Green algae) Growth rate OECD TG 201 Static conditions Measured concentration
Microorganisms	3 h EC50 > 100 mg ac/L	OECD TG 209 Respiration inhibition Measured concentration

Predicted no-effect concentration (PNEC)

A Predicted No-Effect Concentration (PNEC) was calculated based on the above acute endpoint for algae using an assessment factor of 100, with considerations made for intermittent release of the assessed chemical (EPHC 2009, ECHA 2008). The lowest acute endpoint was selected as the basis of the PNEC calculation in the absence of additional chronic endpoints to support the algal growth inhibition NOEC (ECHA 2008). The resulting PNEC is 650 µg/L.

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 the ready biodegradability study with 38 - 45% degradation, the assessed chemical is considered as inherently biodegradable. Therefore, the assessed chemical is categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on the measured log Kow range (log Kow < 4.2), the assessed chemical is categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on the available acute ecotoxicity values above the domestic threshold criteria of 1 mg/L, 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). A Risk Quotient (PEC/PNEC) for the aquatic compartment has not been calculated, but when the assessed chemical is used at up to 0.12% (1200 mg/L) in firefighting foam, the resultant concentration of the assessed chemical in firewater exceeds the PNEC. Based on the end-uses, the assessed chemical has greatest potential to be released to the terrestrial environment at the firefighting events. However, these events are considered to occur infrequently, and releases will be localised. Bunding will be erected to mitigate aquatic release, based on guidance provided by the relevant authorities to the site managers of the users of firefighting foams to take additional measures to prevent the release of firewater to sewers and surface waters.

The assessed chemical is not PBT and is hence unlikely to have unpredictable long-term effects (EPHC 2009). The assessed chemical is harmful to aquatic life. However, any harmful impacts would be short term, based on the assessed chemicals biodegradation properties, and localised, based on the assessed chemicals end-uses at industrial and mining sites. Concurrently, no significant adverse effects to the environment are expected.

Therefore, based on the low toxicity, inherent biodegradation characteristics and low bioaccumulation potential, the assessed chemical is unlikely to pose a significant risk to the environment.

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