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

L-Lysine, *N*-(3-carboxy-1-oxopropyl) derivs., sodium salts

Assessment statement (CA09701)

17 October 2023

Final

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AICIS assessment statement (CA09701)

Chemical in this assessment

Name	CAS registry number
L-Lysine, *N*-(3-carboxy-1-oxopropyl) derivs., sodium salts	1917323-94-4

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 Very Low to Low Risk type.

Defined scope of assessment

The chemical has been assessed:

- as imported into Australia at up to 10 tonnes/year
- as imported neat for local reformulation into construction chemical products at up to 5% concentration for use by professional workers
- as imported as finished end-use construction chemical products containing the assessed chemical at up to 5% concentration for use by professional workers

Summary of assessment

Summary of introduction, use and end use

The assessed chemical will not be manufactured in Australia. The assessed chemical will be imported into Australia in neat form as a raw material in 1,100 kg intermediate bulk containers (IBCs) for local reformulation into gypsum-based construction materials. It will be imported by sea or air into Sydney, Brisbane, Melbourne or Perth and transported by road directly to industrial customers from customs warehouses.

The assessed chemical may also be imported as a component of finished end-use construction chemical products at up to 5% concentration for use in the construction industry. Products containing the assessed chemical will be used by professional workers only and will not be sold to the general public.

Human health

Summary of health hazards

The summary of identified health hazards is based on available data for the assessed chemical and an analogue chemical. Based on the physicochemical properties, the assessed chemical is not expected to be readily absorbed following oral, dermal or inhalation exposure (see **Supporting information)**.

Based on the data submitted on the assessed chemical, the assessed chemical is:

- of low acute oral toxicity (LD50 > 2,000 mg/kg bw in rats)
- not considered to be genotoxic

Based on the data submitted on an analogue chemical, the assessed chemical is:

- not irritating to skin
- a slight eye irritant
- not considered to be a skin sensitiser up to 50% concentration
- not likely to cause systemic health effects following repeated oral exposure (NOAEL is 1,000 mg/kg bw/day in rats)
- not likely to cause adverse effects in reproductive organs, embryotoxicity or teratogenicity following repeated oral exposure (NOAEL is 1,000 mg/kg bw/day in rats).

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

Hazard classifications relevant for worker health and safety

The assessed chemical does not satisfy the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017), as adopted for industrial chemicals in Australia.

Summary of health risk

Public

When introduced and used in the proposed manner, it is unlikely that the public will be exposed to the assessed chemical.

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

Workers

Potential exposure of workers to the assessed chemical at various concentrations, including in its neat form, may occur during reformulation operations and professional end use applications. While the exposure to the assessed chemical will be mainly dermal, ocular and inhalation exposures may also occur.

No risks were identified for workers during these processes that require specific risk management measures. However, control measures to minimise inhalation exposure may be needed if aerosols or mists are formed during these processes.

Environment

Summary of environmental hazard characteristics

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

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

Environmental hazard classification

Based on the ecotoxicological information available for the assessed chemical, it is not expected to be harmful to aquatic life. Therefore, the assessed chemical is not formally classified under the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) for acute and chronic aquatic toxicities (UNECE 2017).

Summary of environmental risk

No significant release of the assessed chemical is expected to occur as a result of its use as an additive in gypsum binders. The assessed chemical is expected to share the fate of the product it is incorporated into and be disposed to landfill at the end of its useful life.

The assessed chemical is not readily degradable and is categorised as persistent. The assessed chemical has a low potential for bioaccumulation and is not expected to cause significant toxic effects in aquatic organisms.

Although the assessed chemical is persistent, it does not meet all three PBT criteria. Significant environmental release of the assessed chemical from its assessed industrial uses in Australia is not expected. Based on its low hazards and assessed use pattern, the environmental risks associated with the assessed chemical can be managed.

Means for managing risk

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

No specific means for managing risk are proposed during the assessment, provided that the assessed chemical is introduced in accordance with the terms of the assessment certificate.

Conclusions

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

Considering the 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. 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 of 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	L-Lysine, *N*-(3-carboxy-1-oxopropyl) derivs., sodium salts
CAS No.	1917323-94-4
Molecular formula	Unspecified

Chemical description

The assessed chemical contains the following components with a combined purity of ≥ 95.99% - ≤ 100%.

Chemical Name	CAS No.	Typical Conc. (%)	Range Conc. (%)
L-Lysine, N^2,N^6-bis(3-carboxy-1-oxopropyl)-, sodium salt (1:3)	1072910-40-7	61	56 - 66
L-Lysine, N^6-(3-carboxy-1-oxopropyl)-, sodium salt (1:?)*	Not assigned	30	25 - 35
L-Lysine, N^2-(3-carboxy-1-oxopropyl)-, sodium salt (1:?)*	Not assigned	9	< 10

* Salt ratio is dependent on pH

Relevant physical and chemical properties

Physical form	Highly viscous semi-solid mass
Melting point	44 °C
Boiling point	136 – 149 °C
Vapour pressure	1.24 x 10^{-5} Pa at 20 °C
Water solubility	> 1,000 g/L
Ionisable in the environment?	Yes*
log K_{ow}	-3.25** at 20 °C, pH 6.5 - 7

* The carboxylates are expected to be mostly in the anionic form at the environmental pH range of 4–9. The organic components of the assessed chemical have the potential to chelate metal ions in aqueous solution.

** Read-across from a suitable analogue. The assessed chemical and its read-across analogue differ only by the nature of the cation: the assessed chemical is a mixture of sodium salts, while the read-across analogue contains calcium salts. The organic components are identical in the assessed chemical and its read-across analogue. The change of cation is not expected to significantly alter the partition coefficient of the substance. The partition coefficient of the main constituent of the read-across chemical is log K_{OW} = -3.25, based on an octanol-water partitioning test. Dissociation effects have not been accounted for in the read-across study. However, based on its chemical structure and solubility, the partition coefficient of the assessed chemical is expected to be low (≤ 0).

Human exposure

Workers

Reformulation

Transport, storage and warehouse workers are not expected to be exposed to the assessed chemical or products containing the assessed chemical, except in an unlikely event of an accidental rupture of containers. In such cases, according to the applicant, the spillage is expected to be contained and collected by workers using applicable personal protective equipment (PPE). Generally, the blending of products is an automated process taking place in an enclosed system. Typical blending facilities are designed to minimise the exposure to workers and are generally well-ventilated using cross-ventilation fans and exhaust fans.

Dermal, ocular and, perhaps, inhalation exposure (if aerosols or mists are formed) of workers to the assessed chemical in its neat form or at up to 5% concentration may occur during weighing and transfer stages, blending, quality control analysis, and cleaning and maintenance of equipment. Given that the assessed chemical has relatively low vapour pressure, significant inhalation exposure is not expected, unless aerosols or mists are formed during the mixing process.

According to the applicant, worker exposure is expected to be minimised through the use of PPE including goggles, chemical resistant gloves, boots, aprons and appropriate face masks as required. Workers involved in quality control, according to the applicant, will also wear laboratory coats, safety goggles and nitrile gloves to minimise any exposure to the assessed chemical.

Professional end use

Construction materials containing the assessed chemical will be prepared on-site by professional workers. The liquid component (water or mixing liquid) will be poured into a mixing vessel and the powder product (if relevant) will be added. For multicomponent systems, the liquid components will be poured or scraped into the mixing vessel and mixed until homogeneous before the powder component (if relevant) is added. The components will then be mixed further until homogeneous.

The prepared end-use products are either spread out on the surface (floors and walls) via rolling, brushing or trowelling, or poured into spraying equipment (airless) and sprayed onto the surface through a handheld nozzle with workers standing upright. In another application scenario, the mixed material is poured onto the prepared substrate and a vibrator or rotating chains or wire loops are used to help to make the material flow more smoothly.

According to the applicant, worker exposure is expected to be minimised through the use of PPE such as coveralls, masks and eye protection.

Public

The products containing the assessed chemical will only be used by professional workers and will not be available to the general public. Therefore, exposure of the general public to the assessed chemical is not expected.

Health hazard information

Toxicokinetics

Based on the low partition coefficient (estimated log K_{OW} value = -3.25 by read-across), dermal absorption is expected to be low. Furthermore, the assessed chemical will dissociate in aqueous solution and ionized substances do not readily diffuse across biological membranes.

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), two groups of fasted female Wistar rats (n = 3/group) were administered the assessed chemical via oral gavage at a dose of 2,000 mg/kg bw. No deaths or signs of systemic toxicity were observed. All animals showed the expected body weight gains over the study period. There were no macroscopic findings in any treated animals. No treatment-related gross necropsy findings were observed. The median lethal dose (LD50) was determined to be > 2,000 mg/kg bw. Based on the results of this study, the assessed chemical is likely to be of low acute oral toxicity.

Corrosion/Irritation

Skin irritation

The skin irritation potential of an analogue chemical was tested using the EpiSkin™ reconstructed human epidermis tissue model (EpiSkin™ Small Model) (OECD TG 439). The relative mean viability of the chemical-treated tissues was 103% after the 15-minute exposure period and 42-hour post-exposure incubation period. All acceptance criteria for this method were considered to be met. Therefore, under the conditions of this study, the analogue chemical was not considered to be irritating to the skin.

Eye irritation

The data from an analogue chemical was provided for assessment of eye irritation potential (OECD TG 405). Treatment of three male New Zealand White rabbits with 0.1 g of test item to the lower conjunctival sac of one eye resulted in no effects on the cornea or iris in any animal at any time point during the 72-hour observation period. Mild conjunctival redness, chemosis and discharge were observed in some animals at the 1-hour time point but were fully resolved by 24 hr. No signs of systemic toxicity were observed during the 72-hour observation period. Based on the results and as per the conditions of this study, the analogue chemical is considered a slight eye irritant.

Sensitisation

Skin sensitisation

The skin sensitisation potential of an analogue chemical was tested using a local lymph node assay (LLNA) (OECD TG 429). Three groups of female CBA mice (CBA strain) (n = 5/dose) were treated by daily application of 25 µL of the test item at concentrations of 10%, 25% or 50% (w/v), to the dorsal surface of each ear for three consecutive days. Due to its viscosity, the test item was not suitable for application at 100 % (w/v) concentration. On Day 6, all animals were injected via the tail vein with 0.25 mL of sterile phosphate buffered saline containing 25 µCi of 3HTdR. After five hours, the animals were euthanised and the draining (auricular) lymph nodes were excised for further processing. There were no deaths or signs of systemic toxicity in the treatment groups and no visible signs of irritation or other local effects. Body weights in the treatment groups were comparable to controls.

The stimulation indices (SI) calculated for the assessed chemical at 10%, 25% and 50% (w/v) concentrations were 0.7, 0.7 and 2.7 respectively. None of the applied concentrations, up to the maximum applicable concentration of 50 % (w/v), induced a biologically relevant increase in lymphocyte proliferation (SI ≥ 3). Under the conditions of the study and as per the test guideline, the analogue chemical was not considered to be sensitising to the skin up to 50% concentration.

Repeat dose toxicity

Oral

A combined repeated dose oral toxicity study with a reproduction/developmental toxicity screening test of an analogue chemical was conducted (OECD TG 422). Details of the reproduction/developmental toxicity screening test are described in the respective section.

Four groups of Wistar rats (n = 12/sex/dose) were administered the analogue chemical by gavage once a day for up to 8 weeks at dose levels of 0 (vehicle), 100, 300 and 1,000 mg/kg bw/day. The application volume was 5 mL/kg bw and the selected dosages were based on a dose range finding study (OECD TG 407). Control animals received the vehicle (distilled water). The concentrations of the test item in the dosing formulations varied in the acceptable range between 92% and 100% of the nominal values, confirming the proper dosing.

There were no treatment-related clinical signs, deaths or treatment-related changes observed in food consumption, body weight, functional tests, haematological parameters, clinical biochemistry, macroscopic examination, organ weight or microscopic examination in any animals at any tested dose.

The no observed adverse effect level (NOAEL) was established as 1,000 mg/kg bw/day in this study, based on no adverse effects being noted in rats up to the highest tested dose.

Genotoxicity

The assessed chemical was found to be non-mutagenic in a bacterial reverse mutation assay using *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 and *Escherichia coli* strain WP2uvrA, 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 dose (16, 50, 160, 500, 1,600, 5,000 µg/plate), with or without metabolic activation.

Another study was performed to assess the potential of an analogue chemical to cause chromosomal aberrations in V79 Chinese Hamster lung cells (OECD TG 473). No statistically significant increases in the proportion of polyploid or endoreplicated metaphase cells were observed after a 3-hour exposure period at any tested dose (500, 1,000, 2,000 µg/mL), with or without metabolic activation. In a separate experiment, the analogue chemical also showed no mutagenic properties after a 20-hour exposure period at any tested dose (250, 500, 1,000, 2,000 µg/mL), without metabolic activation. Under the conditions of this study, the analogue chemical was considered to be non-clastogenic to V79 cells in vitro.

The analogue chemical was also assessed for its potential to induce gene mutations at the hypoxanthine-guanine phosphoribosyl transferase (HPRT) locus in cultured Chinese Hamster Ovary (CHO) cells in vitro (OECD TG 476). The results indicated that treatment with the analogue chemical at any tested dose (125, 250, 500, 1,000, 2,000 µg/mL), with or without metabolic activation, did not lead to a relevant increase in the number of mutant colonies. Thus, under the conditions of this study, the analogue chemical was not mutagenic in CHO cells.

Reproductive and developmental toxicity

In a reproductive/developmental toxicity study (OECD TG 422), four groups of Wistar rats (n = 12/sex/dose) were administered an analogue chemical by gavage once a day at dose levels of 0 (distilled water, vehicle), 100, 300 and 1,000 mg/kg bw/day. All animals of the parent (P) generation were dosed for 14 days prior to mating and throughout mating for male rats, or to lactation days 12–18 for female rats that delivered a litter, up to the day before necropsy. The total duration of dosing was 56 days in males and 55–56 days in females.

No test substance-related changes in mortality, clinical observations, behaviour/physical condition, body weights, body weight gain or food consumption were observed up to the highest tested dose (1,000 mg/kg bw/day). Clinical pathology examinations (haematology, blood coagulation and clinical chemistry) did not reveal alterations related to the test item. Mean T4 hormone levels were lower in parental animals at all dose levels, as compared to the control group. The reported relative decreases were statistically significant in males at all doses (-38%, -54% and -60% at 100, 300 and 1,000 mg/kg bw/day, respectively; $p < 0.01$). However, the reported relative decreases did not reach statistical significance in females (-11%, -10% and -4% at 100, 300 and 1,000 mg/kg bw/day, respectively). High inter-individual variation was noted in the control and treated groups and there were also no related microscopic lesions in the organs of the hypothalamic-pituitary-thyroid axis in the examined animals (high dose group). Therefore, this finding was not considered to be adverse under the conditions of this study.

While slightly lower fertility indices were observed compared to the respective control in the 1,000 mg/kg bw/day group (male and female), the values were comparable with the historical controls. Therefore, this slight change was not considered to be adverse.

No specific macroscopic alterations related to the treatment were found at necropsy. There were also no treatment-related changes in the weights (absolute and relative to body weights) of selected organs in the animals at any dose level. Histopathological examination of selected organs (ovaries, uterus, vagina, testes, epididymides, prostate and seminal vesicles with coagulating gland) did not reveal any treatment-related changes at 1,000 mg/kg bw/day.

There were no adverse findings detected on the development of the offspring (mortality, clinical signs, body weight, anogenital distance and nipple retention in male pups, or at necropsy) to post-natal day 13.

Under the conditions of this study, the NOAEL for systemic toxicity, reproductive performance, and developmental toxicity was reported to be 1,000 mg/kg bw/day, based on no adverse effects observed at the highest tested dose.

Environmental exposure

The assessed chemical will be imported into Australia in a neat highly viscous semi-solid form to be reformulated into finished products or as a component in finished products. The assessed chemical will be used in gypsum binders. The gypsum binders will be used in the construction of articles such as wall boards, partitions and gypsum blocks. The typical concentration of the assessed chemical in finished products is up to 5%.

Reformulation of the assessed chemical into finished products will occur domestically. Generally, the blending of products will be an automated process in an enclosed system. Release of the assessed chemical is only expected to occur from accidental spills during the transport, storage and product transfer stages. Accidental spills and wastes generated during the reformulation process are expected to be collected and disposed of in accordance with state, territory and local government regulations.

The assessed chemical will be used only by professional workers. Products containing the assessed chemical will be applied by spray, brush, roller, or pouring, both in indoor and outdoor settings. After application, the assessed chemical will be incorporated into the product matrix. The assessed chemical is expected to share the fate of the finished products and be disposed of to landfill at the end of its useful life.

During professional use, release of the chemical may occur through overspray and accidental spills. Incidental releases are expected to be collected for appropriate disposal according to local government regulations. Wastes and residues in empty containers are expected to be collected and disposed of to landfill according to local government regulations.

Environmental fate

Dissolution, speciation and partitioning

Based on its ready water solubility, very slight volatility and expected high mobility in soil and sediment, most of the assessed chemical is expected to remain in the water compartment if released. Exposure to the air, soil and sediment compartments is expected to be minimal.

The assessed chemical is a mixture of sodium carboxylate salts that are expected to be mostly in ionic form in the environmental pH range (4–9). The organic component of the main constituent is a tricarboxylate. The carboxylate groups are expected to be largely in their deprotonated, anionic form at neutral and basic pH. In the lower end of the environmental pH range, the carboxylates may be partially or fully protonated to give species with lower valence or the neutral species. The minor constituents of the assessed chemical are dicarboxylate salts that also contain a primary amine group. Similar equilibria between chemical species are expected for the minor constituents. Speciation between the protonated and deprotonated forms of the carboxylate and amine groups is expected to occur. The organic components of the minor constituents are expected to be mostly in an anionic or zwitterionic form in the environmentally relevant pH range.

The assessed chemical is readily soluble, with a measured water solubility > 1,000 g/L. The calculated vapour pressure (1.2×10^{-5} Pa at 20°C) indicates that the components of the assessed chemical are only very slightly volatile. Therefore, exposure or partitioning to the air

compartment is expected to be minimal. The read-across log K_{OW} value (-3.25) indicates that the assessed chemical is hydrophilic. The organic components of the assessed chemical are expected to be mostly negatively charged in the environmental pH range. As the overall surface charge is negative in most soils and sediments in this pH range, minimal sorption of the organic anions to soils and sediments is expected, and the anions are expected to be highly mobile in these compartments (Sigmund et al. 2022). Due to their positive charge, the Na^+ ions may partition to soil and sediments. However, they are not expected to significantly increase background sodium levels in these compartments.

Degradation

Based on the measured degradation in water of a suitable read-across chemical, the assessed chemical is persistent.

An analogue chemical containing Ca^{2+} in place of Na^+, underwent 48.6% degradation after 28 days in an OECD 301 D screening test. The analogue did not meet the pass level and is not readily biodegradable. Additionally, the degradation percentage reached a plateau after 14 days. Consequently, inherent biodegradability has not been demonstrated. The organic anions in the assessed chemical may have chelating properties. Chelation to metal ions is expected to impact the biodegradation of the chelator (Bucheli-Witschel and Egli 2001).

Bioaccumulation

Based on its high solubility in water and on the low measured log K_{OW} value of a suitable read-across substance, the assessed chemical has low bioaccumulation potential and is not expected to be bioaccumulative.

No experimental bioaccumulation data was provided for the assessed chemical or any read-across analogues. Log K_{OW} data for a suitable read-across chemical was provided. The partition coefficient of the main constituent of the read-across chemical is log K_{OW} = -3.25, based on an OECD 107 test. The partition coefficients of all the constituents of the assessed chemical are expected to be below the domestic threshold of log K_{OW} = 4.2 for bioaccumulation in aquatic organisms.

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 pattern.

Environmental effects

Effects on aquatic Life

Acute toxicity

The following median lethal concentration (LC50), effective concentration (EC50), and inhibition concentration (IC50) values for model organisms were supplied for the assessed chemical, or as read-across from a suitable analogue chemical:

Taxon	Endpoint	Method
Fish	96h LC50 > 100 mg/L	*Danio rerio* (zebrafish) OECD TG 203 Static conditions Analytically confirmed nominal concentrations Read-across from the calcium salt analogue
Invertebrate	48h EC50 > 100 mg/L	*Daphnia magna* (water flea) Immobility OECD TG 202 Static Analytically confirmed nominal concentrations Read-across from the calcium salt analogue
Algae	72 hr ErC50 > 100 mg/L	*Raphidocelis subcapitata* (green algae) Growth rate OECD TG 201 Static conditions Analytically confirmed nominal concentrations

The organic components are identical in the assessed chemical and its read-across analogue. The chemicals differ only by the nature of the cation. The change of cation from calcium to sodium is not expected to result in increased adverse effects on aquatic life.

Chronic toxicity

The following measured no effect concentration (NOEC) value for green algae was supplied for the assessed chemical:

Taxon	Endpoint	Method
Algae	72 hr NOEC = 100 mg/L	*Raphidocelis subcapitata* (green algae) Growth rate OECD TG 201 Static conditions Analytically confirmed nominal concentrations

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 1.0 mg/L was calculated for the assessed chemical in the aquatic environment. This value was conservatively derived using the acute endpoint values for all three trophic levels (> 100 mg/L). An assessment factor of 100 was applied to this endpoint as acute toxicity data was available for three trophic levels and chronic

toxicity data was incomplete (EPHC 2009). The acute endpoint was selected, over the algal chronic endpoint, in the absence of additional chronic endpoints to support the algal growth rate NOEC (ECHA 2008).

Categorisation of environmental hazard

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

Persistence

Persistent (P). Based on measured degradation in water of a suitable read-across analogue under ready biodegradability test conditions, the assessed chemical is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on the high solubility in water of the assessed chemical and the low measured log K_{OW} value of a suitable read-across analogue, the assessed chemical is categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available ecotoxicity values above 1 mg/L for the assessed chemical and a suitable analogue, the assessed chemical is categorised as Not Toxic.

Environmental risk characterisation

Although the assessed chemical is persistent, it does not meet all three PBT criteria and is hence unlikely to have unpredictable long-term effects (EPHC 2009). The Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as significant release of the assessed chemical to the aquatic environment is not expected based on its assessed use pattern.

Therefore, based on the hazard profile and limited exposure from the assessed use pattern, the environmental risk from the assessed chemical can be managed within existing frameworks.

References

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