



Australian Government

Department of Health and Aged Care

Australian Industrial Chemicals Introduction Scheme

Glycine, *N*-methyl-*N*-[(9*Z*)-1-oxo-9-alkenyl]-, calcium salt (2:1)

Assessment statement (CA09730)

22 January 2024



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AICIS assessment statement (CA09730)

Chemical in this assessment

AICIS Approved Chemical Name (AACN)

Glycine, *N*-methyl-*N*-[(9Z)-1-oxo-9-alkenyl]-, calcium salt (2:1)

Reason for the assessment

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

Certificate Application type

AICIS received the application in a Very Low to Low Risk type.

Defined scope of assessment

The chemical was assessed as an additive in lubricant products for use only in an industrial setting by workers.

It can be imported into Australia:

- at up to 10 tonnes each year;
- as an additive in lubricant products with a concentration up to 1%.

Summary of assessment

Summary of introduction, use and end use

The assessed chemical will not be manufactured or reformulated in Australia. It will be imported into Australia at up to 1% concentration in end use lubricant products for use only by industrial and professional workers. Repackaging may be carried out in Australia.

The products containing the assessed chemical will be pumped into a filling machine and loaded into cartridges for lubricant guns or dispensers, and then be applied onto equipment.

There will be no consumer use of products containing the assessed chemical.

Human health

Summary of health hazards

The submitted toxicological data on the assessed chemical and analogue chemicals (see **Supporting information**) indicate that the assessed chemical is:

- of low acute oral toxicity
- irritating to skin
- could be irritating to eyes (inconclusive data)
- not expected to be a skin sensitiser
- not expected to cause point mutations

The submitted data warrant hazard classification for skin irritation Category 2 for the assessed chemical (see section below).

No data on inhalation toxicity and repeated dose toxicity were provided.

Hazard classifications relevant for worker health and safety

The chemical satisfies the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) for hazard classes relevant for worker health and safety as follows. This does not consider classification of physical and environmental hazards.

Health hazards	Hazard category	Hazard statement
Skin corrosion/irritant	Skin Irrit. 2	H315: Causes skin irritation

Summary of health risk

Public

The lubricant products containing 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.

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

Workers

End use workers may experience dermal and incidental ocular exposure to the assessed chemical at up to 1% concentration during handling of lubricant products containing the assessed chemical. To mitigate the risks to workers from any irritation effects and repeated exposure, control measures would be required (see **Means for managing risk**) to minimise the exposure. Inhalation exposure is not expected given the low vapour pressure of the assessed chemical and the fact that the products containing the assess chemical will be handled in liquid form and mists or aerosols are not expected to be generated in the proposed use patterns.

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)
- Bioaccumulative (B)
- Not toxic (not T)

Environmental hazard classification

The chemical satisfies the criteria for classification according to the GHS (UNECE 2017) as Acute Category 2 (H401) and Chronic Category 2 (H411) based on the measured toxicity to aquatic plants. Considerations were also made for the assessed chemical being rapidly degradable and potentially bioaccumulative.

Environmental Hazard	Hazard Category	Hazard Statement
Acute Aquatic	Acute aq. - Cat. 2	H401: Toxic to aquatic
Chronic Aquatic	Chronic aq. - Cat. 2	H411: Toxic to aquatic life with long lasting effects

Summary of environmental risk

No significant release of the assessed chemical is expected to occur as a result of its use in lubricant products.

The assessed chemical is expected to share the fate of the lubricant product it is incorporated into.

Used lubricants are expected to be collected by licensed waste management contractors for recycling, re-refining or disposal under local government regulations.

The assessed chemical is readily biodegradable and is not persistent. The assessed chemical has potential to bioaccumulate and it is not toxic to aquatic organisms. Although the assessed chemical is potentially bioaccumulative, it does not meet all three PBT criteria.

The assessed chemical will be sold to industrial or commercial facilities. It is not expected to be available to “do it yourself” (DIY) users, limiting the volume that may be released through incorrect disposal.

Based on its low hazards according to the domestic toxicity criteria and the assessed use pattern, the environmental risk from the introduction and use of the assessed chemical can be managed.

Means for managing risk

Workers

The information in this statement, including recommended hazard classifications, 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.

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 **Hazard classifications relevant for worker health and safety**).

Information relating to safe introduction and use

- The following control measures could be implemented to manage the risk arising from exposure to the assessed chemical during handling of the products containing the assessed chemical:
 - Use of engineering controls such as
 - automated and enclosed systems where possible
 - Use of safe work practices to
 - avoid contact with skin and eyes
 - Workers should wear the following personal protective equipment (PPE)
 - overalls
 - gloves
 - safety glasses/goggles or face mask
- A copy of the Safety Data Sheet (SDS) should be easily accessible to employees.

Conclusions

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

Considering the means for 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 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	Glycine, <i>N</i> -methyl- <i>N</i> -[(9 <i>Z</i>)-1-oxo-9-alkenyl]-, calcium salt (2:1) (AACN)
Molecular weight (g/mol)	< 1,000

Relevant physical and chemical properties

Physical form	Off-white to yellow solid
Melting point	64.5 – 68.5 °C
Boiling point	Decomposes at ~200 °C
Density	1,110 kg/m ³ at 20 °C
Vapour pressure	0.6 Pa at 25 °C
Water solubility	45 mg/L at 20 °C
Ionisable in the environment?	No
log <i>K</i>_{ow}	> 6.2 at 25 °C
Surface tension	34 mN/m (90% saturated solution)

Human exposure

Workers

Professional workers may experience dermal or incidental ocular exposure to products containing the assessed chemical at up to 1% concentration at end use sites when the lubricant product is pumped from the import containers using hoses/pumps and filled using a filling machine, and during the cleaning and maintenance of equipment. End use workers may experience similar exposure when loading cartridges into lubricant guns/dispensers, disconnecting and disposing of cartridges, connecting and disconnecting guns/dispensers, and during the cleaning and maintenance of equipment. It is anticipated by the applicant that engineering controls such as enclosed and automated systems and local ventilation will be implemented where possible. Use of appropriate personal protective equipment (PPE) such as safety glasses, impervious chemical resistant gloves and protective clothing will reduce worker exposure.

Health hazard information

Acute toxicity

Oral

No acute toxicity data were submitted on the assessed chemical. In an acute oral toxicity study (similar to OECD TG 401) conducted on an analogue (acid of the assessed chemical), 5 male and 5 female TIF:RAIf (SPF) rats were administered a single dose of the test substance at 5,000 mg/kg bw. All animals survived and showed slight to moderate clinical signs of toxicity, including dyspnoea, exophthalmos, ruffled fur, diarrhea and hunched body position, but had recovered within 7 days. No test substance-related macroscopic findings were observed. The median lethal dose (LD50) was determined to be greater than 5,000 mg/kg bw. Based on the results of the analogue, the assessed chemical is expected to be of low acute toxicity via the oral route.

Corrosion/Irritation

Skin irritation

In an *in vitro* skin irritation study (OECD TG 439 - EpiDerm™ model) conducted on the assessed chemical, the relative mean viability of the test substance-treated tissues was 21.6% after the 1-hour exposure period. As the tissue viability was $\leq 50\%$, the assessed chemical is identified as requiring classification for skin irritation (Category 1 or Category 2) according to the GHS criteria.

In an *in vitro* skin corrosion study (OECD TG 431 - EpiDerm™ Model) conducted on the assessed chemical, the relative mean tissue viability of the test substance-treated tissues was 95.3% after a 3-minute exposure period and 86.9% after a 60-minute exposure period. As the tissue viability was $\geq 50\%$ and $\geq 15\%$ for 3-minute exposure and 60-minute exposure respectively, the assessed chemical is predicted to be non-corrosive according to the test guideline. The assessed chemical meets the GHS criteria for classification for skin irritation Category 2 based on the results of this study.

Eye irritation

In an *in vitro* eye irritation study (OECD TG 492 - EpiOcular™ model) conducted on the assessed chemical, the relative mean viability of the test substance-treated tissues was 3.4% after 6 hours of exposure. As the tissue viability was $\leq 60\%$, no prediction on eye irritancy can be made from the result in isolation according to the test guideline.

In an *in vitro* eye irritation study (OECD TG 437 – BCOP method) conducted on the assessed chemical, the mean opacity and permeability OD₄₉₀ values were 0.823 and 0.284, respectively. The *in vitro* irritancy score (IVIS) of the test substance was calculated as 5.083, after 10 minutes of exposure. As the IVIS was > 3 and ≤ 55 , no prediction on eye irritancy can be made according to the test guideline.

The assessed chemical has notified classifications by introducers as causing serious eye damage/eye irritation (Category 1 or Category 2) in the ECHA C&L Inventory.

Based on the information provided, the assessed chemical may have potential to cause eye irritation, but the information provided is insufficient to classify the assessed chemical using the GHS criteria. The Defined Approaches (DAs) for Serious Eye Damage and Eye Irritation (OECD TG 467) uses the study results of TG 492 and 437 to differentiate Cat. 1 and 2 eye irritants according to the GHS criteria. The results from the individual TGs cannot be used in DAs if the chemicals are known to clearly fall outside the applicability domains of the test methods. Although the assessed chemical is within the applicability domains of the test methods used in the two studies, TG 467 states that the specific defined approach DAL-1 could only be used for neat non-surfactant liquids, and it is not applicable for surfactants and solids. As the assessed chemical is a solid, DAL-1 cannot be used to classify the assessed chemical according to the GHS criteria.

Sensitisation

Skin sensitisation

No skin sensitisation data were submitted on the assessed chemical. In a skin sensitisation study conducted on an analogue (OECD TG 406 - Magnusson-Kligman Test), 20 female guinea pigs (Dunkin-Hartley Albino) were induced to the test substance by injection (at 0.05% v/v in distilled water), both with and without Freund's Complete Adjuvant (FCA). Six days after injection, the animals were topically induced with the test substance (5% v/v). Two weeks after topical application, the animals were challenged with the test substance (5% v/v). All treated animals survived. No clinical signs of systemic toxicity were observed and all animals showed expected body weight gain over the study period. Signs of irritation were observed during the topical induction, but no evidence of skin sensitisation was observed during the challenge phase.

Based on the results of the analogue, the assessed chemical is not expected to be a skin sensitiser.

Genotoxicity

No genotoxicity data were submitted on the assessed chemical. An analogue (sodium salt of the assessed chemical) was found to be non-mutagenic in a bacterial reverse mutation assay (OECD TG 471). Based on the results of the analogue, the assessed chemical is not expected to cause point mutations.

Environmental exposure

The assessed chemical will be imported into Australia as a component of finished lubricant products. Significant releases of the assessed chemical to the environment are not expected during transport or storage.

Lubricant products containing the assessed chemical will be used within closed systems in machinery. The filling of these systems for new machinery is expected to be automated, but manual filling by professional workers may occur during service activities. Any spills that occur during these filling processes are expected to be collected for appropriate disposal.

The assessed chemical is expected to remain in the finished products during its useful lifetime. Some lubricants are formulated to be “fill for life” but may need replacement during unscheduled servicing. Others are replaced during scheduled servicing. Lubricant replacement is expected to be performed by professional workers. The used lubricants are expected to be collected and disposed of through waste management contractors for recycling, re-refining or disposal under local government regulations. Any spills that occur during these filling processes are expected to be collected for appropriate disposal.

Environmental fate

Partitioning

The assessed chemical is slightly to moderately soluble in water and has a high partition coefficient ($\text{Log } K_{ow} > 6.2$) if released into the environment, it is expected to partition to and become immobile in soils and sediments.

Degradation

Based on the measured biodegradation in water, the assessed chemical is not persistent.

Degradation studies conducted on the assessed chemical indicate that it is readily biodegradable. Test results demonstrated 85.2% degradation after 28 days (OECD TG 301B).

Bioaccumulation

Based on its $\text{log } K_{ow}$ value, the assessed chemical has potential to bioaccumulate.

No bioaccumulation information was provided for the assessed chemical. The experimental partition coefficient of the assessed chemical is $\text{log } K_{ow} > 6.2$, which is above the domestic bioaccumulation threshold of $\text{log } K_{ow} = 4.2$ (EPHC, 2009). This determination is considered to be conservative as the assessed chemical is not considered to be persistent.

Predicted environmental concentration (PEC)

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

Environmental effects

Acute toxicity

The following key measured median lethal concentration (LC50) and effective concentration (EC50) values for model organisms were supplied for the assessed chemical:

Taxon	Endpoint	Method
Invertebrate	48 h EC50 > 2.21 mg/L	<i>Daphnia magna</i> (water flea) Immobility OECD TG 202 Semi-static conditions Geometric mean measured concentration
Algae	72 h ErC50 = 1.21 mg/L	<i>Raphidocelis subcapitata</i> (green algae) Growth rate OECD TG 201 Static conditions Geometric mean measured concentration

Chronic toxicity

The following measured 10th-percentile effective concentration (EC10) values for model organisms were supplied by the applicant:

Taxon	Endpoint	Method
Algae	ErC10 = 0.241 mg/L	<i>Raphidocelis subcapitata</i> (green algae) Growth rate OECD TG 201 Static conditions Geometric mean measured concentration

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 measured degradation under screening test conditions, the assessed chemical is categorised as Not Persistent.

Bioaccumulation

Bioaccumulative (B). Based on the measured log K_{ow} value above 4.2, the assessed chemical is categorised as Bioaccumulative.

Toxicity

Not toxic (Not T). Based on available acute ecotoxicity values above 1 mg/L and a chronic ecotoxicity value above 0.1 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 could not be calculated. However, the assessed chemical is not expected to be toxic to aquatic life, and release of the assessed chemical to the aquatic environment will be negligible based on its assessed use pattern.

Thus, based on its low hazard and the assessed use pattern, the environmental risk from the assessed chemicals can be managed.

References

EPHC (2009) Environment Protection and Heritage Council, Environmental Risk Assessment Guidance Manual for industrial chemicals, Prepared by: Chris Lee-Steere Australian Environment Agency Pty Ltd, February 2009. ISBN 978-1-921173-41-7.

UNECE (United Nations Economic Commission for Europe) (2017). Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition. UNECE.

