Australian Government
Department of Health, Disability and Ageing
Australian Industrial Chemicals Introduction Scheme

Ethanaminium, 2-[3-(dioxoheteromonocycle)propoxy]-*N*,*N*,*N*-trimethyl-, monopolyisobutylene derivs., Me oxalates

Assessment statement (CA10046)

11 August 2025

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AICIS assessment (CA10046)

Chemical in this assessment

AICIS Approved Chemical Name (AACN)
Ethanaminium, 2-[3-(dioxoheteromonocycle)propoxy]-*N*,*N*,*N*-trimethyl-, monopolyisobutylene derivs., Me oxalates

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 polymer has been assessed:

- as imported into Australia at up to 65 tonnes/year
- as imported in formulations containing the assessed polymer at up to 18% concentration
- for end use as a component of fuel additives at up to 150 ppm concentration

Summary of assessment

Summary of introduction, use and end use

The assessed polymer will not be manufactured in Australia. It will be imported into Australia in formulations containing the assessed polymer at up to 18% concentration.

The assessed polymer will be used as a component of fuel additives. The imported fuel additive packages containing the assessed polymer will be transported to industrial fuel blending facilities for reformulation. Reformulation will typically involve transferring the imported formulations through piping and computer-controlled valves into blending vessels, followed by mixing with diesel and other fuel additives. The reformulation process will be carried out in automated and enclosed systems by professional workers. The finished diesel product will contain the assessed polymer at up to 150 ppm.

Finished diesel fuel containing the assessed polymer will be used in diesel engines for trucks, locomotives and other heavy-duty equipment used by mining companies. Diesel fuel containing the assessed polymer will also be available to the public at retail petrol stations.

Human health

Summary of health hazards

The submitted toxicological data on the assessed polymer at approximately 50% concentration in paraffin oils (see **Supporting information**) indicate that the assessed polymer is:

- of low acute oral toxicity (LD50 > 2,000 mg/kg bw in rats)
- a slight skin and eye irritant
- not a skin sensitiser
- of low repeated dose toxicity based on a study in rats
- not expected to cause adverse effects on foetal development
- not considered to have genotoxic potential.

Hazard classifications relevant for worker health and safety

Based on the data provided by the applicant, the assessed polymer does not satisfy 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 adopted for industrial chemicals in Australia.

Summary of health risk

Public

Diesel fuel containing the assessed polymer at up to 150 ppm concentration will be available to the public at retail petrol stations. However, the fuel dispensing equipment at petrol stations is expected to minimise the occurrence of accidental spills and exposure. Once the fuel has been consumed, the assessed polymer will not exist in its original form as it has been combusted together with the fuel. Based on the low concentration of the assessed polymer in diesel fuel, expected low exposure, and low hazard of the assessed polymer, no risks are identified for public health during this assessment that require specific risk management measures.

Workers

Workers may experience dermal and incidental ocular exposure to the assessed polymer at up to 18% concentration during the handling of formulations containing the assessed polymer. According to the applicant, automated systems will be used for transferring the fuel additive formulations containing the assessed polymer from containers to blending tanks where possible. The exposure is expected to be further minimised by use of safe work practices when handling the assessed polymer. To mitigate the risks to workers from potential irritating effects, control measures could be implemented (see **Means for managing risk**) to minimise exposure.

Environment

Summary of environmental hazard characteristics

According to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW, 2022) and based on the available data measured on the assessed polymer, the assessed polymer is:

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

Environmental hazard classification

Based on the ecotoxicological information available for the assessed polymer, it is not expected to be harmful to aquatic life. Therefore, the assessed polymer does not satisfy the criteria for classification under the GHS for acute and chronic aquatic toxicities (UNECE, 2017).

Summary of environmental risk

No significant release of the assessed polymer is expected to occur based on its use as a component of fuel additives. The assessed polymer is expected to be thermally combusted during use.

Although the assessed polymer is persistent according to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW, 2022), it does not meet all three PBT criteria. A Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as the currently available information indicates the assessed polymer is not harmful to aquatic life and there will be no release of the assessed polymer to the aquatic environment based on the assessed use pattern. Therefore, based on the low hazard and low exposure, the environmental risk from the introduction of the assessed polymer can be managed.

Means for managing risk

Workers

Information relating to safe introduction and use

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.

The following control measures could be implemented to manage the risk arising from exposure to the assessed polymer during reformulation:

- Use of safe work practices to avoid contact with skin and eyes

Conclusions

The Executive Director is satisfied that the risks to human health or the environment associated with the introduction and use of the industrial chemical can be managed.

Note:

1. Obligations to report additional information about hazards under s100 of the *Industrial Chemicals Act 2019* apply.
2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

AACN Ethanaminium, 2-[3-(dioxoheteromonocycle)propoxy]-*N*,*N*,*N*-trimethyl-, monopolyisobutylene derivs., Me oxalates

Additional chemical identity information

The assessed chemical is a polymer.

Relevant physical and chemical properties

Physical form	Amber liquid at 20 °C and 1013 hPa*
Glass transition point	-74.2 °C*
Density	917 kg/m^3 at 20 °C*
Vapour pressure	1.2 × 10^{-7} kPa at 20 °C*
Water solubility	< 2 to 139 µg /L at 20 °C*
Surface tension	70.44 mN/m at 20 °C*
Flash point	153 °C*
Auto ignition temperature	380 °C*
Ionisable in the environment	The assessed polymer is a cationic polymer.
pK_a	Not determined
log K_{ow}	2.1-10.2*
Log Koc	< 1.25 to > 5.63*

* Tested on the assessed polymer in paraffin oils (CAS No. 8012-95-1) at approximately 50% concentration

Health hazard information

The test substance in the following toxicological studies refers to the assessed polymer in paraffin oils at approximately 50% concentration.

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), the test substance was administered to female Sprague-Dawley rats (n = 3/group, 2 groups/dose) at 300 and 2,000 mg/kg bw via oral gavage. All animals survived during the 14-day observation period and no signs of systemic toxicity were noted. All animals showed expected body weight gains except one in the 300 mg/kg bw dose group and no treatment-related gross necropsy findings were observed in any animal. The acute oral median lethal dose (LD50) of the test substance was determined to be > 2,000 mg/kg bw.

Dermal

In an acute dermal toxicity study (OECD TG 402), 2 female Sprague-Dawley rats had the test substance applied at 2,000 mg/kg bw for a 24-hour exposure under semi-occlusive conditions. All animals survived during the 14-day observation period. No signs of treatment-related systemic toxicity and no signs of local irritation were noted. All animals showed expected body weight gains over the study period and no treatment-related gross necropsy findings were observed. The acute dermal LD50 of the test substance was determined to be > 2,000 mg/kg bw.

Corrosion/Irritation

Skin irritation

A skin irritation study (OECD TG 404) was conducted on the test substance. The test was conducted in 3 female New Zealand white rabbits using semi-occlusive patches (2.5 cm × 2.5 cm) with 0.5 mL of the test substance applied to different treatment sites for 4 hours. The sites were evaluated for irritation effects upon the patch removal at 30-60 minutes followed by 24, 48 and 72 hours. At the 30-60 minutes observation, all animals showed slight to well-defined erythema and 2 animals showed very slight oedema. At the 24-hour observation, the oedema had recovered. All treated sites had completely recovered by 48 hours. The mean individual erythema scores from gradings at 24, 48 and 72 hours were 0.3, 0, 0.3, respectively. Based on the results, the test substance is considered to be slightly irritating to the skin but not meeting the criteria for skin irritation classification under the GHS.

Eye irritation

An eye irritation study (OECD TG 405) was conducted on the test substance. The test was conducted in 3 female New Zealand white rabbits, with 0.1 mL of the test substance instilled into one eye of each rabbit. The ocular irritation effects were evaluated after the exposure at 1, 24, 48 and 72 hours. Minimal conjunctivitis was observed in 2 animals within 1 hour after treatment. No effects on the cornea and iris were observed. All treated sites had completely recovered by 24 hours. Based on the results, the test substance is considered to be slightly irritating to eyes but not meeting the GHS criteria for hazard classification.

Sensitisation

Skin sensitisation

A skin sensitisation study (OECD TG 406 – Buehler Test) was conducted on the test substance. The test was conducted in male guinea pigs (Hartley Albino) (n = 20), with 0.4 mL of the undiluted test substance topically applied for 6 hours under occlusive conditions, once every week for a total of 3 weeks. Twenty-seven days after the initial induction, untreated sites on the animals were topically challenged with the undiluted test substance. For the duration of the study, no animals showed any signs of dermal irritation on treated sites during the induction phase and the challenge phase. Based on the results of this study, the assessed polymer is not a skin sensitiser.

Repeat dose toxicity

Oral

In a repeated dose oral toxicity study (OECD TG 408), the test substance was administered to Sprague-Dawley rats (n = 10/sex/group) by oral gavage at 0, 100, 300 and 1,000 mg/kg bw/day for 90 days, with an additional 5 animals/sex/group in the control and high dose group given a 28-day recovery period. One male animal in the 1,000 mg/kg bw/day dose group was euthanised in extremis on Day 16 without a determined cause of morbidity. Findings at necropsy included gas filled dilatation in the small intestine (ileum and jejunum) and large intestine (cecum, colon and rectum). The findings had no microscopic correlates and were reported by the study authors to be a perimortem change unrelated to the treatment. No other unscheduled deaths or effects of toxicological importance were observed. Test substance-related clinical observations included slight soft faeces and brown fur staining in the anal region of the males in the 300 mg/kg/day and 1,000 mg/kg/day groups. These observations were reported by the study authors to be non-adverse given there were no other findings that impacted animal health. The No Observed Adverse Effect Level (NOAEL) was considered to be 1,000 mg/kg bw/day.

Genotoxicity

The test substance was found to be non-mutagenic in a bacterial reverse mutation assay (OECD TG 471) using TA98, TA100, TA1535, and TA1537 strains of *Salmonella typhimurium* and WP2*uvrA* strain of *Escherichia coli*.

The test substance was found to be non-clastogenic to human peripheral blood lymphocytes (HPBL) in an *in vitro* mammalian chromosome aberration test (OECD TG 473). There were no biologically relevant increases in the frequency of chromosomal aberrations in cells treated at up to 500 µg/mL in the presence of metabolic activation or 250 µg/mL in the absence of metabolic activation.

The test substance was found to be non-mutagenic in an *in vitro* mammalian cell gene mutation test (OECD TG 490) using the thymidine kinase (TK +/-) locus of the L5178Y mouse lymphoma cell line. There were no dose-dependent increases in mutant frequency observed in cells treated at up to 500 µg/mL concentration in the presence or absence of metabolic activation.

Developmental toxicity

In a prenatal developmental toxicity study (OECD TG 414), the test substance was administered to female Sprague-Dawley rats (n = 22/group) by oral gavage at 0, 100, 300 and 1,000 mg/kg bw/day during gestation Days 6-20. There were no test substance-related mortalities during the study. No effects of toxicological importance or test substance-related effects on developmental parameters were observed. The NOAEL for maternal and developmental toxicity was considered to be 1,000 mg/kg bw/day.

Environmental exposure

The assessed polymer will be imported into Australia for use as a component of fuel additives. The imported fuel additive packages will be further reformulated into diesel fuel at industrial sites in Australia for commercial and consumer uses.

The automated transfer systems used in the reformulation processes limit the potential for accidental spills. The finished fuel products will then be transported to storage depots and eventually to underground storage tanks where they will be pumped into both industrial and consumer vehicles. The assessed polymer will be combusted as a function of its overall use and therefore will not be released into the environment.

Any release of the assessed polymer will be from accidental spills of the blended fuel. Spills which occur during transfer and filling processes are expected to be captured and collected for disposal according to relevant Local, State, Territory and Federal regulations.

Environmental fate

Dissolution, speciation and partitioning

The assessed polymer is a cationic polymer with components ranging from very slightly soluble to slightly soluble in water (< 2 - 139 µg/L at 20 °C for a test substance containing approximately 50% concentration of the assessed polymer in paraffin oils). If being released into the environment, the positively charged assessed polymer is expected to partition to soils or sediments and bind with the negatively charged matrix there.

Degradation

Based on the biodegradation results in water, the assessed polymer is considered not readily biodegradable and is persistent.

The prolonged biodegradation study was conducted according to OECD test guideline 301B on a test substance containing approximately 50% of the assessed polymer in paraffin oils. The results demonstrated 3% degradation of the assessed polymer in 28 days. Therefore, the assessed polymer is categorised as persistent in water.

Bioaccumulation

Based on the available weight of evidence, the assessed polymer does not have the potential to bioaccumulate.

A bioaccumulation study was conducted according to a modified OECD TG 305 on a test substance containing approximately 50% of the assessed polymer in paraffin oils. The results

showed a bioconcentration factor (BCF) of < 1.83 L/kg. Additionally, based on the high molecular weight (NAMW > 1,000 g/mol) the assessed polymer is not expected to be bioavailable.

Predicted environmental concentration (PEC)

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

Environmental effects

The test substance in the following ecotoxicological studies refers to the assessed polymer in paraffin oils at approximately 50% concentration.

Effects on aquatic life

Acute toxicity

The following median lethal loading (LL50) and effective loading (EL50) values for model organisms were supplied for the test substance.

Taxon	Endpoint	Method
Fish	96 h LL50 > 50 mg/L water accommodated fractions (WAF)	*Danio rerio* (Zebra fish) OECD TG 203 Static conditions Nominal concentration
Invertebrate	48 h LC50 > 50 mg/L WAF	*Daphnia magna* (Water flea) Immobilisation test OECD TG 202 Static conditions Nominal concentration
Algae	72 h E_rL50 is not determined	*Desmodesmus subspicatus* (Green algae) Inhibition of growth OECD TG 201 Nominal concentration
Microorganisms in sludge	3 h EC50 > 500 mg/L	Activated sludge from sewage treatment plant OECD TG 209 Nominal concentration

Chronic toxicity

The following measured no effect loading (NOEL) and 10th percentile effective loading values for model organisms were supplied for the test substance.

Taxon	Endpoint	Method
Fish	28 d NOEL = 50 mg/L WAF	*Gobiocypris rarus* (Rare Minnow) OECD TG 215 Semi-Static conditions Nominal concentration
Invertebrates	21 d NOEL = 50 mg/L WAF	*Daphnia magna* (Water flea) Effect on reproduction OECD TG 211 Semi-static conditions Nominal concentration
Algae	72 h E_rL10 = 38.52 mg/L WAF	*Desmodesmus subspicatus* (Green algae) Inhibition of growth OECD TG 201 Nominal concentration

Effects on terrestrial life

The following measured effect concentration (EC50) values for model organisms were supplied for the test substance.

Taxon	Endpoint	Method
Soil macroorganisms	3 h EC50 > 500 mg/kg dry weight of artificial soil	*Eisenia foetida* (Earthworm) OECD TG 207 Nominal concentration
Plant	9 d EC50 > 500 mg/L	*Tomato, cucumber, lettuce, Mung bean, cabbage, watermelon, mustard, wheat, carrot and corn* OPPTS 850.4200 Seed germination/root elongation toxicity test. US EPA 1996 Nominal concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 3.85 mg/L was calculated for the assessed polymer in the aquatic environment. This value was derived using the endpoint value for algae (72 h ErL10 = 38.52 mg/L WAF). An assessment factor of 10 was applied to this endpoint as both acute and chronic toxicity data were provided for all three trophic levels (EPHC, 2009).

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed polymer according to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW, 2022) is presented below:

Persistence

Persistent (P). Based on measured degradation data, the assessed polymer is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on low measured bioconcentration factor in fish, no evidence of biotransformation and high molecular weight, the assessed polymer is categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on measured ecotoxicity values above 1 mg/L for acute toxicity and above 0.1 mg/L for chronic toxicity, the assessed polymer is categorised as Not Toxic.

GHS classification of environmental hazard

The assessed polymer does not satisfy the criteria for classification under the GHS for acute and chronic aquatic toxicities (UNECE, 2017).

Environmental risk characterisation

A Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as no release of the assessed polymer into aquatic environment is expected based on its use as a component of fuel additives.

The assessed polymer is not harmful to aquatic life based on the measured ecotoxicity data available on three trophic levels. Thus, based on its low hazard and the assessed use pattern, the assessed polymer is unlikely to pose a significant risk to the environment.

References

DCCEEW (2022) Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals, DCCEEW, accessed 27 May 2025.

EPHC (Environment Protection and Heritage Council) (2009), 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. Accessed 11 July 2025.