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

Ethanesulfonyl fluoride, 2-[1-[difluoro[(1,2,2-trifluoroethenyl)oxy]methyl]-1,2,2,2-tetrafluoroethoxy]-1,1,2,2-tetrafluoro-, polymer with 1,1,2,2-tetrafluoroethene, hydrolyzed

Assessment statement (CA09922)

20 February 2025

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AICIS assessment (CA09922)

Chemical in this assessment

Name	CAS registry number
Ethanesulfonyl fluoride, 2-[1-[difluoro[(1,2,2-trifluoroethenyl)oxy]methyl]-1,2,2,2-tetrafluoroethoxy]-1,1,2,2-tetrafluoro-, polymer with 1,1,2,2-tetrafluoroethene, hydrolyzed	1378930-04-1

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 Health and Environment Focus type.

Defined scope of assessment

The polymer has been assessed:

- as imported into Australia at up to 10 tonnes/year
- as imported neat or as a dispersion containing the assessed polymer at up to 30% concentration
- as having a number average molecular weight (NAMW) greater than or equal to 10,000 g/mol, and no low molecular weight species less than 1,000 g/mol
- for use at up to 30% concentration as part of proton exchange membranes in electronic components used by professional workers only.

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 neat form as solid pellets, or in a dispersion containing the assessed polymer at up to 30% concentration.

The assessed polymer has an end use in electronic products. At the end use site such as an electrolyser plant, the assessed polymer in neat form or dispersions containing the assessed polymer at up to 30% concentration will be transferred into a mixing tank using pump or hose type equipment, and then mixed with catalysts, other solvents, rheology solutions and electrode additives to produce a coating mixture. The coating mixture containing up to 30% of the assessed polymer will be either applied onto a decal substrate that will be later hot pressed to a proton exchange membrane (PEM) for electronic components, or directly applied onto a PEM membrane. The end use process is expected to be within an enclosed system with localised ventilation.

Human health

Summary of health hazards

No toxicological data were provided for the assessed polymer. Based on the high molecular weight and absence of low molecular weight species less than 1,000 g/mol, systemic effects from absorption are not expected. Therefore, the assessed polymer is expected:

- to have low acute oral toxicity
- not to cause adverse systemic effects following repeated exposure
- not to have genotoxic potential

Toxicological data of a fluorinated monomer of the assessed polymer were used to estimate the irritation and sensitisation potential of the assessed polymer (see **Supporting information**).

Based on the submitted toxicological data, the monomer is not irritating to skin and eyes, However, the assessed polymer contains terminal sulfonic acid functional groups which are not present in the monomer. Therefore, the properties of the monomer may not be representative of the assessed polymer. Overall, the potential for the assessed polymer to cause irritation effects cannot be ruled out.

The fluorinated monomer was a weak sensitiser in a local lymph node assay (LLNA) with an EC3 value of 83%. Although the monomer meets the GHS criteria for classification for skin sensitisation (H317: May cause an allergic skin reaction), the assessed polymer is not expected to be sensitising based on that the sulfonyl fluoride functional group in the monomer responsible for sensitisation is not present in the assessed polymer and the high molecular weight (NAMW > 10,000 g/mol) of the polymer.

Although the monomer meets the GHS criteria for classification for specific target organ toxicity – single exposure category 3 (H336: may cause drowsiness or dizziness), the assessed polymer is not expected to have the same toxicity due to its high molecular weight (NAMW > 10,000 g/mol) and is therefore unlikely to form vapour similar to the monomer.

No inhalation toxicity data are available on the assessed polymer. The potential for lung overloading is not expected given the < 70,000 g/mol NAMW of the assessed polymer.

Hazard classifications relevant for worker health and safety

Based on the limited data provided by the applicant, the assessed polymer cannot be classified 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

The assessed polymer imported as solid pellets or as a dispersion at up to 30% concentration will not be available for use by the public. Once bound onto a PEM, the assessed polymer will not be available for exposure. When introduced and used in the proposed manner, it is unlikely that the public will be exposed to the assessed polymer.

This assessment does not identify any risks to public health that would require specific risk management measures.

Workers

Workers may experience dermal and incidental ocular exposure to the assessed polymer in neat form as a pellet or at up to 30% concentration during the handling and use of formulations containing the assessed polymer, if closed systems are not used. To mitigate the risks to workers from any potential irritation effects, control measures would be required (see **Means for managing risk**) to minimise exposure. According to the applicant, closed systems will be used for transferring the assessed polymer from the container to mixing tank where possible, and during application of the coating mixture. The exposure will be further minimised by use of personnel that have undergone training and workers wearing protective glasses and gloves and carrying out the processes in well-ventilated area when handling the assessed polymer.

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 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

The assessed polymer will be introduced in neat form as solid pellets or as a dispersion at up to 30% concentration, that will be used as part of a proton exchange membrane. Based on its end use, no direct release to the environment is expected. As the assessed polymer will not be manufactured in Australia any environmental release during manufacture is not expected. The assessed polymer will be formulated into a coating or film at industrial sites within enclosed systems. The formulated coating will be applied to the electrode products by a range of methods including, but not limited to slot dye, Mayer rod and screen-printing processes. As such no environmental release is anticipated during these processes. At the end of the products' useful life, the assessed polymer is to be disposed of via incineration, landfill or recycled where possible and no release is expected.

Although the assessed polymer is persistent, according to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW, 2022), it is not toxic or bioaccumulative and therefore, does not meet all three PBT criteria. Based on its use patterns, no direct release to the surface waters or sewers is expected and hence a PEC for this polymer has not been calculated.

When the assessed polymer is introduced in line with the defined scope of assessment, release is expected to be negligible and is not expected to pose a risk to the environment.

Therefore, 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 handling of formulations containing the assessed polymer:

- Use of engineering controls such as
  - Automated and enclosed systems where possible
- Use of safe work practices to
  - Avoid contact with skin and eyes
- Use of personal protective equipment (PPE)
  - Impervious gloves
  - Protective clothing
  - Safety glasses/goggles or face mask
- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

Conclusions

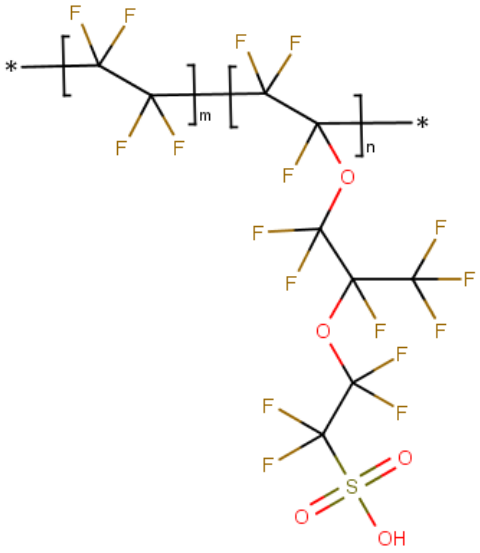
The Executive Director is satisfied that the risks to human health or the environment associated with the introduction and use of the industrial chemical can be managed.

Note:

1. Obligations to report additional information about hazards under s 100 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

CAS number	1378930-04-1
CAS name	Ethanesulfonyl fluoride, 2-[1-[difluoro[(1,2,2-trifluoroethenyl)oxy]methyl]-1,2,2,2-tetrafluoroethoxy]-1,1,2,2-tetrafluoro-, polymer with 1,1,2,2-tetrafluoroethene, hydrolyzed
Molecular formula	Unspecified
Number average molecular weight (NAMW, g/mol)	67,600
Percentage of low molecular weight species (less than 1,000 g/mol)	0
Percentage of low molecular weight species (less than 500 g/mol)	0
Representative structure	

Polymer component	CAS number	Typical conc. (%)	Range conc. (%)
Ethene, 1,1,2,2-tetrafluoro-	116-14-3	55.5	53 - 58
Ethanesulfonyl fluoride, 2-[1-[difluoro[(1,2,2-trifluoroethenyl)oxy]methyl]-1,2,2,2-tetrafluoroethoxy]-1,1,2,2-tetrafluoro-	16090-14-5	44	42 - 47

Relevant physical and chemical properties

Physical form	Off-white solid pellets
Melting point	200 °C
Boiling point	Decomposes before boiling
Density	2,100 kg/m^3
Water solubility*	0.00192 g/L at 20°C, pH 7
Ionisable in the environment	No
log K_{oc}*	< 1.26 at 20°C, pH 7

***** Based on a monomer of the assessed polymer

Health hazard information

No toxicological data were provided for the assessed polymer. Based on the high molecular weight and absence of low molecular weight species less than 1,000 g/mol, systemic effects are not expected. Toxicological data of a fluorinated monomer, ethanesulfonyl fluoride, 2-[1-[difluoro[(1,2,2-trifluoroethenyl)oxy]methyl]-1,2,2,2-tetrafluoroethoxy]-1,1,2,2-tetrafluoro- (CAS No. 16090-14-5), were used to estimate the irritation and sensitisation potential of the assessed polymer.

Acute toxicity

Oral

Based on the high molecular weight and absence of low molecular weight species, the assessed polymer is expected to have low acute oral toxicity.

Inhalation

Although the monomer meets the GHS criteria for classification for specific target organ toxicity – single exposure category 3 (H336: may cause drowsiness or dizziness), the assessed polymer is not expected to cause similar effects. The assessed polymer has high molecular weight (NAMW > 10,000 g/mol) and therefore is unlikely to form vapour similar to the monomer. The potential for lung overloading from inhalation is not expected given the < 70,000 g/mol NAMW of the assessed polymer.

Corrosion/Irritation

Skin irritation

In an *in vitro* skin corrosion study (OECD TG 431 - EpiDerm model) conducted on the monomer, the mean relative viability of the test substance-treated tissues was 92% after a 3-minute exposure period and 60% after a 1-hour exposure period. As the mean relative tissue viability was not below 50% after the 3-minute exposure period and not below 15% after the

1-hour exposure period, based on the prediction model criteria the test substance is identified as not requiring classification for skin corrosion.

In an *in vitro* skin irritation study (OECD TG 439 – EPISKIN Small™ model) conducted on the monomer, the mean relative viability of the test substance-treated tissues was 85% after a 15-minute exposure period. As the mean relative tissue viability was > 50%, based on the prediction model criteria the test substance is identified as not requiring classification for skin irritation.

Based on the submitted toxicological data, the monomer is not irritating to skin. However, the assessed polymer contains terminal sulfonic acid functional groups that are not present in the monomer and therefore the properties of the monomer may not be representative of the assessed polymer. Although the high molecular weight (NAMW > 10,000 g/mol) of the polymer is expected to reduce the irritation potential, the potential for the assessed polymer to cause skin irritation cannot be ruled out.

Eye irritation

In an *in vitro* eye irritation study (OECD TG 492 - EpiOcular™ model) conducted on the monomer, the mean relative viability of the test substance-treated tissues was 39% after a 30-minute exposure period. As the tissue viability was not above 60%, based on the prediction model criteria no prediction for eye irritation could be made for the test substance.

In an *in vitro* eye irritation study (OECD TG 437) conducted on the monomer, the mean *in vitro* irritancy score (IVIS) of the test substance was calculated as 28, after a 10-minute exposure period and a 120-minute incubation period. As the IVIS was > 3 and not above 55, based on the prediction model criteria, no prediction for eye irritation could be made for the test substance.

The OECD Guideline for Defined Approaches (DAs) for Serious Eye Damage and Eye Irritation (OECD TG 467) includes two options for DAL-1 DA using the study results of TG 492 and 437. The DAL-1 DAs differentiate chemicals to assign ‘No Category’ and Cat. 1 or Cat. 2 eye irritants according to the GHS criteria. According to the DAL-1 Option 2, if the results of the TG 492 shows cell viability < 60%, physicochemical properties of the test substance need to be considered prior to further testing using the TG 437. The test substance (monomer) has water solubility of 0.00192 g/L, log Pow > 2.85, vapour pressure of 2.9 kPa at 20 °C and surface tension of 70.4 mN/m at 20 °C. Although the monomer showed cell viability < 60%, its water solubility is < 0.02 mg/mL. Based on the low water solubility of the test substance, it does not require further testing under DAL-1 Option 2. The test substance falls under “No category” according to DAL-1 in OECD TG 467.

Based on the submitted toxicological data, the monomer is not irritating to eyes. However, the assessed polymer contains terminal sulfonic acid functional groups that are not present in the monomer and therefore the properties of the monomer, including water solubility, might not be representative of the assessed polymer. Although the high molecular weight (NAMW > 10,000 g/mol) of the polymer is expected to reduce the irritation potential, the potential for the assessed polymer to cause eye irritation cannot be ruled out.

Sensitisation

Skin sensitisation

A local lymph node assay (LLNA) was conducted on the monomer following OECD TG 429. Female CBA/J mice (5 animals/group) were treated at 25%, 50% or 100% concentration on both ears for 3 consecutive days. All treated animals survived, and no signs of systemic toxicity were observed. The auricular lymph nodes of 1/5 animal from the 50% dose group and 3/5 animals in the 100% dose group became slightly enlarged. The Stimulation Indices (SI) were calculated to be 1.9, 2.2 and 3.4 for 25%, 50% and 100% concentrations respectively, and a EC3 value of 83% was determined. Based on the results, the test substance is considered to be a weak skin sensitiser, warranting a hazard classification for skin sensitisation (Category 1B, H317: May cause an allergic skin reaction) according to the GHS criteria.

A Direct Peptide Reactivity Assay (DPRA) was conducted on the monomer following OECD TG 442C. The test substance was incubated with synthetic peptides containing cysteine (SPCC) or lysine (SPCL) at 25 °C for 24 hours. In the cysteine reactivity assay, the test material showed 57.4% SPCC depletion, while in the lysine reactivity assay, co-elution of the test material with SPCL was observed. As a result, the Cysteine 1:10 prediction model was used. In this prediction model, the test substance was classified in the “moderate reactivity class” for sensitisation, according to the OECD TG 442C, indicating protein binding.

Although the monomer meets the GHS criteria for classification for skin sensitisation (H317: May cause an allergic skin reaction), the assessed polymer is not expected to be sensitising. The QSAR Toolbox indicates that the functional group with structural alerts for skin sensitisation is the sulfonyl fluoride group in the monomer, which is hydrolysed in the assessed polymer. In addition, the high molecular weight (NAMW > 10,000 g/mol) of the polymer is also expected to significantly reduce the sensitisation potential.

Repeat dose toxicity

Oral

Based on the high molecular weight (NAMW > 10,000 g/mol) and lack of low molecular weight species less than 1,000 g/mol, the assessed polymer is not likely to cause specific target organ toxicity after repeated exposure.

Genotoxicity

Based on the high molecular weight (NAMW > 10,000 g/mol) and lack of low molecular weight species less than 1,000 g/mol, the assessed polymer is not likely to be absorbed to cause genotoxicity. The monomer was found to be non-mutagenic in a bacterial reverse mutation assay (OECD TG 471) using the *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 and the *Escherichia coli* strain WP2uvrA. No dose dependent increases in the frequency of revertant colonies were observed at up to 5,000 µg/plate, with the presence or absence of metabolic activation.

Environmental exposure

The assessed polymer will be imported to Australia in neat form as solid pellets, or in a dispersion containing the assessed polymer at up to 30% concentration. The assessed polymer will be reformulated into a coating for its use as a proton exchange membrane in both

fuel cells and electrolysers. Reformulation will occur using closed processes with suitable control measures.

The formulated coating will be applied to the electrode products by a range of methods including, but not limited to slot dye, Mayer rod and screen-printing processes. These processes will occur within enclosed systems and spray application processes will not be used. Therefore, no environmental exposure of the assessed polymer is expected during reformulation, manufacturing and application of coatings containing the assessed polymer.

The assessed polymer is expected to be disposed of via incineration, landfill or through recycling where possible, at the end of the products' useful life. Wastes, residues, any spills or accidents containing the assessed polymer that occur during reformulation or application are also expected to be disposed of as above.

Environmental fate

Partitioning

Based on supplied data on a monomer, the assessed polymer is considered slightly soluble in water (water solubility = 0.00192 g/L).

Due to its high molecular weight (MW > 10,000 g/mol), the assessed polymer is not expected to evaporate or partition to air and will become immobile in soils or sediments if released into the environment (US EPA 2013).

Degradation

Based on its lack of ready biodegradability in water, the assessed polymer is considered persistent.

Results from a supplied biodegradation study for the monomer showed 1% degradation (OECD 301F) over 28 days. The 10-day window criterion was not fulfilled. Hence the assessed polymer is expected to be not readily biodegradable and persist in aquatic environments.

Bioaccumulation

The assessed polymer is unlikely to be bioavailable to accumulate in the food chain, based on its high molecular weight (MW > 10,000 g/mol), slight water solubility and high stability in water.

Predicted environmental concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as no release of the assessed polymer to the aquatic environment is expected based on its assessed use pattern.

Environmental effects

Effects on aquatic Life

Acute toxicity

The following median lethal concentration (LC50) and effective concentration (EC50) values for model organisms were supplied for the monomer of the assessed polymer, which contains the same functional groups at a lower molecular weight representing the worst-case scenario for toxicity. The acute toxicity of the assessed polymer was determined based on loading rates up to 100 mg/L. The values below represent the mean measured concentrations of the highest loading rate samples.

Taxon	Endpoint	Method
Fish	96 hr LC50 > 60 µg/L	*Cyprus carpio* (Common carp) OECD TG 203 Semi-static conditions Measured concentration
Invertebrate	48 hr EC50 > 122 µg/L	*Daphnia magna* (water flea) Immobility OECD TG 202 Semi-static conditions Measured concentration
Algae	72hr E_rC50 > 60 µg/L	*Raphidocelis subcapitata* (green algae) Growth rate OECD TG 201 Static Measured concentration

Chronic toxicity

The following no observed effect concentration (NOEC) values for model organisms were supplied for the monomer of the assessed polymer. The chronic toxicity of the assessed polymer was determined based on a maximum loading rate of 100 mg/L. The value below represents the mean measured concentration of the highest loading rate samples.

Taxon	Endpoint	Method
Algae	72 h NOEC > 60 µg/L	*Raphidocelis subcapitata* (green algae) Growth rate OECD TG 201 Static Measured concentration

Predicted no-effect concentration (PNEC)

A PNEC was not calculated as the assessed polymer is not expected to cause harmful effects on aquatic species at the limit of solubility.

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 study of the monomer of the assessed polymer, the assessed polymer is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on assessed polymer's high molecular weight (MW > 10,000 g/mol), it is categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available acute ecotoxicity studies showing no toxic effects to aquatic organisms at the limit of solubility, the assessed polymer is categorised as Not Toxic.

Environmental risk characterisation

While the assessed polymer is persistent in the aquatic environment, it is not toxic and does not have the potential to bioaccumulate. Therefore, the assessed polymer does not meet all three PBT criteria.

Based on its end use as a component in PEM, the assessed polymer is not expected to be released to the environment. As such no direct release to the surface waters or sewers is expected. Therefore, a PEC or a risk quotient for the assessed polymer has not been calculated. When the assessed polymer is introduced in line with the defined scope of assessment, release is expected to be negligible and is not expected to pose a risk to the environment. Therefore, the environmental risk from the introduction of the assessed polymer can be managed.

As the environmental and toxic effects of perfluorinated chemicals is an area of ongoing research, evaluation may be required if information becomes available that indicates the assessed polymer, or their degradants have greater hazards than those considered in this assessment.

References

DCCEEW (2022) Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals, Department of Climate Change, Energy, the Environment and Water. Accessed 03 December 2024

UNECE (2017). Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition, United Nations Economic Commission for Europe. Accessed 20 December 2024

US EPA (2013) Interpretive Assistance Document for Assessment of Polymers – Sustainable Futures Summary Assessment, US Environmental Protection Agency, https://www.epa.gov/sites/production/files/2015-05/documents/06-iad_polymers_june2013.pdf. Accessed 03 December 2024