

POLYETHYLENE GLYCOL

This dossier on polyethylene glycol presents the most critical studies pertinent to the risk assessment of polyethylene glycol in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

Screening Assessment Conclusion – Polyethylene glycol is classified as a **tier 1** chemical and requires a hazard assessment only.

1 BACKGROUND

Polyethylene glycol is readily biodegradable, and it is not expected to bioaccumulate. It has low potential to adsorb to soil and sediment. Polyethylene glycol is of low toxicity concern to aquatic organisms.

2 CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated

CAS RN: 25322-68-3

Molecular formula: $C_{2n}H_{4n+2}O_{n+1}$

Molecular weight: variable (polymer)

Synonyms: Polyethylene glycol; poly(oxyethylene); polyethylene oxide

3 PHYSICO-CHEMICAL PROPERTIES

Key physical and chemical properties for the substance are shown in Table 1.

Table 1 Overview of the Physico-chemical Properties of Polyethylene Glycol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Pale yellow organic liquid	1	ECHA
Melting Point	No freezing down to -14.08 °C @ 97.4 kPa	1	ECHA
Boiling Point	205.7°C @97.8 kPa	1	ECHA
Density	1,116 kg/m ³ @ 20°C and 97.6 kPa	1	ECHA
Vapour Pressure	10 Pa @ 20°C	1	ECHA
Partition Coefficient (log K _{ow})	-0.698 @ 30°C and pH of 6.44	1	ECHA
Water Solubility	256 g/L at 25°C	1	ECHA
Viscosity	289.87 mPa s @20°C (dynamic)	1	ECHA

Polyethylene glycols are water-soluble linear polymers formed by the addition reaction of ethylene oxide to an ethylene glycol equivalent. The general formula for polyethylene glycol is: $H-(OCH_2CH_2)_n-OH$ where “n” is the average number of repeating oxyethylene groups.

All of the lower molecular weight polyethylene glycols are liquid at room temperature; polyethylene glycols with higher molecular weights (defined as > 600 g/mol) exist as solids at room temperature.

4 DOMESTIC AND INTERNATIONAL REGULATORY INFORMATION

A review of international and national environmental regulatory information was undertaken (Table 2). This chemical is listed on the Australian Inventory of Chemical Substances – AICS (Inventory). No conditions for its use were identified. No specific environmental regulatory controls or concerns were identified within Australia and internationally for polyethylene glycol.

NICNAS has assessed polyethylene glycol in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health¹.

Table 2 Existing International Controls

Convention, Protocol or other international control	Listed Yes or No?
Montreal Protocol	No
Synthetic Greenhouse Gases (SGG)	No
Rotterdam Convention	No
Stockholm Convention	No
REACH (Substances of Very High Concern)	No
United States Endocrine Disrupter Screening Program	No
European Commission Endocrine Disruptors Strategy	No

5 ENVIRONMENTAL FATE SUMMARY

A. Summary

Polyethylene glycol is readily biodegradable, and it is not expected to bioaccumulate. Polyethylene glycol has low potential to adsorb to soil and sediment.

B. Biodegradation

Polyethylene glycol is readily biodegradable. In an OECD 301D test, there was 75% degradation after 28 days, as determined by oxygen consumption (ECHA) [KI. score = 1]. If a chemical is found to be

¹<https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=25322-68-3>

readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

C. Environmental Distribution

Experimental data are available for polyethylene glycol. In the key study, the soil organic carbon partition coefficient (K_{oc}) in soil and in sewage sludge of test chemical was determined by the Reverse Phase High Performance Liquid Chromatographic method according to OECD Guideline No. 121 for testing of Chemicals. The Log K_{oc} value of test chemical was determined to be 1.8568 dimensionless at 25°C (ECHA). [Kl. Score = 1].

Based upon this K_{oc} value, if released to soil, polyethylene glycol is expected to have low potential for adsorption and a high potential for mobility. If released to water, based on its K_{oc} and high water solubility values, polyethylene glycol is likely to remain in water and not adsorb to sediment. From the water surface, the substance will not evaporate into the atmosphere (ECHA).

D. Bioaccumulation

Using BCFBAF in EPISUITE™, the estimated the estimated BCF for polyethylene glycol is 3.162 L/Kg (ECHA). [Kl. Score = 2]. Based on this BCF value, the substance is not expected to bioaccumulate.

6 ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Polyethylene glycol is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on polyethylene glycol.

Table 3 Acute Aquatic Toxicity Studies on Polyethylene Glycol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
<i>Poecilia reticulata</i>	96-hr LC ₅₀	>100	2	ECHA
<i>Daphnia magna</i>	48-hour EC ₅₀	>100	1	ECHA
<i>Scenedesmus subspicatus</i>	96-hour EC ₅₀	>100	2	ECHA

Chronic Studies

Based on the EPISUITE™ ECOSAR version 1.11 predicted model, in 28 days long term fish toxicity (NOEC value) was estimated to be 13,671.586 mg/L on fish for on the basis of mortality effects (ECHA). [Kl. Score = 2].

The calculated value was further supported by 7-day freshwater study conducted on *Poecilia reticulata* (guppy fish) in semi-static conditions. The median lethal concentration of the test chemical (LC₅₀) was determined as 1150 mg/L (ECHA). [Kl. Score = 2].

Based on the EPISUITE™ ECOSAR version 1.10 predicted model, in 21 days long term aquatic invertebrate toxicity (NOEC value) was estimated to be 17,475.27 mg/L to Daphnid on the basis of reproductive effects (ECHA). [Kl. Score = 2].

Data for algae was available for read-across substance diethylene glycol mono-butyl ether (CAS No. 112-34-5). The effect of the test chemical to algae *Scenedesmus quadricauda* was performed for a period of 8 days. Based on the results obtained, the 8-day EC₅₀ value was determined to be 1,000 mg/L (ECHA) [Kl. score = 2].

C. Terrestrial Toxicity

No studies are available.

7 CATEGORISATION AND OTHER CHARACTERISTICS OF CONCERN

A. PBT Categorisation

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (IChEMS, 2022; ECHA, 2017).

Polyethylene glycol has been shown to be readily biodegradable; thus, it does not meet the screening criteria for persistence.

The calculated BCF is 3.162 L/kg. Thus, polyethylene glycol does not meet the screening criteria for bioaccumulation.

The NOECs from the chronic aquatic toxicity studies on polyethylene glycol are >0.1 mg/L. The acute E(L)C₅₀ values from the acute aquatic toxicity studies on polyethylene glycol are >1 mg/L. Thus, polyethylene glycol does not meet the criteria for toxicity.

Therefore, polyethylene glycol is not a PBT substance.

B. Other Characteristics of Concern

No other characteristics of concern were identified for polyethylene glycol.

8 SCREENING ASSESSMENT

Chemical Name	CAS No.	Overall PBT Assessment ¹	Chemical Databases of Concern Assessment Step		Persistence Assessment Step		Bioaccumulative Assessment Step	Toxicity Assessment Step			Risk Assessment Actions Required ³
			Listed as a COC on relevant databases?	Identified as Polymer of Low Concern	P criteria fulfilled?	Other P Concerns	B criteria fulfilled?	T criteria fulfilled?	Acute Toxicity ²	Chronic Toxicity ²	
Polyethylene Glycol	25322-68-3	Not a PBT	No	No	No	No	No	No	1	1	1

Footnotes:

1 - PBT Assessment based on PBT Framework.

2 - Acute and chronic aquatic toxicity evaluated consistent with assessment criteria (see Framework).

3 - Tier 1 - Hazard Assessment only.

Notes:

NA = not applicable

PBT = Persistent, Bioaccumulative and Toxic

B = Bioaccumulative

P = persistent

T = toxic

9 REFERENCES, ABBREVIATIONS AND ACRONYMS

A. References

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra. Available: www.environment.gov.au/water/coal-and-coal-seam-gas/national-assessment-chemicals/consultation-risk-assessment-guidance-manual

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European Chemicals Agency [ECHA]. (2017). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland. Available: <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

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Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

USEPA. (2016). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: <https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface>.

B. Abbreviations and Acronyms

°C	degrees Celsius
AICS	Australian Inventory of Chemical Substances
COC	constituent of concern
EC	effective concentration
ECHA	European Chemicals Agency
EU	European Union
g/L	grams per litre
IChEMS	Industrial Chemicals Environmental Management Standard
IUPAC	International Union of Pure and Applied Chemistry
kg/m ³	kilograms per cubic metre
KI	Klimisch scoring system
kPa	kilopascal

L/kg	litres per kilogram
LC	lethal concentration
mg	milligrams
mg/L	milligrams per litre
NICAS	National Industrial Chemicals Notification and Assessment Scheme
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SGG	Synthetic Greenhouse Gases
USEPA	United States Environmental Protection Agency