Qualitative Tier 2 Assessment

PolyDADMAC

In accordance with the Dawson River Release (DRR) Chemical Risk Assessment Framework (CRAF), chemicals assigned a Tier 2 designation require a hazard assessment and qualitative assessment of risk.

Consistent with National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the human health hazards for each chemical are characterised by analysing the toxicokinetics (the absorption, distribution, metabolism and excretion of the chemical in humans or laboratory animals), acute toxicity, irritation and corrosivity, repeat dose toxicity, genotoxicity, carcinogenicity, reproductive toxicity, and other health effects. The environmental hazards for each chemical are characterised by analysing the environmental fate properties (such as mobility, persistence, bioavailability and bioaccumulation), acute toxicity and chronic toxicity. In support of the hazard assessment, a risk assessment dossier is prepared for each of the chemicals included in the assessment.

Potentially complete exposure pathways (in that a source, a migration pathway, a mechanism for exposure, and a potential receptor are present) are assessed herein to determine the potential for risk. An incomplete pathway precludes an exposure occurring and an associated potential risk. In this context, site setting and management protocols associated with the action are evaluated. Key controls limiting the potential for exposure include:

- Engineering controls (including fencing and secondary containment);
- Storage (drums, totes and storage tanks) constructed in accordance with Australian standards and managed and monitored in accordance with regulatory requirements;
- Maintenance of access control restrictions during site activities that will preclude access by the public, livestock and large native fauna; and,
- Safe Work Australia and Santos Occupational Safety Guidance used to minimise human health exposure.

This qualitative assessment provides information to be used as a complement to the risk assessment dossier to provide a summary of human and ecological hazards that may occur from exposure to the chemical. Where a potential hazard exists, additional information is provided in the risk assessment dossiers and safety data sheets (SDSs) and are available to emergency responders, health and safety managers, and environmental hazard clean-up teams.

As a result, the assessment for this Tier 2 chemical includes the following components: completing the screening; developing a risk assessment dossier and Predicted No Effect Concentrations (PNECs) for water and soil; and, providing a qualitative discussion of risk. Each of these components is detailed within this memorandum.

Background

Santos has been releasing treated water to the Dawson River since 2015. The Dawson River Release Scheme[1] is located in the southeast region of the Fairview Arcadia Project Area (FAPA) (within the hub compressor station four (HCS4) gathering network). Coal seam water produced in the HCS4 gathering network is collected and is treated at Reverse Osmosis Plant 2 (ROP2) with the treated permeate stored within a permeate pond prior to release to the Dawson River. The outfall location is located within a tributary gully of the Dawson River, which joins the Dawson River midway between "Dawson's Bend" and Yebna Crossing.

The permeate pond is connected to the outfall location by a 5.3 kilometre (km) pipeline constructed across farmland with the released water flowing down a 2.9 km tributary gully before discharging to the Waterbody (nominal capacity 500 megalitre [ML]) and then flowing 1.8 km before joining the Dawson River at its downstream confluence.

ROP 2 at FAPA is a reverse osmosis plant with a specification designed to produce high quality water for the intended release of treated coal seam water to the Dawson River. The process removes the suspended and dissolved solids through a set of six processes to produce high quality treated water. These include coagulation/clarification, oxidation, filtration, softening, reverse osmosis, and finally adjustment of sodium adsorption ratio (SAR).

Cationic polymers are a component in a Water Management Facility (WMF) product used as a coagulant during oily water treatment. Process and usage information for this chemical is included in **Attachment 1** and summarised in **Table 1**.

Table 1 Water Management Facility Chemicals

Chemical Name	CAS No.	Use	Approximate Quantity Stored On-Site (plant available storage)
Cationic Polymer[a] Aluminium Hydroxychloride Water	n/a 1327-41-9 7732-18-5	Polymer / coagulant	2 x 1000 L (IBC)

[a] Identity unknown. Read-across to polydiallyldimethylammonium chloride [polyDADMAC (CAS No. 26062-79-3)].
CAS No = Chemical Abstracts Service Number
IBC = intermediate bulk container
L = litre
n/a = not available

As noted above and detailed in the SDS, the identity of the cationic polymer in the vendor product is unknown. Therefore, a read-across to polyDADMAC (CAS RN 26062-79-3)[2] was conducted for this assessment. Information compiled for polyDADMAC is provided in the risk assessment dossier included as **Attachment 2**. Results of the screening assessment are included in the dossier.

[1] Santos obtained an amendment to the Fairview Arcadia Project Area (FAPA) Environmental Authority (EA) (EPPG00928713) on 31st May 2013 to authorise the release of desalinated produced water from the Fairview reverse osmosis plant (ROP) 2 to the Dawson River – the Dawson River Release Scheme (DRRS).

[2] CAS RN - Chemical Abstracts Service Registry Number

The assessment of toxicity of this chemical was used to develop initial screening criteria for human health exposure scenarios and is presented in **Attachment 2**. PolyDADMAC is not a carcinogen, and, as a result, only a non-carcinogenic oral reference dose (RfD) was calculated. A detailed discussion of the derivation of the oral RfD and drinking water guideline values is presented in the attachment. **Table 2** provides a summary of the derivation.

Table 2 Oral Reference Doses and Derived Drinking Water Guidelines

Constituent (CAS No.)	Study	Critical Effect/ Target Organ(s)	NOAEL (mg/kg-day)	Uncertainty Factors	Oral Reference Dose (mg/kg-day)	Drinking Water Guideline (mg/L)
Cationic polymer[a]	6-month rat dietary study	None	2,000	600	3.3	12

[a] Identity unknown. Read-across to polydiallyldimethylammonium chloride [polyDADMAC] (CAS No. 26062-79-3).
CAS = Chemical Abstracts Service
mg/L = milligrams per litre
mg/kg-day = milligrams per litre-day
NOAEL = No observed adverse effect level
Refer to **Attachment 2** for information on the key studies selected for oral reference dose and drinking water level development.

For ecological receptors, the assessment utilises the information presented in the dossiers on the relative toxicity of the aquatic and terrestrial flora and fauna to the chemical. This assessment focuses on the aquatic invertebrate and fish species within the surface water resources and the soil flora and fauna associated with releases to the soil.

The determination of toxicological reference values (TRVs) was conducted according to the PNEC guidance in the *Environmental Risk Assessment Guidance Manual for Industrial Chemicals* prepared by the Australian Environmental Agency (AEA, 2009). PNECs for freshwater and sediment were developed to assess aquatic receptors, and PNECs for soil were developed for terrestrial receptors.

Table 3 present the chemical, the endpoint, no observable effects concentration (NOEC) (milligrams per litre [mg/L]), assessment factor, and the aquatic PNEC (mg/L). A PNEC for soil was not calculated for the chemical. Refer to **Attachment 2** for the development of PNECs, or the rational for PNECs that do not have a calculated PNEC.

Table 3 PNECs Water

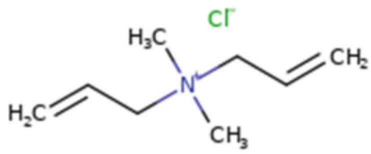
Constituents	Endpoint	EC_{50} or NOEC (mg/L)	Assessment Factor	$PNEC_{water}$ (mg/L)
Cationic polymer[a]	Acute fish	6.5	50	0.13

[a] Identity unknown. Read-across to polydiallyldimethylammonium chloride polyDADMAC (CAS No. 26062-79-3).
EC_{50} = effects concentration – 50%
mg/L = milligrams per litre
NOEC = no observable effects concentration
PNEC = predicted no effect concentration
Refer to **Attachment 2** for information on the development of PNECs listed above.

A detailed assessment of the potential risks posed by this Tier 2 chemical is provided in the following sections.

General Overview

PolyDADMAC is a highly charged cationic homopolymer with high molecular weights; those used in water treatment may have molecular weights less than 500,000 daltons (Lyons and Vasconcellos, 1997). The molecular structure of polyDADMAC is presented in **Figure 1**.



(monomer shown)

Figure 1 Molecular Structure of PolyDADMAC[3]

Synthetic polymers are persistent in the environment. They are expected to be poorly biodegraded, and adsorption would be expected to be the primary process that determines its ecological concentrations and mobility (Lyons and Vasconcellos, 1997). As a cationic polymer, polyDADMAC will rapidly react with many kinds of naturally occurring substances, such as humic acids, lignins, silts, and clays (Lyons and Vasconcellos, 1997). Due to its physical properties (i.e., molecular size and partitioning behaviour), polyDADMAC is not expected to bioaccumulate.

The PBT assessment for polyDADMAC is included in the dossier provided in **Attachment 2**. Based on physico-chemical properties and screening data detailed below, the overall conclusion was that polyDADMAC is not a PBT substance.

Human Health Hazards

There is a low concern for human health hazards. PolyDADMAC is not acutely toxic to humans by the oral route (LD_{50} > 5,000 mg/kg bw)[4]. Likewise, there are no adverse effects observed from repeated exposures through ingestion (lowest observed adverse effect level [LOAEL] of 1,000 milligrams per kilogram per day [mg/kg-day], a no observed adverse effect level [NOAEL] was not established).

Based on a review of repeated dose toxicity studies, TRVs were derived for polyDADMAC. The drinking water guideline value derived using the non-carcinogenic oral RfD is 12 mg/L (see **Table 2**). A detailed discussion of the drinking water guideline values is presented in **Attachment 2**.

Managed release of treated water to the Dawson River would have the potential to affect surface water within the river. As the Dawson River meanders through large areas that are uncontrolled, exposures could potentially occur to downstream agricultural workers and residents. Based on the treatment process described in **Attachment 1**, the cationic polymers would be bound to the solids present in the oily water and removed during clarification. As a result, this chemical would not be present in permeate or brine. Therefore, exposure pathways associated with Dawson River discharge would be incomplete.

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[3] Source https://chem.nlm.nih.gov/chemidplus/rn/26062-79-3

[4] LD50 = lethal dose of 50 percent of population; mg/kg bw – milligrams per kilogram body weight

PolyDADMAC is listed in Attachment B (Substances Considered Not To Require Control By Scheduling) of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) (Therapeutic Goods Administration [TGA], 2014). The reason given for the listing in Attachment B is 'Low Toxicity' and the area of use of the chemical is 'Water treatment' (NICNAS, 2017). NICNAS identified polyDADMAC as a low concern for workers and the public under the operational scenarios assessed. Best practice chemical management was recommended to minimise worker and public exposure (NICNAS, 2017).

Environmental Hazards

In standard acute aquatic toxicity tests, polyDADMAC, as a highly charged cationic polymer, is very toxic to aquatic life. PolyDADMAC will dissociate into polyammonium cations and chloride anions in the aquatic environment. Chloride ions are an essential constituent of electrolytes in all biological fluids responsible for maintaining acid/base balance, transmitting nerve impulses and regulating fluid in and out of cells (NCBI, 2015). The concentration of chloride ions is naturally regulated within organisms. Therefore, the toxicity of cationic polymers to fish is from the binding of the polyammonium cations in the polymer to the gill tissue, disrupting gill structure and function. Physical damage to fish gill by cationic polymers has been shown by Beisinger and Stokes (1986).

However, under environmental conditions, the toxicity of these polymers is mitigated by the presence of dissolved organic carbon (DOC) and suspended solids. Cationic polymers react with DOC in environmental waters to form insoluble complexes, which settle out of water and therefore are not bioavailable to cause toxic effects. It has previously been established that a reduction in likely toxicity by a factor of 110 is appropriate to apply to laboratory test results for cationic polymers with a high charge density to account for the mitigating effects of DOC on toxicity in natural environmental waters (Boethling and Nabholz, 1997).

As described in the previous section (Human Health Hazards), managed release of treated water to the Dawson River would have the potential to affect surface water within the river. As released treated water would become part of the regional surface water resource (i.e., Dawson River water quality and flow), ecological resources (livestock and native flora and fauna) are potential receptors. Specifically, potential receptors include:

- Aquatic ecological receptors within Dawson River downstream of the release point
- Livestock and wildlife that may access Dawson River surface water

However, as discussed earlier, exposure pathways associated with Dawson River discharge would be incomplete, including those associated with the following Matters of National Environmental Significance [MNES] receptors:

- White-throated Snapping Turtle (*Elseya albagula*) – Critically endangered; and
- Fitzroy River Turtle (*Rheodytes leukops*) – Vulnerable.

These findings are consistent with an assessment completed by NICNAS in 2017. Based on an assessment of environmental hazards, NICNAS identified polyDADMAC as a chemical of low concern to the environment (DoEE, 2017). Chemicals of low concern are unlikely to have adverse environmental effects if they are released to the environment from coal seam gas operations.

References

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Attachment 1 Vendor WMF Chemicals and Exposure Point Concentration

Attachment 1
Summary of Exposure Point Concentration Development
(Water Treatment Chemicals)

Product Name	Chemical Name	CAS Number	%	Proper Shipping Name	Supplier	Area	Transport		Onsite Storage		Operation		Annual Usage (ROP volumes based on peak rate of 10ML/d)
							mass/volume	concentration	mass/volume	concentration	mass/volume	concentration	
MAK MFC1 (multi floc coagulant)	Cationic Polymer	n/a	20-40%	MAK MFC1	MAK Water Industrial	Oily Water Treatment Plant	1000L IBC		2 x 1000L (IBC)		0.8mg/L (AVG)		
	Aluminium Hydroxychloride	1327-41-9	40-60%										
	Water	7732-18-5	20-60%										

AVG = average
CAS = Chemical Abstracts Service
COPC = constituent of potential concern
IBC = intermediate bulk container
L = litres
mg/kg = milligrams per kilogram
mg/L = milligrams per litre
ML/d = millilitre per day
NA = not applicable
ROP = reverse osmosis process

Attachment 1
Summary of Exposure Point Concentration Development
(Water Treatment Chemicals)

Product Name	Chemical Name	CAS Number	Purpose / Function	Fate	Permeate Concentration (mg/L)	Permeate notes	COPC concentration in soil from release of permeate (mg/kg)	COPC concentration in soil from 20 years of irrigation mg/kg	Brine Concentration (mg/L)
MAK MFC1 (multi floc coagulant)	Cationic Polymer	n/a	polymer / coagulant	Removed with oily water sludge (solid waste)	NA	Oily water is clarified to remove solids and oils then run through the RO system. The amount relative to flux of RO system is <1%. Therefore, the net on permeate quality is deminimis. Therefore, no concentration of chemical in this product in the permeate.	NA	NA	NA
	Aluminium Hydroxychloride	1327-41-9			NA	Oily water is clarified to remove solids and oils then run through the RO system. The amount relative to flux of RO system is <1%. Therefore, the net on permeate quality is deminimis. Therefore, no concentration of chemical in this product in the permeate.	NA	NA	NA
	Water	7732-18-5			NA		NA	NA	NA

AVG = average
CAS = Chemical Abstracts Service
COPC = constituent of potential concern
IBC = intermediate bulk container
L = litres
mg/kg = milligrams per kilogram
mg/L = milligrams per litre
ML/d = millilitre per day
NA = not applicable
ROP = reverse osmosis process

Attachment 1
Summary of Exposure Point Concentration Development
(Water Treatment Chemicals)

Product Name	Chemical Name	CAS Number	Brine Notes
MAK MFC1 (multi floc coagulant)	Cationic Polymer	n/a	The oily water is clarified to seperate solids and oils; then run through the RO system. Estimate 5% residual in brine, the balance is sludge.
	Aluminium Hydroxychloride	1327-41-9	The oily water is clarified to seperate solids and oils; then run through the RO system. Estimate 5% residual in brine, the balance is sludge. Estimate that chemical will dissociate to aluminium (Al) and Cl- at 40% Al and 55% Cl-.
	Water	7732-18-5	

AVG = average
CAS = Chemical Abstracts Service
COPC = constituent of potential concern
IBC = intermediate bulk container
L = litres
mg/kg = milligrams per kilogram
mg/L = milligrams per litre
ML/d = millilitre per day
NA = not applicable
ROP = reverse osmosis process

Attachment 2 Risk Assessment Dossier

POLYDADMAC
[POLYDIALLYLDIMETHYLAMMONIUM CHLORIDE]

This dossier on polyDADMAC presents the most critical studies pertinent to the risk assessment of polyDADMAC in its use incoal seam gas extraction activities. It does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

Screening Assessment Conclusion – PolyDADMAC was not identified in chemical databases used by NICNAS as an indicator that the chemical is of concern and is not a PBT substance. PolyDADMAC was assessed as a tier 2 chemical for acute and chronic toxicity. Therefore, polyDADMAC is classified overall as a **tier 2** chemical and requires a hazard assessment and qualitative assessment of risk.

1. BACKGROUND

Polydiallyldimethylammonium chloride (polyDADMAC) are highly charged cationic polymers with high molecular weights. They are expected to be poorly biodegraded, and adsorption would be expected to be the primary process that determines its ecological concentrations and mobility. As a cationic polymer, polyDADMAC will rapidly react with many kinds of naturally occurring substances, such as humic acids, lignins, silts and clays. Due to its physical properties (i.e., molecular size), polyDADMAC is not expected to bioaccumulate. PolyDADMAC is not acutely toxic to humans by the oral route; nor does it exhibit any systemic toxicity from repeated exposures through ingestion. PolyDADMAC exhibits a moderate toxicity concern to aquatic organisms. The toxicity of these polymers is mitigated by the presence of dissolved organic carbon (DOC) and suspended solids. Cationic polymers react with DOC in environmental waters to form insoluble complexes, which settle out of water and therefore are not bioavailable to cause toxic effects.

2. CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): Polydiallyldimethylammonium chloride
CAS RN: 26062-79-3
Molecular formula: $(C_8H_{16}N.Cl)_x$-
Molecular weight: Variable

Synonyms: PolyDADMAC; 2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, homopolymer; Poly-2-propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride; N-N-dimethyl-N-2-propenyl-2-propen-1-aminium chloride, homopolymer; poly-N,N-dimethyl-N-N-diallyammonium chloride; polyquaternium-6

3. PHYSICO-CHEMICAL PROPERTIES

PolyDADMAC are highly charged cationic homopolymers with high molecular weights; those used in water treatment may have molecular weights less than 500,000 daltons (Lyons and Vasconcellos, 1997).

Limited information is available on the physico-chemical properties of polyDADMAC. The information contained in Table 1 is based on diallyldimethylammonium chloride (DADMAC) (CAS No. 7398-69-8). PolyDADMAC is a homopolymer of DADMAC.

Table 1 Overview of the Physico-chemical Properties of DADMAC

Property	Value	Klimisch score	Reference
Physical state at 20^oC and 101.3 kPa	Liquid	-	ECHA
Melting Point/Freezing Point	-25 ^oC @ 101.3 kPa	1	ECHA
Boiling Point	118 ^oC @ 101.3 kPa	1	ECHA
Density	1,030 – 1,050 kg/m^3 @ 25^oC	1	ECHA
Partition Coefficient (log K_{ow})	Estimated to be -2.49 @ 20^OC using KOWWIN	2	ECHA
Water Solubility	Estimated to be 1,000 g/L @ 25^oC	2	ECHA

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. PolyDADMAC is also listed in Appendix B (Substances Considered Not To Require Control By Scheduling) of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) (Therapeutic Goods Administration [TGA], 2014). The reason given for listing in Appendix B is 'Low Toxicity' and the area of use of the chemical is 'Water treatment' (NICNAS, 2017). No other specific environmental regulatory controls or concerns were identified within Australia and internationally for polyDADMAC.

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

PolyDADMAC are highly charged cationic polymers with high molecular weights. They are expected to be poorly biodegraded, and adsorption would be expected to be the primary process that determines its ecological concentrations and mobility (Lyons and Vasconcellos, 1997). As a cationic polymer, polyDADMAC will rapidly react with many kinds of naturally occurring substances, such as humic acids, lignins, silts and clays (Lyons and Vasconcellos, 1997).

PolyDADMAC will dissociate into polyammonium cations and chloride anions in the aquatic environment. Chloride ions are an essential constituent of electrolytes in all biological fluids responsible for maintaining acid/base balance, transmitting nerve impulses and regulating fluid in and out of cells (NCBI, 2015). The concentration of chloride ions is naturally regulated within organisms. Therefore, consistent with NICNAS (DoEE, 2017), this discussion is focused on the environmental fate and effects of the synthetic polyammonium cations.

B. Biodegradation

Due to its physical properties (i.e., molecular size), polyDADMAC is expected to be poorly degraded. This finding is consistent with DADMAC which is not readily biodegradable according to the OECD criteria (ECHA). [Kl. score = 1]

C. Bioaccumulation

Due to its physical properties (*i.e.*, molecular size), polyDADMAC is not expected to bioaccumulate.

6. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

PolyDADMAC is not acutely toxic by the oral route; nor does it exhibit any systemic toxicity from repeated exposures through ingestion.

B. Acute Toxicity

There were no deaths in rats given a single oral dose of 5,000 mg/kg polyDADMAC. The oral LD50 in rats is >5,000 mg/kg (USEPA, 2016a).

C. Irritation

No studies were located.

D. Sensitisation

No studies were located.

E. Repeated Dose Toxicity

Oral

Male and female Sprague Dawley (SD) rats were fed in their diet 0, 1,000 or 2,000 mg/kg polyDADMAC for six months. There were no clinical signs of toxicity. Two low-dose males were sacrificed in a moribund condition, while one low-dose male and one high-dose male died during the exposure period. Feed consumption was significantly increased in the treated groups compared to controls. Body weight gain was significantly lower in the treated animals compared to the controls. Final body weights were significantly lower in all dose groups compared to controls (10.4% and 19.5% in males; 6.6% and 10% in females for the low- and high-dose groups, respectively). Hematology and clinical chemistry parameters and urinalysis showed no biologically significant differences between treated and control groups. Relative liver weights were decreased in the >1,000 mg/kg males and 2,000 mg/kg females. Relative heart weights were decreased in the 2,000 mg/kg (both sexes), and relative kidney weights were decreased in the 2,000 mg/kg males. The histopathologic examination showed no treatment-related changes in these organs. No other compound-related pathology was observed, although histopathologic effects were seen in the lungs and urinary tract in animals of all groups. The LOAEL for this study is 1,000 mg/kg-day based on reduced body weights and body weight gain; a NOAEL was not established (USEPA, 2016b).

Inhalation

No studies were located.

Dermal

No studies were located.

F. Genotoxicity

No studies were located.

G. Carcinogenicity

No studies were located.

H. Reproductive Developmental Toxicity

No studies were located.

I. Derivation of Toxicological Reference and Drinking Water Guidance Values

The toxicological reference values developed for polyDADMAC follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

Non-Cancer

PolyDADMAC was tested in a six-month rat feeding study. No target organs were identified, and a NOAEL was not established. The LOAEL was 1,000 mg/kg-day based on reduced body weights and body weight gain. It is unclear from the limited data whether these changes in the treated animals are due to a direct or indirect effect of polyDADMAC. PolyDADMAC has a high molecular weight and would not be expected to be absorbed from the gastrointestinal tract. Feed consumption was significantly increased in the treated rats (both dose groups) even though body weights and body weight gain were reduced. A likely explanation for these findings is that the weight changes and feed consumption reflect the nutritional status of the treated animals due to the bulk presence of high levels of polymer in the feed and not to systemic toxicity. Given the absence of any other effects, it is proposed that the NOAEL for systemic toxicity in this study is 2,000 mg/kg-day, the highest dose tested.

The NOAEL of 2,000 mg/kg-day will be used for determining the oral Reference Dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 3
UF_D (database uncertainty) = 2

Oral RfD = 2,000/(10 x 10 x 1 x 3 x 2) = 2,000/600 = 3.3 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (3.3 x 70 x 0.1)/2 = 12 mg/L

Cancer

No carcinogenicity studies were located; thus, a cancer reference value was not derived.

J. Human Health Hazard Assessment of Physico-Chemical Properties

PolyDADMAC does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7. ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

PolyDADMAC exhibits a moderate toxicity concern to aquatic organisms. However, under environmental conditions, the toxicity of these polymers is mitigated by the presence of DOC and suspended solids. Cationic polymers react with DOC in environmental waters to form insoluble complexes, which settle out of water and therefore are not bioavailable to cause toxic effects. It has previously been established that a reduction in likely toxicity by a factor of 110 is appropriate to apply to laboratory test results for cationic polymers with a high charge density to account for the mitigating effects of DOC on toxicity in natural environmental waters (Boethling and Nabholz, 1997).

B. Aquatic Toxicity

Acute Studies

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

Table 3 Acute Aquatic Toxicity Studies on polyDADMAC

Test Species	Endpoint	Results (mg/L)	Reference
Bluegill	96-hour LC_{50}	0.9	USEPA, 2016c
Bluegill	96-hour LC_{50}	0.32	USEPA, 2016d
Rainbow trout	96-hour LC_{50}	0.32	USEPA, 2016d
Rainbow trout	96-hour LC_{50}	0.42	USEPA, 2016e
Rainbow trout	96-hour LC_{50}	0.77	USEPA, 2016f
Fathead minnow	96-hour LC_{50}	0.3	USEPA, 2016g
Fathead minnow	96-hour LC_{50}	6.51*	USEPA, 2016g
Fathead minnow	96-hour LC_{50}	0.46	Cary et al., (1987)
Fathead minnow	96-hour LC_{50}	6.5***	Cary et al., (1987)
Daphnia magna	48-hour EC_{50}	0.23	USEPA, 2016g
Daphnia magna	48-hour EC_{50}	11.8**	USEPA, 2016g
Daphnia magna	48-hour EC_{50}	0.33	USEPA, 2016h
Daphnia magna	48-hour EC_{50}	0.2	Cary et al., (1987)
Daphnia magna	48-hour EC_{50}	7.4***	Cary et al., (1987)

*10 mg/L humic acid in standard laboratory water.
**10 mg/L TOC in standard laboratory water.
***50 mg/L humic acid in standard laboratory water.

In standard acute aquatic toxicity tests, PolyDADMAC, as a highly charged cationic polymer, is very toxic to fish and *Daphnia magna*. The toxicity of cationic polymers to fish is from the binding of the polymer to gill tissue, disrupting gill structure and function. Physical damage to fish gill by cationic polymers has been shown by Biesinger and Stokes (1986).

The presence of dissolved organic carbon and suspended solids is known to significantly mitigate the toxicity of cationic polymers under typical environmental exposure conditions (Boethling and Nabholz, 1997). Table 3 also shows the change in acute toxicity when suspended solids or total organic carbon (TOC) is added to the standard laboratory water used in the toxicity tests. In the presence of humic acid or TOC, the EC_{50} values for fathead minnow and *Daphnia magna* increase by 21.7-fold and 51.3-fold, respectively. A similar effect of humic acid on the acute toxicity of polyDADMAC on fish and *Daphnia magna* was reported by Cary et al. (1987). The studies by Cary et al. (1987) also showed increases in varying amounts in the EC_{50} values for fathead minnow and *Daphnia magna* with bentonite, illite, kaolin, silica, tannic acid, lignin, lignosite and fulvic acid. The concentrations of suspended solids and DOC in the studies by Cary et al. (1987) were considered to be low estimates of levels found in the natural environments. These findings demonstrate that toxicity tests conducted on cationic polymers, such as polyDADMAC, using water with no organic carbon will likely overestimate the toxicity of these polymers in the environment.

Chronic Studies

No studies were located for polyDADMAC. The ratio of the acute toxicity to chronic toxicity for polyDADMAC is expected to be low. In 21-day *Daphnia magna* reproduction studies, three cationic polymers had 21-day threshold levels for survival that were higher by order of magnitude than the 48-hour TL_{50} values. The test solutions in these studies were renewed several times along with food, which served as new organic matter. The cationic polymer bioavailability was likely reduced from the adsorption to the food (Biesinger et al., 1976). In another study, low acute to chronic ratios was observed for a cationic polymer for *Ceriodaphnia dubia* and fathead minnows (Godwin-Saad et al., 1994).

It cannot be determined from the standard chronic tests if the adsorbed polymer is ingested or simply becomes unavailable by flocculating and/or settling. In any case, the low acute to chronic ratios of these cationic polymers appears to be best correlated with acute effects (Lyons and Vasconcellos, 1997).

C. Terrestrial Toxicity

No studies were located.

D. Calculation of PNEC

The PNEC calculations for polyDADMAC follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for two trophic levels. Acute EC_{50} values are available for fish (0.2 mg/L) and *Daphnia magna* (0.3 mg/L) in standard laboratory water; and for fish (6.5 mg/L) and *Daphnia magna* (11.8 mg/L) in standard laboratory water with the addition of humic acid or TOC. The PNEC water will be based on the EC_{50} values from the acute toxicity tests conducted with humic acid in the dilution water because this most likely represents the environmental conditions for which this assessment is being conducted. Furthermore, an assessment factor of 50 is proposed because chronic toxicity is expected to be similar to the acute toxicity of polyDADMAC (when tested in the presence of humic acid) because of the adsorption of the polymer to organic matter (food source) that would occur in standard test methods; hence, an assessment factor will be used for chronic testing for two trophic levels. An assessment factor of 50 has been applied to the EC_{50} value of 6.5 mg/L for fish. The $PNEC_{water}$ is 0.13 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. The K_{ow} and K_{oc} have not been experimentally derived for polyDADMAC; these values cannot be estimated using QSAR models because of the high molecular weight of polyDADMAC. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$.

PNEC soil

There are no toxicity data for soil-dwelling organisms. The K_{ow} and K_{oc} have not been experimentally derived for polyDADMAC; these values cannot be estimated using QSAR models because of the high molecular weight of polyDADMAC. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$.

8. 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).

PolyDADMAC is a high molecular weight polymer; it is expected to be poorly biodegraded. Thus, it meets the screening criteria for persistence.

PolyDADMAC is a high molecular weight polymer that is not expected to be bioavailable to aquatic or terrestrial organisms. Thus, it is not expected to bioaccumulate.

No chronic aquatic toxicity studies have been conducted on polyDADMAC. The EC_{50} values of fish and *Daphnia magna* for acute toxicity tests conducted with humic acid or TOC in dilution water were >1 mg/L. Thus, polyDADMAC does not meet the screening criteria for toxicity.

The overall conclusion is that polyDADMAC is not a PBT substance.

B. Other Characteristics of Concern

No other characteristics of concern were identified for polyDADMAC.

9. 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]	
PolyDADMAC	26062-79-3	Not a PBT	No	No	Yes	No	No	No	2	2	2

Footnotes:

1 - PBT Assessment based on PBT Framework.

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

3 - Tier 2 - Hazard Assessment and Qualitative Assessment Only. Develop toxicological profile and PNECs for water and soil and provide qualitative discussion of risk.

Notes:

PBT = Persistent, Bioaccumulative and Toxic
B = bioaccumulative
P = persistent
T = toxic

10. REFERENCES, ABBREVIATIONS AND ACRONYMS

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B. Abbreviations and Acronyms

ADWG Australian Drinking Water Guidelines

AICS Australian Inventory of Chemical Substances

COC constituent of concern

DEWHA Department of the Environment, Water, Heritage and the Arts

DOC dissolved organic carbon

EC effective concentration

ECHA European Chemicals Agency

EU European Union

g/L grams per litre

HHRA enHealth Human Risk Assessment

IChEMS Industrial Chemicals Environmental Management Standard

IUPAC International Union of Pure and Applied Chemistry

kg/m^3 kilogram per cubic metre

kg kilogram

Kl Klimisch scoring system

KOWWIN USEPA program to estimate the organic carbon-normalized sorption coefficient for soil and sediment

kPa kilopascal

LC lethal concentration

LD lethal dose

LOAEL lowest observed adverse effect level

mg/kg milligrams per kilogram

mg/L milligrams per litre

NICNAS The National Industrial Chemicals Notification and Assessment Scheme

NOAEL no observed adverse effect level

OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
QSAR	quantitative structure activity relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RfD	Reference Dose
SD	Sprague Dawley
SGG	Synthetic Greenhouse Gases
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Good Administration
TL_{50}	time required for 50% of inoculated population to die
TOC	total organic carbon
USEPA	United States Environmental Protection Agency