Draft Screening Assessment

Poly(amines) Group

Chemical Abstracts Service Registry Numbers

25988-97-0
26062-79-3
26590-05-6
27967-29-9
42751-79-1
52722-38-0
68130-99-4
68134-56-5
69418-26-4

Environment and Climate Change Canada
Health Canada

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Synopsis

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of nine substances referred to collectively as the Poly(amines) Group. Substances in this group were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA. The Chemical Abstracts Service Registry Numbers (CAS RN[1]), their Domestic Substances List (DSL) names and their sub-group are listed in the table below.

Substances in the Poly(amines) Group

CAS RN	Domestic Substances List name	Sub-group
26062-79-3	2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, homopolymer	Poly(DADMAC)
26590-05-6	2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, polymer with 2-propenamide	Poly(DADMAC)
25988-97-0	Methanamine, N-methyl-, polymer with (chloromethyl)oxirane	Poly(EDMA)
42751-79-1	1,2-Ethanediamine, polymer with (chloromethyl)oxirane and N-methylmethanamine	Poly(EDMA)
52722-38-0	Methanamine, N-methyl-, polymer with ammonia and (chloromethyl)oxirane	Poly(EDMA)
69418-26-4	Ethanaminium, N,N,N-trimethyl-2-[(1-oxo-2-propenyl)oxy]-, chloride, polymer with 2-propenamide	Poly(ASPCA)
68130-99-4	Aziridine, homopolymer, ethoxylated	Poly(ASPCA)
27967-29-9	Urea, polymer with ammonia and formaldehyde	Poly(ASPCA)
68134-56-5	2-Oxepanone, polymer with (chloromethyl)oxirane, N-(1,3-dimethylbutylidene)-N’-[2-[(1,3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine, 2-(methylamino)ethanol, 4,4’-(1-methylethylidene)bis[phenol] and 2,2’-oxybis[ethanol], acetate (salt)	Poly(ASPCA)

These nine substances were previously evaluated under the second phase of polymer rapid screening, which identified them as having low potential to cause harm to human health, but requiring further evaluation due to their potential to cause ecological harm (ECCC, HC 2017). The present assessment summarizes the approach applied during

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the second phase of polymer rapid screening and further elaborates on the potential for these nine substances to cause ecological harm, in order to reach an overall conclusion under section 64 of CEPA.

The nine poly(amines) do not occur naturally in the environment. In Canada, they are reported to be mainly used as coagulants and flocculants for water and wastewater treatment, pulp and paper production and oil field applications. In addition, minor uses of both poly(DADMAC) polymers have been reported for personal care products [2]. Minor uses of poly(ASPCA) polymers have also been reported in liquid laundry and dishwashing detergent formulations for CAS RN 68130-99-4, automotive paints and coatings for CAS RN 68134-56-5, and adhesives and sealants for CAS RN 27967-29-9. Minor uses for poly(DADMAC) (CAS 26062-79-3 and 26590-05-6), poly(EDMA) (CAS 25988-97-0, 42751-79-1 and 52722-38-0) and poly(ASPCA) (CAS 69418-26-4) in food packaging materials have also been reported.

These poly(amines) contain cationic amine functional groups which, in general, may be associated with adverse effects to fish, invertebrates, and algae. However, the assessment determined that the nine poly(amines) are expected to show moderate to low toxicity to aquatic organisms, and low toxicity towards sediment dwelling species in natural environments as they quickly form colloidal solids which are not expected to be bioavailable. Considering the use patterns of the nine poly(amines) as noted above, releases of the unbound form of the substances are expected to be low. A high degree of removal during wastewater treatment is also common for these types of substances because of their colloidal nature. In the event of overdosing when being added to wastewater as a flocculant, any unreacted polymer residues which reach the aquatic environment are not expected to be bioavailable because they rapidly and irreversibly form colloidal solids (floc) with anionic materials in water.

Considering all available lines of evidence presented in this draft screening assessment, including the assumption that significant overdosing of waters being treated is avoided, there is low risk of harm to the environment from the nine poly(amines). It is proposed to conclude that the nine poly(amines) do not meet the criteria under paragraphs 64(*a*) or (*b*) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or their biological diversity or that constitute or may constitute a danger to the environment on which life depends.

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[2] For the purpose of this document, a personal care product is defined as a product that is generally recognized by the public for use in personal cleansing or grooming. Depending on how the product is represented for sale and its composition, personal care products may fall into one of three regulatory categories in Canada: cosmetics, drugs or natural health products

Although human exposure was established as high, the human health hazard for these polymers was concluded to be low. Therefore, on the basis of the risk classification performed in the second phase of polymer rapid screening, it is unlikely that exposure to these substances will pose a human health risk (ECCC, HC 2017).

Based on the information presented in this screening assessment, it is proposed to conclude that the nine poly(amines) do not meet the criteria under paragraph 64(*c*) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is proposed to conclude that the nine poly(amines) do not meet any of the criteria set out in section 64 of CEPA.

Table of Contents

List of Tables

List of Figures

1. Introduction

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment of nine substances referred to collectively as the poly(amines) group to determine whether these substances present or may present a risk to the environment or to human health. The substances in this group were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA (ECCC, HC 2007).

While the nine substances considered in this assessment are collectively referred to as the poly(amines) group, they were further sub-grouped for this risk assessment: two are sub-grouped as poly(DADMAC), three as poly(EDMA) and the remaining four as poly(ASPCA). An initial examination of the physical-chemical properties and chemical structures revealed similarities that would support a group approach to exposure, hazard and risk characterization within each sub-group; thus, their exposure and hazard profiles were collectively assessed for risk.

The substances considered in this assessment have been previously evaluated using a rapid screening approach. The approach and results of its application, are presented in the document “Second Phase of Polymer Rapid Screening: Results of the Draft Screening Assessment” (ECCC, HC 2017). The ecological and human health rapid screening approaches are summarized in appendix 1 of this screening assessment. Application of these approaches identified these nine poly(amines) as having low potential to cause harm to human health; however the need for further evaluation due to potential ecological concern was identified. These results, in conjunction with any other relevant information that became available after the publication of the report on the second phase of polymer rapid screening, are considered in support of the conclusions made under section 64 of CEPA in this screening assessment.

This draft screening assessment includes consideration of additional information on chemical properties, environmental fate, hazard, use and exposure, including additional information submitted by stakeholders. Relevant data were identified up to October 2017. Empirical data from key studies as well as results from models were used to reach proposed conclusions. When available and relevant, information presented in assessments from other jurisdictions was considered.

This draft screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments. The document “Second Phase of Polymer Rapid Screening: Results of the Screening Assessment” has undergone external review and was subject to a 60-day public comment period. While external comments were taken into consideration, the final content and outcome of that screening assessment remain the responsibility of Health Canada and Environment and Climate Change Canada.

This draft screening assessment focuses on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA, by examining scientific information and incorporating a weight of evidence approach and precaution[3]. The draft screening assessment presents the critical information and considerations upon which the proposed conclusion is made.

2. Poly(DADMAC)

2.1 Identity of Substances

The two substances, 2-propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, homopolymer (CAS RN 26062-79-3) and 2-propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, polymer with 2-propenamide (CAS RN 26590-05-6), hereafter referred to as poly(DADMAC) type polymers, are represented by the structures shown in Figure 2.1.

Diallyldimethyl-ammonium chloride (DADMAC) is formed by reacting two equivalents of allyl chloride with dimethylamine. Poly(DADMAC) polymers are prepared by homopolymerization of DADMAC [route (a)], or by reaction of DADMAC with acrylamide [route (b)] (Wilson *et al.* 2002, Jia *et al.* 2017). Two polymeric structures are possible when polymerizing DADMAC: a *N*-substituted piperidine structure or a *N*-substituted pyrrolidine structure. According to the literature, the pyrrolidine structure is favored (John *et al.* 2002, Cotanda *et al.* 2017).

The poly(DADMAC) polymers are high charge density cationic polymers with an expected number average molecular weight (Mn) greater than 10,000 Da and low oligomeric content (Bolto 1995, Bolto and Gregory 2007). The Mn typically falls in the range of hundreds of thousands of daltons, and even up to a million for some products (Edzwald 2011, Canada 2015, ECCC 2015). Poly(DADMAC) polymers are usually delivered as a liquid concentrate having a solids level in the range of 10 to 50% (ECCC 2017, Canada 2015, ECCC 2015).

The exact composition and the degree of substitution for the two poly(DADMAC) polymers were not provided with information submitted in response to a voluntary survey (ECCC 2015) or a mandatory survey under section 71 of CEPA (Canada 2015).

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[3] A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products used by consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

However, the degree of substitution is known to vary depending on the different applications. Therefore, representative information from various sources was considered for the purpose of this assessment.

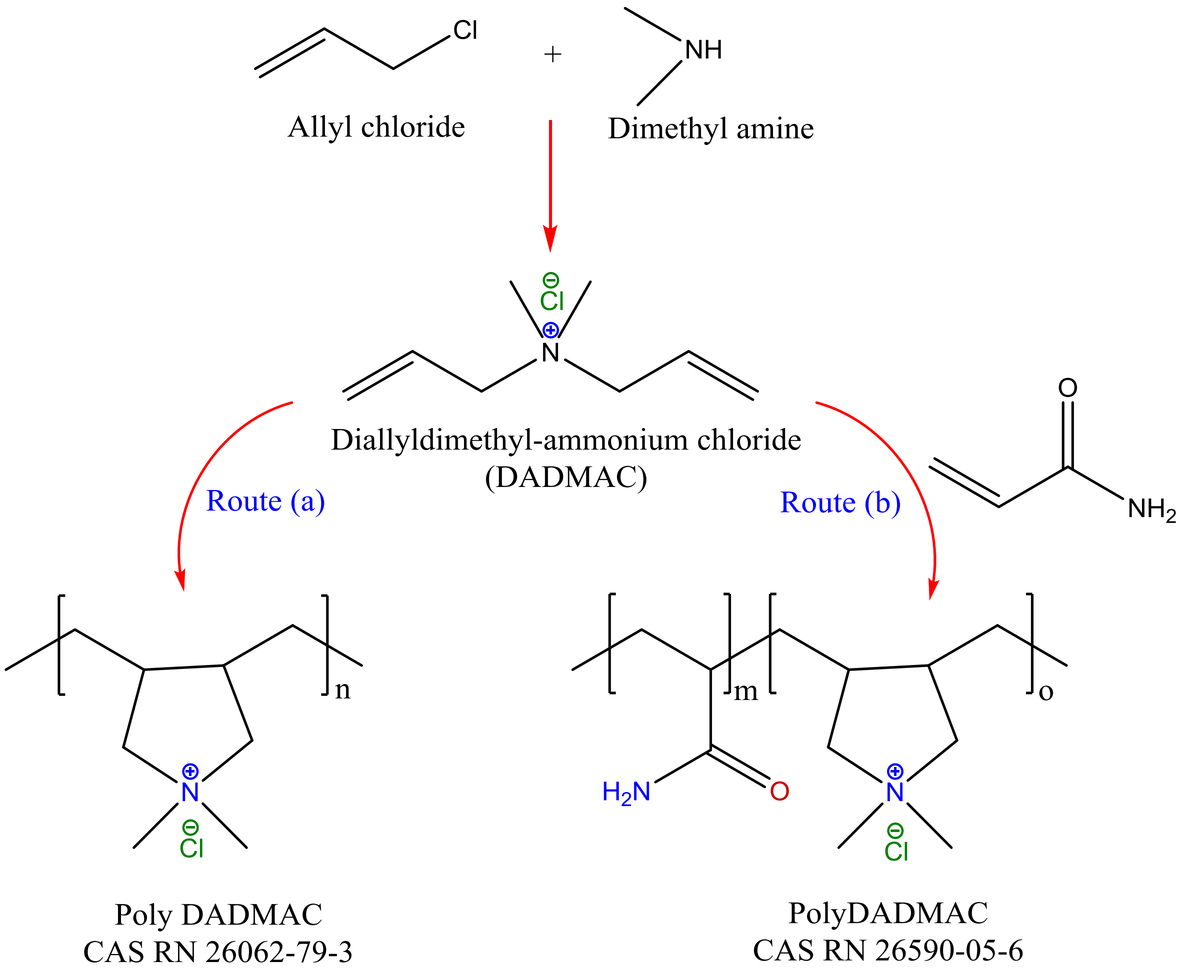


Figure 2-1. Synthesis and representative structures of poly(DADMAC) polymers

Diallyldimethyl-ammonium chloride (DADMAC) is formed by reacting two equivalents of allyl chloride with dimethylamine. The two poly(DADMAC) polymers are prepared by homopolymerization of DADMAC [route (a), CAS RN 26062-79-3], or by reaction of DADMAC with acrylamide [route (b), CAS RN 26590-05-6].

2.2 Physical and Chemical Properties

Table 2-1 presents physical and chemical data obtained for poly(DADMAC) through surveys mentioned earlier. All information reflects summary data provided in safety data sheets (SDS).

Table 2-1. Physical and chemical property values (at standard temperature) for the two poly(DADMAC) polymers.

Corresponding CAS RN	26062-79-3	26590-05-6	Source or Survey References
Physical form	Colorless to light yellow viscous liquid	Clear to light yellow viscous liquid	Canada 2015 ECCC 2015, Wandrey and Jaeger, 1985
Mn[a] (Da)	>10,000	>10,000	ECCC 2017, ECCC 2015, Edzwald 2011, Cumming *et al.* 2011, Bolto and Gregory 2007
Wt % < 1,000 Da[b]	0	0	ECCC 2017, Canada 2015, ECCC 2015
Wt % < 500 Da[c]	0	0	ECCC 2017, Canada 2015, ECCC 2015
Density (g/cm^3)	1.0 to 1.09	1.0 to 1.2	Canada 2015, ECCC 2015
Charge density (mol N$^+$/1,000 g)	6.21	6.10[d]	Cary *et al.* 1987
Water solubility (mg/L)	>1,000	>1,000	Canada 2015, ECCC 2015, Bolto and Gregory 2007, Wilson *et al.* 2002

[a] Number average molecular weight (Mn)
[b] Residual constituents with molecular weights less than 1,000 Da
[c] Residual constituents with molecular weights less than 500 Da
[d] Value estimated based on the representative structure

The properties of the poly(DADMAC) polymers were not modelled using predictive software, since they are expected to have a number average molecular weight of greater than 1,000 Da, which is out of the range where modelling software is considered reliable.

2.3 Sources and Uses

The two poly(DADMAC) polymers do not occur naturally in the environment. They were included in a voluntary survey (ECCC 2015), as well as a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 2-2 presents a summary of the total reported manufacture and import quantities for the substances in 2014. These sources indicate that these polymers are imported into Canada mainly for use as coagulants and flocculants for water treatment, as processing aids in wastewater treatment, and in oil field applications. Minor uses have also been reported in antistatic agents, film formers, hair fixatives and conditioners (personal care products).

Globally, the two poly(DADMAC) polymers are used in wastewater treatment to improve the processes of sludge thickening and dewatering. The substances are also used as coagulants for primary clarification of industrial wastewaters (e.g. colour removal from wastewaters of textile mills, food processing industries, dyestuff industries, etc.) and for primary and secondary clarification of wastewater. The two poly(DADMAC) polymers are also used in the pulp and paper industry as a retention agent (Bolto 2005, OECD 2009). In mining and mineral processing, they are used in treating mineral slurry. They can also be used in treating the oily wastewaters in oil-water separation processes, and as processing aids in petroleum production. The two poly(DADMAC) polymers are used as coagulants in drinking water purification, where they are effective in coagulating and flocculating inorganic and organic particles such as silt, clay, algae, bacteria and viruses (Bolto *et al.* 1999, 2001, Harford *et al.* 2011).

Table 2-2. **Summary of information on Canadian manufacturing and import quantities of poly(DADMAC) polymers in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA**

Substance	Total manufacture[a] (million kg)	Total imports[a] (million kg)	Survey reference
26062-79-3	0	1 to 10	Canada 2015, ECCC 2015
26590-05-6	0	1 to 10	Canada 2015, ECCC 2015

[a] Values reflect quantities reported in response to a voluntary survey (ECCC 2015) and a mandatory survey conducted under section 71 of CEPA (Canada 2015). See mandatory survey for specific inclusions and exclusions (schedules 2 and 3).

2.4 Releases to the Environment

The two poly(DADMAC) polymers are used in water purification processes to coagulate and flocculate particles, aiding their removal from the water (Bolto and Gregory, 2007). They act as coagulants through neutralizing the surface charges of particles (Liber et al., 2005). The two poly(DADMAC) polymers are also flocculants primarily used for the production of drinking water and treatment of wastewater sludge, as well as the reduction of suspended sediment loads of mining effluents. Therefore, they are designed to react with dissolved organic carbon (DOC) and/or suspended solids in water to form neutral insoluble complexes (i.e., floc). The floc then settles out from the water (Boethling and Nabholz 1997, Cumming 2008). With regard to the use of the two poly(DADMAC) polymers in drinking water, wastewater treatment, and oil field applications, if used properly, releases are expected to be negligible, as they rapidly and irreversibly form colloidal solids (floc) with anionic material and become unavailable (ECCC 2017). As shown by Wågberg (2000) and Hubbe (2006) in their review articles, high cationic charge polymers such as poly(DADMAC) bind strongly and permanently within several seconds of contact by electrostatic sorption to anionic material including cellulosic surfaces. The absence of cationic polymers in the bulk water adjacent to cellulosic fibers after their addition at high level to anionic material such as fiber suspensions, has been demonstrated by charge titration of filtrate solutions (Hubbe et *al.* 2003, Lofton et *al.* 2005).

2.5 Environmental Fate and Behaviour

2.5.1 Environmental distribution

The two poly(DADMAC) polymers are water soluble, cationic polymers, with molecular weights greater than 10,000 Da. During industrial use, they are expected to be primarily adsorbed to sludge as mentioned above. If released to the environment, the two poly(DADMAC) polymers are not expected to volatilize into the air compartment as they have high molecular weight and low expected vapour pressure. Considering the high cationic nature of these polymers, it is anticipated that they will rapidly and irreversibly adsorb onto suspended anionic material in rivers or lakes and settle out of the water column to sediments (Wågberg 2000, ECCC 2017).

If released to soil, the resulting polymers would be expected to adsorb strongly onto soil matter and have limited mobility in the soil compartment because of the high cationic charge density. Solubilization of the polymers into soil pore water is expected to be limited, as they are expected to strongly bind to soil particles via electrostatic interaction. Thus, the two poly(DADMAC) polymers are anticipated to be primarily retained in the soil and sediment compartments.

2.5.2 Environmental persistence

Biodegradation data provided through voluntary (ECCC 2015) and mandatory surveys (Canada 2015) are summarized in Table 2-3.

Table 2-3. Biodegradation data for the two poly(DADMAC) polymers

CAS RN	Result	Test Method	Source or Survey Reference
26062-79-3	Not readily biodegradable	NR[a]	ECCC 2015, Canada 2015
26062-79-3	Not inherently biodegradable	OECD 302	SDS 2016a
26590-05-6	Not readily biodegradable	NR[a]	ECCC 2015, Canada 2015

[a] NR: None reported

The biodegradation results for the two poly(DADMAC) polymers show that they are not readily biodegradable.

CAS RN 26062-79-3 has been reported to be not inherently biodegradable according to SDS 2016a. The submission specifies that results are from test protocol OECD 302 but the full report was not provided.

The overall trend shows that these two polymers are not biodegradable.

Although there is no available information to assess the biodegradation potential of the two poly(DADMAC) polymers in sediments, it is generally expected to be slower than in soil or water, where aerobic conditions favour biodegradation. It is therefore anticipated that these two polymers will have lower biodegradation in sediments.

Hydrolysis information for the two poly(DADMAC) polymers was not provided. However, they are used for coagulation, flocculation and other products where they would be formulated with water, thus, hydrolytic stability could be expected.

Padhye *et al.* (2011) have investigated the interactions of ozone with poly(DADMAC) during water treatment at water and wastewater utilities. The study results show that contact with ozone releases N-nitrosodimethylamine (NDMA) but not at significant concentrations.

Considering available information, the two poly(DADMAC) polymers are expected to be stable in the soil, water and sediment compartments.

2.5.3 Bioaccumulation potential

The two poly(DADMAC) polymers are high cationic charge density polymers, which are expected to strongly adsorb to anionic surfaces, such as fish gills, algal cells and negatively charged components of organic particles. This will limit uptake as well as passage of the polymers through biological membranes, but sorption may lead to toxic reactions with dermal tissues. Bioaccumulation potential is therefore expected to be limited (Murgatroyd *et al.* 1996; Cumming 2007, 2008). Furthermore, poly(DADMAC) has a Mn greater than 10,000 Da (i.e., large molecular dimensions) and no significant percentage of low molecular weight constituents. This will further reduce the uptake rate across biological membranes, and is expected to result in a low bioconcentration potential (Arnot *et al.* 2009). Dietary sources (e.g., organic carbon with sorbed substances) are also likely not a route of uptake for bioaccumulation because of the irreversible transformation of the polymer to higher molecular weight substance which is not available to organisms. Data for sediment- and soil-dwelling organisms were not available. However, as for aquatic organisms, bioaccumulation in these media is not expected to be significant.

2.6 Potential to Cause Ecological Harm

2.6.1 Ecological effects assessment

The poly(DADMAC) polymers contain cationic amine functional groups which may be associated with adverse effects to fish, invertebrates, and algae (Boethling and Nabholz 1997, US EPA 2010). Empirical ecotoxicity data for the two polymers were reported in response to the voluntary and mandatory surveys (ECCC 2015, Canada 2015). Many empirical ecotoxicity data for these two polymers were also available in the literature (Cary *et al.* 1987, Cumming *et al.* 2008). The results of ecological studies are summarized in Table 2-4. The data extracted from study reports, safety data sheets (SDS) and summary information provided by stakeholders suggest that the two poly(DADMAC) polymers could have high ecotoxicity to algae and fish and moderate to low toxicity to *Daphnia*. Similar ecotoxicity trends of the two poly(DADMAC) can be seen from a data compilation for cationic polymers published by Boethling and Nabholz (1997) and also from analogue polymers with high degrees of structural similarity that were submitted to the New Substances Notification program. Available ecotoxicity data for the two poly(DADMAC) polymers and various analogues are summarized in Table 2-4.

Table 2-4. Empirical ecotoxicity data for the two poly(DADMAC) polymers

CAS RNs	Organism	Result (mg/L)[a]	Test Method	Source or Survey Reference
26062-79-3	Algae (*C. vulgaris*)	72h EC_{50}=0.16	NR[b]	SDS 2013a
26062-79-3	Algae (*C. vulgaris*)	72 hour NOEC=0.065	NR[b]	SDS 2013a
26590-05-6	Daphnid (*D. magna*)	48h EC_{50}=10-100	OECD 202	SDS 2016c
26062-79-3	Daphnid (*D. magna*)	48h EC_{50}=0.2-100	OECD 202	SDS 2013a SDS 2014a, Cary *et al.* 1987
26062-79-3	Fish (*G. holbrooki*)	96h LC_{50}=0.5	OECD 203	Cumming *et al.* 2008
26062-79-3	Fish (*O. mykiss*)	96h LC_{50}=0.49	NR[b]	SDS 2013a
26062-79-3	Fish (*O. mykiss*)	96 hour NOEC=0.37	NR[b]	SDS 2013a
26062-79-3	Fish (*P. promelas*)	96h LC_{50}=0.46-1.65	NR[b]	SDS 2013a , Cary *et al.* 1987
26062-79-3	Fish (*P. promelas*)	96 hour NOEC=0.15*	NR[b]	SDS 2013a
26590-05-6	Fish (*P. promelas*)	96h LC_{50}=10-100	OECD 203	SDS 2014c, SDS 2015a, SDS 2016b
26062-79-3	Fish (*B. rerio*)	96h LC_{50} = 10 - 100	OECD 203	SDS 2014a, SDS 2016c
26062-79-3	Mysid shrimp	48h LC_{50} = 628.5	NR[b]	SDS 2013a
26062-79-3	Mysid shrimp	48 hour NOEC=125	NR[b]	SDS 2013a

[a] EC_{50} is the effect concentration for 50% of the population; LC_{50} is the lethal concentration for 50% of the population; IC_{50} is the inhibition concentration for 50% of the population; NOEC is the No Observed Effect Concentration.

[b] NR: None reported

*This endpoint was chosen as the critical toxicity value (CTV)

Table 2-5. Ecotoxicity data available for analogues of poly(DADMAC) polymers

Organism	Effect [a]	Result (mg/L)	Sources
Daphnid	48 h EC_{50}	>1[b]	ECCC 2017
Fish[d]	96 h LC_{50}	<1[b]	ECCC 2017
Fish[e]	96 h LC_{50}	0.15-1.18	Boethling and Nabholz 1997[c]

[a] EC_{50} is the effect concentration for 50% of the population; LC_{50} is the lethal concentration for 50% of the population; IC_{50} is the inhibition concentration for 50% of the population.
[b] Analogues identified through the New Substances Notification Program. The identities of the substances are considered to be confidential business information.
[c] Toxicity data reported by Boethling and Nabholz 1997 for cationic polymer with varying degrees of percent amine nitrogen content, molecular weight, location of cation, and amine type (tertiary or quaternary). Values reported are for polymer 46.The specific species tested and the specific molecular structures were unknown.
[d] Three fish species: Rainbow trout (*O. mykiss),* Zebra fish (*B. rerio*) *and carp (C. carpio)*
[e] Fish species unknown.

Poly(DADMAC) polymers have high number average molecular weights (>10,000 Da) that are out of the range where modelling software is generally considered reliable (< 1,000 Da). Thus, ecotoxicity modelling was not conducted.

It is known that the ecotoxicity of polycationic polymers can be mitigated through the presence of organic matter present in the environment (Boethling and Nabholz 1997). According to the authors, toxicity reduction is known to occur by the reaction of polycationics with organic carbon and/or the suspended solids in water to form neutral insoluble complexes (i.e., floc). These authors and several others have therefore proposed that ecotoxicity testing of polycationic polymers using clean laboratory water without the addition of organic carbon may not be representative of the substance’s bioavailability in natural environments (Boethling and Nabholz 1997; Cary *et al.* 1987; Goodrich *et al.* 1991). Boethling and Nabholz (1997) have shown that the addition of approximately 10 mg/L of humic acid to laboratory ecotoxicity tests simulates environmental organic carbon levels.

Cary *et al.* (1987) have studied the effects of suspended solids (bentonite, illite, kaolin and silica) and of dissolved organic carbon compounds (humic, fulvic and tannic acids, lignin and lignosite) on the observed acute toxicity of poly(DADMAC) (CAS RN 26062-79-3) to the fathead minnow *(Pimephales promelas)* and cladoceran (*Daphnia magna*). Bentonite and all of the dissolved organic carbon compounds reduced the toxicities of the polymer by one to two orders of magnitude. On the basis of the study by Cary *et al.* (1987), the acute toxicities of poly(DADMAC) (CAS RN 26062-79-3) will be mitigated by 37 for *Daphnia magna* and by 14 for fathead minnow, all based on addition of 10 mg/L humic acid. Table 2-6 summarizes the toxicity data from this study.

Table 2-6. Acute toxicities and reductions in acute toxicities of poly(DADMAC) (CAS RN 26062-79-3) to Daphnia magna and to fathead minnows in the presence of suspended solids and dissolved organics (Cary *et al.* 1987)

Substrate	Daphnia magna (48h EC_{50}, mg/L)[a]	Mitigation factor for Daphnia magna[b]	Fathead minnow (96h LC_{50}, mg/L)[a]	Mitigation factor for Fathead minnow[b]
Standard laboratory water	0.2	NA	0.46	NA
Bentonite[c]	7.1	36	6.5	14
Illite[c]	1.2	6.0	0.55	1.2
Kaolin[c]	1.1	5.5	0.40	0.87
Silica[c]	0.14	0.70	0.39	0.85
Tannic acid[d]	11.9	59	6.5	14
Lignin[d]	>15.4	>77	3.7	8
Humic acid[d]	7.4	37	6.5	14
Lignosite[d]	7.9	39	3.7	8
Fulvic acid[d]	2.2	11	4.2	9

[a] 48- and 96-h static acute EC_{50} and LC_{50} based on nominal concentrations. EC_{50} is the effect concentration for 50% of the population. LC_{50} is the lethal concentration for 50% of the population
[b] Mitigation factor, estimated on the basis of toxicity, with and without the substrate. This factor reflects the reduction in acute toxicity relative to a standard laboratory water test
[c] Test conducted in presence of 50 mg/L of substrate
[d] Test conducted in presence of 10 mg/L of substrate
NA: Not applicable

A toxicity mitigation factor determined through ecotoxicological testing can be used to correct for the expected reduction in toxicity in the environment due to the presence of organic matter (e.g., humic acids). This is done by multiplying the ecological endpoints determined using clean laboratory water by the expected mitigation factor in order to adjust or reduce the values to reflect actual ecological effects expected under environmental conditions. Therefore, the lowest mitigation value of 14 as reported by Cary *et al.* (1987), is considered to be a reasonable worst case for algae. On the basis of the toxicity data in Table 2.4, Table 2.5 and Table 2.6, the two poly(DADMAC) polymers are anticipated to have low toxicity to daphnid and moderate toxicity to algae and fish after considering thirty seven-fold mitigation for daphnia and fourteen-fold mitigation for fish and algae (see appendix 2 for more detail).

No sediment ecotoxicity data were provided for the two poly(DADMAC) polymers or were otherwise identified. However, Rogers and Witt (1989) have demonstrated that the aquatic toxicity of polycationics is also mitigated when the polymers are mixed with sediment. Available test data with natural sediment contaminated with polycationics and with benthic species that ingest sediment has shown that polycationics with charge densities of greater than 4.2 percent amine-nitrogen (%a-N) are not bioavailable to cause toxicity. The geometric mean of the 48-hr LOEC and the 48-hr NOEC was greater than 100 mg/kg of dry weight sediment, suggesting low concern for toxicity when they partition to sediments.

Overall, the two poly(DADMAC) polymers are expected to show moderate to low toxicity to aquatic organisms and low toxicity to sediment-dwelling species in natural environments. On the basis of available data, the lowest mitigated ecotoxicity endpoint reported for the poly(DADMAC) polymers (fish*:* 96 hour NOEC of 2.1 mg/L, which corresponds to the unmitigated 96 hour NOEC of 0.15 mg/L multiplied by the mitigation factor of 14) was selected as the critical toxicity value (CTV) and is used to estimate the aquatic predicted no effect concentration (PNEC). A PNEC is not considered necessary for sediment species, as the toxicity is anticipated to be greater than 100 mg/L after mitigation.

The aquatic PNEC is derived from the critical toxicity value (CTV), which is divided by an assessment factor (AF) as shown:

$$\text{Aquatic PNEC (mg/L)} = \text{CTV} / \text{AF}$$

An AF of 10 is selected to estimate the aquatic PNEC. The AF selected represents 5 for extrapolation from acute to chronic toxicity, 1 for species sensitivity variation, and 2 for mode of action for cationic polymers. Considering the available ecotoxicity data for the two poly(DADMAC) polymers (more than 7 species, covering 3 categories), a factor of 1 was selected to represent species sensitivity, and 2 for mode of action assuming a non-narcotic mode of action for the two poly(DADMAC) polymers. This results in an aquatic PNEC of 0.21 mg/L (see appendix 2 for more detail).

2.6.2 Ecological exposure assessment

According to the data collected through the voluntary (ECCC 2015) and mandatory surveys (Canada 2015), the two poly(DADMAC) polymers are used as coagulants and flocculants for water and wastewater treatment and as processing aids in oil field applications. During onshore oil field applications, the process water is not usually discarded to a sewer or the aquatic environment. Injection for well stimulation and deep well injection of the process water are the most common methods of disposal in North America (OECD 2012). No data for offshore uses were provided through the conducted surveys. However, the offshore discharges are not expected to result in high environmental concentrations due to high dilution. Based on available information, the two poly(DADMAC) polymers were imported to Canada. Therefore, the exposure scenarios for the manufacturing of the two poly(DADMAC) and their applications in petroleum production are not considered further.

According to the survey data, there are three major poly(DADMAC) uses that can result in releases to the aquatic environment:

1. Drinking water treatment
2. Industrial wastewater treatment
3. Wastewater treatment

Drinking water treatment

Drinking water is produced by treating naturally occurring waters to reduce odour, taste, appearance and sediment to acceptable levels. High cationic charge density polyamines with low to medium molecular weight are widely used as primary coagulants in water treatment applications. The positively charged polymers effectively neutralize negatively charged suspended solids, allowing subsequent agglomeration. As a primary coagulant or a coagulant aid in the clarification of drinking water, organic cationic coagulants can effectively reduce, and in some cases eliminate, the dosage requirements for conventional inorganic coagulants such as aluminum and ferric salts. Polyamines generate substantially smaller amounts of sludge in comparison to the conventional inorganic coagulants. The selection of the appropriate cationic polyelectrolyte and its application rates for drinking water clarification depend on many factors. One of the main factors is water characteristics such as turbidity, acidity and the nature of organic matter and suspended solids. Cary et al. (1987) reports typical treatment rates for raw water supplies of 1 to 10 mg/L. It is expected that most of the applied cationic polymer will rapidly and irreversibly form colloidal solids (floc) with natural impurities in the source water. These impurities present in the source water can be in the form of dissolved and colloidal natural organic matter (NOM), as dissolved salts, and as suspended material such as clays, silica, microbial cells or algae (Bolto and Gregory 2007). The floc ends up in the collected sludge after water clarification processes. It is unlikely that significant quantities of unreacted polymer would be left in the final drinking water if the cationic polyelectrolyte is being used as prescribed for the particular product in use. Attempts to measure detectable levels of these polymers after their use in water treatment applications has not been successful (NAPPA, 2017b). Drinking water with possible polyelectrolyte residues will end up in a wastewater treatment system (WWTS) later in its life cycle (see wastewater treatment section).

Industrial wastewater treatment

Cationic polyamines can be applied as coagulants for industrial wastewater treatment (Rout et al., 1999). They are also widely used by different industries for primary clarification (e.g. colour removal from wastewaters of textile mills, food processing industries, dyestuff industries), and for thickening and dewatering of industrial sludge. Cary et al. (1987) reports typical treatment rates of 10 to 100 mg/L for wastewater clarification applications and 100 to 1,000 mg/L for sludge conditioning and thickening processes. NAPPA (2017a) states that these substances behave differently in different types of water with different solids or organic content. No quantitative data on potential unreacted polymer residues in industrial waste waters have been identified. The majority of industrial wastewater effluents are discharged to WWTS, where any unreacted polymer residues will be further removed by binding with dissolved organic matter, suspended solids and other negatively charged colloidal material. However, non-contact process waters (e.g. cooling water) could be discharged directly to the aquatic environment by industries. In the case where the application rate has not been selected correctly and the overdosing of polymers can occur, unreacted polymer residues may remain in the non-contact process waters. Based on communication with

NAPPA (2017b), and data collected through the New Substances Program (ECCC 2017), non-contact process waters from polycationic polymers are usually re-circulated numerous times before discharge and any potential polymers residues will be bound with other negatively charged colloids that are added to non-contact waters for treatment (e.g. antiscalants). If not, any unreacted polymer residues which reach the aquatic environment are not expected to be bioavailable because they rapidly and irreversibly form colloidal solids (floc) with anionic materials in receiving water.

Wastewater treatment

Cationic, water soluble polyelectrolytes are used extensively in WWTS primarily to improve the processes of sludge thickening and dewatering. Cationic polyelectrolytes are also used as flocculants in primary and secondary sedimentation basins (Flock and Rausch, 1973). Flock and Rausch (1973) reported cationic polyelectrolytes dosages from 1 mg/L to 50 mg/L for conventional primary treatment and 5 mg/l for secondary sedimentation basin. The authors concluded that cationic polyelectrolytes are uneconomical for primary treatments as they generally require higher treatment dosages than anionic polymers. Cationic polyelectrolytes have the greatest flexibility and can considerably improve the overall removal efficiency in secondary sedimentation basins with lower dosages. NAPPA (2017a) has indicated primary clarification as the main application at WWTS for the nine polyamines in the group, and provided a realistic maximum use level of 5 mg active polymer per liter. Cary et al. (1987) reports typical treatment rates of 10 to 100 mg/L for wastewater clarification applications and 100 to 1,000 mg/L for sludge conditioning and thickening processes. It can be concluded that different application rates are employed at wastewater treatment plants. The polymer and its dosage selection are based on the wastewater characteristics, including suspended solids and dissolved organic matter content. Dentel (2000) analyzed polymer fate in wastewater treatment facilities based on hydrogen (proton) nuclear magnetic resonance (^{1}H NMR) measurements from laboratory experiments and plant samples. The results provided strong evidence that virtually all polymers leave the treatment facility with the dewatered biosolids rather than in the treated effluent. Spreadsheet evaluation of a variety of scenarios showed that only exceptional overdoses of polymer or failure to achieve a reasonable solids recovery would divert some polymer to recirculated flows (Dentel, 2000). In such cases, any unreacted polymer residues are not expected to be bioavailable because they rapidly and irreversibly form colloidal solids (floc) with anionic materials within the WWTS facilities or in receiving waters (Hubbe et *al.* 2003, Lofton et *al.* 2005). In summary, the use of polycationic amine polymers in wastewater and biosolids treatment combines them with anionic colloidal solids. As supported by data collected throughout the New Substances Program, there is low likelihood of environmental toxic effects due to polymer release with either treated effluent or biosolids (ECCC 2017).

2.6.3 Characterization of ecological risk

The approach taken in this ecological risk assessment was to examine direct and supporting information and develop conclusions based on a weight-of-evidence approach. Lines of evidence considered include information on sources and fate of the substance, persistence, bioaccumulation, ecological hazard properties and potential for environmental exposure.

The two poly(DADMAC) polymers are mainly used as coagulants and flocculants for water and wastewater treatment and as processing aids in oil field applications. Based on the survey data, the quantity imported into Canada in 2014 was up to 10 million kg/year.

Water solubility information reported for the two poly(DADMAC) polymers indicates that they are highly water soluble. When released into the environment partitioning into the air compartment is not expected because of the high molecular weight. Furthermore, significant amounts are anticipated to adsorb onto dissolved organic matter and settle both within the treatment systems and in the environment if any residual is released.

With respect to long term persistence of these polymers, available biodegradation data for the two poly(DADMAC) polymers suggest that they will not be biodegradable in the environment. Other information on transformative properties suggests these polymers are not hydrolyzable. This is consistent with the absence of readily hydrolyzable groups in the two representative polymer structures.

All empirical data used to assess the bioaccumulation potential support the low bioaccumulation potential of the two poly(DADMAC) polymers for aquatic organisms.

According to the ecological hazard profile of the two poly(DADMAC) polymers, they generally have low toxicity to daphnid and moderate toxicity to algae and fish after considering mitigation by dissolved organic carbon (DOC) which reduces their bioavailability.

No significant residual polymer is expected to remain in the water column resulting from appropriate application as a flocculant in drinking water, industrial wastewater and wastewater treatment. In the event of overdosing when being added to wastewater as a flocculant, any unreacted polymer residues which reach the aquatic environment are not expected to be bioavailable because they rapidly and irreversibly form colloidal solids (floc) with anionic materials in water. As insignificant releases to surface waters are expected from the proper use of the two poly(DADMAC) polymers, a predicted environmental concentration (PEC) has not been derived. Overall, the two poly(DADMAC) polymers are not expected to result in ecological concern based on available information and assumption that significant overdosing of waters being treated is avoided.

2.7 Potential to Cause Harm to Human Health

Classification of the hazard data and exposure profiles used to develop the potential for human health risks associated with the two poly(DADMAC) are presented in the document ‘Supporting Documentation: Final Risk Matrix Location of Polymers’ (Health Canada 2017).

After surveying substance use patterns, it was concluded that exposure to general population was potentially high (see Appendix 1). However, the human health hazard for the two poly(DADMAC) was determined to be low. Therefore, taking into consideration the available data, it is unlikely that exposure to the substance will pose a human health risk (ECCC, HC 2017).

3. Poly(EDMA)

3.1 Identity of Substance

The substances, methanamine, N-methyl-, polymer with (chloromethyl)oxirane (CAS RN 25988-97-0); 1,2-ethanediamine, polymer with (chloromethyl)oxirane and N-methylmethanamine (CAS RN 42751-79-1) and methanamine, N-methyl-, polymer with ammonia and (chloromethyl)oxirane (CAS RN 52722-38-0), hereafter referred to as poly(EDMA) polymers, are represented by the structures shown in Figure 3.1.

Epichlorohydrin-dimethylamine (EDMA) is formed by reacting epichlorohydrin with dimethylamine. The poly(EDMA) polymers are prepared by homopolymerization of EDMA [route (a)], by reaction of EDMA with 1,2-ethanediamine [route (b)], or by reaction of EDMA with ammonia [route (c)] (Vorchheimer 1981, Choi et *al.* 2001). These polymers are usually mixtures of isomers. However, no residual monomers (epichlorohydrin, dimethylamine, 1,2-ethanediamine and ammonia) are expected to remain as these processes involve several purification stages to remove all impurities (Chen and Tu 2017, Choi et *al.* 2001).

Poly(EDMA) polymers are high charge density cationic polymers with an expected number average molecular weight (Mn) greater than 10,000 Da and low oligomeric content (Bolto *et al.* 1998). The Mn are typically in the range of hundreds of thousands of daltons, and even up to a million for some products (Yue et *al.* 2008, Canada 2015, ECCC 2015). The poly(EDMA) polymers are usually imported as a liquid concentrate having a solids level in the range of 10 to 50% (ECCC 2017, Canada 2015, ECCC 2015).

The exact composition and the degree of substitution for poly(EDMA) polymers were not provided with the information submitted through a voluntary survey (ECCC 2015) or a mandatory survey under section 71 of CEPA (Canada 2015). However, the degree of substitution is known to vary depending on the application. Therefore, representative information from various sources was considered for the purpose of this assessment.

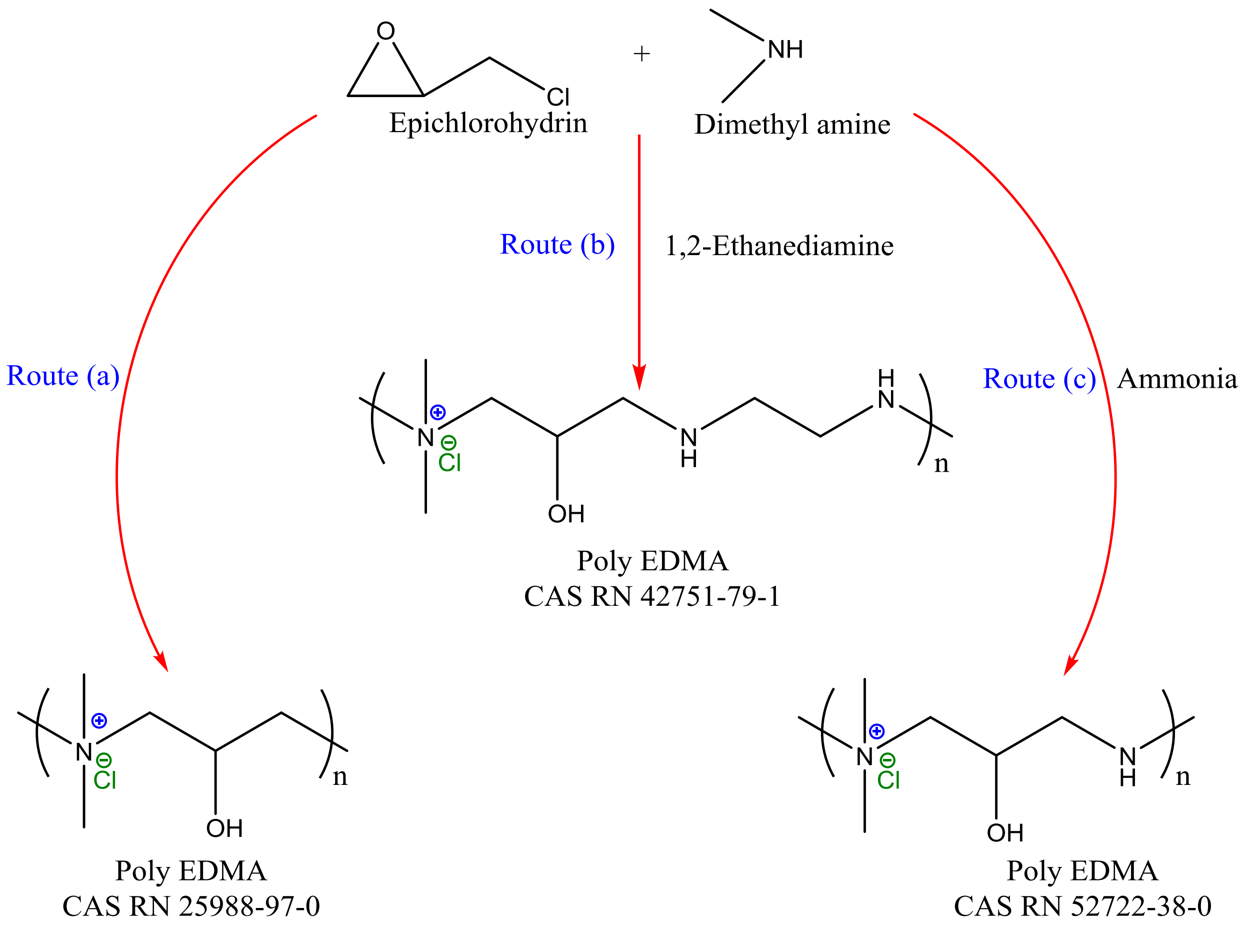


Figure 3-1. Synthesis and representative structure of poly(EDMA) polymers

Epichlorohydrin-dimethylamine (EDMA) is formed by reacting epichlorohydrin with dimethylamine. The three poly(EDMA) polymers are prepared by homopolymerization of EDMA [route (a), CAS RN 25988-97-0], by reaction of EDMA with 1,2-ethanediamine [route (b), CAS RN 42751-79-1], or by reaction of EDMA with ammonia [route (c), CAS RN 52722-38-0].

3.2 Physical and Chemical Properties

Table 3-1 presents physical and chemical data obtained for poly(EDMA) polymers through surveys mentioned earlier. All information reflects summary data provided in safety data sheets (SDS).

Table 3-1. Physical and chemical property values (at standard temperature) for poly(EDMA) polymers

Corresponding CAS RN	25988-97-0	42751-79-1	52722-38-0	**Source or Survey References**
Physical form	Blueish liquid	Colorless to amber liquid	Clear to light yellow liquid	Canada 2015 ECCC 2015
Mn[a] (Da)	>10,000	>10,000	>10,000	ECCC 2017, Canada 2015, ECCC 2015, Edzwald 2011, Cumming *et al.* 2011, Cary *et al.* 1987
Wt % < 1.000 Da[b]	0	0	0	ECCC 2017, Canada 2015, ECCC 2015
Wt % < 500 Da[c]	0	0	0	ECCC 2017, Canada 2015, ECCC 2015
Density (g/cm^3)	1.34	1.1 to 1.2	1.0 to 1.2	Canada 2015, ECCC 2015
Charge density (mol N^+/1,000 g)	7.3	22.07[d]	19.02[d]	Cary *et al.* 1987
Water solubility (mg/L)	>1,000	>1,000	>1,000	Canada 2015, ECCC 2015, Bolto and Gregory 2007; Wilson *et al.* 2002

[a] Number average molecular weight (Mn)
[b] Residual constituents with molecular weights less than 1,000 Da
[c] Residual constituents with molecular weights less than 500 Da
[d] Value estimated based on the representative structure

Properties of the poly(EDMA) polymers were not modelled using predictive software, since they are expected to have a number average molecular weight of greater than 1,000 Da, which is out of the range where modelling software is considered reliable.

3.3 Sources and Uses

The poly(EDMA) polymers do not occur naturally in the environment .They have been included in a voluntary survey (ECCC 2015) as well as a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 3-2 presents a summary of the total reported manufacture and import quantities for these substances in 2014. These sources indicate that these polymers are imported to Canada to be mainly used as coagulants and flocculants for water treatment, and as processing aids in wastewater treatment, oil and natural gas extraction, and in the pulp and paper industry.

Globally, poly(EDMA) polymers are used in wastewater effluent treatments to improve the processes of sludge thickening and dewatering. The substances are also used as coagulants for primary clarification of industrial wastewaters (e.g. colour removal from wastewaters of textile mills, food processing industries, dyestuff industries, etc.) and for primary and secondary clarification of wastewaters. Poly(EDMA) polymers are also used in the pulp and paper industry as retention agents (Bolto 2005, OECD 2009). In mining and mineral processing, they are used in treating mineral slurry. Poly(EDMA) polymers also can be used in oil-water separation processes, and as processing aids in petroleum production. These polymers are also used as coagulants in drinking water purification where they are effective in coagulating and flocculating inorganic and organic particles such as silt, clay, algae, bacteria and viruses (Edzwald 2011; Goodrich 1991).

Table 3-2. Summary of information on Canadian manufacturing and import quantities of poly(EDMA) polymers in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA

Substance	Total manufacture[a] (million kg)	Total imports[a] (million kg)	Survey reference
25988-97-0	0	1 to 10	Canada 2015, ECCC 2015
42751-79-1	0	1 to 10	Canada 2015, ECCC 2015
52722-38-0	0	0.1 to 1	Canada 2015, ECCC 2015

[a] Values reflect quantities reported in response to a voluntary survey (ECCC 2015) and a mandatory survey conducted under section 71 of CEPA (Canada 2015). See mandatory survey for specific inclusions and exclusions (schedules 2 and 3).

3.4 Releases to the Environment

As explained in Section 2.4 and considering the use of the three poly(EDMA) polymers in water and wastewater treatment, oil field applications and pulp and paper industry, if used properly, releases are expected to be negligible, as they rapidly and irreversibly form colloidal solids (floc) with anionic material and become unavailable.

3.5 Environmental Fate and Behaviour

3.5.1 Environmental distribution

The three poly(EDMA) polymers are water soluble cationic polymers, with molecular weight greater than 10,000 Da. As explained in Section 2.5.1, the three poly(EDMA) polymers are expected to be primarily adsorbed onto sludge and anticipated to be primarily retained in the soil and sediment compartments.

3.5.2 Environmental persistence

Biodegradation data provided through voluntary (ECCC 2015) and mandatory surveys (Canada 2015) are summarized in table 3-3.

Table 3-3. Biodegradation data for the three poly(EDMA) polymers

CAS RN	Result	Test Method	Source or Survey Reference
25988-97-0	Not readily biodegradable	OECD 301 B	ECCC 2015, Canada 2015
42751-79-1	< 60 % degradation in 28 days[b]	OECD 301 B	SDS 2017
52722-38-0	Not readily biodegradable	NR[a]	ECCC 2015, Canada 2015

[a] NR: None reported

[b] CO_2 Evolution (Modified Sturm Test) for a formulation

The biodegradation results for the three poly(EDMA) polymers show that they are not readily biodegradable.

Although there is no available information to assess the biodegradation potential of the three poly(EDMA) polymers in sediments, it is generally expected to be slower than in soil or water, where aerobic conditions favour biodegradation. It is therefore anticipated that the three polymers will have lower biodegradation in sediments.

Hydrolysis information for the three poly(EDMA) polymers was not provided. However, they are used for coagulation, flocculation and other products where they would be formulated with water, thus, hydrolytic stability could be expected.

Considering available information, the three poly(EDMA) polymers are expected to be stable in the soil, water and sediment compartments.

3.5.3 Bioaccumulation potential

The three poly(EDMA) polymers have high cationic charge density (7.3-22.1%), Mn greater than 10,000 Da (i.e., large molecular dimensions) and no significant percentage of low molecular weight constituents. Overall, the bioaccumulation of these three polymers in water, soil and sediment is expected to be low. This assessment is based on the same considerations for poly(DADMAC) which were examined in Section 2.5.3, namely: 1) strong adsorption to anionic surfaces which results in low availability of these polymers in the environment; 2) the absence of bioaccumulative material due to high Mn and no oligomer content; and 3) low potential for uptake through dietary consumption due to high Mn and non-lipophilic affinity.

3.6 Potential to Cause Ecological Harm

3.6.1 Ecological effects assessment

The poly(EDMA) polymers contain cationic amine functional groups as shown earlier in the representative structures. Substances containing cationic amine or potentially cationic amine functional groups may be associated with adverse effects to fish, invertebrates, and algae (Boethling and Nabholz 1997, US EPA 2010). Empirical ecotoxicity data for the three poly(EDMA) polymers were reported in response to the surveys mentioned previously (ECCC 2015, Canada 2015). Many empirical ecotoxicity data for the three polymers were also available in the literature (Cary *et al.* 1987, Cumming *et al.* 2008, Goodrich *et al.* 1991). The results of ecological studies are summarized in Table 3-4. The data extracted from study reports, safety data sheets (SDS) and summary information provided by stakeholders suggest that the three poly(EDMA) polymers could have high ecotoxicity to daphnid and fish and moderate toxicity to algae. Similar ecotoxicity trends for the three poly(EDMA) can be seen from a data compilation for cationic polymers published by Boethling and Nabholz (1997) and also from analogue polymers with high degree of structural similarity that were submitted to the New Substances Notification program. Available ecotoxicity data for the three poly(EDMA) and various analogues are summarized in Table 3-5.

Table 3-4. Empirical ecotoxicity data for the three poly(EDMA) polymers

CAS RNs	Organism	Result (mg/L)[a]	Test Method	Sources or Surveys Reference
42751-79-1	Green algae	72h EC_{50}=10-100	OECD 201	SDS 2010, SDS 2013d, SDS 2014d
42751-79-1	Daphnid (*D. magna*)	48h EC_{50}=10-100	OECD 202	SDS 2010, SDS 2013d, SDS 2014d
42751-79-1	Daphnid (*D. magna*)	NOEC=0.04	OECD 202	SDS 2014e
42751-79-1	Daphnid (Ceriodaphnia)	48h EC_{50}=0.17	OECD 202	SDS 2014e
25988-97-0	Daphnid (*D. magna*)	48h EC_{50}=0.08	OECD 202	Cary *et al.* 1987
25988-97-0	Daphnid (*D. magna*)	48 hour NOEC=1.56		SDS 2016e
25988-97-0	Fish (*L. macrochirus*))	96h LC_{50}=0.18	OECD 203	Cary *et al.* 1987
25988-97-0	Fish (*L. macrochirus)*	96 hour NOEC= 0.625	OECD 203	SDS 2016e, Cary *et al.* 1987
25988-97-0	Fish (*P. promelas*)	96h LC_{50}=0.25	NR[b]	Cary *et al.* 1987
25988-97-0	Fish (*O. mykiss*)	96h LC_{50}=0.59-1.49	NR[b]	SDS 2016e, Goodrich *et al.* 1991
25988-97-0	Fish	96 hour NOEC=0.625	NR[b]	SDS 2016e, Goodrich *et al.* 1991

CAS RNs	Organism	Result (mg/L)[a]	Test Method	Sources or Surveys Reference
	(*O. mykiss*)			
25988-97-0	Fish (*B. rerio*)	96h LC_{50} > 10	OECD 203	SDS 2016f
42751-79-1	Fish (*O. mykiss*)	96h LC_{50}=0.16*	OECD 203	SDS 2014e
42751-79-1	Fish (*O. mykiss*)	96-hour NOEC=0.1	OECD 203	SDS 2014e
42751-79-1	Fish (*L. macrochirus)*	96h LC_{50}=0.39	OECD 203	SDS 2014e, SDS 2017
42751-79-1	Fish (*L. macrochirus)*	NOEC=0.24	OECD 203	SDS 2014e, SDS 2017
42751-79-1	Fish (*P. promelas*)	96h LC_{50}=0.67	OECD 203	SDS 2014e, SDS 2017
42751-79-1	Fish (*P. promelas*)	96-hour NOEC=0.31	OECD 203	SDS 2014e, SDS 2017
42751-79-1	Fish (*B. rerio*)	96h LC_{50}=10-100	OECD 203	SDS 2010, SDS 2013d, SDS 2014d
42751-79-1	Mysid shrimp	48h LC_{50} = 2500	NR[b]	SDS 2013c

[a] EC_{50} is the effect concentration for 50% of the population; LC_{50} is the lethal concentration for 50% of the population; IC_{50} is the inhibition concentration for 50% of the population; NOEC is the No Observed Effect Concentration. These results are without mitigation.

[b] NR: None reported

*This endpoint was chosen as the critical toxicity value (CTV)

Table 3-5. Ecotoxicity data available for analogues of poly(EDMA) polymers

Organism	Effect [a]	Result (mg/L)	Sources
Green algae	96h EC_{50}	0.16	Boethling and Nabholz 1997[c]
Daphnid	48 h EC_{50}	<1[b]	ECCC 2017
Daphnid	48 h EC_{50}	0.34	Boethling and Nabholz 1997[c]
Fish[d]	96 h LC_{50}	<1[b]	ECCC 2017
Fish[e]	96 h LC_{50}	0.13	Boethling and Nabholz 1997[c]
Fish (*O. mykiss*)	96 h LC_{50}	0.27 – 0.78	Goodrich et *al.* 1991

[a] EC_{50} is the effect concentration for 50% of the population; LC_{50} is the lethal concentration for 50% of the population; IC_{50} is the inhibition concentration for 50% of the population.

[b] Analogues identified through the New Substances Notification Program. The identities of the substances are considered to be confidential business information.

[c] Toxicity data reported by Boethling and Nabholz 1997 for cationic polymer with varying degrees of percent amine-nitrogen content, molecular weight, location of cation, and amine type (tertiary or quaternary). Values reported are for polymer 49.The specific species tested and the specific molecular structures were unknown.

[d] Four fish species: Rainbow trout (*O. mykiss),* Zebra fish (*B. rerio*), Fathead minnow (*P. promelas*) *and carp (C. carpio)*

[e] Fish species unknown.

The poly(EDMA) polymers have high number average molecular weights (>10,000 Da) and are out of the range where modelling software is generally considered reliable (< 1,000 Da). Thus, ecotoxicity modelling was not conducted.

As mentioned in the Ecological Effects Assessment for poly(DADMAC) polymers (Section 2.6.1), ecotoxicity of polycationic polymers are mitigated through the presence of organic matter present in natural environment. Considering that the three poly(EDMA) are polycationic polymer, similar mitigation of ecotoxicity would be expected.

Cary *et al.* (1987) have studied the effects of suspended solids (bentonite, illite, kaolin and silica) and of dissolved organic carbon compounds (humic, fulvic and tannic acids, lignin and lignosite) on the observed acute toxicities of poly EDMA (CAS RN 25988-97-0) to the fathead minnow *(Pimephales promelas)* and cladoceran (*Daphnia magna*). Bentonite and all of the dissolved organic carbon compounds reduced the toxicities of the polymer by one to two orders of magnitude. On the base of the study by Cary *et al.* (1987), the acute toxicities of poly EDMA (CAS RN 25988-97-0) will be mitigated by 63 for *Daphnia magna* and by 16 for fathead minnow, all based on addition of 10 mg/L humic acid. Table 3-6 summarizes the toxicity data from this study.

Table 3-6. Acute toxicities and reductions in acute toxicities of poly(EDMA) (CAS RN 25988-97-0) to Daphnia magna and to fathead minnows in the presence of suspended solids and dissolved organics (Cary *et al.* 1987)

Substrate	Daphnia magna (48h EC_{50}, mg/L)[a]	Mitigation factor for Daphnia magna[b]	Fathead minnow (96h LC_{50}, mg/L)[a]	Mitigation factor for Fathead minnow[b]
Standard laboratory water	0.08	NA	0.25	NA
Bentonite[c]	6.0	75	6.5	26
Illite[c]	0.95	6.9	0.95	3.8
Kaolin[c]	0.90	11	0.65	2.6
Silica[c]	0.12	1.5	0.42	1.7
Tannic acid[d]	8.0	100	6.5	26
Lignin[d]	4.0	50	3.5	14
Humic acid[d]	5.0	63	4.0	16
Lignosite[d]	4.7	59	3.8	15
Fulvic acid[d]	3.8	48	3.8	15

[a] 48- and 96-h static acute EC_{50} and LC_{50} based on nominal concentrations. EC_{50} is the effect concentration for 50% of the population. LC_{50} is the lethal concentration for 50% of the population
[b] Mitigation factor, estimated on the basis of toxicity, with and without the substrate. This factor reflects the reduction in acute toxicity relative to a standard laboratory water test
[c] Test conducted in presence of 50 mg/L of substrate
[d] Test conducted in presence of 10 mg/L of substrate
NA: Not applicable

A toxicity mitigation factor determined through ecotoxicological testing can be used to correct for the expected reduction in toxicity in the environment due to the presence of organic matter. This is done by multiplying the ecological endpoints determined using clean laboratory water by the expected mitigation factor in order to adjust or reduce the values to reflect actual ecological effects expected under environmental conditions. Based on the reported mitigation factors above, the lowest mitigation value of 16 as reported by Cary *et al.* (1987) is considered to be a reasonable worst case for algae. On the basis of the toxicity data in Table 3.4, Table 3.5 and Table 3.6, the three poly(EDMA) polymers are anticipated to have moderate toxicity to algae, daphnid and fish after considering sixty three-fold mitigation for daphnia and sixteen-fold mitigation fish and algae.

No sediment ecotoxicity data were provided for the two poly(EDMA) polymers or were otherwise identified. However, Rogers and Witt (1989) have demonstrated that the aquatic toxicity of polycationics is also mitigated when the polymers are mixed with sediment. Available toxicity test data with natural sediment contaminated with polycationics and with benthic species that ingest sediment has shown that polycationics with charge densities of greater than 4.2 %a-N are not bioavailable to cause toxicity. The geometric mean of the 48-hr LOEC and the 48-hr NOEC was greater than 100 mg/kg of dry weight sediment, suggesting low concern for toxicity when they are transported to sediments.

Overall, the three poly(EDMA) polymers are expected to show moderate toxicity to aquatic organisms and low toxicity to sediment-dwelling species in natural environments. On the basis of available data, the lowest mitigated ecotoxicity endpoint reported for the three poly EDMA (Fish, *O. mykiss*: 96 h LC_{50} of 2.56 mg/L, which corresponds to the unmitigated 96 h LC_{50} of 0.16 mg/L multiplied by the mitigation factor of 16) was selected as the critical toxicity value (CTV) and is used to estimate the aquatic predicted no effect concentration (PNEC). A PNEC is not considered necessary for sediment species, as the toxicity is anticipated to be greater than 100 mg/L after mitigation.

The aquatic PNEC is derived from the critical toxicity value (CTV), which is divided by an assessment factor (AF) as shown:

$$\text{Aquatic PNEC (mg/L)} = \text{CTV} / \text{AF}$$

An AF of 20 is selected to estimate the aquatic PNEC. The AF selected represents 10 for extrapolation from acute to chronic toxicity, 1 for species sensitivity variation, and 2 for mode of action for cationic polymers. Considering the available ecotoxicity data for the three poly(EDMA) polymers (more than 7 species, covering 3 categories), a factor of 1 was selected to represent species sensitivity, and 2 for mode of action assuming a non-narcotic mode of action for the three poly(EDMA) polymers. This results in an aquatic PNEC of 0.128 mg/L (see appendix 3 for more detail).

3.6.2 Ecological exposure assessment

According to the data collected through the voluntary (ECCC 2015) and mandatory surveys (Canada 2015), the three poly(EDMA) polymers are used as coagulants and flocculants for water treatment, and as processing aids in wastewater treatment, oil and natural gas extraction, and in the pulp and paper industry. Based on available information, the three poly(EDMA) polymers were imported to Canada. As explained in Section 2.6.2, the exposure scenarios for the manufacturing of the three poly(EDMA) polymers and their applications in petroleum production are not considered because they are not expected to result in significant environmental concentrations.

According to the survey data, there are four major poly(EDMA) polymers uses that can result in releases to the aquatic environment:

1. Drinking water treatment
2. Industrial wastewater treatment
3. Wastewater treatment
4. Processing aid in pulp and paper industry

The qualitative scenarios for drinking water treatment, industrial wastewater treatment and wastewater treatment were already discussed in Section 2.6.2. Therefore, only the qualitative scenario for processing aid in pulp and paper industry is discussed in this section.

Processing aid in pulp and paper industry

Papermakers use water-soluble polymer flocculants (1) to improve retention within the sheet of fiber fines, inorganic filler and other small particulate matter, and (2) to improve paper machine drainage/dewatering during the papermaking operation (Foster, 1973). According to the data collected through the voluntary (ECCC 2015) and mandatory surveys (Canada 2015), the three poly(EDMA) polymers are used to control the build-up of pitch, ink, and adhesives on paper machine wires, foils and press rolls. Foster (1973) reports that generally, for any given polymer, larger amounts need to be added for drainage improvement than for retention improvement. The application rates for retention are usually in the range of 0.01% to 0.05%, based on dry paper solids and dry polymer solids. When used as drainage aids, addition levels are in the range of 0.03% to about 0.20% (Foster, 1973). In addition, cationic polyamines are used for removing colour from discoloured wastewater at pulp and paper mills.

High cationic charge polymers are designed to adsorb onto suspended matter such as fibers in the papermaking process or organic matter in wastewater. Adsorption is instantaneous and irreversible (Wågberg 2000, Hubbe 2006). The products are dosed in such a manner that there is no excess polymer, as overcharging the system would result in a dispersion of fibres. Using Particle Charge Detection, an industry recognized analytical technique, it has been shown that potential levels of unreacted high cationic charge polymers in the white water will be extremely low or non-existent (Hubbe et *al.*

2003, Lofton et *al.* 2005). Moreover, pulp and paper mill effluents are treated by primary and/or secondary wastewater treatment facilities that are very effective in the removal of cationic polymers before discharge. Primary treatment usually involves sedimentation by gravity and assisted by premixing the incoming wastewater stream with coagulating chemicals. Essentially, the entire cationic polymer present in the incoming effluent ends up in the primary sludge. Secondary wastewater treatment systems at typical paper mill sites employ bacterial sludge to further purify the water that comes from the primary treatment stage. The bacteria produce various enzymes capable of hydrolyzing cationic polymers. The other efficient way in which secondary treatment removes cationic polymers is by adsorption of the polymer into the biological sludge. Cationic polymers adsorb strongly onto anionic material so that the efficiency of their incorporation into biological sludge is very high, leaving essentially none in the water to be discharged (Möbius and Cordes-Tolle 1999, Wågberg 2000). Therefore, conventional papermaking operations are not expected to result in measurable discharge of highly cationic, high Mn polymers, into the treated outfall from paper manufacturing system.

3.6.3 Characterization of ecological risk

The approach taken in this ecological risk assessment was to examine direct and supporting information and develop conclusions based on a weight-of-evidence approach. Lines of evidence considered include information on sources and fate of the substance, persistence, bioaccumulation, ecological hazard properties and potential for environmental exposure.

The three poly(EDMA) polymers are mainly used as coagulants and flocculants for water treatment, wastewater treatment, oil field applications, and in the pulp and paper industry. Based on the survey data, the quantity imported into Canada in 2014 was up to 10 million kg/year.

Water solubility information reported for the three poly(EDMA) polymers indicates they are highly water soluble. When released into the environment, partitioning into the air compartment is not expected because of the high molecular weight. Furthermore, significant amounts are anticipated to adsorb onto dissolved organic matter and settle both within the treatment systems and in the environment if any residual is released.

With respect to long term persistence of these polymers, available biodegradation data for the three poly(EDMA) polymers suggest that they will not be biodegradable in the environment. Other information on transformative properties suggests these polymers are not hydrolyzable. This is consistent with the absence of readily hydrolyzable groups in the three representative polymer structures.

All empirical data used to assess the bioaccumulation potential support the low bioaccumulation potential of the three poly(EDMA) polymers for aquatic organisms.

According to the ecological hazard profile of the two poly(DADMAC) polymers, they generally have moderate toxicity to algae, daphnid and fish after considering mitigation by dissolved organic carbon which reduces their bioavailability.

No significant residual polymer is expected to remain in the water column resulting from appropriate application as a flocculant in drinking water, industrial wastewater, wastewater treatment, oil field applications, and in the pulp and paper industry. In the event of overdosing when being added to wastewater as a flocculant, any unreacted polymer residues which reach the aquatic environment are not expected to be bioavailable because they rapidly and irreversibly form colloidal solids (floc) with anionic materials in water. As insignificant releases to surface waters are expected from the proper use of the three poly(EDMA) polymers, a predicted environmental concentration (PEC) has not been derived. Overall, the three poly(EDMA) polymers are not expected to result in ecological concern based on available information and assumption that significant overdosing of waters being treated is avoided.

3.7 Potential to Cause Harm to Human Health

Classification of the hazard data and exposure profiles used to develop the potential for human health risks associated with the three poly(EDMA) are presented in the document ‘Supporting Documentation: Final Risk Matrix Location of Polymers’ (Health Canada 2017).

After surveying substance use patterns, it was concluded that exposure to general population was moderate (see Appendix 1). However, the human health hazard for the two poly(EDMA) was determined to be low. Therefore, taking into consideration the available data, it is unlikely that exposure to the substance will pose a human health risk (ECCC, HC 2017).

4. Poly(ASPCA)

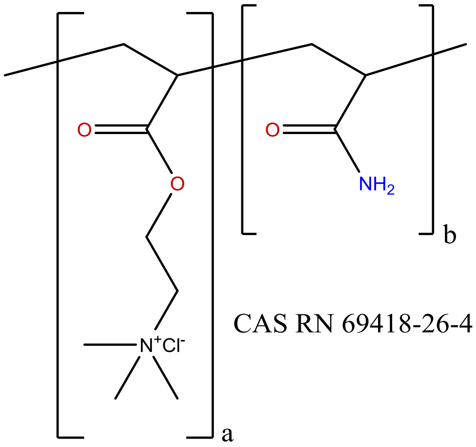
4.1 Identity of Substances

The substances, ethanaminium, N,N,N-trimethyl-2-[(1-oxo-2-propenyl)oxy]-, chloride, polymer with 2-propenamide (CAS RN 69418-26-4); aziridine, homopolymer, ethoxylated (CAS RN 68130-99-4); urea, polymer with ammonia and formaldehyde (CAS RN 27967-29-9), and 2-oxepanone, polymer with (chloromethyl)oxirane, N-(1,3-dimethylbutylidene)-N’-[2-[(1,3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine, 2-(methylamino)ethanol, 4,4’-(1-methylethylidene)bis[phenol] and 2,2’-oxybis[ethanol], acetate (salt) (CAS RN 68134-56-5) hereafter referred to as poly(ASPCA), are represented by the structures shown in Figure 4.1. These substances are chemically different based on structural features, but have been grouped in this assessment based on similar use patterns.

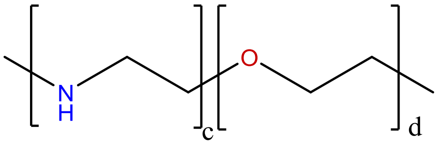
CAS RN 69418-26-4 is prepared by addition polymerization and CAS RNs 68130-99-4, 27967-29-9, and 68134-56-5 are obtained by condensation polymerization (Rasteiro *et al.* 2010, Palomino et *al.* 2012, Costa et *al.* 2014).

The poly(ASPCA) polymers are high charge density cationic polymers with an expected number average molecular weight (Mn) greater than 10,000 Da and low oligomeric content. The Mn values are typically in the range of thousands of daltons, and even up to a million for some products (Barajas and Hunkeler 2004, Canada 2015, ECCC 2015). The poly(ASPCA) polymers are usually imported as a powder or a liquid concentrate having a solids level in the range of 10 to 50% (ECCC 2017, Canada 2015, ECCC 2015).

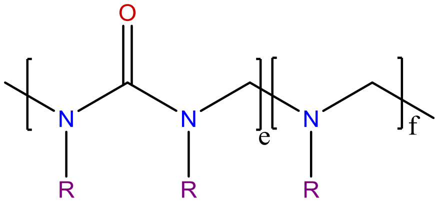
The exact composition and the degree of substitution for poly(ASPCA) polymers were not provided with information submitted through a voluntary survey (ECCC 2015) or a mandatory survey under section 71 of CEPA (Canada 2015). However, the degree of substitution is known to vary depending on the application. Therefore, representative information from various sources was considered for the purpose of this assessment (Barajas et *al.* 2001, 2003a, 2003b).



CAS RN 69418-26-4

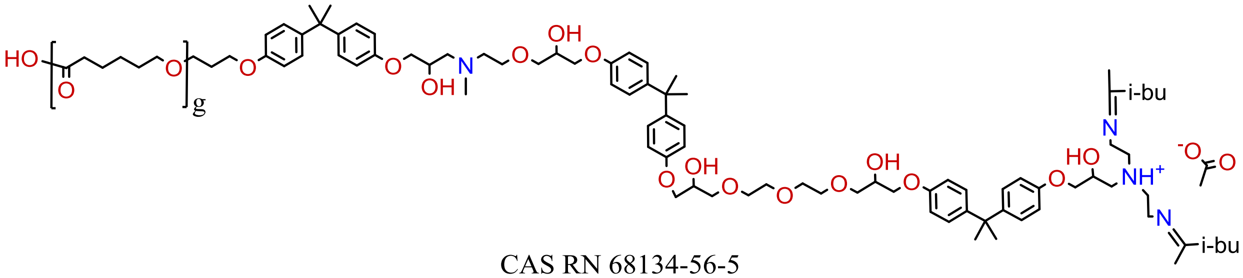


CAS RN 68130-99-4



R is H or another polymer chain

CAS RN 27967-29-9



CAS RN 68134-56-5

Figure 4-1. Representative structures of the four poly(ASPCA) polymers

The four poly(ASPCA) polymers are ethanaminium, N,N,N-trimethyl-2-[(1-oxo-2-propenyl)oxy]-, chloride, polymer with 2-propenamide (CAS RN 69418-26-4); aziridine, homopolymer, ethoxylated (CAS RN 68130-99-4); urea, polymer with ammonia and formaldehyde (CAS RN 27967-29-9), and 2-oxepanone, polymer with (chloromethyl)oxirane, N-(1,3-dimethylbutylidene)-N’-[2-[(1,3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine, 2-(methylamino)ethanol, 4,4’-(1-

methylethylidene)bis[phenol] and 2,2'-oxybis[ethanol], acetate (salt) (CAS RN 68134-56-5).

4.2 Physical and Chemical Properties

Table 4-1 presents physical and chemical data obtained for poly(ASPCA) polymers through surveys mentioned earlier. All information reflects summary data provided in safety data sheets (SDS).

Table 4-1. Physical and chemical property values (at standard temperature) for poly(ASPCA) polymers

Corresponding CAS RN	69418-26-4	68130-99-4	27967-29-9	68134-56-5	**Source or Survey Reference**
Physical form	Cream solid powder	Liquid	Clear to white opaque liquid	Liquid	ECCC 2015, SDS 2011, SDS 2015b, SDS 2016d
Mn[a] (Da)	>10,000	>10,000	>10,000	>10,000	ECCC 2017, Canada 2015, ECCC 2015, Edzwald 2011, Cumming *et al.* 2011, Cary *et al.* 1987
Wt % < 1,000 Da[b]	0	0	0	0	ECCC 2017, Canada 2015, ECCC 2015
Wt % < 500 Da[c]	0	0	0	0	ECCC 2017, Canada 2015, ECCC 2015
Density (g/cm^3)	1.04	1.05 - 1.25	1.1 - 1.3	NA	Canada 2015, ECCC 2015, SDS 2007, SDS 2014b
Charge density (mol N$^+$/1,000 g)	4.8	11.75[d]	3.9[d]	2.7[d]	Cary *et al.* 1987, ECCC 2017
Water solubility (mg/L)	>1,000	>1,000	>1,000	>1,000	Canada 2015, ECCC 2015, Bolto and Gregory 2007, Wilson *et al.* 2002

[a] Number average molecular weight (Mn)
[b] Residual constituents with molecular weights less than 1,000 Da
[c] Residual constituents with molecular weights less than 500 Da
[d] Value estimated based on the representative structure

Properties of the four poly(ASPCA) polymers were not modelled using any predictive software, since they are expected to have a number average molecular weight of greater than 1,000 Da, which is out of the range where modelling software is considered reliable.

4.3 Sources and Uses

The poly(ASPCA) polymers do not occur naturally in the environment .They have been included in a voluntary survey (ECCC 2015) as well as a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 4-2 presents a summary of the total reported manufacture and import quantities for the substances in 2014. These sources indicate that poly(ASPCA) polymers are imported into Canada to be mainly used as coagulants for water treatment and wastewater treatment, and as processing aids for oil and natural gas extraction. Other uses of poly(ASPCA) polymers include liquid laundry and dishwashing detergent formulations for CAS RN 68130-99-4, automotive paints and coatings for CAS RN 68134-56-5 and adhesives and sealants for CAS RN 27967-29-9.

Globally, the four poly(ASPCA) polymers are used in wastewater effluent treatments to improve the processes of sludge thickening and dewatering. The substances are also used as coagulants for primary clarification of industrial wastewaters (e.g. colour removal from wastewaters of textile mills, food processing industries, dyestuff industries, etc.) and for primary and secondary clarification of wastewater.

Table 4-2. Summary of information on Canadian manufacturing, import and use quantities of poly(ASPCA) polymers in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA

Substance	Total manufacture[a] (million kg)	Total imports[a] (million kg)	Survey reference
69418-26-4	0	10 to 20	Canada 2015, ECCC 2015
68130-99-4	0	1 to 10	Canada 2015, ECCC 2015
27967-29-9	0	0.01 to 0.1	Canada 2015, ECCC 2015
68134-56-5	0	0.1 to 1	Canada 2015, ECCC 2015

[a] Values reflect quantities reported in response to a voluntary survey (ECCC 2015) and a mandatory survey conducted under section 71 of CEPA (Canada 2015). See mandatory surveys for specific inclusions and exclusions (schedules 2 and 3).

4.4 Releases to the Environment

As explained in Section 2.4 and considering the use of the four poly(ASPCA) polymers in water and wastewater treatment, oil field applications, in liquid laundry and dishwashing detergent formulations, automotive paints and coatings and adhesives and sealants, if used properly, releases are expected to be negligible, as they rapidly and irreversibly form colloidal solids (floc) with anionic material and become unavailable.

4.5 Environmental Fate and Behaviour

4.5.1 Environmental distribution

The four poly(ASPCA) polymers are water soluble cationic polymers, with molecular weight greater than 10,000 Da. As explained in Section 2.5.1, the four poly(ASPCA) polymers are expected to be primarily adsorbed onto sludge and to be primarily retained in the soil and sediment compartments.

4.5.2 Environmental persistence

Biodegradation data provided through voluntary (ECCC 2015) and mandatory surveys (Canada 2015) are summarized in Table 4-3.

Table 4-3. Biodegradation data for one of the poly(ASPCA) polymers

CAS RN	Result	Test Method	Sources
68130-99-4	Not readily biodegradable	OECD 301C	SDS 2016d
68130-99-4	10-20% DOC reduction (28 d)	OECD 301A	SDS 2016d

CAS RN 68130-99-4 has been reported to be not readily biodegradable according to SDS 2016b. The submission specifies that results are from test protocol OECD 301C and OECD 301A but the full report was not provided.

CAS RN 69418-26-4, another polymer from this group, is a cationic poly(acrylamide) (CPAM) with ester and amide functional groups. The hydrolysis of the ester links in CPAMs is known to be pH and charge density (CD) dependent, and is more facile with increasing pH (Aksberg and Wagberg 1989, Van de Wetering *et al.* 1998). The formation of trimethylamine when CPAMs are used in wastewater sludge treatment has been shown to require biodegradation as well alkaline conditions in the latter stage of the process (Chang *et al.* 2005). From a degradation perspective, amide groups are weak points (Satyanarayana and Chatterji, 1993) as are the ester links in CPAMs (Soponkanaporn and Gehr 1989). Partial cleavage of the latter under both aerobic and anaerobic conditions has been confirmed (Lafuma and Durand 1989, Chang *et al.* 2001). The poly(acrylic acid) that is formed can be degraded in the natural environment, but only material of very low Mn (below 4,000) seems to be affected (Lenz 1993, Smith-Palmer *et al.* 1994). Therefore, CAS RN 69418-26-4 is expected to be stable over time under environmentally relevant conditions.

CAS RN 68134-56-5 also contains ester functional groups which may be susceptible to environmental degradation processes (hydrolysis or biodegradation). Based on the chemical composition, size and structure of the molecules, the substance is expected to be adsorbed to organic and other particulate matter in the environment and anticipated to be stable over time under environmentally relevant conditions.

CAS RN 27967-29-9 has no readily hydrolyzable or biodegradable groups and therefore is not expected to degrade or transform in the environment.

The overall trend shows that the four poly(ASPCA) polymers are not significantly hydrolyzable or biodegradable under environmentally relevant conditions.

Although there is no available information to assess the biodegradation potential of the four poly(ASPCA) polymers in sediments, it is generally expected to be slower than in soil or water, where aerobic conditions favour biodegradation. It is therefore anticipated that these four polymers will have lower biodegradation in sediments.

Considering available information, the four poly(ASPCA) polymers are expected to be stable in the soil, water and sediment compartments.

4.5.3 Bioaccumulation potential

The four poly(ASPCA) polymers have high cationic charge density, Mn greater than 10,000 Da (i.e., large molecular dimensions) and no significant percentage of low molecular weight constituents. Therefore, as explained in Section 2.5.3 for poly(DADMAC) polymers with high cationic charge density, Mn greater than 10,000 Da and no significant percentage of low molecular weight constituents, the bioaccumulation of the four poly(ASPCA) polymers in water, soil and sediment is expected to be low.

4.6 Potential to Cause Ecological Harm

4.6.1 Ecological effects assessment

Substances containing cationic amine or potentially cationic amine functional groups may be associated with adverse effects to fish, invertebrates, and algae (Boethling and Nabholz 1997, US EPA 2010). Empirical ecotoxicity data for the poly(ASPCA) polymers were reported in response to the surveys mentioned previously (ECCC 2015, Canada 2015). Numerous empirical ecotoxicity data for two of the four poly(ASPCA) polymers were also available in the literature (Cary *et al.* 1987, Cumming et al. 2008). The results of ecological studies are summarized in Table 4-4. The data extracted from study reports, safety data sheets (SDS) and summary information provided by stakeholders suggest that the poly(ASPCA) polymers could have high ecotoxicity to algae, daphnid and fish. Similar ecotoxicity trends of the four poly(ASPCA) can be seen from a data compilation for cationic polymers published by Goodrich *et al.* (1991) and also from analogue polymers with high degrees of structural similarity that were submitted to the New Substances Notification program. Available ecotoxicity data for the four poly(ASPCA) polymers and various analogues are summarized in Table 4-5.

Table 4-4. Empirical ecotoxicity data for two poly(ASPCA) polymers

CAS RNs	Organism	Result (mg/L)[a]	Test Method	Source or Survey Reference
68130-99-4	Daphnid	48h EC_{50}>100	OECD	SDS 2016d

CAS RNs	Organism	Result (mg/L)[a]	Test Method	Source or Survey Reference
	(*Ceriodaphnia*)		202	
69418-26-4	Daphnid (*D. magna*)	48h EC_{50}=0.21	OECD 202	Cary *et al.* 1987
69418-26-4	Fish (*P. promelas*)	96h LC_{50}=0.16*	NR[b]	Cary *et al.* 1987
69418-26-4	Fish (*L. macrochirus*)	96h LC_{50}=0.32	NR[b]	Cary *et al.* 1987
69418-26-4	Fish (*I. punctatus*)	96h LC_{50}=0.59	NR[b]	Cary *et al.* 1987
69418-26-4	Fish (*B. rerio*)	96h LC_{50}=5	OECD 203	SDS 2013b
68130-99-4	Aquatic activated sludge	0.5h EC_{20}>1,000	OECD 209	SDS 2016d

[a] EC_{50} is the effect concentration for 50% of the population; LC_{50} is the lethal concentration for 50% of the population; IC_{50} is the inhibition concentration for 50% of the population; NOEC is the No Observed Effect Concentration. These results are without mitigation

[b] NR: None reported

*This endpoint was chosen as the critical toxicity value (CTV)

Table 4-5. Ecotoxicity data available for analogues of poly(ASPCA) polymers

Organism	Effect[a]	Result (mg/L)	Sources
Algae	72 h IC_{50}	<1[b]	ECCC 2017
Daphnid	48 h EC_{50}	<1[b]	ECCC 2017
Fish[d]	96 h LC_{50}	<1[b]	ECCC 2017
Fish[e]	96 h LC_{50}	0.76	Boethling and Nabholz 1997[c]
Fish (*O. mykiss*)	96 h LC_{50}	0.66	Goodrich et al. 1991
Fish (*G. holbrooki*)	96 h LC_{50}	0.5-2.0	Cumming et al. 2008

[a] EC_{50} is the effect concentration for 50% of the population; LC_{50} is the lethal concentration for 50% of the population; IC_{50} is the inhibition concentration for 50% of the population.

[b] Analogue identified through the New Substances Notification Program. The identities of the substances are considered to be confidential business information.

[c] Toxicity data reported by Boethling and Nabholz 1997 for cationic polymer with varying degrees of percent amine nitrogen content, molecular weight, location of cation, and amine type (tertiary or quaternary). Values reported are for polymer 45.The specific species tested and the specific molecular structures were unknown.

[d] Three fish species: Rainbow trout (*O. mykiss),* Zebra fish (*B. rerio*) and Fathead minnow (*P. promelas*)

[e] Fish species unknown.

All poly(ASPCA) polymers have high number average molecular weights (>10,000 Da) and are out of the range where modelling software is generally considered reliable (< 1,000 Da). Thus, ecotoxicity modelling was not conducted.

As mentioned in the Ecological Effects Assessment for poly(DADMAC) polymers (Section 2.6.1), ecotoxicity of polycationic polymers can be mitigated through the presence of organic matter present in natural environment. Considering that the four poly(ASPCA) are polycationic polymers, similar mitigation of ecotoxicity would be expected.

Cary *et al.* (1987) have studied the effects of suspended solids (bentonite, illite, kaolin and silica) and of dissolved organic carbon compounds (humic, fulvic and tannic acids, lignin and lignosite) on the observed acute toxicities of poly ASPCA (CAS RN 69418-26-4) to the fathead minnow *(Pimephales promelas)* and cladoceran (*Daphnia magna*). Bentonite and all of the dissolved organic carbon compounds reduced the toxicities of the polymer by one to two orders of magnitude. On the base of the study by Cary *et al.* (1987), the acute toxicities of poly ASPCA (CAS RN 69418-26-4) will be mitigated by 50 for *Daphnia magna* and by 40 for fathead minnow, all based on addition of 10 mg/L humic acid. Table 4-6 summarizes the toxicity data from this study.

Table 4-6. Acute toxicities and reductions in acute toxicities of poly(ASPCA) (CAS RN 69418-26-4) to Daphnia magna fathead minnows in the presence of suspended solids and dissolved organics (Cary *et al.* 1987)

Substrate	Daphnia magna (48h EC_{50}, mg/L)[a]	Mitigation factor for Daphnia magna[b]	Fathead minnow (96h LC_{50}, mg/L)[a]	Mitigation factor for Fathead minnow[b]
Standard laboratory water	0.21	NA	0.16	NA
Bentonite[c]	20.1	96	7.3	46
Illite[c]	1.0	4.8	1.1	6.9
Kaolin[c]	0.91	4.3	0.41	2.6
Silica[c]	0.26	1.2	0.35	2.2
Tannic acid[d]	17.4	83	4.6	29
Lignin[d]	28.8	137	3.8	24
Humic acid[d]	10.5	50	6.4	40
Lignosite[d]	5.9	28	2.9	18
Fulvic acid[d]	14.9	70	2.2	14

[a] 48- and 96-h static acute EC_{50} and LC_{50} based on nominal concentrations. EC_{50} is the effect concentration for 50% of the population. LC_{50} is the lethal concentration for 50% of the population

[b] Mitigation factor, estimated on the basis of toxicity, with and without the substrate. This factor reflects the reduction in acute toxicity relative to a standard laboratory water test

[c] Test conducted in presence of 50 mg/L of substrate

[d] Test conducted in presence of 10 mg/L of substrate

NA: Not applicable

A toxicity mitigation factor determined through ecotoxicological testing can be used to correct for the expected reduction in toxicity in the environment due to the presence of organic matter. This is done by multiplying the ecological endpoints determined using clean laboratory water by the expected mitigation factor in order to adjust or reduce the values to reflect actual ecological effects expected under environmental conditions. Based on the reported mitigation factors above, the lowest mitigation value of 40 as reported by Cary *et al.* (1987) is considered to be a reasonable worst case for algae. On the basis of the toxicity data in Table 3.4, Table 3.5 and Table 3.6, the four poly(ASPCA) polymers are anticipated to have moderate toxicity to algae, daphnid and fish after considering fifty-fold mitigation for daphnia and forty-fold mitigation for fish and algae (see appendix 4 for more detail).

No sediment ecotoxicity data were provided for the four poly(ASPCA) polymers or were otherwise identified. However, Rogers and Witt (1989) have demonstrated that the aquatic toxicity of polycationics is also mitigated when the polymers are mixed with sediment. Available toxicity test data with natural sediment contaminated with polycationics and with benthic species that ingest sediment has shown that polycationics with charge densities of greater than 4.2 %a-N are not bioavailable to cause toxicity. The geometric mean of the 48-hr LOEC and the 48-hr NOEC was greater than 100 mg/kg of dry weight sediment, suggesting low concern for toxicity when they partition to sediments.

Overall, the four poly(ASPCA) polymers are expected to show moderate to low toxicity to aquatic organisms and low toxicity to sediment-dwelling species in natural environments. On the basis of available data, the lowest mitigated ecotoxicity endpoint reported for the four poly(ASPCA) polymers (fish, *P. promelas*: 96 h LC_{50} of 6.4 mg/L, which corresponds to the unmitigated 96 h LC_{50} of 0.16 mg/L multiplies by the mitigation factor of 40) was selected as the critical toxicity value (CTV) and is used to estimate the aquatic predicted no effect concentration (PNEC). A PNEC is not considered necessary for sediment species, as the toxicity is anticipated to be greater than 100 mg/L after mitigation.

The aquatic PNEC is derived from the critical toxicity value (CTV), which is divided by an assessment factor (AF) as shown:

$$\text{Aquatic PNEC (mg/L)} = \text{CTV} / \text{AF}$$

An AF of 20 is selected to estimate the aquatic PNEC. The AF selected represents 10 for extrapolation from acute to chronic toxicity, 1 for species sensitivity variation, and 2 for mode of action for cationic polymers. Considering the available ecotoxicity data for the four poly(ASPCA) polymers (more than 7 species, covering 3 categories), a factor of 1 was selected to represent species sensitivity, and 2 for mode of action assuming a non-narcotic mode of action for the four poly(ASPCA) polymers. This results in an aquatic PNEC of 0.32 mg/L (see appendix 4 for more detail).

4.6.2 Ecological exposure assessment

According to the data collected through the voluntary (ECCC 2015) and mandatory surveys (Canada 2015), the four poly(ASPCA) polymers are used as coagulants and flocculants for water and wastewater treatment, as processing aids in oil field applications, in liquid laundry and dishwashing detergent formulations, automotive paints and coatings and adhesives and sealants. Based on available information, the four poly(ASPCA) polymers were imported to Canada. As explained in Section 2.6.2, the exposure scenarios for the manufacturing of the four poly(ASPCA) polymers and their applications in petroleum production are not considered because they are not expected to result in significant environmental concentrations. Releases from consumers are treated by wastewater treatment facilities. Therefore, according to the survey data, there are three major poly(ASPCA) polymers uses that can result in releases to the aquatic environment:

1. Drinking water treatment
2. Industrial wastewater treatment
3. Wastewater treatment

However, the qualitative scenarios for drinking water treatment, industrial wastewater treatment and wastewater treatment were already discussed in the Ecological Exposure Assessment for poly(DADMAC) polymers (Section 2.6.2). The higher quantities for the four poly(ASPCA) polymers is not expected to affect the outcome of the exposure assessment.

4.6.3 Characterization of ecological risk

The approach taken in this ecological risk assessment was to examine direct and supporting information and develop conclusions based on a weight-of-evidence approach. Lines of evidence considered include information on sources and fate of the substance, persistence, bioaccumulation, ecological hazard properties and potential for environmental exposure.

The four poly(ASPCA) polymers are mainly used as coagulants for drinking water and wastewater treatment, oil field applications, and as liquid laundry and dishwashing detergent additives, automotive paint and coating additives, and adhesive and sealant additives. Based on the survey data, the quantity imported into Canada in 2014 was up to 20 million kg.

Water solubility information reported for the four poly(ASPCA) polymers indicates they are highly water soluble. When released into the environment, they are not expected to hydrolyze. Given the high molecular weight, partitioning into the air compartment is not expected. Furthermore, significant amounts are anticipated to adsorb onto dissolved organic matter and settle both within the treatment systems and in the environment if any residual is released.

With respect to long term persistence of these polymers, available biodegradation data for the four poly(ASPCA) polymers suggest that they will not be biodegradable in the environment. Other information on transformative properties suggests these polymers are not hydrolyzable.

All empirical data used to assess the bioaccumulation potential support the low bioaccumulation potential of the four poly(ASPCA) polymers for aquatic organisms.

According to the ecological hazard profile of the four poly(ASPCA) polymers, they generally have low toxicity to bacteria and moderate toxicity to algae, daphnid and fish after considering mitigation by dissolved organic carbon which reduces their bioavailability.

No significant residual polymer is expected to remain in the water column resulting from appropriate application as a flocculant in drinking water treatment, industrial wastewater treatment, wastewater treatment, oil field applications, and as liquid laundry and dishwashing detergent additives, automotive paint and coating additives, and adhesive and sealant additives. In the event of overdosing when being added to wastewater as a flocculant, any unreacted polymer residues which reach the aquatic environment are not expected to be bioavailable because they rapidly and irreversibly form colloidal solids (floc) with anionic materials in water. As insignificant releases to surface waters are expected from the proper use of the four poly(ASPCA) polymers, a predicted environmental concentration (PEC) has not been derived. Overall, the four poly (ASPCA) polymers are not expected to result in ecological concern based on available information and assumption that significant overdosing of waters being treated is avoided.

4.7 Potential to Cause Harm to Human Health

Classification of the hazard data and exposure profiles used to develop the potential for human health risks associated with the four poly(ASPCA) are presented in the document ‘Supporting Documentation: Final Risk Matrix Location of Polymers’ (Health Canada 2017).

After surveying substance use patterns, it was concluded that exposure to general population was varied from low to high (see Appendix 1). However, the human health hazard for the two poly(ASPCA) was determined to be low. Therefore, taking into consideration the available data, it is unlikely that exposure to the substance will pose a human health risk (ECCC, HC 2017).

5. Uncertainties in evaluation of risk to environment

There are various uncertainties related to the ecological assessment of the nine poly(amines). It is recognized that a given CAS RN can describe polymers that have different Mn, and composition; and hence, a different range of physical-chemical properties and hazard properties. However, changes in molecular weight or composition are not expected to result in a significant increase in ecological effects. Furthermore, there are uncertainties in the exposure scenarios for the nine poly(amines), such as the dosing and the reactivity. In the event of overdosing when being added to wastewater as a flocculant, any unreacted polymer residues which reach the aquatic environment are not expected to be bioavailable because they rapidly and irreversibly form colloidal solids (floc) with anionic materials in water. Therefore, moderate overdosing is not expected to result in a significant increase in ecological risk.

6. Conclusion

Considering all available lines of evidence presented in this draft screening assessment, there is low risk of harm to the environment from the nine poly(amines). It is proposed to conclude that the nine poly(amines) do not meet the criteria under paragraphs 64(*a*) or (*b*) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

Based on the information presented in this draft screening assessment, it is proposed to conclude that the nine poly(amines) do not meet the criteria under paragraph 64(*c*) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is proposed to conclude that the nine poly(amines) do not meet any of the criteria set out in section 64 of CEPA.

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Appendix 1 - Assessment Approaches Applied during the Second Phase of Polymer Rapid Screening

The approaches applied during the second phase of polymer rapid screening are outlined in this section. The detailed analyses, as well as the results of the second phase of polymer rapid screening for the individual substances, are presented in Chapters 2 to 4.

Characterization of Ecological Risk for poly(amines)

The ecological risks of poly(amines) were characterized using the approach outlined in the report on the second phase of polymer rapid screening. The approach consisted of multiple steps that addressed different factors related to the potential for a polymer to cause ecological harm. At each step in the rapid screening process, any substance that appeared to present a potential for harm was identified as requiring further assessment. The approach was intended to be pragmatic, protective of the environment, and fairly rapid, largely making use of available or easily obtainable data. This section summarizes the approach, which is described in detail in the report; “*Second Phase of Rapid Polymer Screening, Results of the Draft Screening Assessment”* (ECCC, HC 2017).

The ecological component of the second phase of polymer rapid screening approach consisted of four main steps to identify polymers that warrant further evaluation of their potential to cause harm. The first step involved identifying polymers which are not likely to be of ecological concern based on low reported import and manufacture quantities according to Phase Two of the DSL Inventory Update (Canada 2012), a voluntary survey (ECCC 2015) and a mandatory survey conducted under section 71 of CEPA (Canada 2015). Polymers with import and/or manufacture volumes less than 1,000 kg per year are not likely to be of ecological concern. This is consistent with the notifying trigger quantity of 1,000 kg for polymers under section 7 of the New Substances Notification Regulations (Chemicals & Polymers) [NSNR (C&P)] (Canada 2005).

The second step involved determining whether the polymer will likely have water extractability greater than 2% by weight. Water extractability greater than 2% by weight indicates that the polymer may be more bioavailable to aquatic organisms which resulted in these substances being identified as requiring further evaluation of their potential to cause ecological harm. The increased potential for exposure to aquatic organisms may present higher ecological risk. Literature, online safety data sheet (SDS) databases, the internal New Substances database for polymers, data gathered through a voluntary survey (ECCC 2015) and a mandatory section 71 survey under CEPA (Canada 2015), and other reliable sources and databases (e.g., QSAR toolbox, ECHA chemical database) were searched for water extractability and solubility information.

The third step in the ecological component involved identifying polymers with reactive functional groups (RFGs). RFGs are groups with chemical functionality that are considered to be reactive and may have damaging effects on the biological community.

These groups are well described in Schedule 7 of the NSNR (C&P) (Canada 2005) and polymers containing RFGs may be of increased ecological concern, which resulted in these substances being identified as requiring further evaluation of their potential to cause ecological harm. The RFGs include, among others, potentially cationic or cationic functionalities, alkoxy silanes, and phenols with unsubstituted ortho or para positions. To determine the presence of RFGs, structural information was gathered through a voluntary (ECCC 2015) and a mandatory section 71 survey of CEPA (Canada 2015). For polymers where no representative structures were provided, structural representations were derived from information available for similar polymers: 1) obtained from the internal New Substances program database; 2) from the Chemical Abstract Services (CAS) name; or 3) based on professional knowledge on likely polymerization mechanisms.

The final step of the second phase of polymer rapid screening for ecological considerations involved applying environmental release scenarios to estimate environmental exposure. Two generic aquatic exposure scenarios were applied to identify potential concerns near the point of discharge of a polymer into the environment. These scenarios involved comparing conservative (i.e., ecologically protective) estimates of exposure in receiving waters [predicted environmental concentrations (PEC)] with an effects threshold [predicted no-effect concentration (PNEC)] in order to evaluate whether a polymer is likely to cause harm to the local aquatic environment. The approaches made use of quantity information from each reporting company gathered through Phase Two of the DSL Inventory Update (Canada. 2012), and import and/or manufacture volumes through a voluntary survey (ECCC 2015) and a mandatory survey conducted under section 71 of CEPA (Canada 2015). The aquatic PNEC for each of the scenarios was derived from the critical toxicity value (CTV), which was divided by an assessment factor (AF) as shown:

$$\text{Aquatic PNEC (mg/L)} = \text{CTV} / \text{AF}$$

CTVs were based on empirical or modelled data (where appropriate). Experimental ecotoxicity data were gathered through the voluntary survey and polymer survey under section 71 of CEPA, literature information, as well as read-across data from polymers which have been assessed by the New Substances program. If the scenarios indicated a low likelihood of harm to aquatic organisms (i.e., ratio of PEC/PNEC is less than one), the polymer is unlikely to cause ecological harm.

It is recognized that conclusions resulting from the use of the second phase of polymer rapid screening have associated uncertainties, including commercial activity variations. However, the use of a wide range of information sources (relating to both exposure potential and hazard concerns identified for a polymer), as well as the use of conservative exposure scenarios increase confidence in the overall approach that the polymers identified as not requiring further assessment are unlikely to be of concern.

Information on the decision taken at each step for each polymer is presented in a document titled “Information on the Decision Taken at Each Step for Rapid Screening II of Polymers” (ECCC 2016).

Characterization of Risk to Human Health for poly(amines)

The human health risks of poly(amines) were characterized using the approach outlined in the report; “*Second Phase of Polymer Rapid Screening: Results of the Screening Assessment”* (ECCC, HC 2017). This process consisted of determining the location of each polymer in a health risk matrix, assigning a low, moderate or high level of potential concern for substances based on their hazard and exposure profiles. The matrix has three exposure bands that represent different exposure potentials which increase from band 1 to 3 and three hazard bands representing different hazard potentials which increase from band A to C.

The first step involved identifying the degree of direct and indirect exposure for each polymer based on its human exposure potential derived through its use pattern, import, manufacture or use quantity and water extractability. To determine if a polymer is used in or is present in a product available to Canadians, numerous additional sources of information related to both domestic and international use and product information were searched and consulted.

The highest exposure band (3) is designated for polymers which are expected to have high direct exposure resulting from their use in products available to consumers that are intended for consumption or application to the body, such as cosmetics, drugs and natural health products. **The middle exposure band (2)** is designated for polymers which are anticipated to have moderate direct or indirect exposure resulting from the use of polymers in household products that are not intended to be applied to the body or consumed, such as cleaning products, household paint and sealants. **The lowest exposure band (1)** is designated for polymers which are anticipated to have low direct or indirect exposure. This exposure band includes polymers which are used in the industrial sector to form manufactured articles and which are often contained within or reacted into a cured or hardened polymer matrix during industrial manufacturing.

The second step involved identifying the hazard potential, and corresponding hazard band, for each polymer based on the presence of reactive functional groups (RFGs) and available toxicological data. Identification of a hazard band was performed independently of the identification of an exposure band. **The highest hazard band (C)** is associated with polymers which are known or suspected to have a RFG or metals of concern to human health. The highest hazard band is also assigned to polymers for which toxicological data on the polymer or a structurally-related polymer shows or suggests that the polymer may pose a human health risk. **The middle hazard band (B)** is associated with polymers which do not contain any RFGs or metals of concern to human health but may contain other structural features such as ethylene glycol, aliphatic and aromatic amines or maleic acid anhydrides which may be associated with human health effects. **The lowest hazard band (A)** is associated with polymers which do not contain a RFG or other structural feature or metals which are known to be associated with human health concerns and available toxicological data indicates a low concern for human health.

The final step combined the exposure and hazard potentials to determine the overall risk potential as represented by the location in the risk matrix. Polymers which have a moderate-to-high exposure potential and the highest hazard potential (cells 2C or 3C) are identified as requiring further assessment to determine their risk to human health.

Polymers that are placed in all other cells of the risk matrix are considered unlikely to cause harm to human health at current levels of exposure. As a result, these polymers are not identified as requiring further human health assessment.

It is recognized that conclusions resulting from the use of this polymer rapid screening approach have associated uncertainties, including commercial activity variations and limited toxicological information. However, the use of a wide range of information sources (relating to both exposure potential and hazard concerns identified for a polymer), as well as the use of conservative exposure scenarios, increase confidence in the overall approach that the polymers identified as not requiring further assessment are unlikely to be of concern.

Information on the decision taken at each step for the substances in this assessment is presented in Second Phase of Rapid Polymer Screening, Results of the Draft Screening Assessment (Health Canada 2017).

Based on available information, the nine poly(amines) were identified under the second phase of polymer rapid screening as being unlikely to cause harm to human health.

Appendix 2 – PNEC Derivation for Poly(DADMAC) Polymers

Empirical ecotoxicity data for the two poly(DADMAC) polymers

CAS RNs	Organism	Ecotoxicity value (mg/L)	Mitigated ecotoxicity value[a] (mg/L)	F_{ES}[b]	SEV[c] (mg/L)
26062-79-3	Algae (*C. vulgaris*)	72h EC_{50}=0.16	2.24	5	0.448
26062-79-3	Algae (*C. vulgaris*)	72 hour NOEC=0.065	0.91	1	0.91
26590-05-6	Daphnid (*D. magna*)	48h EC_{50}=10-100	370-3700	10	37-370
26062-79-3	Daphnid (*D. magna*)	48h EC_{50}=17.5-100	647.5-3700	10	64.75-370
26062-79-3	Fish (*G. holbrooki*)	96h LC_{50}=0.5	7	10	0.7
26062-79-3	Fish (*O. mykiss*)	96h LC_{50}=0.49	6.86	10	0.686
26062-79-3	Fish (*O. mykiss*)	96 hour NOEC=0.37	5.18	5	1.03
26062-79-3	Fish (*P. promelas*)	96h LC_{50}=0.46-1.65	6.44-23.1	10	0.644-2.31
26062-79-3	Fish (*P. promelas*)	96 hour NOEC=0.15	2.1 **(CTV[d])**	5	0.42 (**Lowest SEV[c]**)
26590-05-6	Fish	96h LC_{50}=10-100	140-1400	10	14-140
26062-79-3	Fish (*B. rerio*)	96h LC_{50} = 10 -100	140-1400	10	14-140
26062-79-3	Mysid shrimp	48h LC_{50} = 628.5	8799	10	879.9
26062-79-3	Mysid shrimp	48 hour NOEC=125	1750	10	175

[a] Mitigated by 37 for *daphnia* and by 14 for fish and algae

[b] F_{ES}: endpoint-standardization factor (converts short term severe effects endpoints to long term no-effects endpoints, similar to acute to chronic ratio).

[c] SEV: Standardized Ecotoxicity Value

[d] CTV: Critical Toxicity Value. Toxicity value which produces the lowest SEV

Aquatic PNEC (mg/L) = CTV / AF

Aquatic PNEC (mg/L) = CTV / ($F_{ES} \times F_{SV} \times F_{MOA}$)

F_{ES}: endpoint-standardization factor

F_{SV}: species variation (considers the number of species and categories). Non-narcotic; 7 species; 3 categories.

F_{MOA}: mode-of-action factor (considers if substance is specifically acting, and possible effects not represented in dataset).

Aquatic PNEC (mg/L) = (2.1 mg/L) / 5×1×2

Aquatic PNEC (mg/L) = (2.1 mg/L) / 10

Aquatic PNEC (mg/L) = 0.21

Appendix 3 – PNEC Derivation for Poly(EDMA) Polymers

Empirical ecotoxicity data for the three poly(EDMA) polymers

CAS RNs	Organism	Ecotoxicity value (mg/L)	Mitigated ecotoxicity value[a] (mg/L)	F_{ES}[b]	SEV[c] (mg/L)
42751-79-1	Green algae	72h EC_{50}=10-100	160-1600	5	32-320
42751-79-1	Daphnid (*D. magna*)	48h EC_{50}=10-100	630-6,300	10	63-630
42751-79-1	Daphnid (*D. magna*)	48 hour NOEC=0.04	2.52	5	0.504
42751-79-1	Daphnid (Ceriodaphnia)	48h EC_{50}=0.17	10.71	10	1.071
25988-97-0	Daphnid (*D. magna*)	48h EC_{50}=0.08	5.04	10	0.504
25988-97-0	Daphnid (*D. magna*)	48 hour NOEC=1.56	98.28	5	19.66
25988-97-0	Fish (*L. macrochirus)*	96h LC_{50}=0.18	2.88	10	0.288
25988-97-0	Fish (*L. macrochirus)*	96 hour NOEC= 0.625	10	5	2
25988-97-0	Fish (*P. promelas*)	96h LC_{50}=0.25	4	10	0.4
25988-97-0	Fish (*O. mykiss*)	96h LC_{50}=0.59-1.49	9.44-23.84	10	0.944-2.384
25988-97-0	Fish (*O. mykiss*)	96 hour NOEC=0.625	10	5	10
25988-97-0	Fish (*B. rerio*)	96h LC_{50} > 10	NA	10	NA
42751-79-1	Fish (*O. mykiss*)	96h LC_{50}=0.16	2.56 **(CTV[d])**	10	0.256 **(Lowest SEV[c])**
42751-79-1	Fish (*O. mykiss*)	96-hour NOEC=0.1	1.6	5	0.3
42751-79-1	Fish (*L. macrochirus)*	96h LC_{50}=0.39	6.24	10	0.624
42751-79-1	Fish (*L. macrochirus)*	96-hour NOEC=0.24	3.84	5	0.768
42751-79-1	Fish (*P. promelas*)	96h LC_{50}=0.67	10.72	10	1.072
42751-79-1	Fish (*P. promelas*)	96-hour NOEC=0.31	4.96	5	0.992
42751-79-1	Fish (*B. rerio*)	96h LC_{50}=10-100	160-1,600	10	16-160
42751-79-1	Mysid shrimp	48h LC_{50} = 2500	40,000	10	4,000

[a] Mitigated by 63 for *daphnia* and by 16 for fish and algae

[b] F_{ES}: endpoint-standardization factor (converts short term severe effects endpoints to long term no-effects endpoints, similar to acute to chronic ratio).

[c] SEV: Standardized Ecotoxicity Value

[d] CTV: Critical Toxicity Value. Toxicity value which produces the lowest SEV

NA: Not applicable

Aquatic PNEC (mg/L) = CTV / AF

Aquatic PNEC (mg/L) = CTV / ($F_{ES} \times F_{SV} \times F_{MOA}$)

F_{ES}: endpoint-standardization factor

F_{SV}: species variation (considers the number of species and categories). Non-narcotic; 7 species; 3 categories.

F_{MOA}: mode-of-action factor (considers if substance is specifically acting, and possible effects not represented in dataset).

Aquatic PNEC (mg/L) = (2.56 mg/L) / 10×1×2

Aquatic PNEC (mg/L) = (2.56 mg/L) / 20

Aquatic PNEC (mg/L) = 0.128

Appendix 4 – PNEC Derivation for Poly(ASPCA) Polymers

Empirical ecotoxicity data for poly(ASPCA) polymers

CAS RNs	Organism	Ecotoxicity value (mg/L)	Mitigated ecotoxicity value[a] (mg/L)	F_{ES}[b]	SEV[c] (mg/L)
68130-99-4	Daphnid (*Ceriodaphnia*)	48h EC_{50}>100	NA	10	NA
69418-26-4	Daphnid (*D. magna*)	48h EC_{50}=0.21	10.5	10	1.05
69418-26-4	Fish (*P. promelas*)	96h LC_{50}=0.16	6.4 **(CTV[d])**	10	0.64 **(Lowest SEV[c])**
69418-26-4	Fish (*L. macrochirus*)	96h LC_{50}=0.32	12.8	10	1.28
69418-26-4	Fish (*I. punctatus*)	96h LC_{50}=0.59	23.6	10	2.36
69418-26-4	Fish (*B. rerio*)	96h LC_{50}=5	200	10	20
68130-99-4	Aquatic activated sludge	0.5h EC_{20}>1,000	NA	10	NA

[a] Mitigated by 50 for *daphnia* and by 40 for fish and algae

[b] F_{ES}: endpoint-standardization factor (converts short term severe effects endpoints to long term no-effects endpoints, similar to acute to chronic ratio).

[c] SEV: Standardized Ecotoxicity Value

[d] CTV: Critical Toxicity Value. Toxicity value which produces the lowest SEV

NA: Not applicable

Aquatic PNEC (mg/L) = CTV / AF

Aquatic PNEC (mg/L) = CTV / ($F_{ES} \times F_{SV} \times F_{MOA}$)

F_{ES}: endpoint-standardization factor

F_{SV}: species variation (considers the number of species and categories). Non-narcotic; 7 species; 3 categories.

F_{MOA}: mode-of-action factor (considers if substance is specifically acting, and possible effects not represented in dataset).

Aquatic PNEC (mg/L) = (6.4 mg/L) / 10×1×2

Aquatic PNEC (mg/L) = (6.4 mg/L) / 20

Aquatic PNEC (mg/L) = 0.32