



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

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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 RN¹), Domestic Substances List (DSL) names and 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, <i>N,N</i> -dimethyl- <i>N</i> -2-propenyl-, chloride, homopolymer	Poly(DADMAC)
26590-05-6	2-Propen-1-aminium, <i>N,N</i> -dimethyl- <i>N</i> -2-propenyl-, chloride, polymer with 2-propenamide	Poly(DADMAC)
25988-97-0	Methanamine, <i>N</i> -methyl-, polymer with (chloromethyl)oxirane	Poly(EDMA)
42751-79-1	1,2-Ethanediamine, polymer with (chloromethyl)oxirane and <i>N</i> -methylmethanamine	Poly(EDMA)
52722-38-0	Methanamine, <i>N</i> -methyl-, polymer with ammonia and (chloromethyl)oxirane	Poly(EDMA)
69418-26-4	Ethanaminium, <i>N,N,N</i> -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, <i>N</i> -(1,3-dimethylbutylidene)- <i>N'</i> -[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 2018). The present assessment summarizes the approach applied during

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the second phase of polymer rapid screening for characterizing the risk to human health 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 RNs 26062-79-3 and 26590-05-6), poly(EDMA) (CAS RNs 25988-97-0, 42751-79-1 and 52722-38-0) and poly(ASPCA) (CAS RN 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 to 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 that 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 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 concluded 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.

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

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

performed in the second phase of polymer rapid screening, it is unlikely that exposure to these substances will pose a human health risk.

On the basis of the information presented in this screening assessment, it is concluded 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 concluded that the nine poly(amines) do not meet any of the criteria set out in section 64 of CEPA.

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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 [modified 2017]).

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 Screening Assessment* (published April 7, 2018), which was subject to a 60-day public comment period (ECCC, HC 2018). 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. The human health rapid screening approach is summarized in Appendix A of this screening assessment. 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 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 conclusions. When available and relevant, information presented in assessments from other jurisdictions was considered.

This 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 draft of this screening assessment was published on November 10, 2018, 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 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 screening assessment presents the critical information and considerations on which the conclusion is based.

2. Poly(DADMAC)

2.1 Identity of substances

The two substances, namely 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-propenamamide (CAS RN 26590-05-6), hereafter referred to as poly(DADMAC) 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)] (Wandrey and Jaeger 1985; John et al. 2002; Abdollahi et al. 2013).

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

The composition for the two poly(DADMAC) polymers was not provided with the information submitted in response to a voluntary survey (ECCC 2015) or a mandatory survey under section 71 of CEPA (Canada 2015). However, the composition is known to vary depending on the different applications. Therefore, representative information from various sources (Bolto and Gregory 2007; Cumming et al. 2011; Canada 2015; ECCC 2015) was considered for the purpose of this assessment.

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.

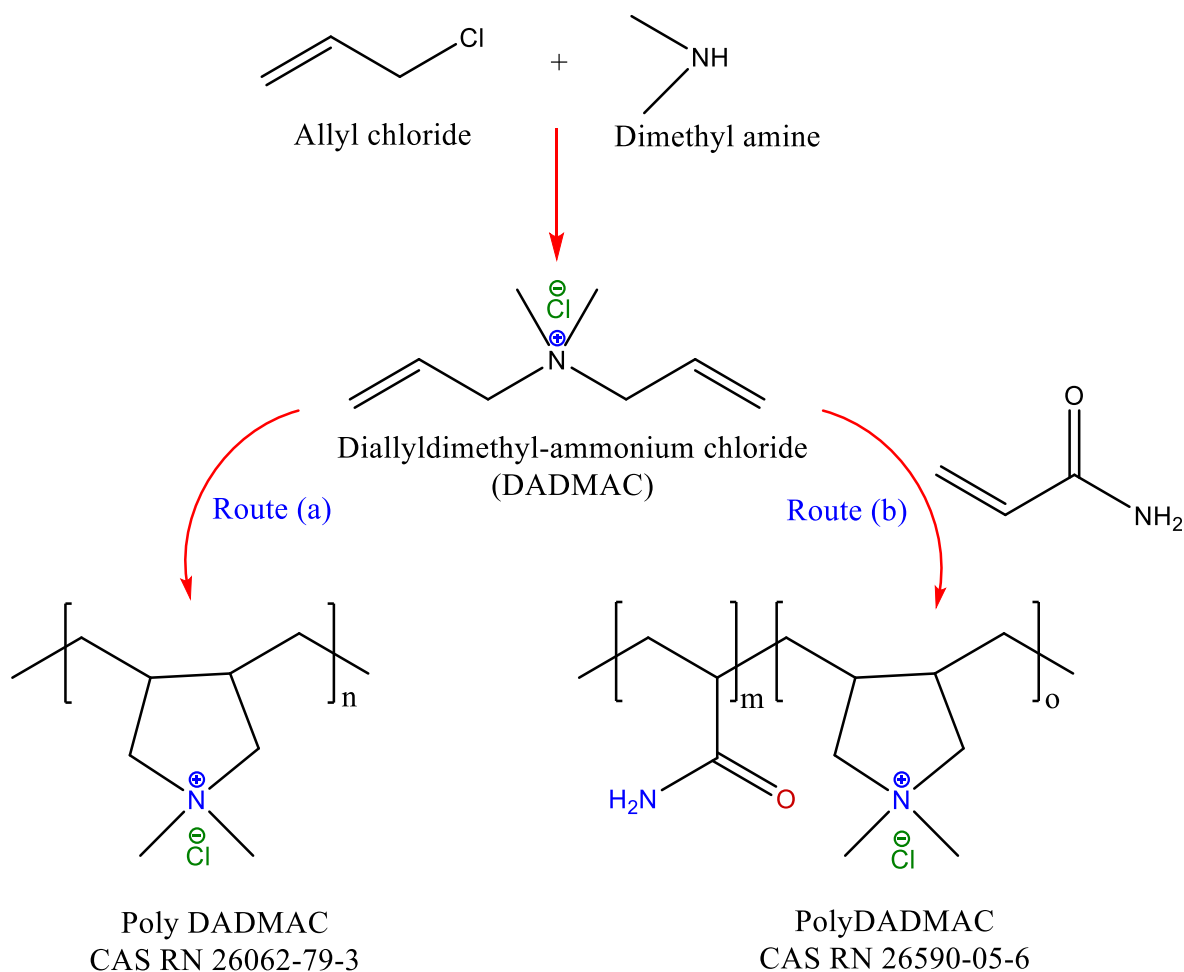


Figure 2-1. Synthesis and representative structures of poly(DADMAC) polymers

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 identified for poly(DADMAC).

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

Corresponding CAS RN	26062-79-3	26590-05-6	References
Physical form	Liquid	Liquid	Canada 2015, ECCC 2015
Mn ^a (Da)	>10 000	>10 000	Canada 2015, ECCC 2015, Cumming et al. 2011, Bolto and Gregory 2007
Wt % < 1000 Da ^b	0	0	Canada 2015, ECCC 2015
Wt % < 500 Da ^c	0	0	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 ⁺ /1000 g)	6.21	4.30 ^d	Cary et al. 1987
Water solubility (mg/L)	Soluble	Soluble	Canada 2015, ECCC 2015, Bolto and Gregory 2007, John et al. 2002

^a Number average molecular weight (Mn).

^b Residual constituents with molecular weights less than 1000 Da.

^c Residual constituents with molecular weights less than 500 Da.

^d Value estimated on the basis of the representative structure (Figure 2-1), where m and o are assumed to be 1. The amine equivalent weight is estimated by dividing the MW of the repeating unit by the number of amines that are or could become cationically charged. The charge density is calculated by dividing 1000 g by the amine equivalent weight. For CAS RN 26590-05-6, the amine equivalent is 232.75 g/mol, where the molecular weight of the repeating unit is 232.75, with one cationic amine.

The physical-chemical properties of the poly(DADMAC) polymers were not modelled using quantitative structural activity relationship (QSAR) models predictive software, since they have a number average molecular weight of greater than 1000 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. Uses in antistatic agents, film formers, hair fixatives and conditioners (personal care products) have also been reported for CAS RN 26590-05-6.

Poly(DADMAC) polymers are used in wastewater and drinking water treatment, where poly(DADMAC) is used as a coagulant for water clarification (Bolto et al. 1999; Bolto et al. 2001; Bolto and Gregory 2007; John et al. 2002). Poly(DADMAC) can also be used in the pulp and paper industry as a coagulant in various stages of paper manufacturing processes (Hubbe et al. 2003; Lofton et al. 2005; OECD 2009).

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

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 by neutralizing the surface charges of particles (Liber et al. 2005). Poly(DADMAC) polymers are also flocculants primarily used in 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., colloidal solids (floc)). The floc then settles out from the water (Boethling and Nabholz 1997; Cumming 2007, 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 floc with anionic material and become unavailable (Balto and Gregory 2007; Cumming 2007, 2008). 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. Therefore, polymers with high cationic charge are expected to adsorb onto anionic particulates and settle out of the water column.

The use of poly(DADMAC) in personal care products will result in releases of these substances into wastewater treatment systems. They are expected to adsorb onto anionic matter in the sewer system before reaching the wastewater treatment plant and will be removed through flocs. This may increase overall cationic polymer load within the wastewater treatment system. However, it is not expected to be significant, as the quantities of cationic polymers used in personal care products are significantly less than those used in water treatment processes. Furthermore, releases of poly(DADMAC)

through personal care products are expected to occur across Canada, and thus overall quantities being released at a single location would be expected to be lower. For the purpose of poly(DADMAC) assessment, only those uses that will result in the greatest release are considered.

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. If released to the environment, the two poly(DADMAC) polymers are not expected to volatilize into the air compartment as they have high molecular weights and expected low 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 (Balto and Gregory 2007; Cumming 2007, 2008).

If released to soil, the 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 compartment and in sediments.

2.5.2 Environmental persistence

Biodegradation data provided through voluntary (ECCC 2015) and mandatory surveys (Canada 2015), are summarized in Table 2-3. Results indicate that the two poly(DADMAC) polymers are not biodegradable.

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

CAS RN	Result	Test Method	Reference
26062-79-3	Not readily biodegradable	NR ^a	Canada 2015 ECCC 2015
26062-79-3	Not inherently biodegradable	OECD 302 Inherent Biodegradability Test	SDS 2016
26590-05-6	Not readily biodegradable	NR ^a	Canada 2015 ECCC 2015

^a NR: None reported

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

water, where aerobic conditions favour biodegradation. It is therefore anticipated that these two polymers will have limited or no biodegradation in sediments.

Abiotic degradation is also not expected. While hydrolysis information for the two poly(DADMAC) polymers was not identified, hydrolytic stability is expected since they are used for coagulation, flocculation and other products where they would be formulated with water. Padhye et al. (2011) 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, 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, and therefore the bioaccumulation potential is expected to be limited (Murgatroyd et al. 1996). 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 (Murgatroyd et al. 1996; 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 a higher molecular weight substance, which is not available to organisms. Data for sediment- and soil-dwelling organisms were not available. However, as in the case of aquatic organisms, bioaccumulation in sediment- and soil-dwelling organisms 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 that 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 previously mentioned voluntary and mandatory surveys (Canada 2015; ECCC 2015). Considerable empirical ecotoxicity data for these two polymers were also available in the literature (Cary et al. 1987; Cumming et al. 2008). The available data 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 can be seen from a data compilation for cationic polymers published by Boethling and Nabholz (1997) and from data for 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 and Table 2-5.

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

CAS RNs	Organism	Result (mg/L) ^a	Test method	Reference
26062-79-3	Algae (<i>Chlorella vulgaris</i>)	72-h EC ₅₀ = 0.16	NR ^b	Canada 2015, ECCC 2015
26062-79-3	Algae (<i>Chlorella vulgaris</i>)	72-h NOEC = 0.065	NR ^b	Canada 2015, ECCC 2015
26590-05-6	Daphnid (<i>Daphnia magna</i>)	48-h EC ₅₀ =10-100	OECD 202 (Daphnia acute immobilization test)	Canada 2015, ECCC 2015
26062-79-3	Daphnid (<i>Daphnia magna</i>)	48-h EC ₅₀ = 0.2–100	OECD 202 (Daphnia acute immobilization test)	Canada 2015, Cary et al. 1987, ECCC 2015
26062-79-3	Fish (<i>Gambusia holbrooki</i>)	96-h LC ₅₀ = 0.5	OECD 203 (fish acute toxicity test)	Cumming et al. 2008
26062-79-3	Fish (<i>Oncorhynchus mykiss</i>)	96-h LC ₅₀ = 0.49	NR ^b	Canada 2015, ECCC 2015
26062-79-3	Fish (<i>Oncorhynchus mykiss</i>)	96-h NOEC = 0.37	NR ^b	Canada 2015, ECCC 2015
26062-79-3	Fish (<i>Pimephales promelas</i>)	96-h LC ₅₀ = 0.46–1.65	NR ^b	Canada 2015, Cary et al. 1987, ECCC 2015
26062-79-3	Fish (<i>Pimephales promelas</i>)	96-h NOEC = 0.15*	NR ^b	Canada 2015, ECCC 2015
26590-05-6	Fish (<i>Pimephales promelas</i>)	96-h LC ₅₀ = 10–100	OECD 203 (fish acute toxicity test)	Canada 2015, ECCC 2015
26062-79-3	Fish (<i>Danio rerio</i>)	96-h LC ₅₀ = 10–100	OECD 203 (fish acute toxicity test)	Canada 2015, ECCC 2015
26062-79-3	Mysid shrimp	48-h LC ₅₀ = 628.5	NR ^b	Canada 2015, ECCC 2015
26062-79-3	Mysid shrimp	48-h NOEC = 125	NR ^b	Canada 2015, ECCC 2015

^a EC₅₀ is the effect concentration for 50% of the population; LC₅₀ is the lethal concentration for 50% of the population; IC₅₀ 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	Notified to the New Substances Program (ECCC)
Fish ^d	96-h LC ₅₀	<1 ^b	Notified to the New Substances Program (ECCC)
Fish ^e	96-h LC ₅₀	0.15-1.18	Boethling and Nabholz 1997 ^c

^a EC₅₀ is the effect concentration for 50% of the population; LC₅₀ is the lethal concentration for 50% of the population; IC₅₀ 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*), zebrafish (*B. rerio*) and carp (*Cyprinus carpio*).

^e Fish species unknown.

Poly(DADMAC) polymers have high number average molecular weights (>10 000 Da) that are out of the range where QSAR modelling is generally considered reliable (< 1000 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 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 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 (Cary et al. 1987; Goodrich et al. 1991; Boethling and Nabholz 1997). Boethling and Nabholz (1997) reported that the addition of approximately 10 mg/L of humic acid to laboratory ecotoxicity tests simulates environmental organic carbon levels.

Cary et al. (1987) studied effects in the fathead minnow (*Pimephales promelas*) and cladoceran (*Daphnia magna*) of acute exposures to poly(DADMAC) (CAS RN 26062-79-3) with 50 mg/L suspended solids (bentonite, illite, kaolin and silica) and 10 mg/L dissolved organic carbon compounds (humic, fulvic and tannic acids, lignin and lignosite). Bentonite and all of the dissolved organic carbon compounds reduced the toxicities of the polymer by one to two orders of magnitude. Cary et al. (1987) present mitigation factors, a correction for the expected reduction in toxicity in the environment due to the presence of organic matter. Toxicity mitigation factor is the ratio between the ecotoxicity of a substance in clean laboratory water to the ecotoxicity of the substance tested in the presence of humic acids. Table 2-6 summarizes the toxicity data from this study.

Table 2-6. Acute toxicities and acute toxicity mitigation factors of poly(DADMAC) (CAS RN 26062-79-3) to *Daphnia magna* and to *Pimephales promelas* (fathead

minnow) in the presence of suspended solids and dissolved organics (Cary et al. 1987)

Substrate	<i>Daphnia magna</i> (48-h EC ₅₀ , mg/L) ^a	Mitigation factor for <i>Daphnia magna</i> ^b	<i>Pimephales promelas</i> (96-h LC ₅₀ , mg/L) ^a	Mitigation factor for <i>Pimephales promelas</i> ^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-h and 96-h static acute EC₅₀ and LC₅₀ based on nominal concentrations. EC₅₀ is the effect concentration for 50% of the population. LC₅₀ 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. Based on the mitigation data presented in Table 2-6, a mitigation factor of 37 is applied to daphnia, and a factor of 14 is applied to fish species. As there are no mitigation factors available for algae with respect to poly(DADMAC) ecotoxicity, the lowest mitigation value of 14 as reported by Cary et al. (1987) for fish 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 daphnids and moderate toxicity to algae and fish after considering 37-fold mitigation for daphnia and 14-fold mitigation for fish and algae (see Appendix B for more detail).

No sediment or soil ecotoxicity data were provided for the two poly(DADMAC) polymers or were otherwise identified. According to summary information from Boethling and Nabholz (1997), highly charged polycationics are expected to irreversibly adsorb onto sediments if released to rivers or lakes. This would significantly reduce the bioavailability of these polymers. In municipalities where biosolids are spread onto land to improve soil quality, it is anticipated that the polycationic polymers would remain bound to these soils and eventually degrade over the long term. Because of their ability

to strongly bind with negatively charged colloidal and suspended matter, there is low potential for runoff from these soils.

Overall, the two poly(DADMAC) polymers are expected to show moderate to low toxicity to aquatic organisms and low toxicity to soil- and 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-h NOEC of 2.1 mg/L, which corresponds to the unmitigated 96-h 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).

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 (e.g. adsorption to fish gills) for the two poly(DADMAC) polymers. This results in an aquatic PNEC of 0.21 mg/L (see Appendix B for more detail).

A PNEC was not developed for soil- and sediment-dwelling species as poly(DADMAC) polymers are anticipated to have low bioavailability, resulting in low toxicity towards such species.

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 imported into Canada for use as coagulants and flocculants for water and wastewater treatment and as processing aids in oil field applications. No manufacturing of these substances in Canada was reported (Canada 2015, ECCC 2015).

Three major poly(DADMAC) uses that can result in releases to the aquatic environment are drinking water treatment, industrial wastewater treatment and wastewater treatment.

Environmental releases of the two poly(DADMAC) polymers from their use in the petroleum sector in onshore and offshore oil field applications are expected to be limited. During onshore oil field applications, the process water is not usually discarded to a wastewater treatment system or to 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). While no data for offshore uses were

provided through the surveys, offshore discharges are not expected to result in high environmental concentrations of the two substances due to high dilution.

Three qualitative ecological exposure scenarios for drinking water treatment, industrial wastewater treatment and wastewater treatment are described below. Because there is no manufacturing of these substances in Canada, and given the limited environmental exposure from applications in petroleum production, these exposure scenarios are not considered further.

Drinking water treatment

Drinking water is produced by treating and disinfecting source waters to remove and inactivate pathogenic organisms, to remove organic matter and to reduce compounds that affect odour and taste. 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 particles (including pathogens), 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) report 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 floc with natural impurities in the source water. These impurities 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 have not been successful (personal communication, North American Polyelectrolyte Producers Association (NAPPA) and Ecological Assessment Division (EAD), Environment and Climate Change Canada (ECCC) teleconference, October 13, 2017; unreferenced). 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, and 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 1000 mg/L for sludge conditioning and thickening processes. NAPPA states that these substances behave differently in different types of water with different solids or organic content (personal communication, email from NAPPA to the Environmental Assessment Division, ECCC, dated November 15, 2017; unreferenced). No quantitative data on potential unreacted polymer residues in industrial wastewaters 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 cases 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. According to NAPPA (personal communication, email from NAPPA, to the Environmental Assessment Division, ECCC, dated November 15, 2017; unreferenced), and data provided to ECCC under the New Substances Program, non-contact process waters from polycationic polymers are usually recirculated numerous times before discharge, and any potential polymer 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 that reach the aquatic environment are not expected to be bioavailable because they rapidly and irreversibly form floc with anionic materials in receiving water.

Wastewater treatment

Cationic, water-soluble polyelectrolytes are used extensively in wastewater treatment systems (WWTS) primarily to improve the sludge thickening and dewatering processes. Cationic polyelectrolytes are also used as flocculants in primary and secondary sedimentation basins. Flock and Rausch (1973) reported cationic polyelectrolytes dosages from 1 to 50 mg/L for conventional primary treatment and 5 mg/L for secondary sedimentation basin. Cationic polyelectrolytes have the greatest flexibility and can considerably improve the overall removal efficiency in secondary sedimentation basins with lower dosages. NAPPA has indicated primary clarification as being the main application for the nine polyamines in the group at WWTS and has provided a realistic maximum use level of 5 mg active polymer per litre (personal communication, email from NAPPA to the Environmental Assessment Division, ECCC, dated November 15, 2017; unreferenced). Cary et al. (1987) reports typical treatment rates of 10 to 100 mg/L for wastewater clarification applications and from 100 to 1000 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 (^1H 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 floc with anionic materials within the WWTS facilities or in receiving waters (Balto and Gregory 2007; Cumming 2007, 2008). In summary, when polycationic amine polymers are used in wastewater and biosolids treatment, they become combined with anionic materials to form floc. As supported by data provided to ECCC under the New Substances Program, there is low likelihood of ecological effects due to polymer release with either treated effluent or biosolids.

2.6.3 Characterization of ecological risk

The approach taken in this ecological risk assessment was to examine available information and develop conclusions based on a weight-of-evidence approach. Lines of evidence considered include information on sources and fate of the substances, 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. According to the survey data, each substance was imported into Canada in 2014 in quantities of up to 10 million kg.

Water solubility information reported for the two poly(DADMAC) polymers indicates that they are highly water-soluble. When released to 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 *Daphnia* 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 that reach the aquatic environment are not expected to be bioavailable because they rapidly and irreversibly form 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 quantitative predicted environmental concentration (PEC) was not derived. Overall, the two poly(DADMAC) polymers are not expected to result in ecological concern based on available information and on the assumption that significant overdosing of waters being treated is avoided.

2.7 Potential to cause harm to human health

The classification of the hazard data and exposure profiles used to develop the potential for human health risks associated with the two poly(DADMAC) polymers is 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 the general population was potentially high (see Appendix A). However, the human health hazard for the two poly(DADMAC) polymers was determined to be low. Therefore, taking into consideration the available data, it is unlikely that exposure to the substances will pose a human health risk (ECCC, HC 2018).

3. Poly(EDMA)

3.1 Identity of substances

The three substances, namely 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 polymerization 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; Balto 1995; Choi et al. 2001). These polymers are usually mixtures of isomers.

Poly(EDMA) polymers are high charge density cationic polymers with an expected number average molecular weight (M_n) greater than 10 000 Da and low oligomeric content (Balto 1995). The M_n are typically greater than 10 000 Da (Canada 2015; ECCC 2015). The poly(EDMA) and similar polymers are usually imported as a liquid

concentrate having a solids level in the range of 10 to 50% (Canada 2015; ECCC 2015).

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

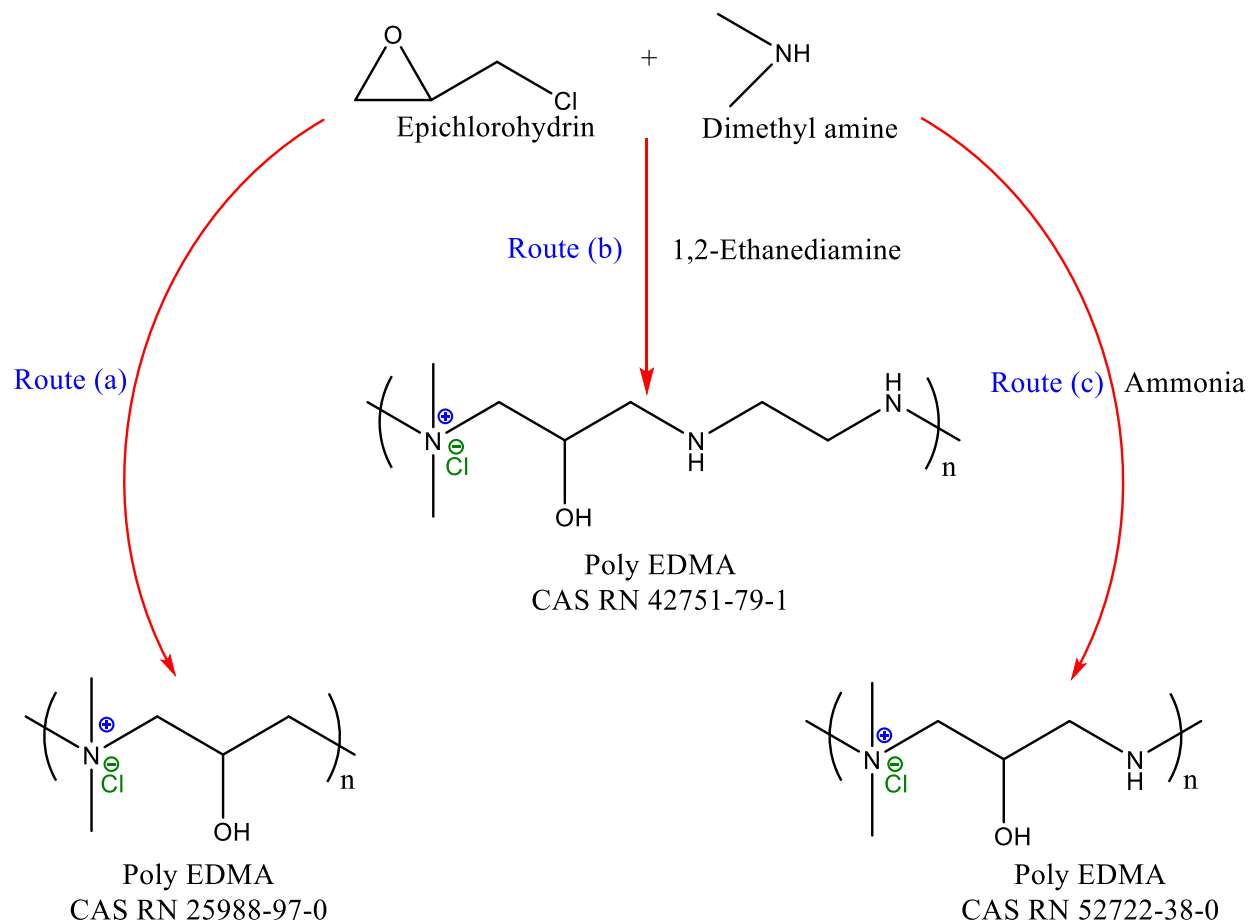


Figure 3-1. Synthesis and representative structure of poly(EDMA) polymers

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 identified for poly(EDMA).

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

Corresponding CAS RN	25988-97-0	42751-79-1	52722-38-0	References
Physical form	liquid	liquid	liquid	Canada 2015, ECCC 2015
Mn ^a (Da)	>10 000	>10 000	>10 000	Canada 2015, ECCC 2015, Bolto 1995, Cary et al. 1987
Wt % < 1.000 Da ^b	0	0	0	Canada 2015, ECCC 2015
Wt % < 500 Da ^c	0	0	0	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 ⁺ /1000 g)	7.3	15.3 ^e	13.1 ^e	Cary et al. 1987
Water solubility (mg/L)	soluble	soluble	soluble	Canada 2015, ECCC 2015, Bolto and Gregory 2007, John et al. 2002

^a Number average molecular weight (Mn).

^b Residual constituents with molecular weights less than 1000 Da.

^c Residual constituents with molecular weights less than 500 Da.

^d The representative structures given in Figure 3-1 are simplified representations of the substances. Values are estimated on the basis of the linear representative structure. The substances may have branching points, leading to complex non-linear structures. The amine equivalent weight is estimated by dividing the MW of the repeating unit by the number of amines that are or could become cationically charged. The charge density is calculated by dividing 1000 g by the amine equivalent weight.

Properties of the poly(EDMA) polymers were not modelled using QSAR models. These polymers are expected to have a number average molecular weight of greater than 1000 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) and 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 the reporting year 2014. These sources indicate that these polymers are imported into Canada for use primarily

as coagulants and flocculants in water treatment and as processing aids in wastewater treatment, oil and natural gas extraction, and the pulp and paper industry.

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)	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

Like poly(DADMAC) polymers, poly(EDMA) polymers have high cationic charge and are also used in water treatment processes, where they are expected to bind irreversibly to natural organic matter and other suspended matter to form floc and become unavailable. Thus, under normal operating conditions, release of poly(EDMA) is not expected.

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. Like poly(DADMAC), poly(EDMA) polymers are expected to be primarily adsorbed onto sludge and to be primarily retained in the soil and sediment compartments.

3.5.2 Environmental persistence

Available biodegradation data are summarized in Table 3-3.

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

CAS RN	Result	Test method	Reference
25988-97-0	Not biodegradable	NR ^a	Canada 2015, ECCC 2015
42751-79-1	< 70% degradation in 28-days ^b	OECD 301B ^a	Canada 2015, ECCC 2015

^a NR: None reported; OECD: Organisation for Economic Co-operation and Development.

^b CO₂ Evolution (Modified Sturm Test) for a formulation.

The biodegradation results for the poly(EDMA) polymers listed above indicate 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 identified. However, as they are used for coagulation, flocculation and other products where they would be formulated with water, hydrolytic stability could therefore be expected.

Considering the available information and the structural similarities between the three poly(EDMA) polymers, they 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 (7.3-15.3), Mn greater than 10 000 Da (i.e., large molecular dimensions) and no significant percentage of low molecular weight constituents. Overall, the bioaccumulation is expected to be low. This assessment is based on the same considerations for poly(DADMAC) that 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 (Canada 2015; ECCC 2015). Many empirical ecotoxicity data for the three polymers were also available in the literature (Cary et al. 1987; Goodrich et al. 1991). The available data suggest that the three poly(EDMA) polymers could have high ecotoxicity to daphnids and fish and moderate toxicity to algae. Similar ecotoxicity trends 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 ECCC under the New Substances Notification Program. Available ecotoxicity data for the three poly(EDMA) polymers and various analogues are summarized in Table 3-4 and Table 3-5.

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

CAS RNs	Organism	Result (mg/L) ^a	Test method	Reference
25988-97-0	Daphnid (<i>D. magna</i>)	48-h NOEL=1.56 ^b	NR ^c	Canada 2015, ECCC 2015
25988-97-0	Daphnid (<i>D. magna</i>)	48-h LC ₅₀ =3.64 ^b	NR ^c	Canada 2015, ECCC 2015
25988-97-0	Daphnid (<i>D. magna</i>)	48-h EC ₅₀ =0.08	ASTM	Cary et al. 1987
25988-97-0	Fish (<i>O. mykiss</i>)	96-h LC ₅₀ =1.49 ^b	NR ^c	Canada 2015, ECCC 2015
25988-97-0	Fish (<i>O. mykiss</i>)	96-h NOEL=0.625 ^b	NR ^c	Canada 2015, ECCC 2015
25988-97-0	Fish (<i>O. mykiss</i>)	96-h LC ₅₀ =0.27- 0.78	NR ^c	Goodrich et al. 1991
25988-97-0	Fish (<i>O. mykiss</i>)	28-d LC ₅₀ =0.04- 0.14	NR ^c	Goodrich et al. 1991
25988-97-0	Fish (<i>O. mykiss</i>)	96-h LC ₅₀ =0.36- 44.3 ^d	NR ^c	Goodrich et al. 1991
25988-97-0	Fish (<i>P. promelas</i>)	96-h LC ₅₀ =1.17 ^b	NR ^c	Canada 2015, ECCC 2015
25988-97-0	Fish (<i>P. promelas</i>)	96-h NOEL=0.625 ^b	NR ^c	Canada 2015, ECCC 2015
25988-97-0	Fish (<i>Lepomis macrochirus</i>)	96-h LC ₅₀ =0.18	ASTM ^c	Cary et al. 1987
25988-97-0	Fish (<i>P. promelas</i>)	96-h LC ₅₀ =0.25	ASTM ^c	Cary et al. 1987
25988-97-0	Fish (<i>B. rerio</i>)	96-h LC ₅₀ > 10	OECD 203 ^c (fish acute toxicity test)	Canada 2015, ECCC 2015
42751-79-1	Green algae	72-h EC ₅₀ =10- 100	OECD 201 ^c (growth inhibition test)	Canada 2015, ECCC 2015
42751-79-1	Daphnid (<i>D. magna</i>)	48-h EC ₅₀ =10- 100	OECD 202 ^c (Daphnia acute immobilization)	Canada 2015, ECCC 2015
42751-79-1	Daphnid (<i>D. magna</i>)	NOEC=0.04	OECD 202 ^c (Daphnia acute immobilization)	Canada 2015, ECCC 2015
42751-79-1	Daphnid (<i>Ceriodaphnia</i>)	48-h EC ₅₀ =0.17	OECD 202 ^c (Daphnia acute immobilization)	Canada 2015, ECCC 2015
42751-79-1	Fish (<i>O. mykiss</i>)	96-h LC ₅₀ =0.16*	OECD 203 ^c (fish acute toxicity test)	Canada 2015, ECCC 2015

CAS RNs	Organism	Result (mg/L) ^a	Test method	Reference
42751-79-1	Fish (<i>O. mykiss</i>)	96-h NOEC=0.1	OECD203 ^c (fish acute toxicity test)	Canada 2015, ECCC 2015
42751-79-1	Fish (<i>L. macrochirus</i>)	96-h LC ₅₀ =0.39	OECD 203 ^c (fish acute toxicity test)	Canada 2015, ECCC 2015
42751-79-1	Fish (<i>L. macrochirus</i>)	96-h NOEC=0.24	OECD 203 ^c (fish acute toxicity test)	Canada 2015, ECCC 2015
42751-79-1	Fish (<i>P. promelas</i>)	96-h LC ₅₀ =0.67	OECD 203 ^c (fish acute toxicity test)	Canada 2015, ECCC 2015
42751-79-1	Fish (<i>P. promelas</i>)	96-h NOEC=0.31	OECD 203 ^c (fish acute toxicity test)	Canada 2015, ECCC 2015
42751-79-1	Fish (<i>B. rerio</i>)	96-h LC ₅₀ =10- 100	OECD 203 ^c (fish acute toxicity test)	Canada 2015, ECCC 2015
42751-79-1	Mysid shrimp	48-h LC ₅₀ =2500	NR ^c	Canada 2015, ECCC 2015
52722-38-0	Fish (<i>L. macrochirus</i>)	96-h LC ₅₀ =0.52	NR ^c	Canada 2015, ECCC 2015
52722-38-0	Fish (<i>O. mykiss</i>)	96-h LC ₅₀ =0.24	NR ^c	Canada 2015, ECCC 2015
52722-38-0	Fish (<i>Cyprinodon variegatus</i>)	96-h LC ₅₀ =2.2	NR ^c	Canada 2015, ECCC 2015
52722-38-0	Fish (<i>Menidia beryllina</i>)	96-h LC ₅₀ =707	NR ^c	Canada 2015, ECCC 2015

^a EC₅₀ is the effect concentration for 50% of the population; LC₅₀ is the lethal concentration for 50% of the population; IC₅₀ is the inhibition concentration for 50% of the population; NOEC is the no observed effect concentration. These results are without mitigation.

^b With humic acid; concentration unknown.

^c NR: None reported; ASTM: American Society for Testing and Materials; OECD: Organisation for Economic Co-operation and Development.

^d With 0.5 mg/L to 50 mg/L of humic acid.

*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	96-h EC ₅₀	0.016	Boethling and Nabholz 1997 ^c
Daphnid	48-h EC ₅₀	<1 ^b	Notified to the New Substances Program (ECCC)
Daphnid	48-h EC ₅₀	0.34	Boethling and Nabholz 1997 ^c
Fish ^d	96-h LC ₅₀	<1 ^b	Notified to the New Substances Program (ECCC)
Fish ^e	96-h LC ₅₀	0.13	Boethling and Nabholz 1997 ^c

^a EC₅₀ is the effect concentration for 50% of the population; LC₅₀ is the lethal concentration for 50% of the population; IC₅₀ 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 (< 1000 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. In addition, Boethling and Nabholz (1997) reported that the addition of approximately 10 mg/L of humic acid to laboratory ecotoxicity tests simulates environmental organic carbon levels. Considering that the three poly(EDMA) polymers are polycationic, similar mitigation of ecotoxicity would be expected.

Goodrich et al. (1991) demonstrated that with increasing humic acid, the apparent LC₅₀ increases with increasing humic acid concentration (Table 3-4). In addition, Cary et al. (1987) studied effects in the fathead minnow (*Pimephales promelas*) and cladoceran (*Daphnia magna*) in acute exposures to poly(EDMA) (CAS RN 25988-97-0) with 50 mg/L suspended solids (bentonite, illite, kaolin and silica) and 10 mg/L dissolved organic carbon compounds (humic, fulvic and tannic acids, lignin and lignosite). Table 3-6 summarizes the toxicity and mitigation factor data from this study.

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

Substrate	<i>Daphnia magna</i> (48-h EC ₅₀ , mg/L) ^a	Mitigation factor for <i>Daphnia magna</i> ^b	<i>Pimephales promelas</i> (96-h LC ₅₀ , mg/L) ^a	Mitigation factor for <i>Pimephales promelas</i> ^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-h and 96-h static acute EC₅₀ and LC₅₀ based on nominal concentrations. EC₅₀ is the effect concentration for 50% of the population. LC₅₀ 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.

Based on the mitigation data presented in Table 3-6, a mitigation factor of 63 is applied to *Daphnia* and a mitigation factor of 16 is applied to fish species. As there is no mitigation factor available for algae to poly(EDMA), the lowest mitigation value of 16 as reported by Cary et al. (1987) for fish 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, daphnids and fish after considering 63-fold mitigation for daphnia and 16-fold mitigation fish and algae (see Appendix C for more detail).

No sediment or soil ecotoxicity data were identified for the two poly(EDMA) polymers. Like poly(DADMAC) polymers, poly(EDMA) polymers are polycationics with high cationicity that are expected to strongly adsorb onto sediments and soil. On the basis of the strong adsorption, poly(EDMA) are anticipated to have low bioavailability to sediment and soil-dwelling organisms. Overall, the three poly(EDMA) polymers are expected to show moderate toxicity to aquatic organisms and low toxicity to soil and sediment-dwelling species in natural environments. On the basis of available data, the lowest mitigated ecotoxicity endpoint reported for the three poly(EDMA) polymers (96-h LC₅₀ of 2.56 mg/L in *O. mykiss*, which corresponds to the unmitigated 96-h LC₅₀ 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).

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 to represent mode of action assuming a non-narcotic mode of action (i.e., adsorption to fish gills) for the three poly(EDMA) polymers. This results in an aquatic PNEC of 0.128 mg/L (see Appendix C for more detail).

A PNEC was not developed for soil and sediment species as poly(EDMA) are anticipated to have low bioavailability, resulting in low toxicity towards soil and sediment.

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 imported into Canada and 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.

The four major poly(EDMA) polymers uses that can result in releases to the aquatic environment are treatment of drinking water, industrial wastewater treatment, wastewater treatment, and use as a processing aid in the pulp and paper industry.

The qualitative scenarios for drinking water treatment, industrial wastewater treatment and wastewater treatment have already been discussed in section 2.6.2 and are also applicable to the three poly(EDMA) polymers. Since manufacturing of poly(EDMA) polymers was not reported in Canada (Canada 2015; ECCC 2015) and given that releases from applications of the three poly(EDMA) polymers in petroleum production are expected to be low (see section 2.6.2), these scenarios are not further considered. The qualitative scenario for use as a processing aid in the pulp and paper industry is discussed below.

Processing aid in the pulp and paper industry

Papermakers use water-soluble polymer flocculants (1) to improve retention within the sheet of fibre 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 fibres 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. 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 systems.

3.6.3 Characterization of ecological risk

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

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. According to the survey data, each substance was imported into Canada in quantities of up to 10 million kg in 2014.

Water solubility information reported for the three poly(EDMA) polymers indicates they are highly water-soluble. When released to 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 in aquatic organisms.

According to the ecological hazard profile of the two poly(DADMAC) polymers, they generally have moderate toxicity to algae, daphnids 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 the treatment of drinking water, industrial wastewater, or wastewater treatment, in 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 that reach the aquatic environment are not expected to be bioavailable because they rapidly and irreversibly form 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 on the 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) polymers is 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 the general population was moderate (see Appendix A). However, the human health hazard for the three poly(EDMA) was determined to be low. Therefore, considering the available data, it is unlikely that exposure to the substances will pose a human health risk (ECCC, HC 2018).

4. Poly(ASPCA)

4.1 Identity of substances

The four substances, namely ethanaminium, N,N,N-trimethyl-2-[(1-oxo-2-propenyl)oxy]-, chloride, polymer with 2-propenamamide (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 were included in the poly(amines) group as they contain cationic or potentially cationic amines; however, they are not structurally similar to each other or to either poly(DADMAC) or poly(EDMA) subgroups. As such, the four substances are considered in this section together. It is acknowledged that the physical and chemical properties and hazard properties of each substance differ. A conservative approach is taken to ensure that, regardless of the substance, the screening assessment would be protective of the environment.

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).

Overall, poly(ASPCA) polymers are high charge density cationic polymers with an expected number average molecular weight (M_n) greater than 1000 Da with low oligomeric content. The M_n values are typically in the range of thousands of daltons, and even up to a million for some products (Barajas et al. 2004; Canada 2015; ECCC 2015). The poly(ASPCA) and similar polymers are usually imported as a powder or a liquid concentrate having a solids level in the range of 10% to 50% (Canada 2015; ECCC 2015).

The composition of poly(ASPCA) polymers was 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 chemical composition is known to vary depending on the application. Therefore, representative information from various sources was considered for the purpose of this assessment.

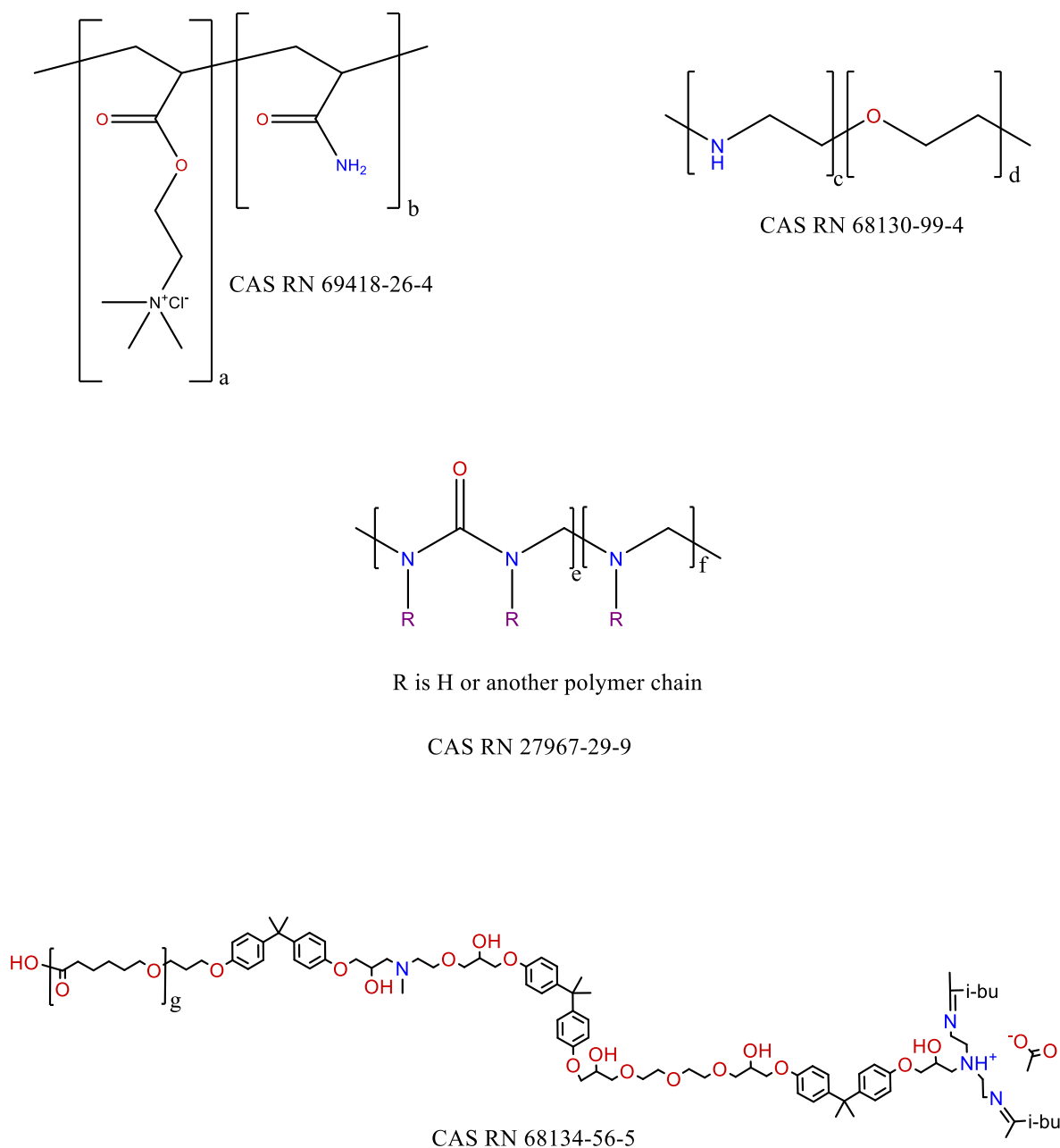


Figure 4-1. Representative structures of the four poly(ASPCA) polymers

The four poly(ASPCA) polymers are ethanaminium, N,N,N-trimethyl-2-[(1-oxo-2-propenyl)oxy]-, chloride, polymer with 2-propenamamide (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 available physical and chemical data identified for poly(DADMAC).

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

Corresponding CAS RN	69418-26-4	68130-99-4	27967-29-9	68134-56-5	Reference
Physical form	Solid powder	Liquid	liquid	Liquid	ECCC 2015, SDS 2015a, SDS 2015b
Mn ^a (Da)	>10 000	>10 000	>1000	>1000 ^b	Canada 2015
Wt % < 1000 Da ^c	0	0	<25	<25 ^b	Canada 2015
Wt % < 500 Da ^d	0	0	<10	<10 ^b	Canada 2015
Density (g/cm ³)	1.04	1.05–1.25	1.1–1.3	Unknown	Canada 2015, ECCC 2015
Charge density (mol N ⁺ /1000 g)	3.8 ^e	11.5 ^e	9.9 ^e	Not determined ^e	
Water solubility (mg/L)	Soluble	Soluble	Unknown	Dispersible ^b	Canada 2015, ECCC 2015

^a Number average molecular weight (Mn)

^b Data obtained for similar polymers, notified to the New Substances Notification Program. Data are masked to protect Confidential Business Information.

^c Residual constituents with molecular weights less than 1000 Da.

^d Residual constituents with molecular weights less than 500 Da.

^e The representative structures given in Figure 4-1 are simplified representations of the substances. Values are estimated on the basis of the linear representative structure. The substances may have branching points, leading to complex non-linear structures. The subscripts (a, b, c, d, e, f and g) in each of the structures are assumed to be 1. The amine equivalent weight is estimated by dividing the MW of the repeating unit by the number of amines that are or could become cationically charged. The charge density is calculated by dividing 1000 g by the amine equivalent weight. The charge density for CAS RN 68134-56-5, was not determined due to the large complex representative structure.

Properties of the four poly(ASPCA) polymers were not modelled using QSAR models. These polymers have a number average molecular weight of greater than 1000 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 the reporting year 2014. According to survey information, the majority of the quantities reported for the poly(ASPCA) polymers are used in water treatment and in oil field applications. 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.

Table 4-2. Summary of information on Canadian manufacturing, import and use quantities of poly(ASPCA) polymers in 2014 reporting year

Substance	Total manufacture ^a (million kg)	Total imports ^a (million kg)	Reference
69418-26-4	0	10–20	Canada 2015, ECCC 2015
68130-99-4	0	1–10	Canada 2015, ECCC 2015
27967-29-9	0	0.01–0.1	Canada 2015, ECCC 2015
68134-56-5	0	0.1–1	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

The majority of the quantities reported for poly(ASPCA) group of polymers are used in water treatment and in oil field applications. Like poly(DADMAC), the poly(ASPCA) polymers have high cationic charge and are also used in water treatment processes, where they are expected to bind irreversibly to natural organic matter and other suspended matters to form floc and become unavailable.

According to the survey information, poly(ASPCA) polymers may be used in laundry products, where they will be released directly into sewage systems. Poly(ASPCA) are expected to be adsorbed onto anionic matter in the sewer system before reaching the wastewater treatment plant, and will be removed through flocs. Although this may increase overall load, it is not expected to be significant, as the quantities used in laundry products are significantly less than those used in water treatment processes. Furthermore, releases of poly(ASPCA) through laundry products are expected to occur throughout Canada, and thus overall quantities being released at a single location would be expected to be lower.

Under normal conditions, poly(ASPCA) polymers used in either adhesives and sealants or in paints and coating applications are not expected to be released into wastewater treatment systems. In either application, poly(ASPCA) are expected to be trapped within cured adhesives/sealants and or paints and coatings. Considering the quantities involved, they are not expected to result in releases greater than those from uses in water treatment and oil field applications.

Therefore, for the purpose of the poly(ASPCA) assessment, only uses that will result in the greatest releases are considered.

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 1000 Da. Like poly(DADMAC) polymers, 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

Available biodegradation data 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	10% to 20% DOC reduction (28-d)	OECD 301A ^a (biodegradation test)	SDS 2015b

^a OECD: Organisation for Economic Co-operation and Development

According to the study results summarized in a SDS (2015b), CAS RN 68130-99-4 has been reported to be not readily biodegradable.

CAS RN 69418-26-4, another polymer from this group, is a cationic poly(acrylamide) (CPAM) with ester and amide functional groups. Under alkaline conditions (pH >10), CPAM may undergo hydrolysis to generate poly(acrylic acid-acrylamide) polymer, which is more stable than CPAM (Aksberg and Wagberg 1989; Lafuma and Durand 1989; Saponkanaporn and Gehr 1989; Smith-Palmer et al. 1994). According to Chang et al. (2001), CPAM will undergo degradation through abiotic processes, to generate free trimethylaminoethanol, which can then be further degraded through anaerobic processes. Furthermore, it has been shown that the resulting polymer is stable and does not undergo additional degradation (Chang et al. 2001; Lafuma and Durand 1989). 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 that may be susceptible to environmental degradation processes (hydrolysis or biodegradation). Given 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 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.

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.

The overall trend shows that the four poly(ASPCA) polymers are not significantly hydrolyzable or biodegradable under environmentally relevant conditions. Therefore, 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 1000 Da (i.e., large molecular dimensions) and no significant percentage of low molecular weight constituents. Similar to poly(DADMAC) polymers, polymers with high cationic charge density, Mn greater than 1000 Da and no significant percentage of low molecular weight constituents, the bioaccumulation potential of the four poly(ASPCA) polymers 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 (Canada 2015; ECCC 2015). The empirical data provided by stakeholders suggest that the poly(ASPCA) polymers could have moderate to low ecotoxicity to daphnids and fish. However, ecotoxicity data for similar substances suggest that poly(ASPCA) substances could have high toxicity towards all three species. Available ecotoxicity data for the two poly(ASPCA) polymers and various analogues are summarized in Table 4-4 and Table 4-5.

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

CAS RNs	Organism	Result (mg/L) ^a	Test method	Reference
68130-99-4	Daphnid (<i>Ceriodaphnia</i>)	48-h EC ₅₀ > 100	OECD 202 ^b (daphnia acute immobilization)	SDS 2015b
69418-26-4	Fish (<i>B. rerio</i>)	96-h LC ₅₀ = 5	OECD 203 ^b (fish acute toxicity test)	SDS 2013
68130-99-4	Aquatic activated sludge	0.5-h EC ₂₀ > 1000	OECD 209 ^b (activated sludge, respiration inhibition test)	SDS 2015b

^a EC₅₀ is the effect concentration for 50% of the population; LC₅₀ is the lethal concentration for 50% of the population; IC₅₀ 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; OECD: Organisation for Economic Co-operation and Development

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

Organism	Effect ^a	Result (mg/L)	Reference
Algae	72-h IC ₅₀	0.1–10 ^b	Notified to the New Substances Program (ECCC)
Daphnid	48-h EC ₅₀	1–100 ^b	Notified to the New Substances Program (ECCC)
Fish ^d	96-h LC ₅₀	0.1–10 ^b	Notified to the New Substances Program (ECCC)
Fish ^e	96-h LC ₅₀	0.76	Boethling and Nabholz 1997 ^c
Fish (<i>O. mykiss</i>)	96-h LC ₅₀	0.66	Goodrich et al. 1991
Fish (<i>O. mykiss</i>)	96-h LC ₅₀	1.2–38.9 ^f	Goodrich et al. 1991
Fish (<i>O. mykiss</i>)	28-d LC ₅₀	0.3	Goodrich et al. 1991
Fish (<i>G. holbrooki</i>)	96-h LC ₅₀	0.5–2.0	Cumming et al. 2008
Daphnid (<i>D. magna</i>)	48-h EC ₅₀	0.21	Cary et al. 1987
Fish (<i>P. promelas</i>)	96-h LC ₅₀	0.16*	Cary et al. 1987
Fish (<i>L. macrochirus</i>)	96-h LC ₅₀	0.32	Cary et al. 1987
Fish (<i>I. punctatus</i>)	96-h LC ₅₀	0.59	Cary et al. 1987

^a EC₅₀ is the effect concentration for 50% of the population; LC₅₀ is the lethal concentration for 50% of the population; IC₅₀ is the inhibition concentration for 50% of the population.

^b Analogue identified through the ECCC's New Substances 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.

^f With 0.5 mg/L to 50 mg/L of humic acid.

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

All poly(ASPCA) polymers have number average molecular weights (>1000 Da) and are out of the range where modelling software is generally considered reliable (< 1000 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. In addition, Boethling and

Nabholz (1997) reported that the addition of approximately 10 mg/L of humic acid to laboratory ecotoxicity tests simulates environmental organic carbon levels. Considering that the four poly(ASPCA) are polycationic polymers, similar mitigation of ecotoxicity would be expected.

Goodrich et al. (1991) demonstrated that the apparent LC₅₀ increases with increasing humic acid concentration (Table 4-5). In addition, Cary et al. (1987) studied effects in the fathead minnow (*Pimephales promelas*) and cladoceran (*Daphnia magna*) in acute exposures to an analogue of poly(ASPCA) (CAS RN 26062-79-3) with 50 mg/L suspended solids (bentonite, illite, kaolin and silica) and 10 mg/L dissolved organic carbon compounds (humic, fulvic and tannic acids, lignin and lignosite). Table 4-6 summarizes the toxicity and mitigation data from this study.

Table 4-6. Acute toxicities and toxicity mitigation factors of an analogue for poly(ASPCA) (CAS RN 69418-26-4) to *Daphnia magna* and to *Pimephales promelas* (fathead minnow) in the presence of suspended solids and dissolved organics (Cary et al. 1987)

Substrate	<i>Daphnia magna</i> (48-h EC ₅₀ , mg/L) ^a	Mitigation factor for <i>Daphnia magna</i> ^b	<i>Pimephales promelas</i> (96-h LC ₅₀ , mg/L) ^a	Mitigation factor for <i>Pimephales promelas</i> ^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-h and 96-h static acute EC₅₀ and LC₅₀ based on nominal concentrations. EC₅₀ is the effect concentration for 50% of the population. LC₅₀ 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

Based on the mitigation data presented in Table 4-6, a mitigation factor of 50 is applied to daphnia, and mitigation factor of 40 is applied to fish species. As there are no mitigation factors available for algae to poly(ASPCA) polymers or the analogue substance, the lowest mitigation value of 40 as reported by Cary et al. (1987) for fish 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, daphnids and fish after considering 50-fold mitigation for daphnia and 40-fold mitigation for fish and algae (see Appendix D for more detail).

No sediment ecotoxicity data were provided for the four poly(ASPCA) polymers or were otherwise identified. As noted in section 2.6.1 for poly(DADMAC) polymers, polycationics with high cationicity are expected to irreversibly adsorb onto sediments and soil. Considering that poly(ASPCA) polymers are also anticipated to have high cationicity, they are expected to have minimal bioavailability to soil- and sediment-dwelling organisms.

Overall, the four poly(ASPCA) polymers are expected to show moderate to low toxicity to aquatic organisms and low toxicity to soil- and sediment-dwelling species in natural environments. On the basis of available data, the lowest mitigated ecotoxicity endpoint reported for an analogue polymer (96-h LC₅₀ of 4 to 40 mg/L in fish, which corresponds to the unmitigated 96-h LC₅₀ of 0.1 to 1 mg/L multiplied 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).

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 (i.e., adsorption to fish gills) for the four poly(ASPCA) polymers. This results in an aquatic PNEC of 0.2 mg/L (see Appendix D for more details).

A PNEC was not developed for soil and sediment species as poly(ASPCA) are anticipated to have low bioavailability, resulting in low toxicity towards soil and sediment.

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 imported into Canada and 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. No manufacturing of these polymers in Canada was reported (Canada 2015; ECCC 2015). Releases from consumers are treated by wastewater treatment facilities.

The three major poly(ASPCA) polymers uses that can result in releases to the aquatic environment include drinking water treatment, industrial waste water treatment and wastewater treatment. These scenarios are described in section 2.6.2, and are applicable to the four poly(ASPCA) polymers. The higher quantities for the four poly(ASPCA) polymers is not expected to affect the outcome of the exposure assessment.

Since manufacturing of poly(ASPCA) polymers was not reported in Canada (Canada 2015; ECCC 2015), and since releases from applications of the four poly(ASPCA) polymers in petroleum production are expected to be low (see section 2.6.2), these scenarios are not considered further.

4.6.3 Characterization of ecological risk

The approach taken in this ecological risk assessment was to examine available information and develop conclusions based upon 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 in drinking water and wastewater treatment, in oil field applications, and as liquid laundry and dishwashing detergent additives, automotive paint and coating additives, and adhesive and sealant additives. According to the survey data, the four polymers were imported into Canada in quantities of up to 20 million kg in 2014.

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 their 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, daphnids 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 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 on the 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) polymers is 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 the general population ranged from low to high (see Appendix A). However, the human health hazard for the Four poly(ASPCA) polymers was determined to be low. Therefore, taking into consideration the available data, it is unlikely that exposure to the substances will pose a human health risk (ECCC, HC 2018).

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 reactivity. In the event of overdosing when being added to wastewater as a flocculant, any unreacted polymer residues that reach the aquatic environment are not expected to be bioavailable because they rapidly and irreversibly form floc with anionic materials in water. Therefore, moderate overdosing is not expected to result in a significant increase in ecological risk.

There are uncertainties associated with the hazard potential of the nine substances considered in this assessment due to a lack of ecotoxicity data for sediment- and soil-dwelling species. However, the high cationic charge of these substances is expected to result in their strong adsorption to sediments and soils, which would significantly reduce their bioavailability. Therefore, the lack of ecotoxicity data is not anticipated to result in

underestimation of the hazard potential or risk of these substances in natural sediment and soil compartments.

6. Conclusion

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to the environment from the nine poly(amines). It is concluded 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.

On the basis of the information presented in this screening assessment, it is concluded 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 concluded that the nine poly(amines) do not meet any of the criteria set out in section 64 of CEPA.

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Appendix A. Human health assessment approach applied during the second phase of polymer rapid screening

The approach applied to characterize the risk to human health during the second phase of polymer rapid screening is outlined in this section.

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 2018). This process consisted of determining the location of each polymer in a health risk matrix, and assigning a low, moderate or high level of potential concern to substances based on their hazard and exposure profiles. The matrix has three exposure bands representing 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 as derived through its use pattern, import, manufacture or use quantity, and water extractability. To determine whether 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 associated with polymers that 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 associated with polymers that 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 associated with polymers that are anticipated to have low direct or indirect exposure. This exposure band includes polymers that are used in the industrial sector to form manufactured articles and that 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 that 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 show or suggest that the polymer may pose a human health risk. **The middle hazard band (B)** is associated with polymers that 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 that may be associated with human health effects. **The lowest hazard band (A)** is associated with polymers that do not contain a RFG or other structural feature or metal that is known to be associated with human health concerns and for which available toxicological data indicate 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 that 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 given polymer), as well as the use of conservative exposure scenarios, increases 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 the document *Second Phase of Polymer Rapid Screening: Results of the Screening Assessment* (ECCC, HC 2018).

Based upon 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 B. PNEC derivation for poly(DADMAC) polymers

Table B-1. 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 (<i>C. vulgaris</i>)	72-h EC ₅₀ =0.16	2.24	5	0.448
26062-79-3	Algae (<i>C. vulgaris</i>)	72-h NOEC=0.065	0.91	1	0.91
26590-05-6	Daphnid (<i>D. magna</i>)	48-h EC ₅₀ =10-100	370-3700	10	37-370
26062-79-3	Daphnid (<i>D. magna</i>)	48-h EC ₅₀ =17.5-100	647.5-3700	10	64.75-370
26062-79-3	Fish (<i>G. holbrooki</i>)	96-h LC ₅₀ =0.5	7	10	0.7
26062-79-3	Fish (<i>O. mykiss</i>)	96-h LC ₅₀ =0.49	6.86	10	0.686
26062-79-3	Fish (<i>O. mykiss</i>)	96-h NOEC=0.37	5.18	5	1.03
26062-79-3	Fish (<i>P. promelas</i>)	96-h LC ₅₀ =0.46-1.65	6.44-23.1	10	0.644-2.31
26062-79-3	Fish (<i>P. promelas</i>)	96-h NOEC=0.15	2.1 (CTV ^d)	5	0.42 (Lowest SEV ^c)
26590-05-6	Fish	96-h LC ₅₀ =10-100	140-1400	10	14-140
26062-79-3	Fish (<i>B. rerio</i>)	96-h LC ₅₀ = 10 - 100	140-1400	10	14-140
26062-79-3	Mysid shrimp	48-h LC ₅₀ = 628.5	8799	10	879.9
26062-79-3	Mysid shrimp	48-h NOEC=125	1750	10	175

^a Mitigated by 37 for daphnids and by 14 for fish and algae (Cary et al. 1987).

^b F_{ES}: endpoint-standardization factor (extrapolates short term effects to long term no-effects).

^c SEV: standardized ecotoxicity value.

^d CTV: critical toxicity value (toxicity value that produces the lowest SEV).

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

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

F_{ES}: 10 for endpoint-standardization factor

F_{SV}: 1 for species variation (considers the number of species in the dataset). ≥7 species (algae and aquatic invertebrates and vertebrates).

F_{MOA}: 2 for mode-of-action factor (considers if substance is specifically acting, and possible effects not represented in dataset). Poly(cationic) substances are considered to be specifically acting due to adsorption to cell membranes and fish gills.

$$\text{Aquatic PNEC (mg/L)} = (2.1 \text{ mg/L}) / 5 \times 1 \times 2$$

$$\text{Aquatic PNEC (mg/L)} = (2.1 \text{ mg/L}) / 10$$

$$\text{Aquatic PNEC (mg/L)} = 0.21$$

Appendix C. PNEC derivation for poly(EDMA) polymers

Table C-1. Ecotoxicity data for poly(EDMA) polymers and analogue polymer

CAS RNs	Organism	Endpoint	Result (mg/L)	Mitigated ecotoxicity value ^a (mg/L)	F _{ES} ^b	SEV ^c (mg/L)
25988-97-0	Daphnid (<i>D. magna</i>)	48-h LC ₅₀	3.64	229.3	-	-
25988-97-0	Daphnid (<i>D. magna</i>)	48-h EC ₅₀	0.08	5.0	10	0.5
25988-97-0	Fish (<i>O. mykiss</i>)	96-h LC ₅₀	48-h1.49	23.8	10	2.38
25988-97-0	Fish (<i>O. mykiss</i>)	96-h LC ₅₀	0.27–0.78	0.36–44.3 _d	10	- ^e
25988-97-0	Fish (<i>O. mykiss</i>)	28-d LC ₅₀	0.04–0.14	0.6–2.2	1	0.6–2.2
25988-97-0	Fish (<i>P. promelas</i>)	96-h LC ₅₀	NA	1.17 ^f	10	-
25988-97-0	Fish (<i>L. macrochirus</i>)	96-h LC ₅₀	0.18	2.9	10	0.29
25988-97-0	Fish (<i>P. promelas</i>)	96-h LC ₅₀	0.25	4	10	0.4
25988-97-0	Fish (<i>B. rerio</i>)	96-h LC ₅₀	>10	>160	-	-
42751-79-1	Green algae	72-h EC ₅₀	10–100	160–1600	-	-
42751-79-1	Daphnid (<i>D. magna</i>)	48-h EC ₅₀	10–100	630–6300	-	-
42751-79-1	Daphnid (Ceriodaphnia)	48-h EC ₅₀	0.17	10.7	10	1.07
42751-79-1	Fish (<i>O. mykiss</i>)	96-h LC ₅₀	0.16* (CTV)	2.6	10	0.26
42751-79-1	Fish (<i>L. macrochirus</i>)	96-h LC ₅₀	0.39	6.2	10	0.62
42751-79-1	Fish (<i>P. promelas</i>)	96-h LC ₅₀	0.67	10.7	10	1.07
42751-79-1	Fish (<i>B. rerio</i>)	96-h LC ₅₀	10–100	160–1600	-	-
42751-79-1	Mysid shrimp	48-h LC ₅₀	2500	>2500	-	-
52722-38-0	Fish (<i>L. macrochirus</i>)	96-h LC ₅₀	0.52	8.3	10	0.83
52722-38-0	Fish (<i>O. mykiss</i>)	96-h LC ₅₀	0.24	3.8	10	0.38
52722-38-0	Fish (<i>C. variegatus</i>)	96-h LC ₅₀	2.2	35.2	10	3.52
52722-38-0	Fish (<i>M. beryllina</i>)	96-h LC ₅₀	707	>707	-	-
N/A ^g	Green algae	96-h EC ₅₀	0.016	0.26	5	-
N/A ^g	Daphnid	48-h EC ₅₀	0.34	21.4	10	-
N/A ^g	Fish ^e	96-h LC ₅₀	0.13	2.1	10	-

^a Mitigated by 63 for daphnids and by 16 for fish and algae (Cary et al. 1987).

^b F_{ES}: endpoint-standardization factor (extrapolates short term effects to long term no-effects).

^c SEV: standardized ecotoxicity value.

^d Experimental ecotoxicity data with 0.5 mg/L to 50 mg/L of humic acid. Additional cationic mitigation not applied.

^e After applying the endpoint standardization factor, the toxicity values would give one of the lowest standardized values (greatest toxicity). However, this value was not used, as the lowest ecotoxicity value was determined with only 0.5 mg/L of humic acid. When the concentration of humic acid increased to 5 mg/L, the substance becomes significantly less toxic. It should be noted that 10 mg/L of humic acid is generally representative of the natural environment's DOC level (Boethling and Nabholz 1997). Therefore, the standardized value is not reported and will not be considered for critical toxicity value determination.

^f Experimental ecotoxicity data with unknown concentration of humic acids. Additional cationic mitigation not applied. As the concentration of humic acid is unknown, the standardized value is not reported and will not be considered for critical toxicity value determination.

^g Experimental ecotoxicity data obtained from Boethling and Nabholz (1997) are used for comparison. As the details of the polymer are unknown, the values not be considered for critical toxicity value determination.

^h CTV: critical toxicity value (toxicity value that produces the lowest SEV).

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

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

F_{ES} : 10 for endpoint-standardization factor

F_{SV} : 1 for species variation (considers the number of species in the dataset). ≥ 7 species (algae and aquatic invertebrates and vertebrates)

F_{MOA} : 2 for mode-of-action factor (considers if substance is specifically acting, and possible effects not represented in dataset).

$$\text{Aquatic PNEC (mg/L)} = (2.56 \text{ mg/L}) / 10 \times 1 \times 2$$

$$\text{Aquatic PNEC (mg/L)} = (2.56 \text{ mg/L}) / 20$$

$$\text{Aquatic PNEC (mg/L)} = 0.128$$

Appendix D. PNEC derivation for poly(ASPCA) polymers

Table D-1. Ecotoxicity data for poly(ASPCA) polymers and analogue polymer

CAS RNs	Organism	Endpoint	Result (mg/L)	Mitigated ecotoxicity value ^a (mg/L)	F _{ES} ^b	SEV ^c (mg/L)
69418-26-4	Fish (<i>B. rerio</i>)	96-h LC ₅₀	5	200	10	20
N/A ^e	Fish	96-h LC ₅₀	0.76	30.4	10	-
N/A ^f	Algae	72-h IC ₅₀	0.1–10	4–400	5	0.8–80
N/A ^f	Daphnid	48-h EC ₅₀	1–100	50–5000	10	5–500
N/A ^f	Fish	96-h LC ₅₀	0.1–10* (CTV)	4–400	10	0.4–40
N/A ^h	Fish (<i>O. mykiss</i>)	96-h LC ₅₀	0.66	1.2–38.9 ^d	10	- ^g
N/A ^h	Fish (<i>O. mykiss</i>)	28-d LC ₅₀	0.3	12	10	1.2
N/A ⁱ	Fish (<i>G. holbrooki</i>)	96-h LC ₅₀	0.5–2.0	20–80	10	2–8
N/A ^j	Daphnid (<i>D. magna</i>)	48-h EC ₅₀	0.21	10.5	10	1.05
N/A ^j	Fish (<i>P. promelas</i>)	96-h LC ₅₀	0.16*	8	10	0.8
N/A ^j	Fish (<i>L. macrochirus</i>)	96-h LC ₅₀	0.32	16	10	1.6
N/A ^j	Fish (<i>I. punctatus</i>)	96-h LC ₅₀	0.59	23.6	10	2.36

^a Mitigated by 50 for daphnids and by 40 for fish and algae (Cary et al. 1987).

^b F_{ES}: endpoint-standardization factor (extrapolates short-term effects to long-term no-effects).

^c SEV: standardized ecotoxicity value.

^d Experimental ecotoxicity data with 0.5 mg/L to 50 mg/L of humic acid. Additional cationic mitigation not applied.

^e Experimental ecotoxicity data obtained from Boethling and Nabholz (1997) are used for comparison. As the details of the polymers is unknown, the values are not considered for critical toxicity value determination.

^f Experimental ecotoxicity data obtained from Notified to the New Substances Program (ECCC), CAS RN are considered confidential business information.

^g After applying the endpoint standardization factor, the toxicity values would give one of the lowest standardized values. However, this value was not used, as the lowest ecotoxicity value was determined with only 0.5 mg/L of humic acid. As the concentration of humic acid increased to 5 mg/L, the toxicity value becomes significantly greater. It should be noted that 10 mg/L of humic acid is generally representative of the natural environment's DOC level (Boethling and Nabholz 1997). The standardized value is therefore not reported and will not be considered for critical toxicity value determination.

^h Ecotoxicity data obtained from Goodrich et al. (1987) are used for comparison. CAS RN were not given.

ⁱ Ecotoxicity data obtained from Cumming (2008) are used for comparison. Data were for multiple CAS RN.

^j Ecotoxicity data obtained from Cary et al. (1987) are used for comparison. CAS RN were not given.

*CTV: critical toxicity value (toxicity value that produces the lowest SEV).

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

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

F_{ES}: 10 for endpoint-standardization factor

F_{SV}: 1 for species variation (considers the number of species in the dataset). ≥7 species (algae and aquatic invertebrates and vertebrates)

F_{MOA}: 2 for mode-of-action factor (considers if substance is specifically acting, and possible effects not represented in dataset).

Aquatic PNEC (mg/L) = (4.0 mg/L) / 10×1×2

Aquatic PNEC (mg/L) = (4.0 mg/L) / 20

Aquatic PNEC (mg/L) = 0.2 mg/L