Draft screening assessment

Epoxy Resins Group

Chemical Abstracts Service Registry Numbers
25036-25-3
25068-38-6
25085-99-8
28064-14-4

Environment and Climate Change Canada
Health Canada

March 2018

Synopsis

Pursuant to section 74 of the Canadian Environmental Protection Act, 1999 (CEPA), the Minister of Environment and the Minister of Health have conducted screening assessments of four substances referred to collectively as the Epoxy Resins Group. Substances in this group [namely three Diglycidyl Ether of Bisphenol A (DGEBA) epoxy resins and Novolac epoxy resin] were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA. The Chemical Abstracts Service Registry Numbers (CAS RN[1]), their Domestic Substances List (DSL) names and their common names are listed in the table below.

Substances in the Epoxy Resins Group

CAS RN[a]	Domestic Substances List name	Common names
25036-25-3	Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2, 2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis[oxirane]	DGEBA epoxy resin
25068-38-6	Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane	DGEBA epoxy resin
25085-99-8	Oxirane, 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis-, homopolymer	DGEBA epoxy resin
28064-14-4	Phenol, polymer with formaldehyde, glycidyl ether	Novolac epoxy resin

These four substances were previously evaluated under the Second Phase of Polymer Rapid Screening, which identified CAS RN 25036-25-3 (one of the DGEBA epoxy resins) and CAS RN 28064-14-4 (Novolac epoxy resin) as having low potential to cause ecological harm. The three DEGBA epoxy resins and Novolac epoxy resin were identified as requiring further assessment for potential human health and/or ecological risks on the basis of structural alerts and/or uses associated with significant consumer exposure. The present assessment further elaborates on the potential for DGEBA epoxy resins to cause harm to human health and ecological harm, and for Novolac epoxy resin to cause harm to human health, in order to reach an overall conclusion

[1] The Chemical Abstracts Service Registry Number (CAS RN) is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

under section 64 of CEPA as to whether they pose a risk to the environment or human health.

The four epoxy resins do not occur naturally in the environment. In Canada, they are reported to be used as crosslinkers and binders in paints/coatings and plating agent, as intermediates, adhesives and sealants in grout, flooring, plastics, concrete, lubricants and lubricant additives, as corrosion inhibitors and anti-scaling agents, and as processing aids specific to petroleum production. In addition, epoxy resins have been identified as components used in the manufacture of some food packaging materials.

DGEBA and Novolac epoxy resins contain epoxy reactive functional groups which are associated with potential adverse human health effects. They have moderate chronic toxicity (primarily associated with the lower molecular weight resins) and are dermal sensitizers however they have low acute toxicity and are not developmental or reproductive toxicants, teratogenic or carcinogenic in animal studies. The overall hazard associated with these substances is considered moderate. Canadians may be exposed to DGEBA epoxy resins from potential transfer of an insignificant amount of the resin from food packaging materials into food including canned liquid infant formula products. Quantities are very low because these substances are used up in the chemical reaction when the packaging is made. Dietary exposure to Novolac epoxy resin from food packaging is also expected to be negligible to the general population including children. Exposure to epoxy resins by inhalation is not expected due to their low vapour pressures. Dermal exposure to epoxy resins is considered minimal due to their usage in cured-form. Indirect exposure of the general public to epoxy resins through media such as drinking water is not expected due to their low water solubility.

A comparison of estimated levels of exposure to DGEBA epoxy resins and the critical effect level result in margins of exposure that are considered adequate to account for uncertainties in the health effects and exposure databases.

Considering all available lines of evidence presented in this draft screening assessment, there is low risk of harm to the environment from DGEBA epoxy resin and Novolac epoxy resin. It is proposed to conclude that DGEBA epoxy resins and Novolac epoxy resin do not meet the criteria under paragraphs 64(*a*) and (*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.

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

Therefore, it is proposed to conclude that the four epoxy resins do not meet any of the criteria set out in section 64 of CEPA.

Table of contents

List of tables

List of figures

1. Introduction

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

While the four substances considered in this assessment are collectively referred to as the epoxy resins group, three of them (DGEBA epoxy resins) have similarities that would support a group approach to exposure, hazard and risk characterization; thus, their exposure and hazard profiles were collectively assessed for risk. The assessment of Novolac epoxy resin forms its own chapter.

The substances considered in this assessment have been previously evaluated using a rapid screening approach. The approach and results of its application, are presented in the document “Second Phase of Polymer Rapid Screening: Results of the Draft Screening Assessment” (ECCC, HC 2017). The ecological and human health rapid screening approaches are summarized in the Appendix of this screening assessment. Application of these approaches identified one of the DGEBA epoxy resins (CAS RN 25036-25-3) and Novolac epoxy resin as having low potential to cause ecological harm however further evaluation of human health risks was warranted. These results, in conjunction with any other relevant information that became available after the publication of the report on the second phase of polymer rapid screening, are considered in support of the conclusions made under section 64 of CEPA in this screening assessment.

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

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

This draft screening assessment focuses on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA, by examining scientific information and incorporating a weight of evidence approach and precaution[2]. The draft screening assessment presents the critical information and considerations upon which the proposed conclusion is made.

2. Diglycidyl Ether of Bisphenol A Epoxy Resins

2.1 Identity of substance

The most commonly used intermediate in epoxy resin technology is Diglycidyl Ether of Bisphenol A (DGEBA or BADGE) (Pascault 2010). It is the reaction product of bisphenol A and epichlorohydrin (Figure 2-1). DGEBA epoxy resins are prepared directly from bisphenol A and epichlorohydrin [route (a)], by homopolymerization of DGEBA [route (b)], or by reaction of DGEBA with bisphenol A [route (c)]. These epoxy resins are usually mixtures, which could be isomers, branched-chain oligomers, and monoglycidyl ethers (Bingham 2012). However, no residual monomers (i.e. bisphenol A and epichlorohydrin) are expected to remain as these processes involve several purification stages to remove all impurities.

The average degree of polymerization, n, varies from 0.1 up to 25. When n is very low (< 0.2), DGEBA epoxy resin is a low molecular weight (MW) liquid substance (comprising mostly DGEBA itself) usually with the CAS RN 25068-38-6. A majority of this low MW substance is used as starting material to produce high MW solid epoxy resins (n = 0.2 to 25) (Kirk-Othmer 2014). The CAS RNs 25085-99-8 (when n ≈ 0.2) and 25036-25-3 (when n > 0.2) are predominately used for higher MW solid DGEBA epoxy resins. These higher MW epoxy resins contain no or a limited amount of DGEBA in their formulations.

The performance characteristics of the DGEBA epoxy resins are due to the presence of the bisphenol A moiety (rigidity, toughness, and elevated temperature performance), the ether linkages (chemical resistance), and the hydroxyl and epoxy groups (reactivity with a variety of curing agents). Theoretically, two terminal epoxy groups are present in DGEBA epoxy resins. Epoxides are a reactive functional group associated with adverse human health effects (US EPA 2010). In polymeric structures such as the one below,

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[2] 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.

flexibility and strength increase as the repeating unit (represented by the coefficient n) increases. Furthermore, the DGEBA epoxy resins can also be cured through the multiple hydroxyl groups along the backbones using cross-linkers (Jin 2015, Ullman's 2012).

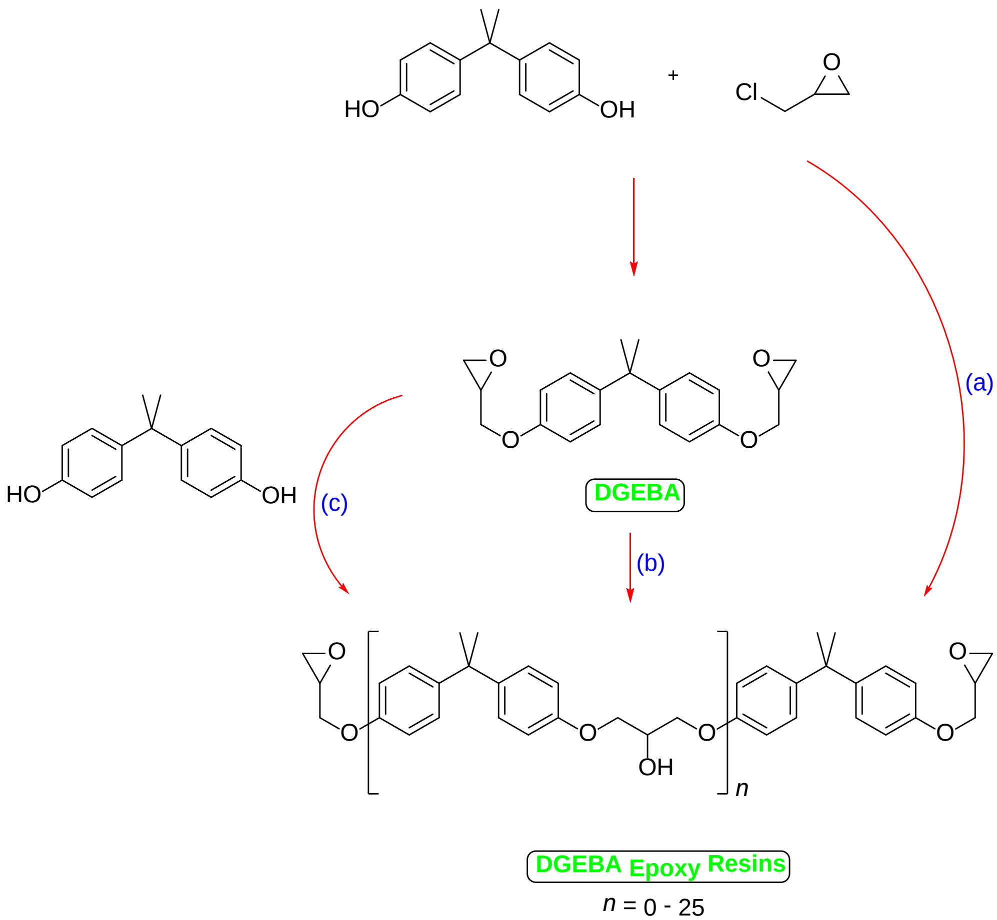


Figure 2-1. synthesis and representative structure of DGEBA epoxy resins

2.2 Physical and chemical properties

A summary of physical and chemical properties for DGEBA epoxy resins are presented in Table 2-1.

Table 2-1. physical and chemical property values (at standard temperature) for DGEBA epoxy resins

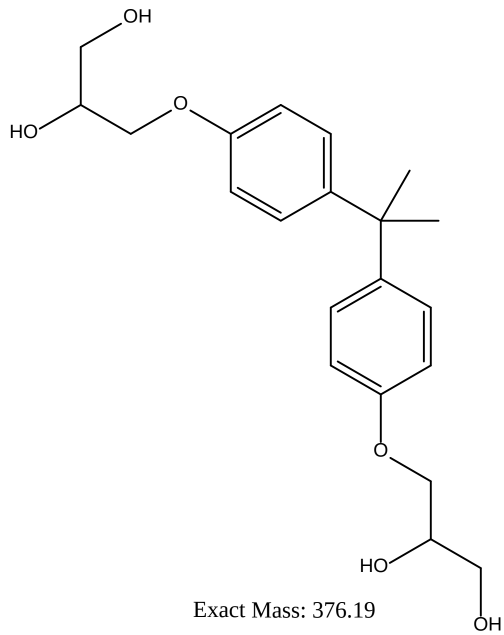
Corresponding CAS RN	**25068-38-6**	**25085-99-8**	**25036-25-3**	**NS**
Degree of polymerization	n ≤ 0.1	n ≈ 0.2	n = 2	n = 9
Physical form	liquid	liquid (viscous)	solid	solid
Number average molecular weight (g/mol)	350-370	380	900	2900
Melting point (°C)	-16-5	44-55	64-95	127-133
Boiling point (°C)	> 260	320 (decom.)	114-118	NA
Water solubility (mg/L)	3.6-6.9 @ 20°C	5.4-8.4 @ 20°C	3.7 @ 25°C	NA
Vapour pressure (Pa)	4.6×10^{-8} @ 25°C	$< 10^{-7}$	1.4×10^{-5} @ 25°C	NA
Density (g/cm^3)	1.16	1.16	1.17-1.20	1.15
Octanol/water partition co-efficient (log K_{ow})	2.8-3.25 @ 25°C, pH 7	3.24 (est.)	3.84	NA
Epoxy equivalent weight[(1)] (g/eq.)	172-185	182-195	450-525	1650-2050
Epoxide content [(1)] (%)	~ 24	~ 23	~ 9	~ 2
Biodegradation (%)	NA	12% @ 28 d	NA	NA
References	Kirk-Othmer 2014 Ullman’s 2012 ECHA c2007-2017b Canada 2015 ECCC 2015	Kirk-Othmer 2014 Ulmann’s 2012 DME 2012 Canada 2015 ECCC 2015	SciFinder Boyle 2001 Bingham 2012	Bingham 2012

NS: Not specifically identified; see Section 2.7.3.1 (Uncertainties in evaluation of risk to human health) for more information

NA: Not Available

[(1)] Epoxy equivalent weight (EEW) is the weight of resin required to obtain one equivalent of epoxy functional group. It is related to the epoxide content (%) of the epoxy resin through the following relationship: EEW = (43.05 ÷ % Epoxide) ×100

Epoxide groups are known to be susceptible to hydrolysis to form diols (Rickborn and Lamke 1967). Therefore, the terminal epoxide rings present in DGEBA epoxy resins are expected to readily hydrolyze under environmental conditions to form terminal diols. As a result, the environmental fate and ecotoxicity of the hydrolysis product in Figure 2-2 will be considered as part of the current assessment. Supplementary physical and chemical data modelled using this hydrolysis product is summarized in Table 2-2.



SMILE: CC(C1=CC=C(OCC(O)CO)C=C1)(C)C2=CC=C(OCC(O)CO)C=C2

Figure 2-2. representative structure of the hydrolysis product used for modelling

Table 2-2. supplementary physical and chemical data of the Hydrolysis Product

Property	Value	Sources
Water Solubility	96.18 mg/L	EPI v4.11 WSKOW v1.42
Octanol/water partition co-efficient (log K_{ow})	1.93	EPI v4.11 KOWWIN v1.68
Adsorption Desorption	Log K_{oc} = 1.28 (Log K_{ow})	EPI v4.11 KOCWIN v2.00
Henry's Law Constant	1.67×10^{-9} Pa-m3/mole	EPI v4.11 HENRYWIN v3.20 (Bond Estimate)
WWTS Removal[a]	Total removal = 2.19% Total biodegradation = 0.09%	EPI v4.11 STP Fugacity (10000 hr Bio P,A,S)

[a] wastewater treatment system (WWTS) removal

2.3 Sources and uses

DGEBA epoxy resins are prepared industrially. Uncured epoxy resins are frequently encountered in industrial settings (Ellis 1993). They are marketed in different physical forms and require an admixture with curing agents to form nonreactive cross-linked polymers (Boyle 2001).

DGEBA epoxy resins were included in a voluntary survey (ECCC 2015) as well as a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 2-3 presents a summary of the total manufacture and total import reported for the substance in 2014. These sources indicate that the functional uses for DGEBA epoxy resins in Canada included use as binders, coating agents, plating agents, adhesives, sealants, intermediates, lubricant additives, corrosion inhibitors, anti-scaling agents, and processing aids. Moreover, DGEBA epoxy resins in Canada have commercial and consumer uses, including toner and colorants, fence post backfill, epoxy primer, garage floor coating, and pesticides.

DGEBA epoxy resins are the most widely used epoxy resins (> 75% of resin sales volume) (Kirk-Othmer 2014). Globally, the largest use of epoxy resins is in protective coatings (> 50%), with the remainder being in structural applications such as printed circuit board laminates, semiconductor encapsulants, structural composites; tooling, molding, casting; flooring; adhesives (Petrie 2006); lithographic inks and photoresists for the electronics industry (Ullmann's 2012).

Table 2-3. **summary of information on Canadian manufacturing and import of DGEBA epoxy resins 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
25036-25-3	0	1-10	Canada 2015, ECCC 2015
25068-38-6	0.1-1	1-10	Canada 2015, ECCC 2015
25085-99-8	<0.1	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 surveys for specific inclusions and exclusions (schedules 2 and 3).

A number of domestic government databases were searched to determine if DGEBA epoxy resins are approved, licensed, and/or registered for uses in Canada. These uses for DGEBA epoxy resins are listed in Table 2-4.

Table 2-4. additional uses in Canada for DGEBA epoxy resins

Use	25068-38-6	25085-99-8	25036-25-3
Food additive[a]	No	No	No
Food packaging materials[b]	Yes	Yes	Yes
Internal Drug Product Database as medicinal or non-medicinal ingredients in final pharmaceutical, disinfectant or veterinary drug products in Canada[c]	No	No	No
Natural Health Products Ingredients Database[d]	No	No	No
Licensed Natural Health Products Database as medicinal or non-medicinal ingredients in natural health products in Canada[e]	No	No	No
List of Prohibited and Restricted Cosmetic Ingredients[f]	No	No	No
Notified to be present in cosmetics, based on notifications submitted under the Cosmetic Regulations to Health Canada[g]	Yes	No	No
Formulant in pest control products registered in Canada[h]	Yes (list 3)	No	No
Known Toy Use[i]	No	Yes (adhesive)	Yes (Paint)

[a] Health Canada (modified 2013)
[b] Food Directorate, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced
[c] DPD [modified 2015]
[d] NHPID [modified 2017]
[e] LNHPD [modified 2016]
[f] Health Canada [modified 2015]
[g] Consumer Product Safety Directorate, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced
[h] PMRA (2010)
[i] Toy Industry Spreadsheet (2016)

2.4 Releases to the environment

According to available information, large quantities of each of the three DGEBA epoxy resins was manufactured and/or imported into Canada in 2014 (see table 2-3) to be used mainly as components in two types of products: (1) adhesives and sealants, and (2) paints and coatings, according to the data collected under a regulatory survey (Canada 2015). The main functional uses for DGEBA epoxy resins in Canada are as binders, coating agents, adhesives, and intermediates to form epoxy coatings in industrial facilities.

Release to the environment of DGEBA epoxy resins is possible from the epoxy coating industries during use as an intermediate in further manufacturing of another substance, in the production of articles, formulation of mixtures and in processing aids at industrial sites.

Epoxy coatings are generally packaged in two parts that are mixed prior to application. The two parts consist of 1) an epoxy resin which is cross-linked with 2) a co-reactant or hardener. Epoxy coatings are formulated based upon the performance requirements for the end product. When properly catalyzed and applied, epoxies produce a hard, chemical and solvent resistant finish. The substance is consumed in the reaction with the curing agent to form an epoxy coating.

2.5 Environmental fate and behaviour

2.5.1 Environmental distribution

The three DGEBA epoxy resins have molecular weights between 350 and 900 daltons, and have water solubility less than 10 mg/L (see Table 2-1). During industrial use, DGEBA epoxy resins are expected to be mostly consumed in the reaction with the curing agent to form an epoxy coating as mentioned above. Small quantities of DEGBA epoxy resins may still be released into the environment during the various steps involved during application of the resins. Once in the environment, the three DGEBA epoxy resins are expected to hydrolyze and the hydrolysis products are not expected to volatilize into the air compartment as they have low expected Henry's Law constant (based on estimation, see Table 2-2). The hydrolysis products are anticipated to adsorb onto dissolve organic matter and settle to sediments. Any residual polymer is expected to remain in the water column.

2.5.2 Environmental persistence

Biodegradation data provided through voluntary (ECCC 2015) and mandatory surveys (Canada 2015) are summarized in Table 2-5.

Table 2-5. biodegradation data for the three DGEBA epoxy resin

CAS RN	Result (% degradation)	Test Method	Sources
25036-25-3	12	OECD 302	ECCC, HC 2007
25068-38-6	11	OECD 306	Canada 2015
25068-38-6	5	OECD 301F	SDS 2014
25068-38-6	0	OECD 301	SDS 2015a
25085-99-8	12	OECD 302	SDS 2011a

Biodegradation in sea water for CAS RN 25068-38-6 has been reported to be 11% in 28 days (Canada 2015). The low biodegradation value is supported by submitted Safety Data Sheet (SDS) data depicting 0 and 5% degradation.

The inherent biodegradation value for CAS RN 25085-99-8 has been reported to be 12% in 28 days according to SDS. It also specifies results are from test protocol OECD 302 but the full report was not provided.

The overall trend shows that the three DGEBA epoxy resins are not biodegradable.

Although there is no available information to assess the biodegradation potential of the three DGEBA epoxy resin in sediments, it is generally expected to be slower than in soil or water, where aerobic conditions favour biodegradation. As such, it is anticipated that the three DGEBA epoxy resins will have lower biodegradation in sediments.

Hydrolysis information for the three DGEBA epoxy resins was not provided. Based on their chemical structure, DGEBA epoxy resins are expected to be readily susceptible to hydrolysis where the terminal epoxide rings open and form terminal diols. The hydrolysis products are expected to be stable (May 1987).

Based on the experimental biodegradation data, the three DGEBA epoxy resins are not expected to be degraded rapidly in the aquatic environment. However, they are expected to be hydrolytically unstable under environmental conditions.

Although experimental data on the biodegradation of the three DGEBA epoxy resin are available, a QSAR-based weight-of-evidence approach was also applied using the degradation models shown in Table 2-6.

The predicted degradation parameters in Table 2-6 were based on the representative structure in Figure 2-2 representing the hydrolysis product, as the three DGEBA epoxy resins are expected to readily hydrolyze in the environment.

Table 2-6. summary of modelled data for degradation of a hydrolysis product[a]

Fate process	Model and model basis	Model prediction	Extrapolated half-life (days)
Water: Hydrolysis	EPI v4.11 HYDROWIN v2.00	NA[b]	NA
Ready Biodegradability Prediction	EPI v4.11 BIOWIN v4.10	No	≥182
Ultimate aerobic biodegradation: Probability	DS TOPKAT c2005-2009	[0][c] "biodegrades very slowly"	≥182
Ultimate aerobic biodegradation: % BOD (biological oxygen demand)	Catalogic 301C v.9.13	% BOD = 0 "biodegrades very slowly"	≥182

[a] The predicted degradation parameters were based on the representative structure of 376.19 Da with the following SMILES: CC(C1=CC=C(OCC(O)CO)C=C1)(C)C2=CC=C(OCC(O)CO)C=C2
[b] Model does not provide an estimate for this type of structure
[c] Output is a probability score
NA – Not available

Modelled results presented in Table 2-6 provide additional and relatively consistent evidence for the degradation potential of the three DGEBA epoxy resins.

Based on empirical and modelled data, the three DGEBA epoxy resins are expected to undergo environmental hydrolysis to form diols which are not readily biodegradable in the water, soil and sediment compartments.

2.5.3 Bioaccumulation potential

Empirical Octanol/Water Partition Coefficient (log Kow) and Bioconcentration Factor (BCF) data provided through voluntary (ECCC 2015) and mandatory surveys (Canada 2015) are summarized in Table 2-7.

Table 2-7. empirical octanol/water partition coefficient (log Kow) and Bioconcentration Factors (BCF)

CAS RNs	Property	Value	Test Method	Sources
25068-38-6	Octanol/Water Partition Coefficient (log K_{ow})	Log K_{ow} > 3	NA	SDS 2015a
25068-38-6	Octanol/Water Partition Coefficient (log K_{ow})	Log K_{ow}=3.2	NA	SDS 2014
25068-38-6	Octanol/Water Partition Coefficient (log K_{ow})	Log K_{ow}=3.6	OECD 117	Canada 2015
25068-38-6	Bioconcentration Factor (BCF)	BCF = 0.56~ 0.67	NA	SDS 2015a
25068-38-6	Bioconcentration Factor (BCF)	BCF = 31	NA	SDS 2014
25085-99-8	Bioconcentration Factor (BCF)	BCF = 100-3000	NA	SDS 2011a

The empirical Octanol/Water Partition Coefficient (log Kow) and BCFs summarized in Table 2-7 support low to moderate bioaccumulation potential of the three DGEBA epoxy resins for aquatic organisms.

Although experimental data on the bioaccumulation of the three DGEBA epoxy resins are available, a QSAR-based weight-of-evidence approach was also applied to a hydrolysis product and results are summarized in Table 2-8.

Table 2-8. modelled octanol/water partition coefficient (log Kow) and Bioconcentration Factors (BCF) of a hydrolysis product[a]

Property	Value	Sources
Octanol-Water Partition Coefficient	Log K_{ow} 2.69 at 25°C	EPI v4.11 KOWWIN v1.68
BCF/BAF	27.88 L/kg wet-wt (mid trophic)	EPI v4.11 BCFBAF v3.01

[a]The predicted degradation parameters were based on the representative structure of 376.19 Da with the following SMILES: CC(C1=CC=C(OCC(O)CO)C=C1)(C)C2=CC=C(OCC(O)CO)C=C2

Modelled results of a hydrolysis product presented in Table 2-8 provide additional and relatively consistent evidence for the bioaccumulation potential of the three DGEBA epoxy resins.

From Table 2-7 and Table 2-8, it can be seen that the bioaccumulation potential for DEGBA epoxy resins are generally low to moderate. The empirical BCF value for CAS

RN 25085-99-8 suggests that the substance could have moderate bioaccumulation potential. This differs from the predicted BCF/BAF values reported in Table 2-8, where the predicted values suggest that the hydrolysis products of DEGBA (see Figure 2-2) have very low bioaccumulation potential. The difference could be due to the fact that the predicted BCF/BAF are based on metabolism rate for mid trophic fish. Furthermore, the model is also predicting that the fragment could be metabolized by the organism, both of which could differ significantly between living organism and modelled organism. Considering the Log K_{ow} (empirical and predicted) and BCF (values) available, the overall bioaccumulation potential of DEGBA epoxy resin is anticipated to range from low to moderate.

2.6 Potential to cause ecological harm

2.6.1 Results of the second phase of Polymer Rapid Screening for CAS RN 25036-25-3

Critical data and considerations used during the second phase of polymer rapid screening to evaluate the three DGEBA epoxy resins with respect to potential to cause ecological harm are presented in ECCC (2016).

The above report identified one of the DGEBA epoxy resins (CAS RN 25036-25-3; Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis[oxirane]) as having low water extractability and is therefore not available to aquatic organisms. This substance was characterized as having a low potential for ecological risk. It is unlikely that this substance will result in concerns for organisms or the broader integrity of the environment in Canada.

2.6.2 Ecological effects assessment

According to the US EPA (2010), substances containing epoxide functional groups may be associated with adverse effects to fish, invertebrates, and algae.

The aquatic toxicity for epoxides and poly(epoxides) has been determined through Structure Active Relationship (SAR) analysis by US EPA using ECOSAR, a hazard estimation tool that uses chemical structure descriptors to estimate the acute and chronic toxicity of a substance to aquatic organisms. This analysis indicated that structures with epoxy equivalent weights (EEW_{epoxy}) of greater than 1 000 Da are presumed not to pose a hazard under any conditions. Concerns are confined to those species with Number Average Molecular Weight (M_n) less than 1 000 Da.

As indicated in Table 2-1, the three DGEBA epoxy resins have M_n and EEW_{epoxy} less than 1 000 Da and may therefore be hazardous to aquatic biota.

Empirical ecotoxicity data for the three DGEBA epoxy resin were reported in response to government surveys mentioned previously (ECCC 2015, Canada 2015). The results of ecological studies are summarized in Table 2-9. The data were extracted from SDS and summary information provided by stakeholders, and suggest that the three DGEBA epoxy resins could have low to moderate toxicity towards algae, daphnid and fish.

Table 2-9. empirical ecotoxicity data for DGEBA epoxy resins

CAS RNs	Organism	Result (mg/L)[a]	Test Method	Sources
25068-38-6	Algae (P.subcapitata)	48h EC_{50}=9.4	NA	SDS 2015d
25068-38-6	Algae (P.subcapitata)	72h EC_{50}=9.4	NA	SDS 2014
25068-38-6	Daphnid (D. magna)	48h EC_{50}=1.4-1.7	NA	SDS 2013
25068-38-6	Daphnid (D. magna)	24h EC_{50}=3.6	NA	SDS 2012b
25068-38-6	Daphnid (D. magna)	24h EC_{50}=2.6	NA	SDS 2012c
25068-38-6	Fish (S. gairdneri)	96h LC_{50}=3.6	NA	SDS 2015c
25068-38-6	Fish (P. promelas)	96h LC_{50}=3.1	NA	SDS 2013
25068-38-6	Fish (O. latipes)	96h LC_{50}=1.41	NA	SDS 2015a
25068-38-6	Fish	96h LC_{50}=1.3	OECD 203	SDS 2012a
25085-99-8	Algae (S.capricornutum)	72h E_rC_{50}=11	NA	SDS 2011a
25085-99-8	Fish (O.mykiss)	96h LC_{50}=2	NA	SDS 2011a
25085-99-8	Fish (P. promelas)	96h LC_{50}=3.1	NA	SDS 2010

[a] EC_{50} is the Effect Concentration for 50 percent of the population; LC_{50} is the Lethal Concentration for 50 percent of the population; NOEC is the No Observed Effect Concentration.
NA: Not Available

The European Chemical Agency (ECHA) database contained several ecotoxicity data for CAS RN 25068-38-6. The results of these ecological studies are summarized in Table 2-10.

Table 2-10. empirical ecotoxicity data of CAS RN 25068-38-6 obtained from the ECHA database

Organism	Result (mg/L)[a]	Test Method	Sources
Fish (O.mykiss)	96h LC_{50}=1.2	NA	ECHA c2007-2017a
Fish (O.mykiss)	96h LC_{50}=1.5	OECD 203	ECHA c2007-2017a, Canada 2015
Fish (O.mykiss)	96h LC_{50}=2.3	NA	ECHA c2007-2017a
Fish (O.mykiss)	96h LC_{50}=3.6	NA	ECHA c2007-2017a
Fish (O.mykiss)	96h LC_{50}=74.8	NA	ECHA c2007-2017a
Fish (D. rerio)	96h LC_{50}=2.4	NA	ECHA c2007-2017a
Daphnid (D. magna)	24h EC_{50}=2.7	NA	ECHA c2007-2017a
Daphnid (D. magna)	48h EC_{50}=1.1*	NA	ECHA c2007-2017a
Daphnid (D. magna)	48h EC_{50}=1.4	NA	ECHA c2007-2017a
Daphnid (D. magna)	48h EC_{50}=1.7	OECD 202	ECHA c2007-2017a
Daphnid (D. magna)	48h EC_{50}=2.8	NA	ECHA c2007-2017a
Daphnid (D. magna)	21 days NOEC=0.3	OECD 211	ECHA c2007-2017a
Algae (S. capricornutum)	72h E_rC_{50}>11 [b]	NA	ECHA c2007-2017a
Algae (S. capricornutum)	72-hour NOEC=4.2[b]	NA	ECHA c2007-2017a
Algae (S. capricornutum)	72h NOEC=2.4[c]	NA	ECHA c2007-2017a
Algae (S. capricornutum)	72h E_bC_{50}=9.4 [c]	NA	ECHA c2007-2017a
Algae (P.subcapitata)	72h E_rC_{10}=4.51[b]	NA	ECHA c2007-2017a
Algae (P.subcapitata)	72h E_rC_{50}>100[b]	NA	ECHA c2007-2017a
Algae (P.subcapitata)	72h E_bC_{10}=1.96[c]	NA	ECHA c2007-2017a
Algae (P.subcapitata)	72h E_bC_{50}=13.81[c]	NA	ECHA c2007-2017a
Activated Sludge	3h IC_{50} >100	NA	ECHA c2007-2017a
Bacteria (P. putida)	18-hour NOEC = 42.6	NA	ECHA c2007-2017a

[a] EC_{50} is the Effect Concentration for 50 percent of the population; LC_{50} is the Lethal Concentration for 50 percent of the population; NOEC is the No Observed Effect Concentration.
[b] Based on growth rate
c Based on biomass
*This endpoint was chosen as the critical toxicity value (CTV)
NA: Not Available

As summarized in Table 2-10, the ECHA database contains six acute freshwater fish studies for CAS RN 25068-38-6. Four studies were conducted with rainbow trout (Oncorhynchus mykiss), one study was conducted with zebrafish (Danio rerio) and one study was conducted with the fathead minnow (Pimephales promelas). Based on review of publically available study summaries,the fathead minnow study was deemed unacceptable for use due to inappropriate temperature for the test species and due to the fact that the test solutions in the study were above the limit of the solubility. A total of five studies (four with rainbow trout and one with zebrafish) were determined to be of good quality and acceptable for use in risk assessment. The acute tests with rainbow trout gave varying 96-hour LC_{50} values of 1.2, 1.5, 3.6, 2.3 and 74.8 mg/L. The acute test with zebrafish reported a 96-hour LC_{50} of 2.4 mg/L. The discrepancy in toxicity values is likely the result of one study testing above the limit of solubility for the test material (however no specific mention of insolubility was made in the study reporting the 96-hour LC_{50} of 74.8 mg/L).

The ECHA database also contains five acute toxicity studies with Daphnia magna. One study was deemed not reliable due to insufficient data and the fact that the test material was reported to have come out of solution and was not wholly soluble at the concentrations tested. Of the four studies that were deemed to be of good quality and reliable, one study was only 24 hours in duration, and was therefore classified as a supporting study, and not a key study. Three studies reported 48-hour EC_{50} values ranging from 1.1 to 2.8 mg/L. The ECHA database also contains one long term test with Daphnia magna which was conducted on CAS RN 25068-38-6. This test was deemed reliable. In this test, D. magna were exposed to five concentrations of CAS RN 25068-38-6 ranging from 0.03 - 3 mg/L and control dilution water for 21 days in a static renewal test design. Survival, growth, and reproduction rate were all significantly reduced at 1 mg/L of Epikote 828, but were all unaffected at 0.3 mg/L.

As summarized in Table 2-10, the ECHA database also contains two aquatic toxicity studies for algae. These studies were found to be of good quality and reliable. The two algal toxicities measured both growth rate (r) and biomass (b) as indicators of growth inhibition over 72 hours of exposure. One of these studies tested CAS RN 25068-38-6 with Scenedesmus capricornutum and reported the NOEC and E_rC_{50} as 4.2 and >11 mg/L, respectively. The 72-hour E_rC_{50} value (based on growth rate) could not be exactly determined since no significant effects were noted at the limit of solubility for the test material. The 72-hour NOEC and E_bC_{50} (based on biomass) in this same study with S. capricornutum were reported as 2.4 and 9.4 mg/L, respectively. In the other algal toxicity test with Pseudokirchneriella subcapitata, the 72-hour E_rC_{10} and E_rC_{50} for growth rate was reported as 4.51 and >100 mg/L, respectively. As in the previous study, the E_rC_{50} value for the specific growth rate could not be exactly determined due to effects occurring above the limit of solubility. The 72-hour E_bC_{10} and E_bC_{50} based on biomass were reported as 1.96 and 13.81 mg/L, respectively, for P. subcapitata.

As summarized in Table 2-10, the ECHA database also contains two microorganism studies. Both studies were deemed reliable. One study examined the response of respiration inhibition of activated sludge over a 3 hour exposure period, while the other study measured growth inhibition of Pseudomonas putida over an 18-hour exposure period. The activated sludge inhibition test reported a 3-hour IC_{20}, IC_{50} and IC_{80} all >100 mg/L. Furthermore, inhibition of respiration did not exceed 10% at the highest dose level (nominal) of 109 mg/L test substance. The study report for the growth inhibition study with P. putida reported an 18-hour NOEC of 42.6 mg test substance /L.

The ecotoxicity data identified through the ECHA database suggest that CAS RN 25068-38-6 could have low to moderate toxicity towards algae, daphnia, fish and bacteria.

Two ecotoxicological analogues of DGEBA epoxy resin were identified through New Substances Notification Program (ECCC 2017). However, the ecotoxicological data of these two analogues are not described in this report because they are considered to be confidential business information. These two analogue polymers with high degrees of structural similarity exhibited moderate toxicity towards algae, daphnia and fish.

The ECHA database contained three ecotoxicity endpoints for Oxirane, 2,2'-[1,4-butanediylbis (oxymethylene)]bis- (CAS# 2425-79-8) which can be considered an ecotoxicological analogue of the three DGEBA epoxy resins (ECHA c2007-2017b). The results of ecological studies of this analogue are summarized in Table 2-11.

Table 2-11. empirical ecotoxicity data of the analogue from ECHA database

CAS RNs	Organism	Result (mg/L)	Test Method
2425-79-8	Fish (B. rerio)	24h-LC_{50}=19.8	OECD 203
2425-79-8	Daphnid (D. magna)	48h- EC_{50}=75	OECD 202
2425-79-8	Algae (S. subspicatus)	72h-EC_{r50}>100[a] 72h-EC_{b50}=160[b]	OECD 201 OECD 201

[a] 72h-ECr50 based on growth rate of water accommodated fraction (WAF)
[b] 72h-ECb50 based on biomass of water accommodated fraction (WAF)

Zebra fish (Brachydanio rerio) were exposed to the analogue substance (CAS# 2425-79-8) under static conditions using the OECD Guideline 203 (Fish, Acute Toxicity Test). A 96h-LC_{50} of 24 mg/L was reported based on nominal concentrations. The 96h-LC_{50} based on measured concentrations was reported to be 19.8 mg/L

Using the OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) Daphnia magna was exposed under static conditions to the analogue substance (CAS# 2425-79-8). The effect concentrations were reported based on nominal concentrations.

Pseudokirchneriella subcapitata (green algae) were exposed to the analogue substance (CAS# 2425-79-8) under static conditions using the OECD Guideline 201 (Alga, Growth Inhibition Test). The effect concentrations were based on loading rate using Water Accommodated Fractions (WAF).

These ecotoxicological analogues data suggest that the three DGEBA epoxy resins could have low to moderate toxicity towards algae, daphnia and fish.

Ecotoxicity is predicted based on the representative structure of the hydrolysis product depicted in Figure 2-2. ECOSAR predictions were generated for neutral organics classes. However, no effects at saturation were reported for all organisms.

No sediment ecotoxicity data were provided for the three DGEBA epoxy resins, or were available for other DGEBA epoxy resins. However, as neutral organics in the environment, the three DGEBA epoxy resins are expected to be of low ecotoxicological concern to sediment dwelling species.

Overall, based on empirical, analogue and model data, the three DGEBA epoxy resins are expected to show moderate to low toxicity to aquatic organisms, and low toxicity to sediment dwelling species in natural environments. Based on available data, the lowest ecotoxicity end point, daphnid 48h EC_{50}=1.1 mg/L was selected to be the Critical Toxicity Value (CTV), and is used to estimate the aquatic Predicted No Effect Concentration (PNEC). A PNEC is not considered necessary for sediment species, as the toxicity value is anticipated to be greater than 100 mg/L.

The aquatic PNEC is derived from the Critical Toxicity Value (CTV), which is divided by an assessment factor (AF) as shown:

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

$$\text{Aquatic PNEC (mg/L)} = \text{(1.1 mg/L) / 10}$$

$$\text{Aquatic PNEC (mg/L)} = 0.11$$

An AF of 10 is selected to estimate an aquatic PNEC, and assuming a narcotic mode of action for this polymer and hydrolysis products. The AF selected represents 10 for extrapolation from acute to chronic toxicity and 1 for species sensitivity variation. Considering the available ecotoxicity data for the three DGEBA epoxy resin (more than 7 species, covering 3 categories), a factor of 1 was selected to represent species sensitivity.

2.6.3 Ecological exposure assessment

According to the data collected through the voluntary (ECCC 2015) and mandatory surveys (Canada 2015), DEGBA epoxy resins are used as components in (1) adhesives and sealants, and (2) paints and coatings. Based on available information, the majority of DEGBA epoxy resins were imported in to Canada. Therefore, the exposure scenario for the manufacturing of DEGBA epoxy resins is not considered further as its release is expected to be lower than other scenarios described below.

According to the survey data, there are three major industrial scenarios:

1. Formulation of the three CASRNs into adhesives and sealants

2. Formulation of the three CASRNs into paints and coatings

3. Application of the formulated products in the production of toys, automobiles, etc.

In estimating the aquatic exposure under each scenario, a fraction of a substance is assumed to end up in wastewater. This assumption is conservative for cases where no water is used in the formulation or application, or equipment cleaning. Based on this assumption, a small amount of each substance enters the wastewater generated from an industrial facility. The industrial wastewater is then discharged to a wastewater collection system. The substance is subsequently released to the aquatic environment via the effluent after wastewater treatment. The predicted environmental concentration (PEC) of each CAS RN in receiving water depends upon its use quantity at a given facility as well as the conditions associated with its off-site wastewater treatment and the receiving water. The aquatic PEC resulting from a facility is estimated by

$$\text{PEC} = \frac{10^9 \times Q \times E \times (1-R)}{F \times D \times N}$$

where

PEC: predicted environmental concentration in receiving water near discharge point, µg/L

Q: a substance's annual use quantity at a facility, kg/year

E: emission factor to wastewater, unitless

R: wastewater treatment removal, unitless

F: daily wastewater flow rate, L/d

D: receiving water dilution factor near discharge point, unitless

N: number of annual operation days, d/y

10^9: conversion factor from kg to µg, µg/kg

In the formulation of adhesives and sealants, organic solvent is used based on information provided by a formulator (response to 2015 CEPA Section 71 CMP3 polymers survey, and 2017 follow-up questions). According to a number of site visits to formulation facilities conducted by Environment and Climate Change Canada in 2013, no water was used or no material was released to wastewater during solvent-based formulation equipment cleaning. Releases of the three CAS RNs to off-site wastewater treatment systems and aquatic environment are therefore not expected from the formulation of adhesives and sealants.

In the formulation of paints and coatings, no information is available about the type of carriers used. As a conservative estimate, water is assumed to be used in the formulation and to be released to wastewater treatment systems. In addition, a set of conservative conditions are selected in the PEC determination. These conservative conditions include the upper limit for annual use quantity found at a formulation facility (Q = 1 000 000 kg/y), the lower limit for daily wastewater flow rate associated with a formulation facility (F = 27 000 000 L/d) and nil for wastewater treatment removal (R = 0). The number of annual operation days and the emission factor or the fraction lost to wastewater are 300 days per year (N) and 0.3% (E), respectively according to a technical guidance document on risk assessment from the European Chemicals Bureau (2003). The receiving waterbodies of the wastewater treatment systems associated with the formulation facilities are generally large and 10-fold dilution is used for dilution near the discharge point (D = 10). Based on the above conservative conditions and assumptions, the PEC is determined as

Aquatic PEC for formulation of paints and coatings = 37 µg/L

The aquatic PEC for the application scenario is also determined conservatively based on the largest industrial user in Canada in terms of annual use quantity. The upper limit for this annual use quantity is 10 million kg/y (Q) and the off-site wastewater treatment facility has a daily flow rate of 456 million L/d (F). The values of the other parameters used in the PEC calculation are selected to be the same as those for the formulation of paints and coatings. The PEC is determined as

Aquatic PEC for application scenario = 22 μg/L

2.6.4 Characterization of ecological risk

The approach taken in this ecological risk assessment was to examine direct and supporting information and develop conclusions based on a weight-of-evidence approach. Lines of evidence considered include information on sources and fate of the substance, persistence, bioaccumulation, and ecological hazard properties. The three DGEBA epoxy resins are used as components in adhesives and sealants, and paints and coatings. Based on available information, the quantity of each substance imported into Canada in 2014 from the survey data was up to 10 million kg.

Water solubility information reported for the three DGEBA epoxy resins, indicates they are slightly water soluble. When the three DGEBA epoxy resins are released into the environment, they are expected to hydrolyze. Given the high molecular weight, partitioning into the air compartment is not expected. Furthermore, significant amounts are anticipated to adsorb onto dissolve organic matter and settle to sediments. Any residual polymer is expected to remain in the water column.

With respect to long term persistence of these polymers, available biodegradation data for the three DGEBA epoxy resins suggest that they will not be biodegradable in the environment. Other information on transformative properties suggests these polymers are hydrolyzable.

All empirical and modelled data used to assess the bioaccumulation potential support the low to moderate bioaccumulation potential of the three DGEBA epoxy resin for aquatic organisms.

Reported information on the current use pattern of the three DGEBA epoxy resins indicates that they are used as components in two types of products: (1) adhesives and sealants, and (2) paints and coatings. The majority of DEGBA epoxy resins was imported and only minor quantities are manufactured in Canada. A conservative exposure estimation for the formulation and application of the three DGEBA epoxy resins generated the PEC is shown in Table 2-12.

According to the ecological hazard profile of the three DGEBA epoxy resins, they generally have low to moderate toxicity towards fish, daphnia, algae and bacteria. For the purpose of this assessment, the highest toxicity value was selected as the CTV and used to estimate the PNEC.

The risk quotient was estimated based on the PNEC and conservative PEC. Table 2-12 summarizes the risk quotients calculated.

Table 2-12. estimated risk quotients for release of the three DGEBA epoxy resin based on formulation and application release scenarios

Scenarios	PNEC (mg/L)	PEC (mg/L)	Risk Quotient (PEC/PNEC)
Aquatic PEC for formulation of adhesives and sealants	0.11	0	0
Aquatic PEC for formulation of paints and coatings	0.11	0.037	0.34
Aquatic PEC for application of the formulated products	0.11	0.022	0.2

Based on Table 2-12, neither the formulation scenario nor the application scenario for the three DGEBA epoxy resin are expected to result in environmental concern (i.e., risk quotients are less than 1). Considering that conservative values, such as the high emission factor, volumes, number of sites and flow rates, were used to estimate the PEC, it is anticipated that the risk quotients are an over estimation of the potential risk. Overall, the three DGEBA epoxy resins are not expected to result in ecological concern based on available information and conservative estimation of PEC values for the main exposure scenarios.

2.6.4.1 Uncertainties in evaluation of risk to environment

There are various uncertainties related to the ecological assessment of DEGBA. 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. Furthermore, there are uncertainties in the exposure scenarios for DEGBA, such as the maximum quantity that a formulation could utilize in a year, the flow rates of the dilution river and the emission factor. However, considering that conservative assumptions were used to determine the exposure potential for DEGBA, changes in molecular weight, quantities, or other factors are not expected to result in a significant increase in ecological risk.

2.7 Potential to cause harm to human health

2.7.1 Exposure assessment

2.7.1.1 Direct exposure

As indicated above (Section 2-1), low molecular weight DGEBA epoxy resins ($n \leq 0.5$) contain a substantial amount of DGEBA. Conversely, higher molecular weight DGEBA epoxy resins contain a limited amount of DGEBA but are primarily oligomeric forms of DGEBA. Therefore, the studies performed on DGEBA may apply to DGEBA epoxy resins in some cases.

When used industrially, direct exposure of the general population to DGEBA epoxy resins is not expected. Furthermore the release of DGEBA from end-use applications is very limited as epoxy resins are reacted with hardeners/curing agents into cross-linked systems that are stable against thermal and hydrolytic breakdown (DME 2012; SPII 1997, Bingham 2012).

2.7.1.1.1 Oral exposure

The primary exposure to DGEBA is from food and drink cans lined with epoxy-based coatings. Residues of non-crosslinked DGEBA in epoxy resin can coating could migrate into foods due to incomplete polymerization, especially at elevated temperatures (e.g., for hot fill or heated processed canned foods) (Cao et al 2009, Lipke 2016). A number of surveys of DGEBA and their derivatives have been conducted in various countries in Europe to investigate the potential migration of DGEBA used in the interior coating for food and beverage cans. One study showed the amount of DGEBA derivatives contained in canned food was 100-600 µg/kg food (DME 2012). In 2001, the United Kingdom Food Standards Agency (FSA) conducted a market survey of DGEBA in canned food (Dionisi and Oldring 2002). Migration levels of DGEBA detected in the canned foodstuff were around 100 µg/kg food. The FSA calculated exposure to DGEBA as 0.05-0.13 µg/kg bw/day for a 60 kg individual considering the available information on European consumption pattern for canned food, total surface areas of cans, and the FSA survey data. The major sources of exposure appear to arise mostly from canned vegetables (48%), canned fish (18%) and pre-prepared meals (5%) (DME 2012). Another study used a Monte Carlo simulation which is a computational method based on the measured average content of DGEBA in various canned foods. The estimated average DGEBA exposure was found to be 0.004 µg/kg bw/day with a maximum of 0.19 µg/kg bw/day for a 60 kg individual (European Commission 2002).

In 2004, market surveillance in the Netherlands was repeated on the potential migration of DGEBA derivatives from can coatings into fish. The method was suitable to determine the presence of these substances in fish-in oil and fish-in aqueous sauces. A total of 64 cans of fish were sampled and analysed. Epoxy derivatives were only detected in 9 cans or 14% of the total cans sample. Of those, 6 cans or 9% of the total number of canned fish sampled were found to contain DGEBA derivatives at average concentrations of 100 µg/kg food. This market surveillance was also performed previously in 2001 and 2002; a visible trend showed that all cans complied with the specific migration limit (SML) of 1 mg/kg in food or food simulants established by the European Commission for the sum of DGEBA, DGEBA.H_2O and DGEBA.2H_2O (DME 2012, European Commission 2005, Simal-Gandara 1998).

Several seafood products such as sardines, tuna fish, mackerel, mussels, cod, and mackerel eggs were manufactured in different conditions changing covering sauce, time and temperature of storage and heat-treatment for sterilization in cans. Migration kinetics of DGEBA from varnish into canned products was evaluated in 70 samples after 6, 12 or 18 months of storage. All samples analyzed presented values lower than 1 mg DGEBA/kg net product without exceeding European limits (i.e. 1 mg/kg). The highest rate of migration took place in mackerel reaching a value of 340 µg DGEBA/kg net product, in a red pepper sauce (Cabado 2008).

Health Canada's Food Directorate also measured the levels of some epoxy resins, including DGEBA, in canned liquid infant formula products sampled in Canada in 2007. In that study, DGEBA was detected in samples of all 21 products from 2.4 – 262 ng/g. The probable daily intakes of DGEBA due to consumption of canned liquid infant formula were estimated for infants from premature to 12–18 months of age. The maximum Probable Daily Intake (PDI) was 22 µg/kg bw/d for the 12–18 months old with the maximum formula intake. The probable daily intake of DGEBA for infants less than 12 months ranged from 1.2 to 5.6 µg/kg bw/d (Cao 2009). However, it is also likely that overall dietary exposure to DGEBA epoxy resins is significantly lower since in recent years, alternative resins that do not contain DGEBAs have been replacing the DGEBA-containing resins in the manufacture of food packaging materials including for infant formula.

Using a worst-case scenario that assumes that DGEBA migrates at the same level as in canned foods into all types of food, the estimated per capita daily intake for a 60-kg individual is approximately 0.098 - 0.16 µg/kg bw/day, which is considered low for adults (Poole et al. 2004, Dionisi and Oldering 2002).

For children, the intake of DGEBA epoxy resins through exposure to toys is considered to be minimal as it will be contained within a hardened polymer matrix from which it is not likely to be released.

2.7.1.1.2 Exposure through dust

DGEBA epoxy resins have low vapour pressure, thus inhalation exposure is not expected. In one study, 158 indoor dust samples were collected from the U.S., China, Korea, and Japan and the concentrations of DGEBA and its three hydrolysis products (DGEBA·H_2O, DGEBA·$2H_2O$, and DGEBA·HCl-H_2O) were determined. Among the four countries, all DGEBA target compounds were found in dust samples and the geometric mean concentrations ranged from 1.3 to 2.9 µg/g. The estimated intake for DGEBAs through dust ingestion was 6.5 ng/kg bw/day (Wang 2012).

2.7.1.1.3 Dermal exposure

Notifications for DGEBA epoxy resins (CAS RN 25068-38-6) submitted under the Cosmetic Regulations to Health Canada indicate that 8 cosmetics contain this substance at levels up to 10%. The products are listed as non-permanent make-ups and adhesives (nails, eye, face, body). Although DGEBA epoxy resins have been used in cosmetics, due to their usage in the cured-form, dermal absorption is not expected (Ellis 1993).

Liquid epoxy resins are used in two-component epoxy glues sold to the general public in retailer shops. These two components of epoxy glues would be mixed immediately before use. The prepared glue would contain only cured-form of epoxy resins; therefore, dermal exposure to DGEBA epoxy resins is expected to be negligible (Petrie 2006).

2.7.1.1.4 Drug products

DGEBA epoxy resins are not listed in the Natural Health Products Ingredients Database (NHPID [modified 2017]). They are not found in any drug products, including natural health products (LNHPD [modified 2016, DPD [modified 2015]).

In summary, based on the sources of exposure described above, oral exposure to DGEBA epoxy resins is estimated to range from 1.2-22 µg/kg bw/d for Canadian infants from premature to 12–18 months of age (Cao et al 2009) and 0.05-0.19 µg/kg bw/d for European adults. The estimated intake for DGEBAs through dust ingestion was found to be 6.5 ng/kg bw/day. Exposure to DGEBA epoxy resins by inhalation is not expected due to their low vapour pressures. Dermal exposure to DGEBA epoxy resins is not expected due to their usage in cured-form.

2.7.1.2 Indirect exposure

When released to water, DGEBA epoxy resin (25036-25-3) is assumed to adsorb to particulate matter and sediment. Leaching to the groundwater compartment is not expected. Products containing DGEBA epoxy resins may be disposed of in landfills.DGEBA was identified as leachate from a DGEBA-based epoxy coating used to coat lead and copper pipe specimens. Identified DGEBA hydrolysis products included DGEBA-H_2O and DGEBA-2H_2O, with DGEBA-2H_2O being the end product under the time, temperature, and pH conditions studied, which encompass conditions representative of those encountered in drinking water distribution systems (Lane 2015).

Although DGEBA has been identified as a leachate (Xue 2015), in the event of an unforeseen environmental release of DGEBA epoxy resins, they are not expected to become widely distributed in the aquatic environment based on their low water solubility and predicted hydrolysis.

2.7.2 Health effects assessment

During evaluation under the second phase of polymer rapid screening (ECCC, HC 2017), DGEBA based epoxy resins (CAS RN 25085-99-8, 25068-38-6 and 25036-25-3) were identified as requiring further assessment as a result of the presence of epoxy reactive functional groups which are associated with adverse human health effects including subchronic toxicity and dermal sensitization.

2.7.2.1 DGEBA -based epoxy resins

Commercial DGEBA-based epoxy resins have a low acute oral toxicity in rats, mice and rabbits with an LD_{50} > 15,000 mg/kg bw. The acute dermal toxicity of commercial DGEBA-based resins is also low when tested on rabbits with an LD_{50} of 20 mL/kg bw. It also has a low dermal toxicity in rats and mice with a LD_{50} > 1200 and > 800 mg/kg bw, respectively. Lower molecular weight DGEBA-based liquid resins are only slightly irritating to either intact or abraded rabbit skin, however prolonged and repeated exposure may cause a more severe irritation. Higher molecular weight solid resins were less likely to cause irritation, even with prolonged and repeated exposure. Lower molecular weight DGEBA-based resins were moderate dermal sensitizers in both Guinea pigs and mice with a NOEL of 3% and an EC3 of 5.7% respectively, the latter of which translates to an exposure threshold of 1425 $\mu g/cm^2$. Liquid resins were only minimal eye irritants while solid resins were moderate eye irritants as a result of their abrasive properties (Bingham and Cohrssen, 2012).

Cured resins added to the diet at 1, 5 and 10% for 6 weeks did not result in any behaviour or organ weight differences (Bingham and Cohrssen, 2012).

In a dermal teratology study, rabbits were administered doses of 0, 100, 300, or 500 mg/kg/day on days 6–18 of gestation. No evidence of embryo/fetal toxicity or teratogenicity was observed at any dose. Gavage teratology studies using both rats and rabbits with a low molecular weight BADGE-based epoxy resin were conducted at dose levels of 0, 60, 180, and 540 mg/kg/day were used for rats, and dose levels of 0, 20, 60, and 180 mg/kg/day. There were no adverse effects on mean litter size, pre- and post-implantation losses, or any evidence of a teratogenic or embryotoxic effect at any dose level (Bingham and Cohrssen, 2012). Dermal exposure in pregnant rabbits at doses of 100, 300 or 500 mg/kg bw/day between gestational days 6-18 was not embryo toxic or teratogenic. Teratology studies in rats at oral doses of 60, 80 and 540 mg/kg bw/day and rabbits at oral doses of 20, 60, and 180mg/kg bw/day did not result in changes in litter size, pre or post-implantation losses or any evidence of teratogenic or embryo toxicity. A one generation reproductive study in rats at oral doses of 20, 60, 180 and 540 mg/kg bw/day did not affect reproductive parameters in either sex and any of the doses tested (Poole et al., 2004). A diet carcinogenicity study in at a concentration of 10% or dermal studies in mice at concentrations up to 5% 3 times weekly for 2 years did not result in any increases in the presence of tumors, therefore the resins have a low subchronic toxicity and are not reproductive/developmental toxicants or carcinogenic in vivo (Bingham and Cohrssen, 2012).

In humans, contact dermatitis has been noted in individuals exposed in an occupational setting. The authors of one study established that the 340 molecular weight oligomer was responsible for the dermal sensitization potential of the resin (Bingham and Cohrssen, 2012).

2.7.2.2 DGEBA

Low molecular weight resin may contain a significant proportion of DGEBA which may leach out of the cured resins and result in direct human exposure. DGEBA has a low acute oral toxicity in rats with an LD_{50} greater than 2000 mg/kg bw/day. In a subchronic study, rats feed a diet containing 0.1%, 0.3%, 1.0% or 3% (corresponding to 150, 450, 1500, and 4500 mg/kg bw/day) DGEBA for 3 months did not show any gross or histopathological changes, although animals at the highest dose rejected the diet and failed to gain weight. Animals dosed at 1500 mg/kg bw/day exhibited slight enlargement of the kidneys, therefore the NOAEL was established at 450 mg/kg bw/day (Poole et al., 2004).

In a subchronic study, rats were fed a low molecular weight epoxy resin 300, 1500 or 7500 mg/kg bw/day for 26 weeks. All animals at the highest dose died by week 20 but no evidence of systemic toxicity was observed in gross and histopathological examinations. The low and mid dose treated animals also did not show any gross or histopathological findings other than an increase in kidney weights. No NOAEL was reported for the study (Poole et al., 2004).

A NOAEL of 15 mg/kg bw/day was generated in a 2 year oral gavage chronic toxicity/carcinogenicity study based on a decrease in spleen weight at 100 mg/kg bw/day (Poole et al., 2004).

Dermal application of DGEBA at doses of 10, 100, and 1000 mg/kg bw for 13 weeks in Fisher 344 rats did not cause any apparent systemic toxicity, although high dose animals ate less and lost weight. Dermal application did not alter mortality, clinical observations and behaviour, gross pathology or histopathology with the exception of a local dermatitis therefore a NOAEL of 100 mg/kg bw/day was established (Bingham and Cohrssen, 2012).

Reproductive studies with DGEBA at doses of 50, 540 and 750 mg/kg bw/day did not result in any effects on reproduction even though males and females lost weight at the two highest doses tested (Bingham and Cohrssen, 2012).

A 2 year dermal carcinogenicity study in CF1 mice with DGEBPA at concentrations of 1% and 10% did not show any increase in tumor formation at either of the two concentrations tested. (Zakova et al.,1985).

According to toxicity data for DGEBA (CAS 1675-54-3) and DGEBA containing substances (CAS 25036-25-3 and CAS 25068-38-6) dermal sensitization potential is the main concern associated with these substances. A completely cured epoxy resin contains no free monomer and is non-sensitizing, However, substances containing up to 20% DGEBA monomer, which is a known skin sensitizing substance, and also having an average molecular weight of approximately 1000 daltons or less, produced allergic contact dermatitis in guinea pigs(DME 2012). A NOAEL of 15 mg/kg bw/day was observed in a chronic/carcinogenicity study in rats treated with low molecular weight resins. Although no specific organ toxicity was identified, the NOAEL was established based on atrophy and a decrease in spleen weight at higher doses (EFSA 2005). The hazard for the substance is considered moderate based on the NOAEL of 15 mg/kg bw/day obtained from chronic/carcinogenicity studies

2.7.3 Characterization of risk to human health

In this assessment, the human health risks were established through consideration of both the hazard and the direct and indirect exposure of the substance for current uses identified from a survey under section 71 of CEPA.

The human health hazard associated with the presence of reactive epoxy groups in DGEBA-based substances is considered moderate on the basis of the available toxicological information. Although exposure to DGEBA epoxy resins through food sources is not expected, there is the potential for unreacted DGEBA present in some can coatings to migrate into the food. However, dietary exposure to DGEBA epoxy resins is unlikely to pose a risk to human health. Dionisi and Oldering (2002) compared the exposure of DGEBA from food sources which resulted in an exposure of 0.16 µg/kg bw/day for European adults, while Cao et al. (2009) found the highest exposure in 12-18 month olds at 22 µg/kg bw/day. When compared to NOAELs of 15 mg/kg bw/day from animal chronic studies, based on splenic effects, there are Margins of Exposure (MOE) of 93,750 and 682 for adults and children (0-18 months), respectively, and which are considered adequate to account for uncertainties in the health effects and exposure databases. In addition, dietary estimates are reasonably expected to be lower in the future, given the gradual change to DGEBA-free epoxy resins in food packaging applications. Dermal sensitization is not expected to pose a health risk as it requires a threshold value of 1425 $\mu g/cm^2$ which is not expected to be reached at the current dermal exposure levels. Taking into consideration the direct and indirect exposure to products intended for consumer use, the overall human health risk has been determined to be low.

2.7.3.1 Uncertainties in evaluation of risk to human health

While the higher molecular weight DGEBA epoxy resins contain a limited amount of free DGEBA, the low molecular weight resins contain a significant proportion of DGEBA which may leach out of the cured resins and result in direct human exposure. Therefore, an assumption was made that DGEBA is an indicator for leaching DGEBA epoxy resins.

Some inconsistencies have been found in CAS RNs for DGEBA epoxy resins. For instance CAS RNs 25085-99-8 and 25068-38-6 have been preferably used by U.S. companies and in European Union countries, respectively (DME 2012). Inconsistencies have also been found in each CAS RN for DGEBA epoxy resins. For instance some references used only one CAS RN for all DGEBA epoxy resins but others used two or three (DME 2012, Kirk-Othmer 2014, Bingham 2012, European Commission 2005). In addition, some references used the method of preparation (see routes a, b, and c in Figure 2-2) for categorizing DGEBA epoxy resins. For instance, routes (b) and (c) for the preparation of DGEBA epoxy resins with $n \leq 4$ and $n = 4\text{-}10$, respectively (Boyle 2001, Ullman’s 2012). Despite all the above inconsistent representation, it is believed that the DGEBA epoxy resins have been identified here adequately.

3. Novolac Epoxy Resin

3.1 Identity of substance

Novolac epoxy resin is a multifunctional epoxy oligomer based on phenolic formaldehyde novolac (Figure 3-1). It is made by epoxidation of novolac obtained from condensation of phenol and formaldehyde (Kirk-Othmer 2014). This produces random ortho and para-methylene bridges. An excess of epichlorohydrin is used to minimize the reaction of the phenolic OH groups with epoxidized phenolic groups and, as a result, to prevent branching (Jin 2015). Novolac epoxy resin ranges from a high viscosity liquid of n ≈ 0.2 to a solid of n > 3. Low molecular weight Novolac epoxy resin (n ≤ 0.5) contains a substantial amount of Bisphenol F diglycidyl ether (BFDGE) mixture (ortho-ortho, para-ortho, para-para). Conversely, higher molecular weight Novolac epoxy resin (n > 1) contains a limited amount of BFDGE but is present in oligomeric forms. The epoxy functionality (which is a functional group of concern for human health) is between 2.2 and 3.8.

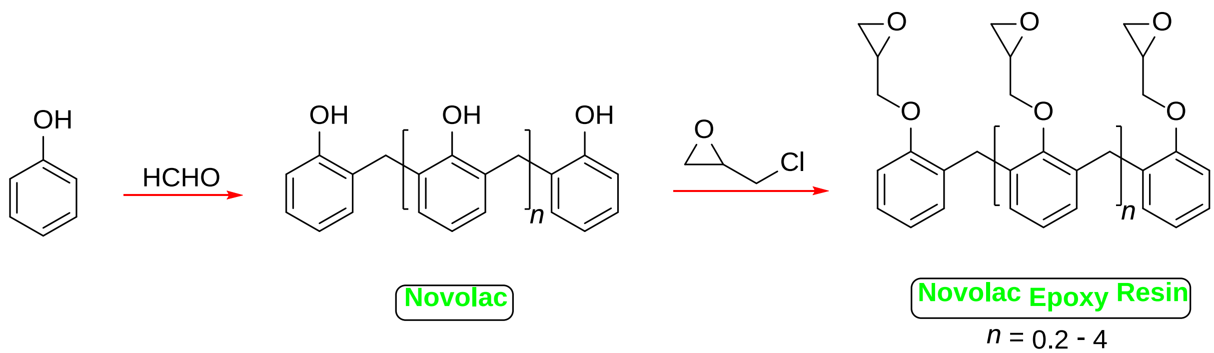


Figure 3-1. Representative structure of Novolac epoxy resin

3.2 Physical and chemical properties

A summary of physical and chemical properties for Novolac epoxy resin is presented in Table 3-1.

Table 3-1. physical and chemical property values (at standard temperature) for Novolac epoxy resin

	n = 0.2	**n = 1.6**	**n = 1.8**
Physical form	Liquid	solid	solid
Molecular weight (g/mol)	~ 344	~ 570	~ 605
Melting/Softening point (°C)	NA	NA	53
Boiling point (°C)	> 90	≥ 245	NA
Water solubility (mg/L)	slightly soluble (< 1% @ 25°C)	insoluble	insoluble

Vapour pressure (Pa)	NA	< 133 @ 20°C	NA
Density (g/cm^3)	1.18-1.20 @ 25°C	1.22 @ 25°C	NA
Epoxy equivalent weight (g/eq.)	172-179	176-181	200
Epoxide content (%)	~ 25	~ 24	~ 22
Biodegradation (%)	t 1/2 ≈ 5 years	10-16% @ 28d	NA
Sources	Kirk-Othmer 2014 Canada 2015 ECCC 2015	Bingham 2012 Ullman's 2012 Canada 2015 ECCC 2015	Kirk-Othmer 2014

NA: Not available

3.3 Sources and uses

Novolac epoxy resin has been included in a voluntary survey (ECCC 2015), as well as a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 3-2 presents a summary of the total manufacture and total import quantities for the substance in 2014. These sources indicate that the functional uses for Novolac epoxy resin in Canada are as a binder, crosslinker, and intermediate in adhesive/sealant, paints/coatings, grout, flooring, plastics, metal materials (such as can coating), and auto sealants.

In general, Novolac epoxy resins, when cured, produce tightly cross-linked systems with improved high-temperature performance, chemical resistance, and adhesion over the DGEBA epoxy resins. The thermal stability of Novolac epoxy resins has made them useful for structural and electrical laminates and as coatings and castings for elevated temperature service. Chemical resistance of Novolac epoxy resins makes them useful for lining storage tanks, pumps, and other process equipment as well as for corrosion-resistant coatings (Bingham 2012).

Table 3-2. summary of information on Canadian manufacturing and import quantities of Novolac epoxy resin in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA

Substance	Total manufacture (million kg)	Total[a] imports (million kg)	Survey reference
28064-14-4	0.01-0.1	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 surveys for specific inclusions and exclusions (schedules 2 and 3).

A number of domestic government databases were searched to determine if Novolac epoxy resin is registered and/or approved for uses in Canada. These uses for Novolac epoxy resin are listed in Table 3-3.

Table 3-3. additional uses in Canada for Novolac epoxy resin

Use	28064-14-4
Food additive[a]	No
Food packaging materials[b]	Yes
Internal Drug Product Database as medicinal or non-medicinal ingredients in final pharmaceutical, disinfectant or veterinary drug products in Canada[c]	No
Natural Health Products Ingredients Database[d]	No
Licensed Natural Health Products Database as medicinal or non-medicinal ingredients in natural health products in Canada[e]	No
List of Prohibited and Restricted Cosmetic Ingredients[f]	No
Notified to be present in cosmetics, based on notifications submitted under the Cosmetic Regulations to Health Canada[g]	No
Formulant in pest control products registered in Canada[h]	No
Known Toy Use[i]	No

[a] Health Canada (modified 2013)
[b] Food Directorate, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced
[c] DPD [modified 2015]
[d] NHPID [modified 2017]
[e] LNHPD [modified 2016]
[f] Health Canada [modified 2015]
[g] Consumer Product Safety Directorate, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced
[h] PMRA (2010)
[i] Toy Industry Spreadsheet (2016)

3.4 Potential to cause ecological harm

Critical data and considerations used during the second phase of polymer rapid screening to evaluate the substance-specific potential to cause ecological harm are presented in ECCC (2016).

The above report identified Novolac (CAS RN 28064-14-4; Phenol, polymer with formaldehyde, glycidyl ether) as having low water extractability and is therefore not available to aquatic organisms. This substance was characterized as having a low potential for ecological risk. It is unlikely that this substance will result in concerns for organisms or the broader integrity of the environment in Canada.

3.5 Potential to cause harm to human health

3.5.1 Exposure assessment

3.5.1.1 Direct exposure

When used industrially, direct exposure of the general population to Novalac epoxy resin would be similar to DGEBA epoxy resins and thus considered negligible (Bingham 2012).

In Canada, Novalac epoxy resin has been identified as a component used in the manufacture of some food packaging materials, i.e., can coatings and where it is used as a crosslinking agent. Only unreacted crosslinking agent will be available for migration into food. Even considering a worst-case scenario, including the assumption that all of the unreacted crosslinking agent would migrate into food, any exposure from such uses is expected to be negligible (personal communication, emails from Food Directorate, Health Products and Food Branch, Health Canada, dated February, 2017; unreferenced.).

Health Canada's Food Directorate measured the levels of some epoxy resins, including BFDGE, in canned liquid infant formula products in Canada. In that study, BFDGE (the main constituent in low molecular weight Novolac epoxy resin) was found in only 1 sample of the 21 products tested, at a level of 0.04 µg/kg food (Cao et al., 2009).

Novolac epoxy resin is not listed in the Natural Health Products Ingredients Database (NHPID [modified 2017]). It is not found in any drug products, including natural health products (LNHPD [modified 2016], DPD [modified 2015]). Novolac epoxy resin is not used in cosmetics.

Regardless of the products used, the exposure to Novalac epoxy resin by inhalation is not expected due to its predicted low vapour pressure (for solid polymers) and its presence as a cured resin. Dermal exposure to Novalac epoxy resin is not expected as it is available mostly in a cured form.

3.5.1.2 Indirect exposure

In the event of an unforeseen environmental release of Novolac epoxy resin, the substance is not expected to become widely distributed in the aquatic environment based on its low water solubility and predicted hydrolysis. Since Novalac epoxy resin is not biodegradable, there is the possibility that it may be persistent in the environment.

3.5.2 Health effects assessment

The only toxicological information found on Novolac resins was data reported in a Huntsman SDS for RENLAM® 5052 US which is 60-100% Epoxy phenol Novolac resin (CAS RN 28064-14-4) and 30-60% Butanedioldiglycidyl ether (CAS RN 2425-79-8).

Toxicity studies were identified as being conducted based on the referenced OECD protocol but were unavailable for review. Epoxy phenol Novolac resin has a low acute oral and dermal toxicity in rats with an LD_{50} > 2000 mg/kg bw. It is a mild skin and eye irritant in rabbits and was a dermal sensitizer in mice (SDS, 2014). The closest surrogate to the Novolac epoxy resin (BFDGE; CAS RN 2095-03-6) has a moderate dermal sensitization potential with EC3 value of 1.1 which translates to exposure value of 275 µg/cm^2 (Delaine et al., 2011). It was mutagenic in vitro when tested in an AMES test or with mammalian cells but was negative for mutagenicity in vivo for both mammalian germ and somatic cells. Novolac resins were not carcinogenic in 2 year chronic studies in rats dosed at 1 or 15 mg/kg bw/ 5 and 7 days/week respectively, or in mice dosed at 0.1 mg/kg bw/ 3 days/week. It was not a reproductive toxicant in a two generation reproductive study in rats and was not teratogenic in a prenatal development studies performed with rats via the oral route or rabbits via the oral or dermal routes. It had a moderate oral subchronic toxicity in a 90-day repeated dose toxicity assay in rats with a NOAEL of 50 mg/kg bw/day and a NOEL of 10 mg/kg bw/day in a rat subchronic dermal assay and a NOAEL of 100 mg/kg bw/day in a 90 day subchronic dermal study performed in mice (SDS, 2014).

3.5.3 Characterization of risk to human health

In this assessment, the human health risks were established through consideration of both the hazard and the direct and indirect exposure of the substance for current uses identified from a survey under section 71 of CEPA.

The human health hazard associated with the presence of reactive epoxy groups in Novolac epoxy resins is considered moderate on the basis of the available toxicological information. Consumption of the resin through food sources is not expected and release of epichlorhydrin is also not expected. Therefore, the human health risk associated with this substance is low. Dermal sensitization is not expected to pose a health risk as it requires a threshold value of 275 µg/cm^2, a value that is not expected at current exposure levels.

3.5.3.1 Uncertainties in evaluation of risk to human health

The structure presented for Novolac epoxy resins in Figure 3-1 has been simplified. In reality, a mixture of branched epoxy resin in ortho and/or para positions would be generated during the manufacture processes.

There were also uncertainties associated with the toxicity as only one reference was identified and the studies were not available for a detailed review.

Despite the above uncertainties, it is believed that the risk conclusions made for GEGBA and Novolac are accurate.

4. Conclusion

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

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

Therefore, it is proposed to conclude that the four epoxy resins do not meet any of the criteria set out in section 64 of CEPA.

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Appendices

Appendix A: Assessment approaches applied during the second phase of Polymer Rapid Screening

The approaches applied during the second phase of polymer rapid screening are outlined in this section. The detailed analyses, as well as the results of the second phase of polymer rapid screening for the individual substances, are presented in Chapters 2 to 3.

Characterization of ecological risk for Epoxy Resins

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

The ecological component of the second phase of polymer rapid screening approach consisted of four main steps to identify polymers that warrant further evaluation of their potential to cause harm. The first step involved identifying polymers which are not likely to be of ecological concern based on low reported import and manufacture quantities according to Phase Two of the DSL Inventory Update (Canada 2012), a voluntary survey (ECCC 2015) and a mandatory survey conducted under section 71 of CEPA (Canada 2015). Polymers with import and/or manufacture volumes less than 1000 kg per year are not likely to be of ecological concern. This is consistent with the notifying trigger quantity of 1000 kg for polymers under section 7 of the New Substances Notification Regulations (Chemicals & Polymers) [NSNR (C&P)] (Canada 2005).

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

The third step in the ecological component involved identifying polymers with reactive functional groups (RFGs). RFGs are groups with chemical functionality that are considered to be reactive and may have damaging effects on the biological community. These groups are well described in Schedule 7 of the NSNR (C&P) (Canada 2005) and polymers containing RFGs may be of increased ecological concern, and require further screening. The RFGs include, among others, potentially cationic or cationic functionalities, alkoxy silanes, and phenols with unsubstituted ortho or para positions. To determine the presence of RFGs, structural information was gathered through a voluntary (ECCC 2015) and a mandatory section 71 survey of CEPA (Canada 2015). For polymers where no representative structures were provided, structural representations were derived from information available for similar polymers: 1) obtained from the internal New Substances program database; 2) from the Chemical Abstract Services (CAS) name; or 3) based on professional knowledge on likely polymerization mechanisms.

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

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

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

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

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

Based on available information, DGEBA epoxy resin (25036-25-3) and Novolac epoxy resin (28064-14-4) were identified under the second phase of polymer rapid screening, as not requiring further ecological assessment. It is therefore unlikely that DGEBA epoxy resin (25036-25-3) and Novolac epoxy resin (28064-14-4) result in concerns for organisms or the broader integrity of the environment in Canada.

Characterization of risk to human health for Epoxy Resins

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

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

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

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

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

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

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

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