Draft Screening Assessment

Phenol-Formaldehyde Resins Group

Chemical Abstracts Service Registry Numbers

9003-35-4

25085-50-1

26022-00-4

32610-77-8

54579-44-1

55185-45-0

67700-42-9

71832-81-0

Environment and Climate Change Canada
Health Canada

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Synopsis

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

Substances in the 'Phenol-Formaldehyde Resins' Group

CAS RN [a]	Domestic Substances List name	Acronyms
9003-35-4	Phenol, polymer with formaldehyde	PFR
25085-50-1	Formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol	*t*-BPF
26022-00-4	Formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol, 4,4'-(1-methylethylidene)bis[phenol] and 4-methylphenol	*p*C-BPA-*t*BPF
32610-77-8	Formaldehyde, polymer with *N,N'*-bis(2-aminoethyl)-1,2-ethanediamine and phenol	TETA-PF
54579-44-1	Formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol and 4,4'-(1-methylethylidene)bis[phenol]	BPA-*t*BPF
55185-45-0	Formaldehyde, polymer with ammonia, 2-methylphenol and phenol	*o*C-A-PF
67700-42-9	Cashew, nutshell liq., polymer with formaldehyde and phenol	CNSL-PF
71832-81-0	Benzenesulfonic acid, hydroxy-, monosodium salt, polymer with formaldehyde and 4,4'-sulfonylbis[phenol]	NaPS-BPSF

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These eight substances were previously evaluated under the Second Phase of Polymer Rapid Screening, which identified phenol-formaldehyde resins as having low potential to cause ecological harm. However, these substances were identified as requiring further assessment due to their potential human health risk on the basis of structural alerts and/or uses associated with significant consumer exposure. The present assessment summarizes the approach applied during the second phase of polymer rapid screening and further elaborates on the potential for phenol-formaldehyde resins to cause harm to human health in order to reach an overall conclusion under section 64 of CEPA as to whether they pose a risk to the environment or human health.

Phenol-formaldehyde resins do not occur naturally in the environment but are prepared industrially. They do not contain any reactive functional group (RFG) associated with

adverse human health effects. In addition, most phenol-formaldehyde resins in commercial and consumer applications are present in cured-form. In Canada, phenol-formaldehyde resins are reported to be used as adhesives, sealants, process aids, intermediates, corrosion inhibitors, fillers, bleaching agents, encapsulating agents, surface active agents, fixing agents (dying auxiliary), and abrasives. They are used in several industries, such as plastics and rubbers, paints/inks, food packaging (including cans), coatings, building/construction, printed circuit board, electronics, oil and gas, metal, auto care, fabrics, textile, leather, cosmetics, and toys (as thermoset plastic).

No information regarding the manufactured amount of phenol-formaldehyde resins in Canada has been reported. However, it has been reported that volumes as low as 100 kilograms (for NaPS-BPSF) and in the range up to 10,000,000 kilograms (for PFR) were imported into Canada in 2014.

Ecological screening of the eight phenol-formaldehyde resins was performed in the Second Phase of Polymer Rapid Screening (ECCC, HC 2018). These eight resins were identified as either substances with low import and manufacturing quantities or low water solubility/extractability, or were otherwise determined to pose low ecological risk.

Considering all available lines of evidence presented in this assessment, there is low risk of harm to the environment from phenol-formaldehyde resins. It is proposed to conclude that these substances 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.

Both direct exposure (oral, inhalation, dermal) and indirect exposure (through drinking water) of the general population to phenol-formaldehyde resins are not expected or are thought to be minimal. Therefore, these substances likely present low or no risk of harm to human health.

In addition, on the basis of further evaluation, one of the phenol-formaldehyde resins (*p*C-BPA-*t*BPF, CAS RN 26022-00-4) was identified as a substance which could meet the same criteria that are used to designate a substance as being of low concern under the *New Substances Notification Regulations (Chemicals and Polymers)* of CEPA, in particular, the reduced regulatory requirement (RRR) polymers criterion in paragraph 9(b) of those Regulations. Polymers that are described by this criterion have a limited percentage of low-molecular-weight components, are chemically stable and do not contain reactive components; therefore, they present low human health concern. This substance is therefore unlikely to be a concern to human health.

On the basis of the information presented in this screening assessment, it is proposed to conclude that phenol-formaldehyde 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 to human life or health in Canada.

Therefore, it is proposed to conclude that phenol-formaldehyde resins 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* (CEPA) (Canada 1999), the Minister of Environment and the Minister of Health have conducted a screening assessment of eight substances referred to collectively as the 'Phenol-formaldehyde resins' (also known as 'Phenolic resins') group in order 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 eight substances considered in this assessment are collectively referred to as the 'Phenol-formaldehyde resins' group, they possess few similarities that would support a structurally based group approach to exposure, hazard and risk characterization; thus, their exposure and hazard profiles were independently assessed for risk.

The substances considered in this assessment have been previously evaluated using a rapid screening approach. The approach and results of that screening are presented in the document "Second Phase of Polymer Rapid Screening: Results of the Draft Screening Assessment" (ECCC, HC 2018). The ecological and human health rapid screening approaches are summarized in the Appendix of this screening assessment. Application of these approaches identified these Phenol-formaldehyde resins as having low potential to cause ecological harm; however, the need for further evaluation due to potential human health concern was identified. These results, in conjunction with any other relevant information that became available after the publication of the report on the second phase of polymer rapid screening, are considered in support of the conclusions made under section 64 of CEPA in this screening assessment.

This 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 2016. 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 screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments. The document "Second Phase of Polymer Rapid Screening: Results of the Screening Assessment" has undergone external review and was subject to a 60-day public comment period. While external comments were taken into consideration, the final content and outcome of the 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[1]. The draft screening assessment presents the critical information and considerations upon which the proposed conclusion is made.

2. PFR

2.1 Substance identity

Phenol-formaldehyde resins (PFR) (CAS RN 9003-35-4), phenolic resins, or simply 'phenolics' are well-established thermosetting polymers. Their history goes back more than a century (Gardziella et al. 2000, Pilato 2010). They are generally produced by the condensation of phenol (or substituted phenol) with formaldehyde (or other aldehydes)(Hesse and Lang 2012, Kopf 2003). The simplest phenol-formaldehyde resin, *i.e*. PFR; CAS# 9003-35-4, is prepared from a variable ratio of phenol vs. formaldehyde in the presence of an acidic or basic catalyst (see Figure 2-1)(Cragg 2012). An excess of phenol under acidic condition results in the formation of a PF resin called 'novolac' (Casiraghi et al. 1982, Fink 2013). On the other hand, addition of excess formaldehyde in a basic medium would generate 'resol' (Gogotov et al. 2009). No residual monomers (*i.e*., phenol and formaldehyde) are expected to remain as these processes involve several purification stages to remove all impurities (Hesse and Lang 2003, Kopf 2003). Both resol and novolac can be cured by heating or using a cross-linker, respectively, to form a three-dimensional cross-linked insoluble, infusible polymer called 'bakelite' (Hirano and Asami 2013, Crespy et al. 2008). PFRs contain no reactive functional groups associated with adverse human health effects (EPA 2010). Theoretically, both the *ortho* and *para* positions in phenols are prone to react with formaldehyde (Rego et al. 2004, Ottenbourgs et al. 1995). This would result in further substitution and side-chain polymerization in phenols. The simplified structures of PFRs are shown here for clarity (Figure 2-1).

[1]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.

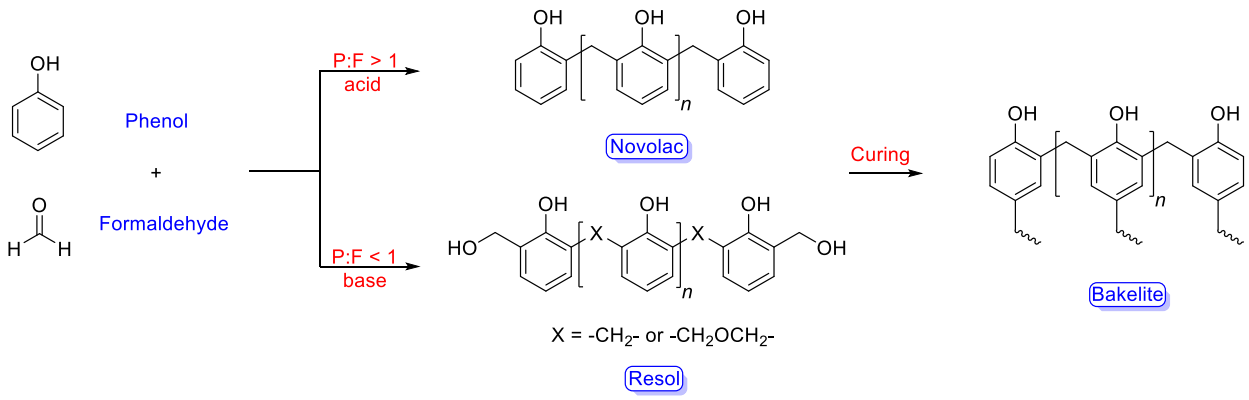

Figure 2-1. Synthesis and representative structure of PFR

Figure 2-1: The simplest phenol-formaldehyde resin, that is PFR, is prepared from a variable ratio of phenol vs. formaldehyde in the presence of an acidic or basic catalyst. An excess of phenol under acidic condition results in the formation of a PF resin called 'novolac'. On the other hand, addition of excess formaldehyde in a basic medium would generate 'resol'.

2.2 Physical and chemical properties

A summary of physical and chemical properties for PFR is presented in Table 2-1.

Table 2-1. Physical and chemical property values (at standard temperature) for PFR

Property	Value [PFR: Novolac(N), Resol(R), Bakelite(B)]	Key reference(s)
Physical state	Solid	Canada 2015 Wypych 2016
Number Average Molecular weight (Mn)(daltons)	N: 200-800 R: 360-950 B: 2550-3870	Canada 2015 Holopanien 1997 Yamagishi 1994 Rego 2004 Ottenbourgs 1995 Siling 1976 Casiraghi 1982

Property	Value [PFR: Novolac(N), Resol(R), Bakelite(B)]	Key reference(s)
Weight Average Molecular Weight (Mw)(daltons)	N: 630-910 R: 620-6600 B: 12100-75700	Canada 2015 Holopanien 1997 Yamagishi 1994
Components having molecular weight < 1000 Daltons (%)	N: 39.0-47.8	Canada 2015
Components having molecular weight < 500 Daltons (%)	N: 20.1-25.1	Canada 2015
Repeating unit number (*n*)	N: 2.8-5.1 R: 1.6-2.4 B: > 7	Rego 2004 Casiraghi 1982
Melting point (°C)	90-107	Wypych 2016
Boiling point (°C)	420 (decomposition)	Wypych 2016
Vapour pressure (Pa)	3.18	ECHA 2018
Water solubility (g/L)	N,R: 2.1 B: Insoluble	ECHA 2018 Izumi 2015
Density (g/cm^3)	1.24-1.32	Wypych 2016
Octanol-water partition co-efficient (log K_{ow})	- 1.88	ECHA 2018
Absorption-desorption (log K_{oc})	2.3	ECHA 2018
Biodegradation	Non-biodegradable	ECHA 2018 Kaplan 1979 Bouajila 2003

2.3 Sources and uses

PFRs are prepared industrially. Uncured PFRs are predominantly encountered in industrial settings. Uncured PFRs are marketed in different physical forms and require an admixture with curing agents to form the nonreactive cross-linked polymer (Pizzi and Ibeh 2014).

PFRs were included in a voluntary survey (ECCC 2015) as well as in a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 2-2 presents a summary of the total reported manufacture and total reported import quantities for the

substance in 2014. These sources indicate that the primary reported uses for PFR in Canada are as adhesives, sealants, process aids, intermediates, corrosion inhibitors, fillers, bleaching agents, and abrasives. PFRs are used in plastics and rubbers, paints/inks, coatings (including cans), printed circuit boards, electronics, and in the building/construction industry, oil and gas industry, metal industry, and by the toy industry as thermoset plastic.

Table 2-2. Summary of information on Canadian manufacturing and import quantities of PFR in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA

Total manufacture[a] (kg)	Total imports[a] (kg)	Survey reference
NR[b]	1,000,000-10,000,000	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).
[b] Not Reported

Globally, PFRs have widespread applications. They have been used in coatings, dispersions, adhesives, carbonless copy paper, molding compounds, abrasives, friction materials, foundry resins, laminates, air and oil filters, wood and fiber bonding materials, composites (including wood), nanocomposites, liquid-injection molding, foams, honeycombs, spheres, fibers, mineral wool insulation binders, photoresists, refractories, etc. (Mark and Kroschwitz 2003, Pilato 2010, Gardziella et al. 2000).

A number of domestic government databases were searched to determine if PFR is registered and/or approved for uses in Canada. These uses for PFR are listed in Table 2-3.

Table 2-3. Additional uses in Canada for PFR

Use	PFR
Food additive[a]	No
Food packaging materials[b]	Yes
Internal Drug Product Database as medicinal or non-medicinal ingredients in disinfectant, human 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]	Yes
Formulant in pest control products registered in Canada[h]	No
Known toy use[i]	Yes

[a] Health Canada [modified 2017]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017; unreferenced
[b] Health Canada [modified 2017]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017; unreferenced
[c] DPD [modified 2017]; personal communication, email from the Therapeutic Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[d] NHPID [modified 2017]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[e] LNHPD [modified 2016]]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[f] Health Canada [modified 2015]
[g] personal communication, email from the Consumer Product Safety Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Sep. 2017; unreferenced
[h] personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[i] Toy Industry Association (TIA 2017)

2.4 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).

PFR was identified as having low water extractability/solubility in the Second Phase of Polymer Rapid Screening (ECCC, HC 2018). Therefore, this substance was characterized as having a low potential for ecological risk. It is unlikely that this substance will result in concerns for the environment in Canada.

2.5 Potential to cause harm to human health

2.5.1 Exposure assessment

2.5.1.1 Direct exposure

When used industrially, direct exposure of the general population to PFR is not expected. The release of PFR from end-use applications (commercial and consumer) is very limited as this resin is reacted with hardeners/curing agents to form a cross-linked matrix that is stable against thermal and hydrolytic breakdown. In general, it is expected that PFR would react completely to form part of a stable polymer matrix from which it is no longer able to be released.

When PFR is used in food packaging materials (as a component of can coatings), the exposure potential is expected to be negligible (personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated December 2017; unreferenced).

Based on notifications submitted under the *Cosmetic Regulations* to Health Canada, PFR resin is used in certain cosmetics in Canada functioning as an adhesive for non-

permanent makeup in temporary tattoos. No information is available for additional products available to consumers (email correspondence from the Consumer Product Safety Directorate, Health Canada, to the NSACB, dated December 2017; unreferenced).

Although PFR resin has been used in cosmetics and toys (as plastic), dermal absorption is not expected to be significant due to its usage in the cured-form (Pizzi and Ibeh 2014). Moreover, very low log K_{ow} (~ -2) with mostly high molecular weight (> 80% above 500 g/mol) would result in poor dermal absorption (WHO 2006).

Despite its moderate vapour pressure, inhalation exposure to PFR is very limited as this substance is mixed with other materials into a system that is stable against thermal and hydrolytic breakdown (*i.e*. components' releases).

In conclusion, direct exposure (oral, inhalation, dermal) of the general population to PFR is expected to be minimal.

2.5.1.2 Indirect exposure

In the event of an unforeseen environmental release of the PFR bakelite, it is not expected to become distributed in the aquatic environment based on its water insolubility. In the case of the PFRs novolac and resol, it is expected to become distributed in the aquatic environment based on their high water solubility. The low adsorption-desorption (log K_{oc} = 2.3) would indicate a low sorption to soil and sediment and moderate migration potential to ground water. However, a high density for these PFRs (≈ 1.3 g/cm^3) increases the chance of their precipitation in aqueous media. Consequently, the indirect exposure of the general population to PFRs through environmental media such as drinking water is expected to be low.

2.5.2 Health effects assessment

During evaluation under the second phase of polymer rapid screening (ECCC, HC 2018), phenol formaldehyde resin (CAS RN 9003-35-4) was identified as requiring further assessment as a result of the presence of ortho para substituted groups which are reactive and associated with adverse human health effects such as dermal sensitization.

According to data found in ECHA (2018), the polymer has low acute oral and dermal toxicity in rats. It is not a skin irritant in humans but is slightly irritating to rabbit eyes. It is positive for dermal sensitization in a human patch test at a concentration of 35% however, the test substance contained 0.5% residual formaldehyde which may affect dermal sensitization. It was negative in an Ames test using the S. typhimurium strain TA 1537 (a test for frameshift mutagens). A cytogenic analysis of workers exposed to phenol formaldehyde resins showed increase in chromosomal aberrations as a result of occupational exposures (ECHA, 2018). No additional toxicological information was found for the polymer.

2.5.3 Characterization of risk to human health

The polymer is composed of two monomers (formaldehyde and phenol) which are known to have human health concerns (Gelbke 2014, IRIS 1997-2018). However, when polymerized together, the formaldehyde is consumed and cannot be regenerated by degradation of the substance. The phenol groups are chemically linked together with a carbon bond derived from the formaldehyde through their ortho and para positions, therefore these reactive regions of the phenol are no longer available to react with other substances. The reacted polymer is chemically stable under normal environmental conditions and cannot regenerate its monomers. Given that there are negligible amounts of residual monomers, the polymer is not expected to pose a health risk as a result of direct exposure.

The polymer is not water soluble and is not expected to distribute readily through the environment, therefore, there are no human health risks expected as a result of indirect exposure from drinking water.

3. *t*-BPF

3.1 Substance identity

4-*tert*-butylphenolformaldehyde (or *p*-*tert*-butylphenolformaldehyde; *t*-BPF) (CAS RN 25085-50-1) is prepared by the condensation of 4-*tert*-butylphenol (*t*-BP) with formaldehyde (Figure 3-1)(Ellis et al. 2008, Yamagishi et al. 1993, Casiraghi et al. 1983). Usually, an excess of formaldehyde is used in production (the molar ratio: Formaldehyde>*t*-BP). No residual monomers (*i.e.*, *t*-BP and formaldehyde) are expected to remain as the process involves several purification stages to remove all impurities (Wang et al. 2015). *t*-BPF contains no reactive functional group associated with adverse human health effects (EPA 2010). Compared to PFR, *t*-BPF has better oil-solubility, better adhesive properties, as well as lower cost (Wang et al. 2015).

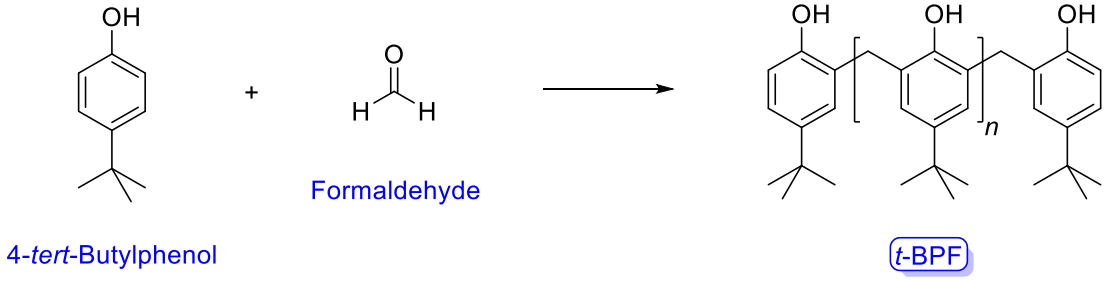

Figure 3-1. Synthesis and representative structure of *t*-BPF

Figure 3-1: 4-*tert*-butylphenolformaldehyde (or *p*-*tert*-butylphenolformaldehyde; *t*-BPF) is prepared by the condensation of 4-*tert*-butylphenol with formaldehyde. Usually, an excess of formaldehyde is used in production (the molar ratio: Formaldehyde>*t*-BF).

3.2 Physical and chemical properties

A summary of physical and chemical properties for *t*-BPF is presented in Table 2-1.

Table 3-1. Physical and chemical property values (at standard temperature) for *t*-BPF

Property	Value (*t*-BPF)	Key reference(s)
Physical state	Solid	SciFinder 2018
Number Average Molecular weight (Mn)(daltons)	1080-1260 1376-1712 (F>*t*-BP)	Canada 2015 Wang 2015
Components having molecular weight < 1000 Daltons (%)	23.9-28.8	Canada 2015
Components having molecular weight < 500 Daltons (%)	5.5-8.0	Canada 2015
Repeating unit number (*n*)	6-10	Canada 2015
Melting point (°C)	60-100	Canada 2015 SciFinder 2018 Ellis 2008
Softening point (°C)	76-122	Wang 2015 Ellis 2008
Boiling point (°C)	233.7	Canada 2015 ChemNet 2018
Vapour pressure (Pa)	4.8	Canada 2015 ChemNet 2018
Water solubility	Insoluble	Ellis 2008
Solubility in organic solvents	Soluble	Ellis 2008
Density (g/cm^3)	1.2	Ellis 2008
Biodegradation	Stable (non-biodegradable)	Ellis 2008

3.3 Sources and uses

t-BPF is prepared industrially. Uncured *t*-BPF is predominantly encountered in industrial settings. It is marketed in different physical forms and requires an admixture with other materials to form the nonreactive polymeric matrix (Ellis 2008, Choi 1999).

t-BPF has been included in a voluntary survey (ECCC 2015) as well as a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 2-2 below presents a summary of the total reported manufacture and total reported import quantities for the substance in 2014. These sources indicate that the primary reported uses for *t*-BPF in Canada are as adhesives, sealants, and intermediates. It is used in coatings (including cans), paints, and auto care products.

Table 3-2. Summary of information on Canadian manufacturing and import quantities of *t*-BPF in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA

Total manufacture[a] (kg)	Total imports[a] (kg)	Survey reference
NR[b]	10,000-100,000	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).
[b] Not reported

Globally, *t*-BPF is used as an adhesive in leather and rubber goods (Herro and Jacob 2012) as well as for electrical insulation varnishes, as coatings for metals, ceramics and plastic surfaces, as an antioxidant, as an antimicrobial agent, as a chemical intermediate, as a curing agent of natural and synthetic rubber, and as a tackifier of rubber, printing ink, sticking tape, etc. (Ellis 2008).

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

Table 3-3. Additional uses in Canada for *t*-BPF

Use	***t*-BPF**
Food additive[a]	No
Food packaging materials[b]	Yes
Internal Drug Product Database as medicinal or non-medicinal ingredients in disinfectant, human or veterinary drug products in Canada[c]	No
Natural Health Products Ingredients Database[d]	Yes
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 2017]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017; unreferenced

[b] Health Canada [modified 2017]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017; unreferenced
[c] DPD [modified 2017]; personal communication, email from the Therapeutic Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
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[h] personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[i] Toy Industry Association (TIA 2017)

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).

t-BPF was identified as having low water extractability/solubility in the Second Phase of Polymer Rapid Screening (ECCC, HC 2018). Therefore, this substance was characterized as having a low potential for ecological risk. It is unlikely that this substance will result in concerns for 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 *t*-BPF is not expected. In commercial and consumer applications, *t*-BPF is mainly used in adhesives; it possesses good binding qualities and has a particular tackiness useful for the surfaces of leather and rubber. For these reasons, *t*-BPF is principally found in glued leather goods such as shoes, handbags, belts and watchstraps. This would result in possible dermal exposure, especially for lower molecular weight *t*-BPF (MW < 250 g/mol) (Zimerson et al. 2002). However, *t*-BPF is a solid polymeric substance with a high molecular weight (greater than 500 g/mol) and a predicted high log K_{ow} which suggests that it is soluble in oils and insoluble in water; these characteristics suggest that the substance has low dermal absorption potential (WHO 2006).

When *t*-BPF is used in food packaging materials as a component of can coatings, exposure potential is expected to be negligible (personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated December 2017; unreferenced).

t-BPF is listed as a non-NHP ingredient in the Natural Health Products Ingredients Database (NHPID 2018).

Despite its moderate vapour pressure, inhalation exposure to *t*-BPF is very limited as this substance is mixed with other materials into a system that is stable against thermal and hydrolytic breakdown (*i.e*. constituent components are unlikely to be released).

In conclusion, the direct exposure (oral, inhalation, dermal) of the general population to *t*-BPF is expected to be minimal.

3.5.1.2 Indirect exposure

In the event of an unforeseen environmental release of *t*-BPF, it is not expected to become widely dispersed in the aquatic environment based on its water insolubility. Consequently, indirect exposure of the general population to *t*-BPF through environmental media such as drinking water is not expected.

3.5.2 Health effects assessment

During evaluation under the second phase of polymer rapid screening (ECCC, HC 2018), *t*-BPF (CAS RN 25085-50-1) was identified as requiring further assessment as a result of the presence of ortho and para substituted functional groups which are reactive and associated with adverse human health effects such as dermal sensitization.

t-BPF has a low acute oral and dermal toxicity when tested in Sprague-Dawley rats. It was not a skin irritant and a minimal eye irritant in rabbits. A subchronic toxicity assay generated a NOEL of 150 mg/kg bw/day in rats which is indicative of moderate subchronic toxicity but no additional details were provided. It was not mutagenic in an Ames test. No teratogenic effects were observed when tested on Wistar rats exposed between days 7-17 of gestation (ECHA 2018a).

3.5.3 Characterization of risk to human health

The polymer is composed of two monomers (formaldehyde and 4-tert butylphenol) which are known to have human health concerns (Gelbke 2014, EC 2008). However, when polymerized together, the formaldehyde is consumed and cannot be regenerated through degradation of the substance. The phenolic groups are chemically linked together with a carbon bond derived from the formaldehyde through their ortho and para positions, therefore these reactive regions of the phenolic groups are no longer available to react with other substance. The reacted polymer is chemically stable under normal environmental conditions and cannot regenerate its monomers. Given that there are negligible amounts of residual monomers, the polymer is not expected to pose a health risk as a result of direct exposure.

The polymer is not water soluble and is not expected to disperse through the aquatic environment, therefore, there are no human health risks expected as a result of indirect exposure from drinking water.

4. *p*C-BPA-*t*BPF

4.1 Substance identity

The condensation reaction between 4-*tert*-butylphenol, bisphenol A (BPA), *p*-cresol, and formaldehyde results in the formation of *p*-cresol-bisphenol A-*t*-butylphenol-formaldehyde copolymer (*p*C-BPA-*t*BPF) (CAS RN 26022-00-4) (Figure 4-1). No residual monomers (i.e., BPA, *p*-cresol, *t*BP, and formaldehyde) are expected to remain as the process involves several purification stages to remove all impurities (Petersen 1969). *p*C-BPA-*t*BPF contains no reactive functional groups associated with adverse human health effects (EPA 2010). Theoretically, the *ortho* positions in *p*-cresol, *t*-butylphenol, and BPA are prone to react with formaldehyde. Moreover, hydroxyl groups in BPA could potentially be involved in the polymerization. However, only the simplified structure for *p*C-BPA-*t*BPF is shown here for clarity.

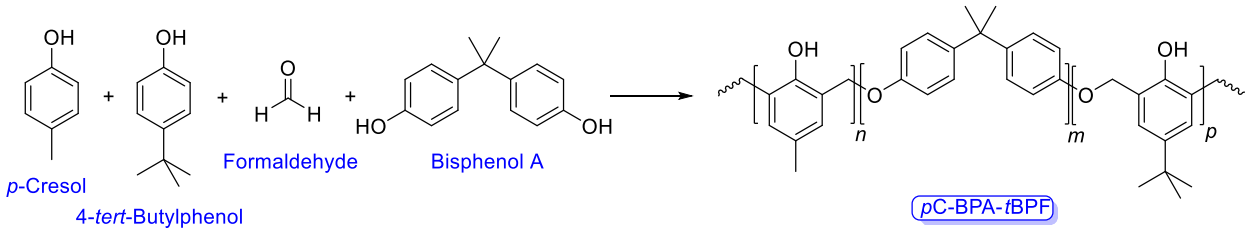

Figure 4-1. Synthesis and representative structure of *p*C-BPA-*t*BPF

Figure 4-1: The condensation reaction between 4-*tert*-butylphenol, bisphenol A (BPA), *p*-cresol, and formaldehyde results in the formation of *p*-cresol-bisphenol A-*t*-butylphenol-formaldehyde copolymer (*p*C-BPA-*t*BPF).

4.2 Physical and chemical properties

A summary of physical and chemical properties for *p*C-BPA-*t*BPF is presented in Table 2-1.

Table 4-1. Physical and chemical property values (at standard temperature) for *p*C-BPA-*t*BPF

Property	Value (*p*C-BPA-*t*BPF)	Key reference(s)
Physical state	Solid	Canada 2015

Property	Value (*p*C-BPA-*t*BPF)	Key reference(s)
Number Average Molecular weight (Mn)(daltons)	1283-1374	Canada 2015
Components having molecular weight < 1000 Daltons (%)	21.3-22.8	Canada 2015
Components having molecular weight < 500 Daltons (%)	7.6-8.8	Canada 2015
Melting point (°C)	74-88	Canada 2015 ChemCAS 2018
Water solubility	< 1%	ChemCAS 2018
Density (g/cm^3)	1.10	ChemCAS 2018

4.3 Discussion regarding the criteria for designation of low concern status for the substance

International jurisdictions, including the United States (US), Australia and Canada, recognize that polymers that meet predetermined and established physical-chemical and toxicological criteria generally possess low ecological and human health hazard. As outlined in detail below, polymers that meet these sets of criteria are known internationally as Polymers of Low Concern (PLC) or in Canada as Reduced Regulatory Requirement (RRR) polymers under the *New Substances Notification Regulations (Chemicals and Polymers)* (NSNR C&P) (Canada 2005) and as stated in the 'Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers' (Environment Canada, Health Canada 2005). To study the applicability of PLC, the Organization for Economic Co-operation and Development (OECD) analyzed over 100 polymers that meet the criteria for PLC in various OECD member countries[2]. Based on the available information submitted by participating jurisdictions (i.e., Canada, Australia, US, and Korea), polymers that met the PLC criteria generally showed low human health and ecological concerns. As such, the use of the PLC criteria [such as those described in NSNR (C&P) (Canada 2005)] for screening of polymers is recognized as appropriate (OECD 2009).

The criteria for determining whether a polymer meets the PLC status are set out by each jurisdiction but they are generally equivalent. In Canada, the RRR criteria are set out in section 9 of the NSNR (C&P) (Canada 2005), where:

"9. A reduced regulatory requirement polymer is

[2] The term "polymer of low concern" is used in other countries to describe polymers that share the same structural characteristics as polymers that meet Reduced Regulatory Requirements in Canada.

(a) a polymer that is not one of the types listed in items 1 to 4 of Schedule 7 and that has a number average molecular weight greater than 10,000 daltons, with less than 2% of its components having molecular weights of less than 500 daltons and less than 5% of its components having molecular weights of less than 1000 daltons;
(b) a polymer that is not one of the types listed in Schedule 7 and that has a number average molecular weight greater than 1000 daltons and equal to or less than 10,000 daltons, with less than 10% of its components having molecular weights of less than 500 daltons and less than 25% of its components having molecular weights of less than 1000 daltons; or
(c) a polymer that is a polyester manufactured solely from reactants listed in Schedule 8, or an anhydrous form of those reactants, other than the reactants or their anhydrous forms that include both 1-butanol and fumaric or maleic acid."

In summary, RRR polymers are polymers with a high number average molecular weight (Mn) that have a limited percentage of low-molecular-weight components (<1000 daltons), are chemically stable and do not contain certain reactive or cationic moieties (Environment Canada, Health Canada 2005).

In the 'Polymer Rapid Screening' stage, the PLC criteria were utilized to first broadly screen the polymers to determine whether they would be of low ecological and human health concern. Polymers with sufficient evidence to determine their PLC status were concluded as not meeting criteria in section 64 of CEPA, and were removed from further assessment. Similarly, polymers with insufficient or conflicting information that suggests the polymer may be synthesized in different forms not meeting the PLC criteria were identified for further evaluation (ECCC, HC 2018).

Substance *p*C-BPA-*t*BPF in this phenol-formaldehyde grouping was further-assessed against the PLC criteria, as described above. On the basis of additional information considered after completion of the second phase of polymer rapid screening (see Table 4-1), it was identified as meeting the PLC criteria. Any toxic monomers in this polymer (such as bisphenol A) are expected to be reacted onto the polymer backbone and not to be readily released from the polymer, and are therefore not considered to be available for uptake in their neat form (Personal communications, emails from manufacturers, Aug. 2017, unreferenced). As such, this polymer is proposed not to be a concern to human health.

4.4 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).

*p*C-BPA-*t*BPF was identified as having low water extractability/solubility in the Second Phase of Polymer Rapid Screening (ECCC, HC 2018). Therefore, this substance was

characterized as having a low potential for ecological risk. It is unlikely that this substance will result in concerns for the environment in Canada.

4.5 Potential to cause harm to human health

p-cresol-bisphenol A-*t*-butylphenol-formaldehyde copolymer (*p*C-BPA-*t*BPF) meets the criteria for RRR polymers and as a result, is not a concern for human health. Therefore, detailed exposure and hazard assessments are not required for this substance. The exposure and hazard are mitigated based on the large molecular weight of the substance, the low quantity of small molecular components, as well as its use in cured form.

5. TETA-PF

5.1 Substance identity

The condensation reaction between triethylenetetramine (TETA), phenol, and formaldehyde forms an intermediate named bis-benzoxazine (Figure 5-1). Under curing condition, the benzoxazine transforms to the triethylenetetramine-phenol-formaldehyde copolymer (TETA-PF) (CAS RN 32610-77-8) also called polybenzoxazine (Ishida and Agag 2011). No residual monomers (*i.e.*, TETA, phenol, and formaldehyde) are expected to remain as these processes involve several purification stages to remove all impurities (Patil 2017). TETA-PF contains secondary amine groups and is considered a cationic polymer.

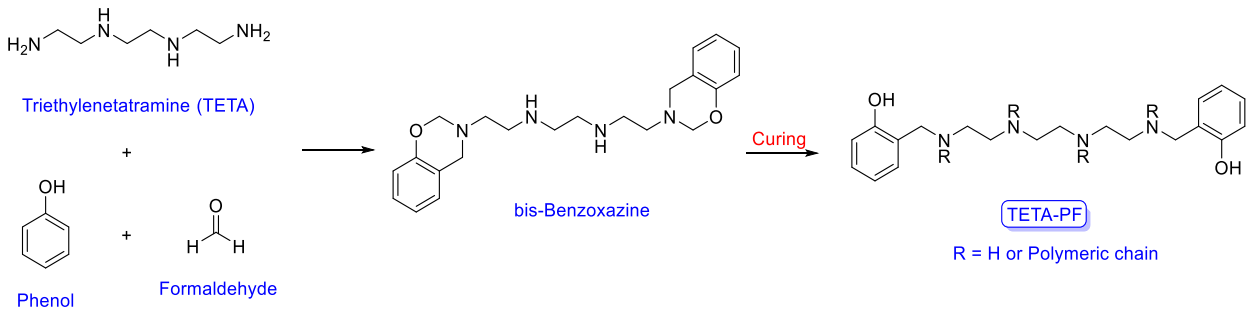

Figure 5-1. Synthesis and representative structure of TETA-PF

Figure 5-1: The condensation reaction between triethylenetetramine (TETA), phenol, and formaldehyde forms an intermediate named bis-benzoxazine. Under curing condition, the benzoxazine transforms to the triethylenetetramine-phenol-formaldehyde copolymer (TETA-PF) also called polybenzoxazine.

5.2 Physical and chemical properties

A summary of physical and chemical properties for TETA-PF is presented in Table 2-1.

Table 5-1. Physical and chemical property values (at standard temperature) for TETA-PF

Property	Value (TETA-PF)	Key reference(s)
Physical state	Solid	ChemSrc 2018
Molecular weight (g/mol)	> 500 (polybenzoxazine)	Ishida and Agag 2011
Boiling point (°C)	266.5	ChemSrc 2018 ChemNet 2018
Vapour pressure (Pa)	1.15	ChemNet 2018
Water solubility	Soluble	-
Density (g/cm^3)	≈1.08	Canada 2015
Octanol-water partition co-efficient (log K_{ow})	2.1	ChemSrc 2018
Adsorption-desorption (log K_{oc})	1.3	Estimated[a]

[a] The estimation of organic carbon partition co-efficient (adsorption-desorption) was performed using the formula log K_{oc}= 0.99 log K_{ow} – 0.81 (Seth et al. 1999).

5.3 Sources and uses

TETA-PF resin is prepared industrially. Uncured TETA-PF is predominantly encountered in industrial settings. It is marketed in different physical forms and requires an admixture with other materials to form the nonreactive polymer (Ishida and Agag 2011).

TETA-PF has been included in a voluntary survey (ECCC 2015) as well as a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 2-2 below presents a summary of the total reported manufacture and total reported import quantities for the substance in 2014. These sources indicate that the primary reported use for TETA-PF in Canada is as intermediate in paints/inks, coatings, toner and colourants.

Table 5-2. Summary of information on Canadian manufacturing and import quantities of TETA-PF in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA

Total manufacture[a] (kg)	Total imports[a] (kg)	Survey reference
NR[b]	1,000-10,000	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).
[b] Not reported

Globally, TETA-PF is used as a curing agent, an ion exchange resin for water treatment [(such as for the removal of chromate)(Bryjak 2016)] as well as for food treatment (Ishida and Agag 2011, Burdock 1996), and for fractionation of natural organic matter in water (Kucukcongar et al. 2013).

A number of domestic government databases were searched to determine if TETA-PF is registered and/or approved for uses in Canada. None of these specific use patterns were linked to TETA-PF as indicated in Table 5-3.

Table 5-3. Additional uses in Canada for TETA-PF

Use	TETA-PF
Food additive[a]	No
Food packaging materials[b]	No
Internal Drug Product Database as medicinal or non-medicinal ingredients in disinfectant, human 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 2017]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017; unreferenced
[b] Health Canada [modified 2017]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017; unreferenced
[c] DPD [modified 2017]; personal communication, email from the Therapeutic Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[d] NHPID [modified 2017]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[e] LNHPD [modified 2016]]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[f] Health Canada [modified 2015]
[g] personal communication, email from the Consumer Product Safety Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Sep. 2017; unreferenced
[h] personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[i] Toy Industry Association (TIA 2017)

5.4 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).

TETA-PF was classified as having moderate hazard potential according to information considered in the Second Phase of Polymer Rapid Screening (ECCC, HC 2018). On the basis of low exposure potential, this substance was characterized as having a low

potential for ecological risk. It is unlikely that this substance will result in concerns for the environment in Canada.

5.5 Potential to cause harm to human health

5.5.1 Exposure assessment

5.5.1.1 Direct exposure

When used industrially, direct exposure of the general population to TETA-PF is not expected. The release of TETA-PF from end-use applications (commercial and consumer) is very limited as this resin is mixed/reacted with other materials into a system that is stable against thermal and hydrolytic breakdown. Given the anticipated use patterns in paints/inks, coatings, toner and colourants, no oral exposure is expected. TETA-PF is a solid polymeric substance with high molecular weight (greater than 500 g/mol). Therefore, dermal absorption and inhalation exposure to TETA-PF are not expected to be significant (WHO 2006). In conclusion, the direct exposure (oral, inhalation, dermal) of the general population to TETA-PF is expected to be minimal.

5.5.1.2 Indirect exposure

In the event of an unforeseen environmental release of TETA-PF, it is expected to become distributed in the aquatic environment based on its high water solubility. The estimated very low adsorption-desorption (log $K_{oc} \approx 1.3$) would indicate a negligible sorption to soil and sediment and migration potential to ground water. Consequently, indirect exposure of the general population to TETA-PF through environmental media such as drinking water is possible in the event of unforeseen environmental release.

5.5.2 Health effects assessment

During evaluation under the second phase of polymer rapid screening (ECCC, HC 2018), TETA-PF (CAS RN 32610-77-8) was identified as requiring further assessment as a result of the presence of ortho and para substituted functional groups which are reactive and are associated with adverse human health effects such as dermal sensitization.

No toxicological information was found from searching various online databases. A Safety Data Sheet (SDS) on the substance also does not have data but indicates that the substance may be harmful if inhaled, swallowed or absorbed through the skin and is an eye irritant (Aldrich, 2017). Another SDS by Keystone Industries on a product containing 87-89% TETA-PF, 9-11% phenol and < 2% formaldehyde, only provided toxicological information on the monomers (Keystone 2002).

5.5.3 Characterization of risk to human health

The polymer is composed of 3 monomers (formaldehyde, phenol and triethylenetetramine) some of which are known to have human health concerns (Gelbke 2014, IRIS 1997-2018). However, when polymerized, the formaldehyde is consumed and cannot be regenerated by degradation of the substance. The phenol and triethylenetetramine groups are chemically linked together with a carbon bond through their ortho and para positions, therefore these reactive regions of the phenol are no longer available to react with other substances. The reacted polymer is chemically stable under normal environmental conditions and cannot regenerate component monomers. Given that there are negligible amounts of residual monomers and that Table 5-3 shows that the polymer is not known to be used in applications which typically result in increased direct exposure, the polymer is not expected to pose a human health risk as a result of direct exposure.

Although the polymer is soluble in water, it is not manufactured in Canada and is used in a limited number of applications that do not typically result in “down the drain” disposal; hence, the potential for release into the aquatic environment is low and there are no significant human health risks anticipated as a result of indirect exposure through drinking water.

6. BPA-*t*BPF

6.1 Substance identity

The condensation reaction between 4-*tert*-butylphenol, bisphenol A (BPA), and formaldehyde results in the formation of bisphenol A-*t*-butylphenol-formaldehyde copolymer (BPA-*t*BPF) (CAS RN 54579-44-1) (Figure 6-1). BPA is usually used in significantly lower amounts than t-butylphenol during the polymerization reaction. No residual monomers (i.e., BPA, *t*BP, and formaldehyde) are expected as these processes involve several purification stages to remove all impurities (Toyoda 2004). BPA-*t*BPF contains no reactive functional group associated with adverse human health effects (EPA 2010). Theoretically, the *ortho* positions in both *t*-butylphenol and BPA are prone to react with formaldehyde. Moreover, hydroxyl groups in BPA could potentially be involved in the polymerization reaction. However, only the simplified structure for BPA-*t*BPF is shown here for clarity.

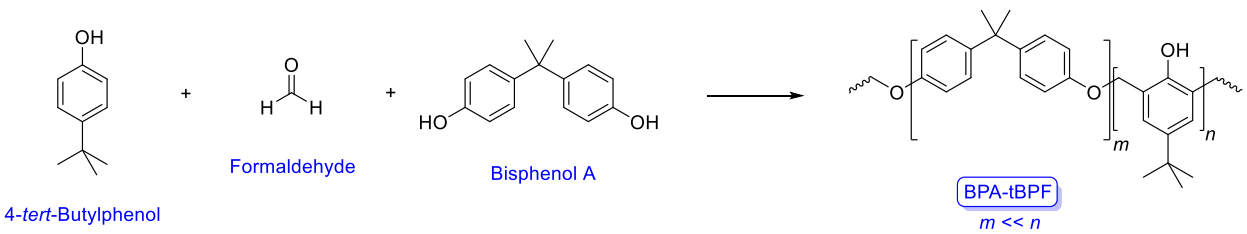

Figure 6-1. Synthesis and representative structure of BPA-*t*BPF

Figure 6-1: The condensation reaction between 4-*tert*-butylphenol, bisphenol A (BPA), and formaldehyde results in the formation of bisphenol A-*t*-butylphenol-formaldehyde copolymer (BPA-*t*BPF). BPA is usually used in significantly lower amounts than *t*-butylphenol during the polymerization reaction.

6.2 Physical and chemical properties

A summary of physical and chemical properties for BPA-*t*BPF is presented in Table 2-1.

Table 6-1. Physical and chemical property values (at standard temperature) for BPA-*t*BPF

Property	Value (BPA-*t*BPF)	Key reference(s)
Physical state	Solid	Canada 2015
Number Average Molecular weight (Mn)(daltons)	913-1092	Canada 2015
Components having molecular weight < 1000 Daltons (%)	29.4-35.0	Canada 2015
Components having molecular weight < 500 Daltons (%)	10.1-13.6	Canada 2015
Melting point (°C)	104-114	Canada 2015
Softening point (°C)	85-95	Canada 2015
Water solubility	Insoluble (< 1%)	Canada 2015 ChemCAS 2018
Density (g/cm^3)	1.10	ChemCAS 2018

6.3 Sources and Uses

BPA-*t*BPF is prepared industrially. Uncured BPA-*t*BPF is predominantly encountered in industrial settings. It is marketed in different physical forms and requires an admixture with curing agents to form the nonreactive cross-linked polymer (Fukunaga 1991).

BPA-*t*BPF has been included in a voluntary survey (ECCC 2015) as well as in a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 2-2 below presents a summary of the total reported manufacture and total reported import quantities for the substance in 2014. BPA-*t*BPF is reported to be used as a component in inks used in food packaging materials. Moreover, it is believed that BPA-*t*BPF is used in general purpose elastomer adhesives, epoxy curing, and printed-circuit board assembly applications.

Table 6-2. Summary of information on Canadian manufacturing and import quantities of BPA-*t*BPF in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA

Total manufacture[a] (kg)	Total imports[a] (kg)	Survey reference
NR[b]	10,000-100,000	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).
[b] Not reported

Globally, BPA-*t*BPF is used in epoxy curing, as an intermediate in printed-circuit board assembly applications (Hexion, SP-134), as an elastomer adhesive (Toyoda 2004, SDS Dyphene 669). In its general purpose adhesive, BPA-*t*BPF gives heat resistance, lightness in colour, and optimum cohesive strength (Flick 1991).

A number of domestic government databases were searched to determine if BPA-*t*BPF is registered and/or approved for uses in Canada.

Table 6-3. Additional uses in Canada for BPA-*t*BPF

Use	BPA-*t*BPF
Food additive[a]	No
Food packaging materials[b]	Yes
Internal Drug Product Database as medicinal or non-medicinal ingredients in disinfectant, human 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 2017]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017; unreferenced
[b] Health Canada [modified 2017]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017; unreferenced
[c] DPD [modified 2017]; personal communication, email from the Therapeutic Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[d] NHPID [modified 2017]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[e] LNHPD [modified 2016]]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[f] Health Canada [modified 2015]
[g] personal communication, email from the Consumer Product Safety Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Sep. 2017; unreferenced

[h] personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[i] Toy Industry Association (TIA 2017)

6.4 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).

BPA-*t*BPF was identified as having low water extractability/solubility in the Second Phase of Polymer Rapid Screening (ECCC, HC 2018). Therefore, this substance was characterized as having a low potential for ecological risk. It is unlikely that this substance will result in concerns for the environment in Canada.

6.5 Potential to cause harm to human health

6.5.1 Exposure assessment

6.5.1.1 Direct exposure

When used industrially, direct exposure of the general population to BPA-*t*BPF is not expected. The release of BPA-*t*BPF from end-use applications (commercial and consumer) is very limited as this substance is mixed/reacted with hardeners/curing agents into a cross-linked matrix that is stable against thermal and hydrolytic breakdown. According to its anticipated usage, no oral exposure is expected. BPA-*t*BPF may be used as a component in inks used in food packaging materials, with no potential for direct food contact, therefore exposure is not expected (personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017). BPA-*t*BPF is a solid substance with relatively high molecular weight (mostly greater than 500 g/mol). Therefore, dermal absorption and inhalation exposure to BPA-*t*BPF are not expected to be significant (WHO 2006). In conclusion, the direct exposure (oral, inhalation, dermal) of the general population to BPA-*t*BPF is expected to be minimal.

6.5.1.2 Indirect exposure

In the event of an unforeseen environmental release of BPA-*t*BPF, it is not expected to become widely distributed in the aquatic environment based on its very low water solubility. Consequently, indirect exposure of the general population to BPA-*t*BPF through environmental media such as drinking water is not expected.

6.5.2 Health effects assessment

During evaluation under the second phase of polymer rapid screening (ECCC, HC 2018), 4-tert-butylphenol bisphenol A (CAS RN 54579-44-1) was identified as requiring

further assessment as a result of the presence of ortho and para substituted functional groups which are reactive and associated with adverse human health effects such as dermal sensitization.

No toxicological information was found for the polymer from searching various online databases. An SDS on the substance with reported 97-99% purity, indicated that it may be a dermal sensitizer (SDS 2015, Western Reserve chemical).

6.5.3 Characterization of risk to human health

The polymer is composed of 3 monomers (4-*tert*-butylphenol, bisphenol A (BPA), and formaldehyde) which are known to have human health concerns (Gelbke 2014, EC 2008, Konieczna 2015, HC 2008). However, when polymerized together, the formaldehyde is consumed and cannot be regenerated by degradation of the substance. The BPA and 4-*tert*-butylphenol groups are chemically linked together with a carbon bond derived from the formaldehyde through their ortho and para positions, therefore these reactive regions of the phenol are no longer available to react with other substances. The reacted polymer is chemically stable under normal environmental conditions and cannot regenerate constituent monomers. Given that there are negligible amounts of residual monomers and given that Table 6-3 shows that the polymer is not known to be used in applications which typically result in direct human exposure, the polymer is not expected to pose a human health risk as a result of direct exposure.

The polymer is not water soluble and is not expected to disperse through the aquatic environment, there are no expected human health risks associated with indirect exposure.

7. *o*C-A-PF

7.1 Substance identity

The condensation reaction between *ortho*-cresol, ammonia, phenol, and formaldehyde forms an intermediate named benzoxazine (Figure 7-1). Under curing conditions, the benzoxazine transforms to the *o*-cresol-ammonia-phenol-formaldehyde copolymer (*o*C-A-PF) (CAS RN 55185-45-0) (Ghosh et al. 2007, Hotta et al. 1974, Calo 2007). No residual monomers (*i.e.*, *o*-cresol, ammonia, phenol and formaldehyde) are expected to remain as these processes involve several purification stages to remove all impurities (Kumar and Nair 2010, Ishida Agag 2011). *o*C-A-PF contains no reactive functional groups associated with adverse human health effects (EPA 2010). Theoretically, both *ortho* and *para* positions in *o*-cresol and phenol are prone to react with formaldehyde. However, the simplified structure of *o*C-A-PF is shown here for clarity.

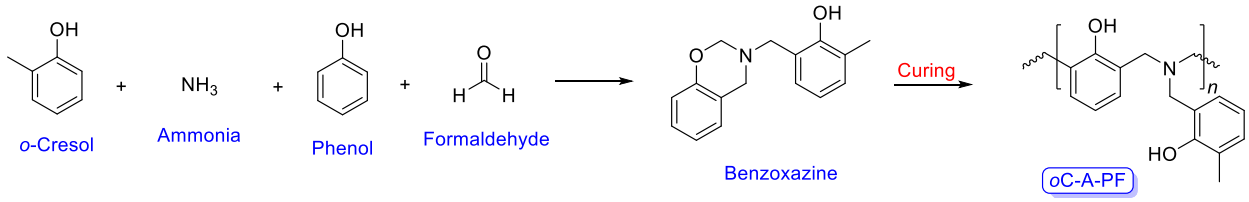

Figure 7-1. Synthesis and representative structure of *o*C-A-PF

Figure 7-1: The condensation reaction between ortho-cresol, ammonia, phenol, and formaldehyde forms an intermediate named benzoxazine. Under curing conditions, the benzoxazine transforms to the *o*-cresol-ammonia-phenol-formaldehyde copolymer (*o*-C-A-PF).

7.2 Physical and chemical properties

A summary of physical and chemical properties for *o*C-A-PF is presented in Table 2-1.

Table 7-1. Physical and chemical property values (at standard temperature) for *o*C-A-PF

Property	Value (*o*C-A-PF)	Key reference(s)
Physical state	Solid	Canada 2015
Molecular weight (g/mol)	> 500 (n > 2)	-
Melting point (°C)	67.5	Canada 2015
Boiling point (°C)	225.8	Canada 2015
Water solubility	Insoluble	Canada 2015
Density (g/cm^3)	1.22-1.24	Canada 2015
Biodegradation	Biodegradable (uncured form); shelf-life: 6 months	Canada 2015

7.3 Sources and uses

*o*C-A-PF is prepared industrially. It is predominantly encountered in industrial settings (Raquez et al. 2010).

*o*C-A-PF was included in a voluntary survey (ECCC 2015) as well as in a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 2-2 below shows that no information regarding the total manufacture and total import quantities for the substance in 2014 was reported. No direct information was found for the uses of *o*C-A-PF in Canada. However, it is believed that *o*C-A-PF could be used as a thermosetting resin in metal coating formulations.

Table 7-2. Summary of information on Canadian manufacturing and import quantities of *o*C-A-PF in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA

Total manufacture[a] (kg)	Total imports[a] (kg)	Survey reference
NR[b]	NR	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).
[b] Not reported

Globally, *o*C-A-PF is used as an ion exchange resin (Holl 2003) and as a plasticizer in metal coating formulations (Rimdusit et al. 2013, Hotta et al. 1974, Durez 29111).

A number of domestic government databases were searched to determine if *o*C-A-PF is registered and/or approved for uses in Canada. None of these specific uses were identified for *o*C-A-PF as indicated in Table 7-3.

Table 7-3. Additional uses in Canada for *o*C-A-PF

Use	*o*C-A-PF
Food additive[a]	No
Food packaging materials[b]	No
Internal Drug Product Database as medicinal or non-medicinal ingredients in disinfectant, human 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 2017]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017; unreferenced
[b] Health Canada [modified 2017]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Dec. 2017; unreferenced
[c] DPD [modified 2017]; personal communication, email from the Therapeutic Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[d] NHPID [modified 2017]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[e] LNHPD [modified 2016]]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[f] Health Canada [modified 2015]
[g] personal communication, email from the Consumer Product Safety Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Sep. 2017; unreferenced

[h] personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[i] Toy Industry Association (TIA 2017)

7.4 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).

*o*C-A-PF was identified as having reported import and manufacturing quantities less than 1000 kg per year in the Second Phase of Polymer Rapid Screening (ECCC, HC 2018). Therefore, this substance was characterized as having a low potential for ecological risk. It is unlikely that this substance will result in concerns for the environment in Canada.

7.5 Potential to cause harm to human health

7.5.1 Exposure assessment

7.5.1.1 Direct exposure

*o*C-A-PF is used industrially but not directly as a product available to consumers, thus direct exposure of the general population to *o*C-A-PF is not expected. The release of *o*C-A-PF from end-use applications (commercial and consumer) is very limited as this substance is mixed with hardeners/curing agents into cross-linked matrix that is stable against thermal and hydrolytic breakdown. According to its usage, no oral exposure is expected. *o*C-A-PF is a solid substance with relatively high molecular weight (mostly greater than 500 g/mol). Therefore, dermal absorption and inhalation exposure to *o*C-A-PF are not expected to be significant (WHO 2006). In conclusion, the direct exposure (oral, inhalation, dermal) of the general population to *o*C-A-PF is expected to be minimal.

7.5.1.2 Indirect exposure

In the event of an unforeseen environmental release of *o*C-A-PF, it is not expected to become widely distributed in the aquatic environment based on its water insolubility. Despite being inherently biodegradable and hydrolyzable in its uncured form, *o*C-A-PF in end-use products (i.e. cured form) is found to be stable. Consequently, the indirect exposure of the general population to *o*C-A-PF through environmental media such as drinking water is not expected.

7.5.2 Health effects assessment

During evaluation under the second phase of polymer rapid screening (ECCC, HC 2018), *o*C-A-PF (CAS RN 55185-45-0) was identified as requiring further assessment

as a result of the presence of ortho para functional groups which are reactive and associated with adverse human health effects such as dermal sensitization.

No toxicological information was found for the polymer from searching various online databases. An SDS on a product that is 93-98% substance only provided data toxicological information on formaldehyde, o-cresol and phenol, suggesting that the toxicity of the polymer is much less that its components(Varcum, 2004).

7.5.3 Characterization of risk to human health

The polymer is composed of 4 monomers (*ortho*-cresol, ammonia, phenol, and formaldehyde) some of which are known to have human health concerns (Gelbke 2014, IRIS 1997-2018). However, when polymerized together, the formaldehyde is consumed and cannot be regenerated by degradation of the substance. The other monomers are chemically linked together at their ortho and para positions, therefore these reactive regions of the phenol are no longer available to react with other substances. The reacted polymer is chemically stable under normal environmental conditions and cannot regenerate the constituent monomers. There are negligible amounts of residual monomers following reaction. Although little toxicological data was available, an SDS containing the polymer shows that it is present at concentrations of 1-5% in products such as adhesives and sealants. In addition, table 7.3 shows that the polymer is not typically used in applications which result in direct exposure of consumers. Therefore, the polymer is not expected to pose a human health risk resulting from direct exposure.

The polymer is not water soluble and is not expected to disperse through the aquatic environment, therefore, there are no human health risks expected as a result of indirect exposure through drinking water.

8. CNSL-PF

8.1 Substance identity

The major component in natural cashew nutshell liquid (CNSL), *i.e.* anacardic acid, transforms and the resulting technical CNSL contains cardanol and cardol as main components, i.e. 85-95% (Lomonaco et al. 2017). The condensation reaction between technical CNSL, phenol and formaldehyde results in the formation of CNSL-phenol-formaldehyde copolymer (CNSL-PF) (CAS RN 67700-42-9) as shown in Figure 8-1. Usually, CNSL is used in lower amounts as compared to phenol (Cardona 2012). No residual monomers (*i.e*. CNSL, phenol, and formaldehyde) are expected to remain as the process involves several purification stages to remove all impurities (Lubi 2007). CNSL-PF contains no reactive functional groups associated with adverse human health effects (EPA 2010).Theoretically, both *ortho* and *para* positions in cardanol and phenol, as well as all free positions in cardol, are prone to react with formaldehyde. However, the simplified structure of CNSL-PF is shown here for clarity.

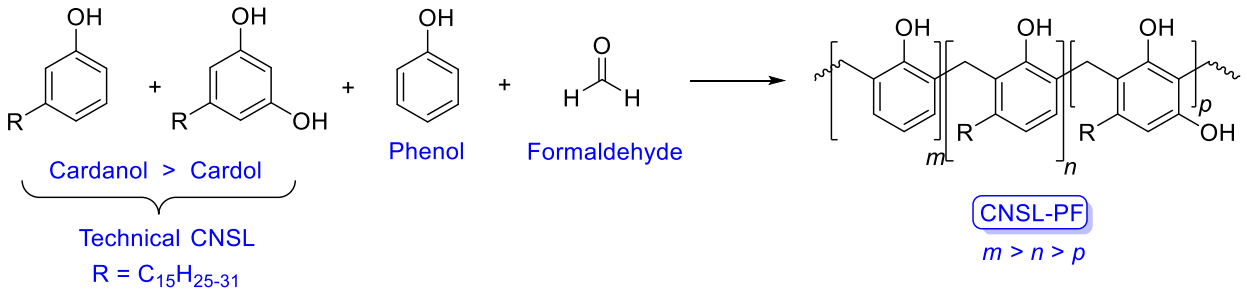

Figure 8-1. Synthesis and representative structure of CNSL-PF

Figure 8-1: The major component in natural cashew nutshell liquid (CNSL), i.e. anacardic acid, transforms and the resulting technical CNSL contains cardanol and cardol as main components, that is 85-95%. The condensation reaction between technical CNSL, phenol and formaldehyde results in the formation of CNSL-phenol-formaldehyde copolymer (CNSL-PF). Usually, CNSL is used in lower amounts as compared to phenol.

8.2 Physical and chemical properties

A summary of physical and chemical properties for CNSL-PF is presented in Table 2-1.

Table 8-1. Physical and chemical property values (at standard temperature) for CNSL-PF

Property	Value (CNSL-PF)	Key reference(s)
Physical state	Solid	-
Number Average Molecular weight (Mn)(daltons)	835-1153	Canada 2015 Lubi 2007
Components having molecular weight < 1000 Daltons (%)	27.1-31.3	Canada 2015
Components having molecular weight < 500 Daltons (%)	14.4-17.2	Canada 2015
Softening point (°C)	90-100	Canada 2015
Boiling point (°C)	> 148 (starting degradation) 309 (decomposition)	Lubic 2007 Rodrigues 2011
Water solubility	insoluble	Voirin 2014
Density (g/cm^3)	1.16	Canada 2015

8.3 Sources and uses

CNSL-PF is prepared industrially, and uncured CNSL-PF is predominantly encountered in industrial settings. It is marketed in different physical forms and requires an admixture with other materials to form the nonreactive cross-linked polymer (Mwaikambo 2001, Lubic 2007).

CNSL-PF was included in a voluntary survey (ECCC 2015) as well as in a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 2-2 below presents a summary of the total reported manufacture and total reported import quantities for the substance in 2014. These sources indicate that the primary reported uses for CNSL-PF in Canada are as filler, intermediate, adhesive, sealant, corrosion inhibitor, and encapsulating agent. It is used in the plastic, rubber, and oil/gas industries.

Table 8-2. Summary of information on Canadian manufacturing and import quantities of CNSL-PF in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA

Total manufacture[a] (kg)	Total imports[a] (kg)	Survey reference
NR[b]	100,000-1,000,000	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).
[b] Not reported

Globally, CNSL-PF is used in rubber based materials as a reinforcing resin in many applications that require high hardness compounds that process easily, such as shoe soles, co-extruded window profiles, weather-stripping (such as car window sealing strips), and tires (Balgude 2013). CNSL-PF can function as an adhesion promoter. It is also used to eliminate scorch tendencies in high temperature mill or banbury mixing (in rubber and plastics industries)(Lomonaco et al. 2017, Mahanwar 1996). CNSL-PF cures to a heat resistant chemically inert product with superior reinforcement and hardness properties (Rodrigues 2011, O'Connor 1987).

A number of domestic government databases were searched to determine if CNSL-PF is registered and/or approved for uses in Canada. None of these specific uses were found for CNSL-PF as indicated in Table 8-3.

Table 8-3. Additional uses in Canada for CNSL-PF

Use	CNSL-PF
Food additive[a]	No
Food packaging materials[b]	No
Internal Drug Product Database as medicinal or non-medicinal ingredients in disinfectant, human or veterinary drug products in Canada[c]	No
Natural Health Products Ingredients Database[d]	No

Use	CNSL-PF
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 2016]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Sep. 2016; unreferenced
[b] Health Canada [modified 2016]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Sep. 2016; unreferenced
[c] DPD [modified 2017]; personal communication, email from the Therapeutic Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[d] NHPID [modified 2017]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[e] LNHPD [modified 2016]]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[f] Health Canada [modified 2015]
[g] personal communication, email from the Consumer Product Safety Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Sep. 2017; unreferenced
[h] personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[i] Toy Industry Association (TIA 2017)

8.4 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).

CNSL-PF was identified as having low water extractability/solubility in the Second Phase of Polymer Rapid Screening (ECCC, HC 2018). Therefore, this substance was characterized as having a low potential for ecological risk. It is unlikely that this substance will result in concerns for the environment in Canada.

8.5 Potential to cause harm to human health

8.5.1 Exposure assessment

8.5.1.1 Direct exposure

When used in industrial settings, direct exposure of the general population to CNSL-PF is not expected. The release of CNSL-PF from end-use applications (commercial and consumer) is very limited as this substance is mixed/reacted with hardeners/curing agents into cross-linked matrix that is stable against thermal and hydrolytic breakdown.

Given the anticipated use pattern of the substance, no oral exposure is expected. CNSL-PF is a solid substance with relatively high molecular weight (mostly greater than 500 g/mol). Therefore, dermal absorption and inhalation exposure to CNSL-PF are not expected to be significant (WHO 2006). In conclusion, direct exposure (oral, inhalation, dermal) of the general population to CNSL-PF is expected to be minimal.

8.5.1.2 Indirect exposure

In the event of an unforeseen environmental release CNSL-PF, it is not expected to become widely distributed in the aquatic environment based on its water insolubility. Consequently, indirect exposure of the general population to CNSL-PF through environmental media such as drinking water is not expected.

8.5.2 Health effects assessment

During evaluation under the second phase of polymer rapid screening (ECCC, HC 2018), CNSL-PF (CAS RN 67700-42-9) was identified as requiring further assessment as a result of the presence of ortho and para substituted groups functional groups which are reactive and associated with adverse human health effects such as dermal sensitization.

No toxicological information was found on the polymer from searching various online databases. No SDS with a high purity was found, only products containing a small percentage of the polymer and were not considered representative of the substance.

8.5.3 Characterization of risk to human health

The polymer is composed of 4 monomers (cardianol, cardol, phenol, and formaldehyde) some of which are known to have human health concerns (Gelbke 2014, IRIS 1997-2018). However, when polymerized together, the formaldehyde is consumed and cannot be regenerated through degradation of the substance. The other monomers are chemically linked together via their ortho and para positions, therefore these reactive regions of the phenol are no longer available to react with other substances. The reacted polymer is chemically stable under normal environmental conditions and cannot regenerate its monomers. Although little toxicological data was available, an SDS was found containing the polymer which showed that it is present at concentrations of 1-5% in products such as brake pads or rubberized bonded abrasives. In addition table 8.3 shows that the polymer is not used in applications which typically result in direct consumer exposure among the general population. Given that there are negligible amount of residual monomers in the finished polymer, the polymer is not expected to pose a human health risk resulting from direct exposure to members of the general population.

The polymer is not water soluble and is not expected to disperse through the aquatic environment, therefore, there are no human health risks expected as a result of indirect exposure through drinking water.

9. NaPS-BPSF

9.1 Substance identity

The condensation reaction between sodium phenolsulfonate (NaPS), bisphenol S (BPS), and formaldehyde results in the formation of sodium phenolsulfonate-bisphenol S-formaldehyde copolymer (NaPS-BPSF)(CAS RN 71832-81-0)(Figure 9-1)(Kinugasa 1984, Konishi 2010). Compared to BPS, NaPS is usually used in lower amounts during reaction and formation. No residual monomers (*i.e.*, BPS, sodium phenolsulfonate, and formaldehyde) are expected to remain as the process involves several purification stages to remove all impurities (Guo 217). NaPS-BPSF contains no reactive functional groups associated with adverse human health effects (EPA 2010).Theoretically; the *ortho* positions in both NaPS and BPS are prone to react with formaldehyde. Moreover, hydroxyl groups in BPS could potentially be involved in the polymerization reaction. However, only the simplified structure for NaPS-BPSF is shown here for clarity.

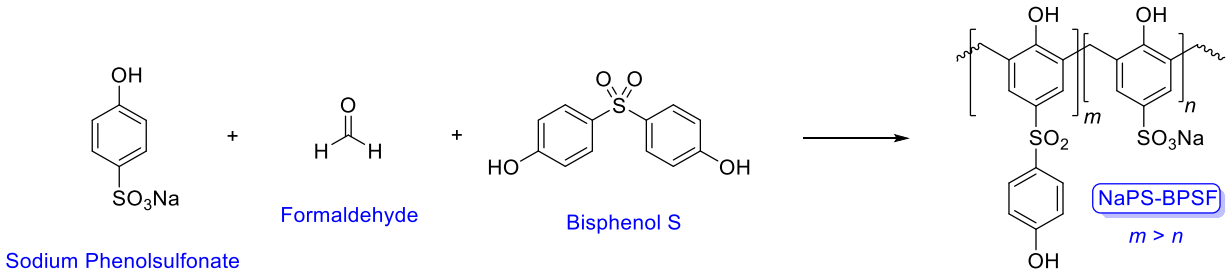

Figure 9-1. Synthesis and representative structure of NaPS-BPSF

Figure 9-1: The condensation reaction between sodium phenolsulfonate (NaPS), bisphenol S (BPS), and formaldehyde results in the formation of sodium phenolsulfonate-bisphenol S-formaldehyde copolymer (NaPS-BPSF). Compared to BPS, NaPS is usually used in lower amounts during reaction and formation.

9.2 Physical and chemical properties

A summary of physical and chemical properties for NaPS-BPSF is presented in Table 2-1.

Table 9-1. Physical and chemical property values (at standard temperature) for NaPS-BPSF

Property	Value (NaPS-BPSF)	Key reference(s)
Physical state	Solid	ChemSrc 2018 ChemNet 2018 Konishi 2010
Molecular weight (g/mol)	476 ~ 900-2850 (*n*=2-6)	Canada 2015 Kinugasa 1985
Melting point (°C)	505.3	ChemNet 2018
Vapour pressure (Pa)	10^{-8}	ChemNet 2018
Water solubility	Soluble	Konishi 2010
*p*H	9-10	Konishi 2010
Octanol-water partition co-efficient (log K_{ow})	5.6	ChemSrc 2018
Adsorption-desorption (log K_{oc})	4.7	Estimated[a]

[a] The estimation of organic carbon partition co-efficient (adsorption-desorption) was performed using the formula log K_{oc}= 0.99 log K_{ow} – 0.81 (Seth et al. 1999).

9.3 Sources and uses

NaPS-BPSF is prepared industrially. It is predominantly used in industrial settings.

NaPS-BPSF has been included in a voluntary survey (ECCC 2015) as well as in a mandatory survey conducted under section 71 of CEPA (Canada 2015). Table 2-2 below presents a summary of the total reported manufacture and total reported import quantities for the substance in 2014. These sources indicate that the primary reported uses for NaPS-BPSF in Canada are as surface active agents and dyeing auxiliary or fixing agents. It is used in fabrics, textile, and leather industries.

Table 9-2. Summary of information on Canadian manufacturing and import quantities of NaPS-BPSF in 2014 submitted pursuant to a voluntary survey and to a survey under section 71 of CEPA

Total manufacture[a] (kg)	Total imports[a] (kg)	Survey reference
NR[b]	100-1,000	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).
[b] Not reported

Globally, NaPS-BPSF is used as a fixing agent for nylon and paper (Yongtang et al. 2015, Konishi 2010), masking agent (Kingusa 1985), binder for polyester and cellulose

fibers (Konishi 2010), and electrochemical gas sensor (Tomohiro et al. 2006). It is also used as syntan (synthetic tanning agent)(Guo 2017).

A number of domestic government databases were searched to determine if NaPS-BPSF is registered and/or approved for uses in Canada. None of these specific uses were found for NaPS-BPSF as indicated in Table 9-3.

Table 9-3. Additional uses in Canada for NaPS-BPSF

Use	NaPS-BPSF
Food additive[a]	No
Food packaging materials[b]	No
Internal Drug Product Database as medicinal or non-medicinal ingredients in disinfectant, human 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 2016]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Sep. 2016; unreferenced
[b] Health Canada [modified 2016]; personal communication, email from the Food Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Sep. 2016; unreferenced
[c] DPD [modified 2017]; personal communication, email from the Therapeutic Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[d] NHPID [modified 2017]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[e] LNHPD [modified 2016]]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[f] Health Canada [modified 2015]
[g] personal communication, email from the Consumer Product Safety Directorate, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated Sep. 2017; unreferenced
[h] personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the New Substances Assessment and Control Bureau, Health Canada, dated 2017; unreferenced
[i] Toy Industry Association (TIA 2017)

9.4 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).

NaPS-BPSF was identified as having reported import and manufacturing quantities less than 1000 kg per year in the Second Phase of Polymer Rapid Screening (ECCC, HC 2018). Therefore, this substance was characterized as having a low potential for ecological risk. It is unlikely that this substance will result in concerns for the environment in Canada.

9.5 Potential to cause harm to human health

9.5.1 Exposure assessment

9.5.1.1 Direct exposure

When used industrially, direct exposure of the general population to NaPS-BPSF is not expected. The release of NaPS-BPSF from end-use applications (commercial and consumer) is very limited as this resin is mixed/reacted with hardeners/curing agents into matrices that are stable against thermal and hydrolytic breakdown. Given the anticipated use patterns of the substance, no oral exposure is expected. NaPS-BPSF is an ionic solid substance with high molecular weight (> 500 g/mol), high log K_{ow} (5.6), and very low vapour pressure (10^{-8} Pa). Therefore, dermal absorption and inhalation exposure to NaPS-BPSF are not expected to be significant (WHO 2006). In conclusion, the direct exposure (oral, inhalation, dermal) of the general population to NaPS-BPSF is expected to be minimal.

9.5.1.2 Indirect exposure

In the event of an unforeseen environmental release of NaPS-BPSF, it is expected to become distributed in the aquatic environment based on its high water solubility. However, the estimated high adsorption-desorption (log $K_{oc} \approx 4.7$) would suggest strong sorption to soil and sediment and negligible migration potential to ground water. Consequently, indirect exposure of the general population to NaPS-BPSF through environmental media such as drinking water in the event of unforeseen environmental release is not expected.

9.5.2 Health effects assessment

During evaluation under the second phase of polymer rapid screening (ECCC, HC 2018), Benzenesulfonic acid, hydroxy-, monosodium salt, polymer with formaldehyde and 4,4'-sulfonylbis[phenol] (CAS 71832-81-0) was identified as requiring further assessment as a result of the presence of ortho and para substituted functional groups which are reactive and associated with adverse human health effects such as dermal sensitization.

No toxicological information was found on the polymer from searching various online databases. No SDS with a high purity was found, only products containing a small percentage of the polymer and were not considered representative of the substance.

9.5.3 Characterization of risk to human health

The polymer is composed of 3 monomers (sodium phenolsulfonate, bisphenol S, and formaldehyde) some of which are known to have human health concerns (Gelbke 2014, Rochester 2015). However, when polymerized, the formaldehyde is consumed and cannot be regenerated by degradation of the substance. The other two monomers are chemically linked together at their ortho and para positions, therefore these reactive regions of the phenol are no longer available to react with other substances. The reacted polymer is chemically stable under normal environmental conditions and cannot regenerate the constituent monomers. Table 9.3 shows that the polymer is not typically used in consumer applications which could result in increased direct exposure to members of the general population. Given that there are negligible amounts of residual monomers, the polymer is not expected to pose a human health risk to the general population as a result of direct exposure to the substance.

Although the polymer is soluble in water, it is not manufactured in Canada and is used in a limited number of applications that do not typically result in “down the drain” disposal; hence, the potential for release into the aquatic environment is low and would be expected to partition to soil and sediment. Therefore, there are no significant human health risks anticipated as a result of indirect exposure through drinking water.

No toxicological data was available. The substance has been Pre-registered in Reach.

10. Uncertainties in evaluation of risk to human health

The several structures presented for phenol-formaldehyde resins have been simplified. In reality, a mixture of branched resins in *ortho* and/or *para* positions would be generated during the manufacture processes. Moreover, hydroxyl groups in phenol derivatives (such as BPA, BPS, CNSL, etc.) could potentially be involved in the polymerization.

In polymers (including the ones in this report), the degree of polymerization (*n*) and molecular weight are rarely identified with exact values but as a range instead. Consequently, physical and chemical properties vary (sometimes considerably) resulting in different behaviour in environmental and physiological media.

These polymers can be synthesized at different molecular weights. The smaller molecular weight substances can have a different toxicity profile and different bioavailability and /or potential to absorb than the higher molecular weight polymers. Information on the size of the polymer for each application is not always available which adds uncertainty to the risk evaluation.

There is limited toxicological information on the polymers and the potential hazard was established based on general polymer knowledge and chemistry which results in some uncertainties.

Despite the above uncertainties, it is believed that the overall risk conclusions made for phenol-formaldehyde resins are sound.

11.Conclusion

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to the environment from phenol-formaldehyde resins. It is proposed to conclude that these substances 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 screening assessment, it is proposed to conclude that phenol-formaldehyde 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 phenol-formaldehyde resins do not meet any of the criteria set out in section 64 of CEPA.

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Appendix - 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 Section 2 to 9.

Characterization of ecological risk for phenol-formaldehyde resins

The ecological risks of phenol-formaldehyde resins were characterized using the approach outlined in the report; "*Second Phase of Polymer Rapid Screening: Results of the Screening Assessment"* (ECCC, HC 2018). 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 Screening Assessment"* (ECCC, HC 2018).

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 Domestic Substances List 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 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, phenol-formaldehyde resins were identified in “Second Phase of Polymer Rapid Screening: Results of the Screening Assessment” (ECCC, HC 2018), as being unlikely to cause ecological harm.

Characterization of risk to human health for phenol-formaldehyde resins

The human health risks of phenol-formaldehyde resins 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, 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 Health Canada (2017).