Draft Screening Assessment

Substances Identified as Being of Low Concern Usingthe Ecological Risk Classification of Organic Substances and the Threshold of Toxicological Concern (TTC)-based Approach for Certain Substances

Environment and Climate Change Canada
Health Canada

June 2017

Synopsis

Pursuant to sections 68 or 74 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of 74 substances. These substances were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health or ecological concerns.

The ecological risks of the substances in this assessment were characterized using the ecological risk classification of organic substances (ERC) approach. The ERC is a risk-based approach that employs multiple metrics for assessing both hazard and exposure to create a weight of evidence to determine risk classification. Hazard profiles based primarily on metrics associated with mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity are established. Metrics considered in the exposure profiles include potential emission rate, overall persistence, and long-range transport potential. A risk matrix is used to assign a low, moderate or high level of potential concern for substances according to their hazard and exposure profiles. Of the 640 substances examined using this approach, 548 were identified as being of moderate or low ecological concern and do not require further assessment work at this time.

The human health risk of substances in this assessment was characterized using a threshold of toxicological concern (TTC)-based approach. The TTC-based approach establishes a human exposure threshold value for a chemical, below which there is a low probability of risk to human health. The TTC-based approach examined 237 substances for which exposure to the general population was expected to be limited. As a result of this approach, 89 substances were determined to have exposure estimates below TTC values and are considered to be of low concern to human health on the basis of current levels of exposure.

When the results of ERC and TTC-based approaches are considered together, a subset of 74 substances were identified as being of low concern to both human health and the environment. Conclusions on the remaining substances (i.e., those identified as being either of low concern to the environment through the ERC or of low concern to human health through the TTC-based approach, but not both) will be made in future assessments.

Considering all available lines of evidence presented in this draft screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from the 74 substances identified in Appendix A. It is proposed to conclude that these 74 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.

On the basis of the information presented in this draft screening assessment, it is proposed to conclude that these 74 substances 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 these 74 substances do not meet any of the criteria set out in section 64 of CEPA.

Table of Contents

List of Figures

List of Tables

1. Introduction

Pursuant to sections 68 and 74 of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment of 74 substances to determine whether these substances present or may present a risk to the environment or to human health. The substances were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health or ecological concerns (ECCC, HC [modified 2007]).

Two science approach documents, the Ecological Risk Classification of Organic Substances (ERC) (ECCC 2016a) and the Threshold of Toxicological Concern (TTC)-based Approach for Certain Substances (HC 2016), were published in 2016. This draft screening assessment incorporates results from these two documents.

The ecological risks of substances in this assessment were characterized using the ERC (ECCC 2016a). The ERC approach describes the hazard of a substance using key metrics including mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity and considers the possible exposure of organisms in the aquatic and terrestrial environments on the basis of factors including potential emission rates, overall persistence and long-range transport potential in air. The various lines of evidence are combined to identify substances as warranting further evaluation of their potential to cause harm to the environment or as having a low likelihood of causing harm to the environment.

The human health risks of substances in this assessment were characterized using a threshold of toxicological concern (TTC)-based approach (HC 2016). The TTC-based approach was applied to substances for which exposure to the general population was expected to be limited. The approach establishes a human exposure threshold value for a chemical, below which there is a low probability of risk to human health. For each substance, exposure estimates were compared to assigned TTC values to determine which substances have a low likelihood of causing harm to human health.

This draft screening assessment proposes conclusions for substances that were identified as having a low likelihood of causing harm to human health and the environment.

This draft screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments. The Threshold of Toxicological Concern (TTC)-based Approach for Certain Substances and the Ecological Risk Classification of Organic Substances science approach documents were subject to external peer-review by expert reviewers. Comments on the TTC-based approach document were received from Susan Felter (Procter & Gamble), Mitch Cheeseman (Steptoe & Johnson), Susan Barlow (consultant in toxicology and risk assessment) and Krul Lisette (TNO, the Netherlands Organisation for Applied Scientific

Research). Comments on the technical portions of the ERC document were received from Dr. Jon Arnot (ARC Arnot Research and Consulting) and Mr. Geoff Granville (GCGranville Consulting Corp.). Additionally, the two science approach documents were subject to a 60-day public comment period. While external comments were taken into consideration, the final content and outcome of the draft screening assessment remain the responsibility of Environment and Climate Change Canada and Health 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 on which the proposed conclusions are based.

2. Approach

2.1 Potential to Cause Ecological Harm

The ecological risks of substances in this assessment were characterized using ERC (ECCC 2016a). The ERC is a risk-based approach that considers multiple metrics for assessing both hazard and exposure on the basis of weighted consideration of various lines of evidence to determine risk classification. The various lines of evidence are combined to discriminate between substances of lower or higher potency and lower or higher potential for exposure in various media. This approach reduces the overall uncertainty with risk characterization compared to an approach that relies on a single metric in a single medium (e.g., LC_{50}) for characterization. A summary of the approach is outlined below; the approach is described in detail in the ERC approach document (ECCC 2016a).

Data on physical-chemical properties, fate (chemical half-lives in various media and biota, partition coefficients, fish bioconcentration), acute fish ecotoxicity, and chemical import or manufacture volume in Canada were collected from scientific literature, from available empirical databases (e.g., OECD QSAR Toolbox), and in response to surveys under section 71 of CEPA, or they were generated using selected quantitative structure-activity relationship (QSAR) or mass-balance fate and bioaccumulation models. These

[1]A determination of whether one or more of the criteria of section 64 of CEPA are met is based on 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 available to 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.

data were used as inputs to other mass-balance models or to complete the substance hazard and exposure profiles.

Hazard profiles based primarily on metrics associated with mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity were established. Exposure profiles were also established using multiple metrics including potential emission rate, overall persistence, and long-range transport potential. The hazard and exposure profiles were compared to decision criteria in order to classify the hazard and exposure potentials for each organic substance as low, moderate, or high. Additional rules were applied (e.g., classification consistency, margin of exposure) to refine the preliminary classifications of hazard or exposure.

A risk matrix was used to assign a low, moderate or high classification of potential risk for each substance on the basis of its hazard and exposure classifications. ERC classifications of potential risk were verified using a two-step approach. The first step adjusted the risk classification outcomes from moderate or high to low for substances that had a low estimated rate of emission to water after wastewater treatment, representing a low potential for exposure. The second step reviewed low risk potential classification outcomes using relatively conservative, local-scale (i.e., in the area immediately surrounding a point-source of discharge) risk scenarios, designed to be protective of the environment, to determine whether the classification of potential risk should be increased.

The ERC uses a weighted approach to minimize the potential for both over- and under-classification of hazard, exposure and subsequent risk. The balanced approaches for dealing with uncertainties are described in greater detail in ECCC 2016a. The following describes two of the more substantial areas of uncertainty. Error in empirical or modeled acute toxicity values could result in changes in classification of hazard, particularly metrics relying on tissue residue values (i.e., mode of toxic action), many of which are predicted values from QSAR models. However, the impact of this error is mitigated by the fact that overestimation of median lethality will result in a conservative (protective) tissue residue value used for critical body residue (CBR) analysis. Error in underestimation of acute toxicity will be mitigated through the use of other hazard metrics, such as structural profiling of mode of action, reactivity and/or estrogen-binding affinity. Changes or errors in chemical quantity could result in differences in classification of exposure as the exposure and risk classifications are highly sensitive to emission rate and use quantity. The ERC classifications thus reflect exposure and risk in Canada based on what is believed to be the current use quantity and may not reflect future trends (see Table A-1).

Critical data and considerations used to create substance-specific profiles and classifications associated with ecological hazard, exposure and risk, as well as identification of potential need for tracking of future use patterns, are presented in ECCC 2016b.

2.2 Potential to Cause Harm to Human Health

The human health risks of substances in this assessment were characterized using a TTC-based approach (HC 2016). In the approach, a decision tree was used considering chemical-structural features and chemical-specific data on genotoxicity (e.g., Ames test), when available, to assign a human exposure threshold value for a chemical, below which there is a low probability of risk to human health (i.e., TTC value). Structural representations of substances were retrieved and used to derive TTC values, substances were examined against exclusion criteria, and, for each substance in the TTC-based approach, conservative estimates of exposure were generated. Environmental concentrations were generated using the Canadian environmental fugacity model ChemCAN v6.00 (ChemCAN 2003) and were used to estimate exposure of the general population through environmental media (i.e., ambient air, surface water and soil). Direct exposure was estimated for substances found to be used in products available to consumers, such as fragrances in cosmetics, lubricants, and adhesives, as well as substances that may be used as food flavouring agents or that have been identified for use in food packaging materials. For each substance, exposure estimates were compared to their assigned TTC value, and substances that had exposure estimates below TTC values were considered to be of low concern to human health at current levels of exposure (see Table A-2).

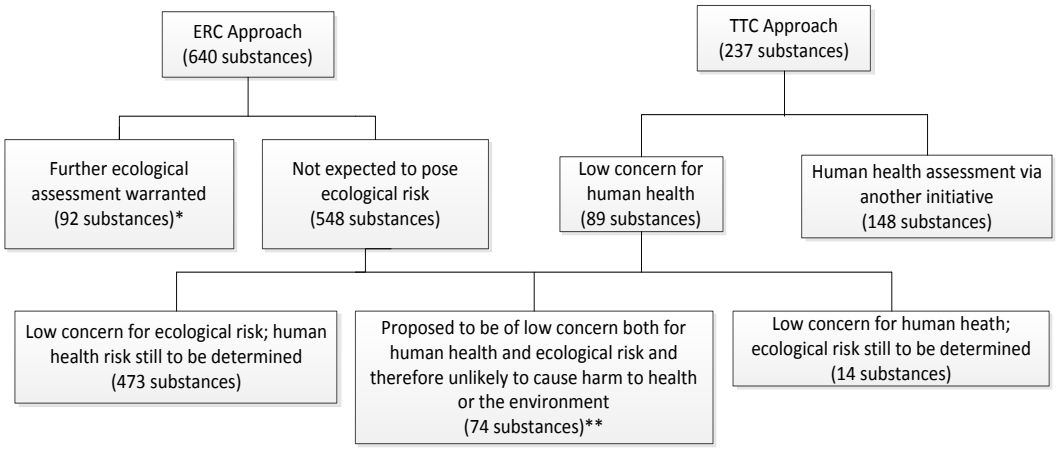
Uncertainties associated with the TTC-based approach have been outlined in the science approach document (HC 2016). Sources of uncertainty include the comparison of oral-based TTC-values to dermal exposure estimates. The application of dermal factors was considered conservative, while still reflecting some parameters that may influence internal dose via this route. Another source of uncertainty relates to confidence in predictive models for genotoxicity; for substances that are predicted negative, there is increased uncertainty in the prediction if the substance is outside of a model's applicability domain. Detailed information regarding models and applicability domains for each substance for the genotoxicity determination is presented in the TTC-based approach science approach document (HC 2016).

For substances assigned TTC values based on the Cramer classification, there is uncertainty regarding how well represented each substance is within the original Munro data set used to derive the threshold values. However, when physicochemical properties and chemotypes for these substances were compared with those in the Munro dataset, most substances were found to be within the range of the original Munro dataset (HC, 2016).

Critical data and considerations used in the TTC-based approach are presented in HC (2016).

3. Summary of Screening Assessment Results

Figure 3-1 outlines how the results of the ERC and TTC-based approaches were combined for the purpose of this screening assessment.



* four substances originally identified as warranting further ecological assessment in the ERC have been subsequently identified as not expected to pose ecological risk.

**One substance was removed from the TTC-based approach and will be assessed in the Rapid Screening of Substances with Limited Human Health Exposure (ECCC,HC 2017)

Of the 640 substances examined in the ERC approach, 98 substances were originally identified as being of moderate or high concern and 542 were identified as moderate or low ecological concern. On the basis of additional evaluation, the ERC classification of ecological risk for 6 of the substances (including 4 substances in this assessment) decreased following publication of the science approach document. As a result, 92 substances have been identified as requiring additional assessment because of potential ecological concerns and 548 substances are not expected to pose an ecological risk given current information.

Of the 237 substances examined in the TTC-based approach, 89 substances were considered not to be a concern for human health at current levels of exposure while the remaining 148 substances were identified as requiring further assessment.

Combining the results from both approaches, 75 substances were identified to be of low concern for human health and ecological risk. One substance (CAS RN 118-96-7) was found to be associated with an international classification for carcinogenicity based on empirical data with positive results, thereby excluding it from the TTC-based approach. This substance is being assessed in the Rapid Screening Approach for Substances with Limited Human Health Exposure (ECCC, HC 2017). A total of 74 substances were therefore addressed in this assessment and are listed in Appendix A. Table A-1

provides results of the ERC approach for these 74 substances and Table A-2 provides results of the TTC-based approach (i.e., TTC values and exposure estimates). Given the low ecological and human health concern associated with these 74 substances, there is low risk of harm to organisms and the broader integrity of the environment from these substances and the potential risk to human health is considered to be low.

The complete list of substances addressed under the ERC and TTC-based approaches are available in the respective science approach documents (ECCC 2016a; HC 2016).

Conclusions on substances addressed in the science approach documents that are not included in this assessment (i.e., those identified as being either of low concern to the environment through the ERC or of low concern to human health through the TTC-based approach, but not both), will be made in future screening assessments conducted under section 68 or 74 of CEPA.

While exposure to any of the 74 substances is not of concern at current levels, 36 of the 74 substances in this assessment are associated with effects of concern. Thirty-five substances are associated with ecological effects of concern (see Table A-1); criteria for identification of these substances include:

- low current exposure, but high hazard;
- low current exposure, but possible endocrine-disrupting properties due to binding to the estrogen receptor (ER);
- moderate potential for risk; member of a substance group that was not prioritized for assessment at this time;
- low current exposure, but high potential for reactivity with biological tissues;
- possible substitute for substance having a high potential for risk; or
- greater potential for local-scale exposures.

One substance has been identified as having potential human health effects of concern, namely 2,5,8,11-tetraoxadodecane (CAS RN[2] 112-49-2; see Table A-2), on the basis of a classification by another national or international agency for developmental/reproductive toxicity. Although current use patterns and quantities in commerce are not of concern, there may be concerns if quantities were to increase in

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

Canada, given the ecological or human health effects associated with these 36 substances.

4. Conclusion

On the basis of the information available, it is proposed to conclude that 74 substances (listed in Appendix A) 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, that constitute or may constitute a danger to the environment on which life depends, or that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is proposed to conclude that these 74 substances do not meet any of the criteria set out in section 64 of CEPA.

References

[ECCC] Environment and Climate Change Canada. 2016a. Science Approach Document: Ecological Risk Classification of Organic Substances. July 2016. http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=A96E2E98-1.

[ECCC] Environment and Climate Change Canada. 2016b. Data used to create substance-specific hazard and exposure profiles and assign risk classifications in the ecological risk classification of organic substances. Gatineau (QC). ECCC. Available from: substances@ec.gc.ca.

[ECCC, HC] Environment and Climate Change Canada, Health Canada. 2017. Rapid Screening of Substances with Limited Human Health Exposure. Ottawa (ON): ECCC, HC June 2017. www.ec.gc.ca/ese-ees/default.asp?lang=En&n=1D06D668-1

[HC] Health Canada. 2016. Science Approach Document. Threshold of Toxicological Concern (TTC)-based Approach for Certain Substances. Ottawa (ON): Health Canada. September 2016. http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=326E3E17-1.

Appendix A. ERC and TTC-based substances addressed in this screening assessment

Table A-1. ERC classifications for the 74 substances addressed in this screening assessment

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classifi-cation	Ecological High Hazard
60-24-2	Ethanol, 2-mercapto-	low	low	low	
77-47-4	1,3-Cyclopentadiene, 1,2,3,4,5,5-hexachloro-	high	low	lowa	Yes[b]
78-67-1[c]	Propanenitrile, 2,2'-azobis[2-methyl-	low	moderate	low	
79-74-3	1,4-Benzenediol, 2,5-bis(1,1-dimethylpropyl)-	high	low	low[a]	Yes[b]
85-42-7[c]	1,3-Isobenzofurandione, hexahydro-	low	low	low	
87-66-1[c]	1,2,3-Benzenetriol	low	low	low	
92-70-6[c]	3-Hydroxy-2-naphthoic acid	moderate	low	low	Yes[d]
101-37-1[c]	1,3,5-Triazine, 2,4,6-tris(2-propenyloxy)-	moderate	low	low	
103-24-2	Nonanedioic acid, bis(2-ethylhexyl) ester	low	low	low	
111-55-7[c]	1,2-Ethanediol, diacetate	low	low	low	
111-96-6[c]	Ethane, 1,1'-oxybis[2-methoxy-	low	low	low	
112-49-2[c]	2,5,8,11-Tetraoxadodecane	low	low	low	
120-11-6	Benzene, 2-methoxy-1-(phenylmethoxy)-4-(1-propenyl)-	low	low	low	
120-24-1	Benzeneacetic acid, 2-methoxy-4-(1-propenyl)phenyl	low	low	low	

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classifi-cation	Ecological High Hazard
	ester				
121-91-5	1,3-Benzenedicarboxylic acid	low	low	low	
122-68-9	2-Propenoic acid, 3-phenyl-, 3-phenylpropyl ester	low	low	low	
122-79-2[c]	acetic acid, phenyl ester	low	low	low	
126-33-0c	Thiophene, tetrahydro-, 1,1-dioxide	low	low	low	
132-65-0	Dibenzothiophene	moderate	low	low	
133-14-2	Peroxide, bis(2,4-dichlorobenzoyl)	high	low	low[a]	Yes[b]
288-88-0[c]	1*H*-1,2,4-Triazole	low	low	low	
614-45-9[c]	Benzenecarboperoxoic acid, 1,1-dimethylethyl ester	low	low	low	
632-51-9	Benzene, 1,1',1'',1'''-(1,2-ethenediylidene)tetrakis-	low	low	low	
793-24-8	1,4-Benzenediamine, *N*-(1,3-dimethylbutyl)-*N*'-phenyl-	moderate	high	moderate	Yes[e]
2379-79-5	Anthra[2,3-d]oxazole-5,10-dione, 2-(1-amino-9,10-dihydro-9,10-dioxo-2-anthracenyl)-	high	low	low[a]	Yes[b]
3006-86-8	Peroxide, cyclohexylidenebis[(1,1-dimethylethyl)	moderate	low	low[f]	Yes[g]
3081-14-9	1,4-Benzenediamine, *N*,*N*'-bis(1,4-dimethylpentyl)-	high	low	low[a]	Yes[b]
3327-22-8c	1-Propanaminium,	moderate	low	low	Yesh

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classification	Ecological High Hazard
	3-chloro-2-hydroxy-*N*,*N*,*N*-trimethyl-, chloride				
3851-87-4	Peroxide, bis(3,5,5-trimethyl-1-oxohexyl)	moderate	low	low	
4979-32-2	2-Benzothiazolesulfenamide, *N*,*N*-dicyclohexyl-	moderate	low	low	Yes[h]
5285-60-9	Benzenamine, 4,4'-methylenebis[*N*-(1-methylpropyl)-	high	low	moderate	Yes[e]
6858-49-7	Propanedinitrile, [[4-[ethyl[2-[[(phenylamino)carbonyl]oxy]ethyl]amino]-2-methylphenyl]methylene]-	high	low	low[a]	Yes[b]
8001-04-5[c]	Musks	low	low	low	
13082-47-8	Xanthylium, 9-(2-carboxyphenyl)-3,6-bis(diethylamino)-, hydroxide	high	low	low[a]	Yes[b]
13472-08-7[c]	Butanenitrile, 2,2'-azobis[2-methyl-	low	moderate	low	Yes[i]
15791-78-3	9,10-Anthracenedione, 1,8-dihydroxy-4-[[4-(2-hydroxyethyl)phenyl]amino]-5-nitro-	high	low	low[a]	Yes[b]
19720-45-7	9,10-Anthracenedione, 1,4-bis[(2-methylpropyl)amino]-	high	low	low[a]	Yes[b]
21652-27-7	1*H*-Imidazole-1-ethanol, 2-(8-heptadecenyl)-4,5-dihydro-, (*Z*)-	high	low	low[a]	Yes[b]

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classification	Ecological High Hazard
26266-77-3	1-Phenanthrenemethanol, dodecahydro-1,4a-dimethyl-7-(1-methylethyl)-	low	low	low	Yes[h]
26544-38-7	2,5-Furandione, dihydro-3-(tetrapropenyl)-	low	low	low[j]	
27193-86-8	Phenol, dodecyl-	high	low	low[a]	Yes[b]
28173-59-3	Carbonic acid, 2-[(1-amino-9,10-dihydro-4-hydroxy-9,10-dioxo-2-anthracenyl)oxy]ethyl phenyl ester	high	low	low[a]	Yes[b]
28777-98-2[c]	2,5-Furandione, dihydro-3-(octadecenyl)-	low	high	low[j]	
28984-69-2	4,4(5*H*)-Oxazoledimethanol, 2-(heptadecenyl)-	high	low	low[a]	Yes[b]
29036-02-0	Quaterphenyl	high	low	low[a]	Yes[b]
29350-73-0	Naphthalene, decahydro-1,6-dimethyl-4-(1-methylethyl)-, [1*S*-(1α,4α,4aα,6α,8aβ)]-, didehydro deriv.	low	low	low	
32072-96-1c	2,5-Furandione, 3-(hexadecenyl)dihydro-	low	high	low[j]	
38640-62-9c	Naphthalene, bis(1-methylethyl)-	high	low	low	
53894-23-8	1,2,4-Benzenetricarboxylic acid, triisononyl ester	low	low	low	
61788-72-5[c]	Fatty acids, tall-oil, epoxidized, octyl esters	high	low	low[a]	Yes[b]
61789-01-3[c]	Fatty acids, tall-oil, epoxidized, 2-	high	low	moderate	Yes[e]

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classification	Ecological High Hazard
	ethylhexyl esters				
61790-28-1	Nitriles, tallow	low	high	low	
61790-29-2	Nitriles, tallow, hydrogenated	low	low	low	
64754-95-6	Castor oil, hydrogenated, lithium salt	low	low	low	
64800-83-5	Benzene, ethyl(phenylethyl)-	low	low	low	
68082-35-9	Fatty acids, soya, epoxidized, Me esters	high	low	low[a]	Yes[b]
68139-89-9	Fatty acids, tall-oil, maleated	high	low	moderate	Yes[e]
68140-48-7	Ethanone, 1-[2,3-dihydro-1,1,2,6-tetramethyl-3-(1-methylethyl)-1*H*-inden-5-yl]-	low	low	low	
68398-19-6	Benzene, ethyl(phenylethyl)-, mono-ar-ethyl deriv.	low	low	low	
68442-69-3	Benzene, mono-C_{10-14}-alkyl derivs.	low	low	low	Yes[h]
68515-60-6	1,2,4-Benzenetricarboxylic acid, tri-C_{7-9}-branched and linear alkyl esters	low	low	low	
68603-15-6	Alcohols, C_{6-12}	low	low	low	
68783-36-8	Fatty acids, C_{16-22}, lithium salts	high	low	moderate	Yes[e]
68784-12-3	2,5-Furandione, dihydro-, mono-C_{15-20}-alkenyl derivs.	low	high	lowj	
68784-26-9	Phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased	low	low	low	
68909-18-2	Pyridinium, 1-(phenylmethyl)-, Et	low	low	low	Yes[i]

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classification	Ecological High Hazard
	Me derivs., chlorides				
68916-97-2	Horehound oil	low	low	low	
68955-53-3	Amines, C_{12-14}-*tert*-alkyl	low	low	low	Yes[h]
71486-79-8[c]	Benzenesulfonic acid, mono-C_{15-30}-branched alkyl and di-C_{11-13}-branched and linear alkyl derivs., calcium salts, overbased	low	moderate	low	Yes[h]
73984-93-7	1,3,4-Thiadiazole-2(3*H*)-thione, 5-(*tert*-dodecyldithio)-	high	low	low[a]	Yes[b]
80584-90-3	1*H*-Benzotriazole-1-methanamine, *N*,*N*-bis(2-ethylhexyl)-4-methyl-	high	low	low[a]	Yes[b]
94270-86-7	1*H*-Benzotriazole-1-methanamine, *N*,*N*-bis(2-ethylhexyl)-ar-methyl-	high	low	low[a]	Yes[b]
125328-64-5	Nitriles, rape-oil, hydrogenated	low	moderate	low	
174333-80-3	Benzaldehyde, 2-hydroxy-5-nonyl-, oxime, branched	high	low	low[a]	Yes[b]

[a] The risk classification outcome for substances which had a low risk based on low potential for exposure.
[b] Ecological high hazard – ERC classified this substance as having low potential for risk given current use patterns; however, given the high hazard of the substance identified in ERC, significant increases in use quantities could result in risk.
[c] This substance was not identified under subsection 73(1) of CEPA but was included in this assessment as it was considered a priority based on other human health concerns or ecological concerns.
[d] Ecological high hazard – ERC classified this substance as having low risk given current use patterns; however, given the possible endocrine disrupting properties of the substance, significant increases in use quantities could result in risk.
[e] Ecological high hazard – ERC classified this substance as having a moderate potential for risk; however, its chemical group was not prioritized for assessment at this time.

[f] Ranking of this substance was revised following application of the classification consistency rule (see ECCC 2016a section 6).
[g] Ecological high hazard – ERC classified this substance as having low risk given current use patterns; however, given the high potential for reactivity of the substance with biological tissues, significant increases in use quantities could result in risk.
[h] Ecological high hazard – ERC classified this substance as having low potential for risk given current use patterns; however, it is structurally similar to substances having a higher potential for risk, so could be used as a substitute for them in future.
[i] Ecological high hazard – ERC classified this substance as having low potential for risk given current use patterns; however, greater potential for local-scale exposure and risk in future was identified if quantities were to increase significantly.
[j] As a result of additional evaluation, the ERC classification of ecological risk of the substance decreased following publication of the science approach document.

Table A-2. TTC values, environmental intake estimates and direct exposure estimates for the 74 substances addressed in this screening assessment (HC 2016)

CAS RN	TTC value (µg/kg bw/day)	Environmental intake estimate (µg/kg bw/day)	Direct exposure estimate (µg/kg bw/day)	Direct exposure scenario	Human health high hazard[a]
60-24-2	30	1.04E-4	0.74	Food packaging	
77-47-4	0.0025	3.42E-5	n/a	n/a	
78-67-1	1.5	5.32E-3	0.0006	Food packaging	
79-74-3	30	1.32E-6	n/a	n/a	
85-42-7	1.5	6.86E-4	n/a	n/a	
87-66-1	0.0025	6.92E-5	n/a	n/a	
92-70-6	1.5	6.92E-4	n/a	n/a	
101-37-1	1.5	3.86E-3	n/a	n/a	
103-24-2	30	5.57E-3	n/a	n/a	
111-55-7	0.0025	6.31E-5	n/a	n/a	
111-96-6	30	6.92E-5	n/a	n/a	
112-49-2	0.0025	6.92E-4	n/a	n/a	Yes[b]
120-11-6	1.5	1.65E-6	0.014	Flavouring agent	
120-24-1	30	8.12E-7	0.0042	Flavouring agent	
121-91-5	30	6.91E-2	0.050 (adults) 8.61 (infant)	Food packaging	
122-68-9	30	1.57E-6	25 0.52	Fragrance Flavouring agent	
122-79-2	0.0025	8.98E-7	0.00014	Flavouring agent	
126-33-0	0.0025	6.91E-4	n/a	n/a	
132-65-0	0.0025	8.76E-4	n/a	n/a	
133-14-2	0.0025	6.45E-6	n/a	n/a	
288-88-0	1.5	1.18E-4	1.2	Consumer product (lubricant)	
614-45-9	0.0025	8.68E-5	0.005 (amortized) 28 (per event)[c]	Consumer product (tube adhesive)	
632-51-9	1.5	1.18E-6	n/a	n/a	
793-24-8	1.5	1.65E-1	n/a	n/a	
2379-79-5	0.0025	3.42E-5	n/a	n/a	
3006-86-8	1.5	1.95E-2	0.0014	Food	

CAS RN	TTC value (µg/kg bw/day)	Environmental intake estimate (µg/kg bw/day)	Direct exposure estimate (µg/kg bw/day)	Direct exposure scenario	Human health high hazard[a]
				packaging	
3081-14-9	1.5	1.20E-4	n/a	n/a	
3327-22-8	0.0025	6.93E-4	0.0020	Food packaging	
3851-87-4	30	3.51E-5	n/a	n/a	
4979-32-2	0.0025	1.63E-5	n/a	n/a	
5285-60-9	1.5	2.54E-4	n/a	n/a	
6858-49-7	0.0025	3.42E-5	n/a	n/a	
8001-04-5	1.5	1.03E-6	0.0042	Flavouring agent	
13082-47-8	0.0025	3.42E-5	n/a	n/a	
13472-08-7	1.5	5.33E-3	0.51	Food packaging	
15791-78-3	0.0025	3.42E-4	n/a	n/a	
19720-45-7	1.5	2.08E-6	n/a	n/a	
21652-27-7	1.5	3.42E-3	n/a	n/a	
26266-77-3	30	1.18E-6	n/a	n/a	
26544-38-7	1.5	5.64E-4	n/a	n/a	
27193-86-8	0.0025	5.68E-5	n/a	n/a	
28173-59-3	0.0025	3.42E-4	n/a	n/a	
28777-98-2	1.5	1.11E-1	0.15	Food packaging	
28984-69-2	1.5	3.42E-4	1.1	Consumer product (antifreeze/ de-icing)	
29036-02-0	0.0025	1.12E-3	n/a	n/a	
29350-73-0	30	9.17E-7	0.00071	Flavouring agent	
32072-96-1	1.5	1.11E-2	0.55	Food packaging	
38640-62-9	0.0025	9.99E-4	n/a	n/a	
53894-23-8	30	3.42E-2	n/a	n/a	
61788-72-5	1.5	5.38E-6	n/a	n/a	
61789-01-3	1.5	5.27E-4	n/a	n/a	
61790-28-1	0.0025	3.38E-4	n/a	n/a	
61790-29-2	0.0025	9.09E-4	n/a	n/a	
64754-95-6	1.5	3.42E-3	n/a	n/a	
64800-83-5	0.0025	1.02E-4	n/a	n/a	
68082-35-9	1.5	6.11E-7	n/a	n/a	
68139-89-9	1.5	5.66E-4	n/a	n/a	

CAS RN	TTC value (µg/kg bw/day)	Environmental intake estimate (µg/kg bw/day)	Direct exposure estimate (µg/kg bw/day)	Direct exposure scenario	Human health high hazard[a]
68140-48-7	1.5	2.30E-4	n/a	n/a	
68398-19-6	1.5	1.05E-4	n/a	n/a	
68442-69-3	1.5	5.60E-5	n/a	n/a	
68515-60-6	30	1.05E-4	n/a	n/a	
68603-15-6	30	3.42E-5	n/a	n/a	
68783-36-8	1.5	3.42E-2	n/a	n/a	
68784-12-3	1.5	1.11E-1	0.59	Food packaging	
68784-26-9	1.5	3.42E-1	1.2	Consumer product (lubricant)	
68909-18-2	1.5	1.68E-1	n/a	n/a	
68916-97-2	0.0025	1.08E-6	n/a	n/a	
68955-53-3	30	1.11E-4	n/a	n/a	
71486-79-8	1.5	3.42E-2	n/a	n/a	
73984-93-7	1.5	3.42E-5	n/a	n/a	
80584-90-3	1.5	1.12E-4	0.9	Consumer product (lubricant)	
94270-86-7	1.5	1.12E-4	0.9	Consumer product (lubricant)	
125328-64-5	0.0025	1.99E-3	n/a	n/a	
174333-80-3	1.5	1.34E-3	n/a	n/a	

[a] High health hazards were identified on the basis of classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity.

[b] High health hazard designation based on European Commission harmonized classification and labelling (CLP) – Annex VI (reproductive toxicity).

[c] The substance has structural alerts for genotoxicity; exposure to tube adhesive is expected to be intermittent; a lifetime average daily dose (LADD) was calculated on the basis of the number of days per year the product is expected to be used. The risk associated with non-cancer endpoints is addressed by comparing a “per event” exposure estimate to the Cramer class TTC value (Class I or 30 µg /kg bw/day).