Screening Assessment

Substances Identified as Being of Low Concern Using the 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

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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 72 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), which 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, and after further adjustments were made for three substances[1,2], a subset of 72 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 other assessments. Considering all available lines of evidence presented in this screening assessment, there is low risk

[1] Conclusion for CAS RNs 118-96-7 is provided in the Rapid Screening of Substances with Limited General Population Exposure Screening Assessment.

[2] Proposed conclusions for CAS RNs 4979-32-2 and 94270-86-7 are provided in an upcoming Benzotriazoles and Benzothiazoles Group Screening Assessment.

of harm to the environment from the 72 substances identified in Appendix A. It is concluded that these 72 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 screening assessment, it is concluded that these 72 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 concluded that these 72 substances do not meet any of the criteria set out in section 64 of CEPA.

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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 72 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 2017]).

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 screening assessment incorporates results from these two documents.

The ecological risks of substances in this assessment were characterized using the ERC approach (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 exposures to the general population were 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 screening assessment concludes on substances that were identified as having a low likelihood of causing harm to human health and the environment.

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 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). Additionally, the ERC document (published July 30, 2016), the TTC-based Approach for Certain Substances (published October 1, 2016) and the draft of this screening assessment (published on June 17, 2017) 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 screening assessment focuses on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA by examining scientific information and incorporating a weight of evidence approach and precaution.[3] This screening assessment presents the critical information and considerations on which the conclusions are based.

2. Approach

2.1 Potential to Cause Ecological Harm

The ecological risks of substances in this assessment were characterized using the ERC approach (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. Since some of the substances are UVCB (unknown or variable composition, complex reaction products, or biological materials) substances and could not be suitably represented by a single chemical structure, a manual judgement-based approach to classification was used. The following summarizes the approach, which is described in detail in 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

[3]A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products 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. However, in the case of the UVCBs, hazard and exposure could not be fully profiled because of the lack of a representative structure to estimate needed properties and the lack of empirical data for these properties. Therefore, manual classification of hazard and exposure was performed through examination of the UVCB constituents and information obtained from section 71 surveys under CEPA and decisions were based on consideration of similar substances and application of expert judgement.

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 on the basis of 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 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 exposures of the general population through environmental media (i.e., ambient air, surface water and soil). Direct exposures were 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).

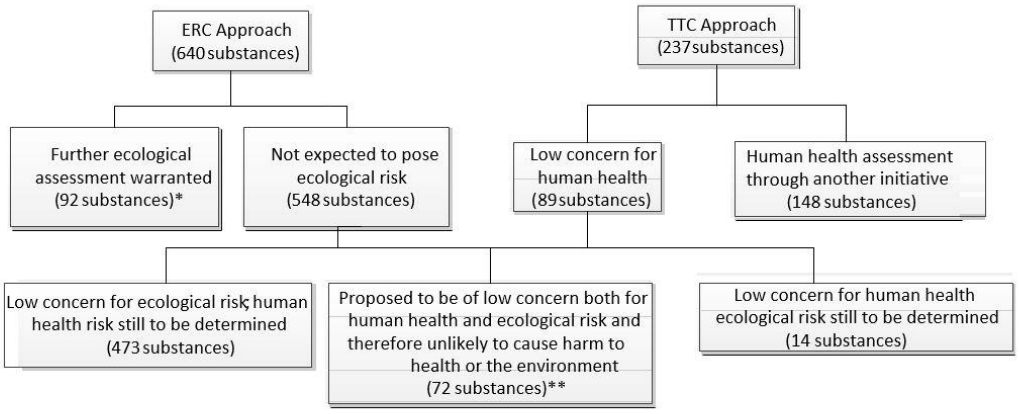
Uncertainties associated with the TTC-based approach have been outlined in the science approach document (HC 2016). Sources of uncertainty include the comparison of oral-based TTC-values to dermal exposure estimates. The application of dermal factors was considered conservative, while still reflecting 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). Two additional substances have been removed from the TTC-based approach and will be assessed under another initiative.

This figure shows the total number of substances examined in the ERC (640 substances) and TTC-based (237 substances) approaches. In the ERC approach, 92 substances were identified as requiring further assessment because of potential ecological concerns and 548 were not expected to pose an ecological risk on the basis of current information. In the case of the TTC-based approach, 89 of the 237 substances examined were identified as low concern for human health and 148 substances will undergo further human health assessment under separate initiatives. On examination of the 548 and 89 substances identified as not expected to pose an ecological risk and as low concern for human health, respectively, 72 substances were found to be in both categories and therefore are proposed to be of low concern both for human health and ecological risk and thus unlikely to cause harm to health or the environment.

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 later 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). Also, as a result of new information on uses and volumes submitted pursuant to a CEPA section 71 notice (Canada 2017), two additional substances (CAS RNs 4979-32-2 and 94270-86-7) that were included in the draft of this Screening Assessment have been removed for further assessment due to potential human health concerns. These substances will be assessed as part of the Benzotriazoles and Benzothiazoles Group. Therefore, a total of 72 substances are addressed in this assessment and are listed in Appendix A. Table A-1 provides results of the ERC approach for these 72 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 72 substances, there is low risk of harm to 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 2016b; 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 other screening assessments conducted under section 68 or 74 of CEPA.

While exposure to any of the 72 substances is not of concern at current levels, two substances have been identified as having potential human health effects of concern, namely 2,5,8,11-tetraoxadodecane (CAS RN[4] 112-49-2) and ethane, 1,1’-oxybis[2-methoxy- (CAS RN 111-96-6; see Table A-2), on the basis of a classification by another national or international agency for developmental/reproductive toxicity. While exposures of the general population to these two substances are not of concern at

[4] 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.

current levels, these substances are considered to have a health effect of concern on the basis of their potential for developmental/reproductive toxicity. Therefore, there may be a concern for human health if exposures were to increase.

In addition, 31substances associated with potential ecological effects of concern include those that are potential DNA and/or RNA binders, potential endocrine disrupting chemicals which target estrogen receptor signalling, possible substitutes for a substance in a high concern ERC group, moderate concern substances not associated with a high concern ERC group, substances having greater potential for local-scale exposures, or substances having high hazard but low current exposure according to ERC results. The potential effects and how they may manifest in the environment were not further investigated due to the low overall exposure to these substances.

4. Conclusion

On the basis of the information available, it is concluded that 72 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 concluded that these 72 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. Ottawa (ON): Government of Canada.

[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). Available from: eccc.substances.eccc@canada.ca

[ECCC, HC] Environment and Climate Change Canada, Health Canada. [modified 2017 Mar 12]. Categorization. Ottawa (ON): Government of Canada. [accessed 2017 Oct 30].

[ECCC, HC] Environment and Climate Change Canada, Health Canada. 2017. Rapid Screening of Substances with Limited Human Health Exposure. Ottawa (ON): Government of Canada.

Canada, Dept. of the Environment. 2017. Canada Environmental Protection Act, 1999: Notice with respect to substances included as part of the 2017 Inventory Update. Canada Gazette, Part I, vol. 151, no. 2.

[HC] Health Canada. 2016. Science approach document: threshold of toxicological concern (TTC)-based approach for certain substances. Ottawa (ON): Government of Canada.

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

Table A-1. ERC classifications for the 72 substances addressed in this screening assessment

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classifi-cation
60-24-2	Ethanol, 2-mercapto-	low	low	low
77-47-4	1,3-Cyclopentadiene, 1,2,3,4,5,5-hexachloro-	high	low	low[a,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,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[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-	low	low	low

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classification
	propenyl)phenyl 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
126-33-0[c]	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,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[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,b]
3006-86-8	Peroxide, cyclohexylidenebis[(1,1-dimethylethyl)	moderate	low	low[f]
3081-14-9	1,4-Benzenediamine, *N*,*N*'-bis(1,4-dimethylpentyl)-	high	low	low[a,b]

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classification
3327-22-8c	1-Propanaminium, 3-chloro-2-hydroxy-*N*,*N*,*N*-trimethyl-, chloride	moderate	low	low[g]
3851-87-4	Peroxide, bis(3,5,5-trimethyl-1-oxohexyl)	moderate	low	low
5285-60-9	Benzenamine, 4,4'-methylenebis[*N*-(1-methylpropyl)-	high	low	moderate[e]
6858-49-7	Propanedinitrile, [[4-[ethyl[2-[[(phenylamino)carbonyl]oxy]ethyl]amino]-2-methylphenyl]methylene]-	high	low	low[a,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,b]
13472-08-7[c]	Butanenitrile, 2,2'-azobis[2-methyl-	low	moderate	low[h]
15791-78-3	9,10-Anthracenedione, 1,8-dihydroxy-4-[[4-(2-hydroxyethyl)phenyl]amino]-5-nitro-	high	low	low[a,b]
19720-45-7	9,10-Anthracenedione, 1,4-bis[(2-methylpropyl)amino]-	high	low	low[a,b]
21652-27-7	1*H*-Imidazole-1-ethanol, 2-(8-heptadecenyl)-4,5-dihydro-, (*Z*)-	high	low	low[a,b]
26266-77-3	1-Phenanthrenemethanol, dodecahydro-	low	low	low[g]

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classification
	1,4a-dimethyl-7-(1-methylethyl)-			
26544-38-7	2,5-Furandione, dihydro-3-(tetrapropenyl)-	low	low	low[f]
27193-86-8	Phenol, dodecyl-	high	low	low[a,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,b]
28777-98-2[c]	2,5-Furandione, dihydro-3-(octadecenyl)-	low	high	low[f]
28984-69-2	4,4(5*H*)-Oxazoledimethanol, 2-(heptadecenyl)-	high	low	low[a,b]
29036-02-0	Quaterphenyl	high	low	low[a,b]
29350-73-0	Naphthalene, decahydro-1,6-dimethyl-4-(1-methylethyl)-, [1*S*-(1α,4α,4aα,6α,8aβ)]-, didehydro deriv.	low	low	low
32072-96-1[c]	2,5-Furandione, 3-(hexadecenyl)dihydro-	low	high	low[f]
38640-62-9[c]	Naphthalene, bis(1-methylethyl)-	moderate	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,b]
61789-01-3[c]	Fatty acids, tall-oil, epoxidized, 2-ethylhexyl esters	high	low	moderate[e]
61790-28-1	Nitriles, tallow	low	high	low

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classification
61790-29-2	Nitriles, tallow, hydrogenated	low	low	low[f]
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,b]
68139-89-9	Fatty acids, tall-oil, maleated	high	low	moderate[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[g]
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[e]
68784-12-3	2,5-Furandione, dihydro-, mono-C_{15-20}-alkenyl derivs.	low	high	low[f]
68784-26-9	Phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased	low	low	low
68909-18-2	Pyridinium, 1-(phenylmethyl)-, Et Me derivs., chlorides	low	low	low

CAS RN	Chemical Name	ERC Hazard	ERC Exposure	ERC Classification
68916-97-2	Horehound oil	low	low	low
68955-53-3	Amines, C_{12-14}-*tert*-alkyl	low	low	low[g]
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[g]
73984-93-7	1,3,4-Thiadiazole-2(3*H*)-thione, 5-(*tert*-dodecyldithio)-	high	low	low[a,b]
80584-90-3	1*H*-Benzotriazole-1-methanamine, *N*,*N*-bis(2-ethylhexyl)-4-methyl-	high	low	low[a,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,b]

[a] This substance was initially classified as having a moderate potential for ecological risk, however, the risk classification was decreased to low potential for ecological risk following the adjustment of risk classification based on current use quantities (see section 7.1.1 of the ERC approach document, ECCC 2016a).
[b] ERC classified this substance as potentially having a high potency. The potential effects and how they may manifest in the environment were not further investigated due to the low ecological exposure of this substance.
[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] Structural alerts from the OECD toolbox identified this substance as potentially being an endocrine receptor binder. The potential effects and how they may manifest in the environment were not further investigated due to the low ecological exposure of this substance.
[e] 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] ERC classified this substance as having low potential for risk on the basis of current use patterns; however, it is structurally similar to substances having a higher potential for risk. The potential effects and how they may manifest in the environment were not further investigated due to the low ecological exposure of this substance.[h] ERC classified this substance as having low potential for risk on the basis of current use patterns; however, greater potential for local-scale exposure was identified.
[i] 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 72 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	Yes[b]
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	Product available to consumers (lubricant)	
614-45-9	0.0025	8.68E-5	0.005 (amortized) 28 (per event)[c]	Product available to consumers (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	

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]
2379-79-5	0.0025	3.42E-5	n/a	n/a	
3006-86-8	1.5	1.95E-2	0.0014	Food 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	
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	Product available to consumers(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	

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]
68082-35-9	1.5	6.11E-7	n/a	n/a	
68139-89-9	1.5	5.66E-4	n/a	n/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	Product available to consumers (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	Product available to consumers (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).