Draft Screening Assessment

Commercial Naphthenic Acids and Group

Chemical Abstracts Service Registry Numbers:
1338-24-5
61789-36-4

Environment and Climate Change Canada
Health Canada

August 2018

Synopsis

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of two substances referred to collectively under the Chemicals Management Plan as the naphthenic acids and salts group, hereinafter referred to as the commercial naphthenic acids group. Substances in this group were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA (ECCC, HC [modified 2017]).

The Chemical Abstracts Service Registry Numbers (CAS RN[1]), their *Domestic Substances List* (DSL) names and their common name or abbreviation are listed in the table below.

Substances in the Commercial Naphthenic Acids Group

CAS RN	DSL name	Common name/abbreviation
1338-24-5 [a]	naphthenic acids	NAs
61789-36-4 [a]	naphthenic acids, calcium salts	calcium naphthenates

a The substance bearing this CAS RN is a UVCB (unknown or variable composition, complex reaction products, or biological materials).

[1]This assessment addresses two commercial NAs obtained via the extraction of petroleum distillates. Nineteen other commercial NAs have been or are being addressed through various approaches under the Chemicals Management Plan (CMP)[2]. The commercial NAs differ from complex mixtures of naphthenic acids present as a by-product in oil-sand processed water (OSPW) generated from oil sands mining, extraction and processing of bitumen. Activities to better understand OSPW naphthenic acids are occurring under the Canada-Alberta Joint Oil Sands Monitoring Program (JOSM) . In addition, Environment and Climate Change Canada is proposing to add naphthenic acids and their salts that are present in waste generated by processing of oil sands to the National Pollutant Release Inventory (NPRI), beginning with the 2020 reporting year.

In Canada, NAs and calcium naphthenates were not reported to be manufactured above the reporting threshold in 2011 in response to a survey under section 71 of CEPA. Import quantities reported were in the range of 100 000 to 1 000 000 kg for NAs and from 1 000 to 10 000 kg for calcium naphthenates according to information submitted under section 71 of CEPA.

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[2] Substances are being or have been addressed under: An approach for a subset of substances prioritized during categorization that have already been addressed; various rapid screening assessments; and, assessments of various metal moieties.

In Canada and internationally, NAs are mainly found in lubricants and greases, and in paints and coatings that are intended for professional/industrial use only. Lubricants and greases containing NAs are used primarily in the industrial, transportation and aviation sectors while paints and coatings containing NAs are used in the automotive and industrial sectors. NAs have also been identified as a component of inks used in the manufacture of polymeric coatings used to package some foods. No use of calcium naphthenates in products available to consumers was identified.

The ecological risks of NAs and calcium naphthenates were characterized using the ecological risk classification (ERC) of organic substances. The ERC is a risk-based approach that employs multiple metrics for both hazard and exposure based on weighted consideration of multiple lines of evidence for determining risk classification. Hazard profiles based primarily on metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity were 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 based on their hazard and exposure profiles. The ERC identified NAs and calcium naphthenates as having a low potential to cause ecological harm.

Considering all available lines of evidence presented in this draft screening assessment, there is low risk of harm to the environment from NAs and calcium naphthenates. It is proposed to conclude that NAs and calcium naphthenates 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.

NAs and calcium naphthenates were not identified as posing a high hazard to human health on the basis of absence of classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity. In addition, exposure of the general population to NAs and calcium naphthenates through environmental media, food, or the use of products available to consumers is expected to be minimal and the potential risk to human health is considered to be low.

On the basis of the information presented in this draft screening assessment, it is proposed to conclude that NAs and calcium naphthenates 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.

It is therefore proposed to conclude that NAs and calcium naphthenates do not meet any of the criteria set out in section 64 of CEPA.

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1. Introduction

Pursuant to section 74 of the *Canadian Environmental Protection Act*, 1999 (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment of naphthenic acids and naphthenic acids, calcium salts, hereinafter referred to as NAs and calcium naphthenates respectively, to determine whether these substances present or may present a risk to the environment or to human health. These substances met categorization criteria under subsection 73(1) of CEPA (ECCC, HC [modified 2017]). The two substances are referred to collectively under the Chemicals Management Plan as the naphthenic acids and salts group, hereinafter referred to as commercial naphthenic acids group.

This assessment addresses two commercial NAs obtained via the extraction of petroleum distillates. Nineteen other commercial NAs that met categorization criteria are being or have been addressed through various approaches, as outlined in Table 1a and 1b.

Table 1a: Commercial naphthenic acid substances addressed under other approaches - Salts.

CAS RN	**Substance Name**	**Approach under which the substance is addressed**
12001-85-3	Naphthenic acids, zinc salts	Zinc moiety assessment (under development)
1338-02-9	Naphthenic acids, copper salts	Copper moiety assessment (under development)
61788-56-5	Naphthenic acids, lithium salts	Rapid Screening of Substances Identified from Phase Two of the Domestic Substances List Inventory Update (ECCC, HC 2016a)
61788-69-0	Naphthenic acids, chromium salts	Approach for a Subset of Substances Prioritized during Categorization That Have Already Been Addressed (Environment Canada, Health Canada 2015) (based on chromium having been previously assessed)
61788-71-4	Naphthenic acids, nickel salts	Rapid Screening of Substances of Lower Concern (Environment Canada, Health Canada 2013)
61789-34-2	Naphthenic acids, cadmium salts	Rapid Screening of Substances from Phase One of the Domestic Substances List Inventory Update (Environment Canada, Health Canada 2014)
61789-51-3	Naphthenic acids, cobalt salts	Screening assessment Cobalt and Cobalt-Containing substances (ECCC, HC 2017a) (based on the substance contributing to cobalt moiety)
61790-14-5	Naphthenic acids, lead salts	Approach for a Subset of Substances Prioritized during Categorization That Have Already Been Addressed (Environment Canada, Health Canada 2015) (based on lead having been previously addressed)
61790-20-3	Naphthenic acids, rare earth salts	Rapid Screening of Substances Identified from Phase Two of the Domestic Substances List

		Inventory Update (ECCC, HC 2016a)
68815-09-8	Naphthenic acids, vanadium salts	Rapid Screening of Substances from Phase One of the Domestic Substances List Inventory Update (Environment Canada, Health Canada 2014)
85736-59-0	Naphthenic acids, bismuth salts	Rapid Screening of Substances Identified from Phase Two of the Domestic Substances List Inventory Update (ECCC, HC 2016a)
68514-63-6	Naphthenic acids, cerium(4++) salts	Rapid Screening of Substances Identified from Phase Two of the Domestic Substances List Inventory Update (ECCC, HC 2016a)

Table 1b: Commercial naphthenic acid substances addressed under other approaches - Non-Salts.

CAS RN	**Substance Name**	**Approach under which the substance is addressed**
61790-54-3	Naphthenic acids, compds. with N-tallow alkyltrimethylenediamines	Rapid Screening of Substances Identified from Phase Two of the Domestic Substances List Inventory Update (ECCC, HC 2016a)
64754-89-8	Naphthenic acids (petroleum), crude	Rapid Screening of Substances Identified from Phase Two of the Domestic Substances List Inventory Update (ECCC, HC 2016a)
64755-04-0	Naphthenic acids, reaction products with polyethylenepolyamines	Second phase of polymer rapid screening (ECCC, HC 2017b)
68139-87-7	Fatty acids, tall-oil, compds. with diethylenetriamine-naphthenic acid reaction products	Rapid Screening of Substances Identified from Phase Two of the Domestic Substances List Inventory Update (ECCC, HC 2016a)
68553-60-6	Naphthenic acids, vanadyl complexes	Rapid Screening of Substances Identified from Phase Two of the Domestic Substances List Inventory Update (ECCC, HC 2016a)
68606-78-0	Naphthenic acids, esters with polytriethanolamine	Rapid Screening Assessment: Polymers Identified from Phase Two of the Domestic Substances List Inventory Update (ECCC, HC 2016b)
68956-65-0	Naphthenic acids, polymers with ethylenimine, compds. with linoleic acid dimer	Rapid Screening Assessment: Polymers Identified from Phase Two of the Domestic Substances List Inventory Update (ECCC, HC 2016b)

The commercial NAs differ from complex mixtures of naphthenic acids present as a by-product in oil-sand processed water (OSPW) generated from oil sands mining,

extraction and processing of bitumen. As OSPW NAs differ in composition, properties and use compared to commercial NAs, they are not considered here. Activities to better understand OSPW naphthenic acids are occurring under the Canada-Alberta Joint Oil Sands Monitoring (JOSM) program. In addition, Environment and Climate Change Canada is proposing the addition of naphthenic acids and their salts to the National Pollutant Release Inventory (NPRI), beginning with the 2020 reporting year. The addition is proposed to be based on classically-defined naphthenic acids and their salts, a broad category of substances that are present in waste generated by processing of oil sands.

The ecological risks of NAs and calcium naphthenates were characterized using the ecological risk classification of organic substances (ERC) (ECCC 2016a). The ERC 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 based on 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.

This draft screening assessment includes consideration of information on chemical properties, environmental fate, hazards, uses and exposures. Relevant data were identified up to July 2017. Empirical data from key studies as well as some results from models were used to reach proposed conclusions. When available and relevant, information 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, based on a draft developed by staff at Sanexen Environmental Services Incorporated, and incorporates input from other programs within these departments. The ecological portion of this assessment is based on the ERC document (published July 30, 2016), which was peer-reviewed and subject to a 60-day public comment period. While external comments were taken into consideration, the final content and outcome of this draft screening assessment remain the responsibility of Health Canada and Environment and Climate Change Canada.

This draft screening assessment focuses on information critical to determining whether a substance meets 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 draft

[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.

screening assessment presents the critical information and considerations on which the proposed conclusions are based.

2. Identity of substances

The Chemical Abstracts Service Registry Numbers (CAS RN[4]), *Domestic Substances List* (DSL) names and acronyms for NAs and calcium naphthenates are presented in Table 2-1. These substances are UVCBs (unknown or variable composition, complex reaction products or biological materials). UVCBs are derived from natural sources or complex reactions and cannot be characterized in terms of constituent chemical compounds because their composition is too complex or variable. A UVCB is not an intentional mixture of discrete substances and is considered a single substance.

Naphthenic acids (CAS RN 1338-24-5) are complex mixtures of carboxylic acids with varying numbers of carbons (typically from 6 to 16). The carboxylic acids are principally monobasic with the general formula RCOOH where R represents a (cyclo)alkane moiety. This moiety can be acyclic (typically highly branched) or include a single or multiple fused rings (typically cyclopentane and/or cyclohexane). Aromatic, olefinic, hydroxy and dibasic acids are present as minor components in such mixtures (Brient et al., 2000). Commercial NAs are distinct from naphthenic acids present as a by-product of OSPW generated from oil sands mining and extraction by their respective differences regarding their compositions[5], their properties[6], and their sources and uses in Canada (Brient et al. 2000).

Calcium naphthenates (CAS RN 61789-36-4) can be represented by the general formula $Ca^{2+}(\text{-OOCR})_2$, where one calcium atom forms bonds with two naphthenic acid molecules.

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.

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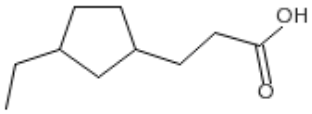
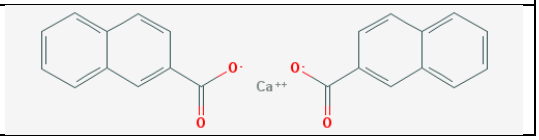
[5] Compositional differences between commercial and OSPW NAs refer to their number of carbons and their distributions of hydrogen deficiency resulting from ring formation (Clemente et al. 2003). Commercial NA mixtures contain only approximately 30% of the OSPW NAs (ECCC 2012).

[6] For example, commercial NAs are less resistant to biodegradation than OSPW NAs (which are more highly alkyl branched) (Han et al. 2008). The few studies comparing commercial and OSPW NAs toxicity suggest possible differences. For instance, commercial NAs were shown to reduce the phagocytosis of macrophages from the peritoneal cavity of exposed mice whereas OSPW NAs enhanced it (Garcia-Garcia et al. 2011).

Table 2-1. Substances identity

CAS RN	DSL name (acronym/synonym)	UVCB general formula	Example of chemical structure [a]
1338-24-5	Naphthenic acids (NAs)	RCOOH or $C_nH_{2n+z}O_2$	
61789-36-4	Naphthenic acids, calcium salts (calcium naphthenates)	$Ca^{2+}(^{-}OOCR)_2$	

Abbreviations: DSL, Domestic Substances List; n, carbon number; R, alkylated chain, acyclic or including a single ring or condensed rings (typically cyclopentane and/or cyclohexane); z, number of hydrogen atoms lost to ring formations (i.e., z = 0: acyclic NA, z = -2: 1-ring NA, z = -4: 2-rings NA, etc.).

[a] Chemical structures obtained from ChemIDplus (1993-). The chemical structure provided for CAS RN 1338-24-5 is one example of structure corresponding to a monocyclic NA with formula $C_{10}H_{18}O_2$ (many other structures are possible for this formula). For CAS RN 61789-36-4, the structure ($Ca[C_{11}H_7O_2]_2$) is the only one to be displayed by suppliers of calcium naphthenates.

3. Physical and chemical properties

Commercial NAs are complex mixtures of carboxylic acids produced from petroleum distillates. Their composition varies depending on the crude oil composition and on the degree of refining (Brient et al. 2000; API 2012).

As physical and chemical properties of commercial NAs or calcium naphthenates depend on their composition, the parameter values determined experimentally reflect the composition of the tested mixture and may not be representative of another test material. Similarly, values measured or predicted for individual components are not representative of the properties of the mixture. Consequently, no single value, either empirical or predicted, was selected as representative of either substance; rather their properties are described qualitatively, below.

NAs can generally be described as viscous liquids with a light yellow to dark amber colour; phenolic and sulfur impurities are responsible for their characteristic odour (Brient et al. 2000). They are weak acids with pKa values of 5 to 6. Their water solubility is low and varies with the pH (i.e., due to a greater proportion of ionized constituents in alkaline solutions, solubility is increased by at least two orders of magnitude as compared with neutral solutions) (CEATAG 1998; Brient et al. 2000). NAs are completely soluble in organic solvents and oils. With their dual hydrophilic (carboxyl group) and hydrophobic (non-polar aliphatic group) ends, NAs are surfactants and will concentrate at aqueous/non-aqueous interfaces (Armstrong 2008). Based on their vapour pressure (low) and boiling point, NAs may be characterised as being semi-volatile.

Calcium naphthenates (commercial preparations at 4 to 5% [w/w] of Ca) are liquid at room temperature (CMA 1983). They are insoluble in water, but extremely soluble in non-polar solvents (CMA 1983; US EPA 1983; Lewis 2007). Based on their negligible vapour pressure, calcium naphthenates are not expected to be volatile.

4. Sources and uses

In Canada, NAs and calcium naphthenates were not reported in response to a survey under section 71 of CEPA to be manufactured above the reporting threshold of 100 kg in 2011, while import quantities were reported in the range of 100 000 to 1 000 000 kg for NAs and of 1 000 to 10 000 kg for calcium naphthenates (Environment Canada 2013). In the United States, NAs production quantities were reported to be in the range of 1 000 000 to 10 000 000 lb (450 000 to 4 500 000 kg) in 2016 (no data available for calcium naphthenates) (CDAT [modified 2014]). In the European Union, NAs manufacture and/or import quantities were reported to be in the range of 100 000 to 1 000 000 kg per year (no data available for calcium naphthenates) (ECHA 2016).

Naphthenic acids occur naturally in crude oil. However, NAs are not extracted from crude petroleum. Rather, NAs are recovered from the extraction of petroleum distillates such as jet fuel, kerosene, and diesel during oil processing. This recovery reduces corrosion in the refinery and improves the petroleum distillates characteristics (Brient et al. 2000). It also provides a source of crude NAs that can be further refined to produce commercial NAs (McKee et al. 2014). Commercial NAs sold by the petroleum industry are available in various grades of purity and are marketed by acid number, impurity level and colour (Brient et al. 2000; API 2003).

Salts of NAs such as calcium naphthenates do not occur naturally. Calcium naphthenates can be produced either intentionally (through the interaction of calcium with NAs from the petroleum industry) or unintentionally (in oil production facilities, calcium naphthenates deposits occur and affect crude oil productivity) (Havre 2002; Mohammed 2010).

In Canada, NAs are used in lubricants and greases, and as intermediates (Environment Canada 2013). Material safety data sheets (MSDSs) for products in Canada report NAs concentrations ranging from 0.1 to 5% (w/v) in lubricants and greases; these products are used in the industrial, transport and aviation sectors to lubricate specialized equipment and machinery and are exposed to atypical conditions (e.g., severe vibrations, high temperatures) (MSDS 2005; MSDS 2012a,b; MSDS 2013d; MSDS 2015b,c,d; MSDS 2017c,d). Other MSDSs indicate that NAs are also used in paints and coatings (concentrations ranging from 0.5 to 25% [w/v]) used in the automotive and industrial sectors; these products have various purposes such as automobile refinishing, sealing and protecting concrete pavements, and tank linings (MSDS 2013a; MSDS 2015a; MSDS 2017a). NAs may also be present as a component in a mixture or product where they function as an adhesive or sealant agent (i.e., promote bonding between other substances or adhesion to substances) (Environment Canada 2013).

Uses of calcium naphthenates and additional uses of NAs in Canada are listed in Table 4-1.

Table 4-1. Additional uses in Canada for naphthenic acids and calcium naphthenates

Use	Naphthenic acids	Calcium naphthenates
Food additive[a]	N	N
Food packaging materials[b]	Y (component in inks)	N
Internal drug product database as medicinal or non-medicinal ingredients in final pharmaceutical, disinfectant or veterinary drug products in Canada[c]	N	N
Natural Health Products Ingredients Database[d]	N	N
Licensed Natural Health Products Database as medicinal or non-medicinal ingredients in natural health products in Canada[e]	N	N
List of prohibited and restricted cosmetic ingredients[f]	N	N
Notified to be present in cosmetics, based on notifications submitted under the *Cosmetic Regulations* to Health Canada[g]	N	N
Formulant in pest control products registered in Canada[h]	Y (7 remedial wood preservatives and one insecticide)	Y (anti-fouling paints)

Abbreviations: N = no; Y = yes

[a] Health Canada 2017

[b] Personal communication, email from the Food Directorate, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada; dated July, 2015; unreferenced

[c] Personal communications, emails from the Veterinary Drugs Directorate and from the Therapeutic Products Directorate, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, dated May 24, 2017 and November 14, 2016, respectively; unreferenced

[d] NHPID (modified 2017)

[e] LNHPD (modified 2016); Personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, dated May 2017; unreferenced

[f] Health Canada (modified 2015)

[g] Personal communication, email from the Consumer Product Safety Directorate, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, dated May 11, 2017; unreferenced

[h] PMRA 2010; Personal communication, emails from the PMRA, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada; May 16, 2017 (NAs) and November 22, 2016 (calcium naphthenates); unreferenced; MSDS 2017b

Internationally, other major uses identified for NAs include lacquers and varnishes, construction materials, colouring agents, metalworking fluids, hydraulic fluids, corrosion inhibitors, adhesives or sealants, and biocides/fungicides (MSDS 2009a,b; MSDS 2010a; MSDS 2011; MSDS 2013b,c; MSDS 2014a,b; CPCat 2014; ECHA 2017; SPIN 2017). For calcium naphthenates, major uses identified internationally include use in

lubricants and greases, and in paints, lacquers and varnishes (function as a drying accelerant during the drying process for oleoresinous paints) (CMA 1983; US EPA 1983; Hansen et al. 1987; MSDS 2008; MSDS 2010b; MSDS 2012c; SPIN 2017).

5. Potential to cause ecological harm

The ecological risks of NAs and calcium naphthenates were characterized using the ecological risk classification of organic substances (ERC) (ECCC 2016a). The ERC is a risk-based approach that considers multiple metrics for both hazard and exposure based on weighted consideration of multiple lines of evidence for determining 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., LC50) for characterization. Since NAs and calcium naphthenates are UVCB substances and could not be suitably represented by single chemical structures, a manual judgement-based approach to classification was used. The following paragraphs in this section summarize the approach, which is described in detail in ECCC (2016a).

Hazard profiles were established based principally on metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity. Exposure profiles were also composed of multiple metrics, including potential emission rate, overall persistence and long-range transport potential. Hazard and exposure profiles were compared to decision criteria 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 NAs and calcium naphthenates, hazard and exposure could not be fully profiled due to 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 by examining the UVCB constituents and DSL Inventory Update information and making decisions on the basis of 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 based on 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.

ERC uses a weighted approach to minimize the potential for both over and under classification of hazard and 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 of 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.

Critical data and considerations used to develop the substance-specific profiles for NAs and calcium naphthenates and the hazard, exposure, and risk classification results are presented in ECCC (2016b).

The hazard and exposure classifications for NAs and calcium naphthenates are summarized in Table 5-1.

Table 5-1. Ecological risk classification results for NAs and calcium naphthenate

Common name	ERC hazard classification	ERC exposure classification	ERC risk classification
NAs	moderate	low	low
Calcium naphthenates	low	low	low

Although NAs were initially classified as having low hazard potential, the classification was revised to a moderate hazard potential based on a high terrestrial food web hazard assessment factor. On the basis of low exposure potentials, NAs are unlikely to result in concerns for the environment in Canada.

On the basis of low hazard and low exposure classifications according to ERC, calcium naphthenates was classified as having a low potential for ecological risk. It is therefore unlikely that this substance will result in concerns for the environment in Canada.

6. Potential to cause harm to human health

6.1 Exposure assessment

Considering reported uses in Canada, their low solubility in water, their limited volatility, significant releases of NAs or calcium naphthenates to the environment are not expected. Accordingly, environmental media is not expected to be a significant source of exposure to the general population.

In Canada, NAs are mainly found in lubricants and greases, and in paints and coatings that are intended for professional/industrial use only (based on the MSDSs for these products). These products are not available to consumers, and thus, exposure to NAs from products is not expected.

In Canada, NAs have been identified as a component of inks used in the manufacture of polymeric coatings used to package some foods. However, there is no direct contact of the packaging with those foods and exposure via this source is expected to be negligible (personal communication, email from the Food Directorate, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, dated July, 2015; unreferenced).

6.2 Health effects assessment

NAs and calcium naphthenates were not identified as posing a high hazard to human health on the basis of absence of classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity, or reproductive toxicity. They are also not on the European Chemicals Agency's Candidate List of Substances of Very High Concern for Authorisation (ECHA [2017]). A limited number of laboratory studies provide information regarding the toxicity of commercial NAs and calcium naphthenates; no toxicological data is available for the inhalation route. This information is summarized below.

Naphthenic acids

There are no data available on the carcinogenic potential for NAs, and *in vitro* (i.e., bacterial reverse mutation assay) and *in vivo* (i.e., micronucleus test) assay results did not indicate genotoxicity (McKee et al. 2014). NAs are not acutely toxic (oral and dermal LD_{50} ≥ 3,000 mg/kg (Rockhold 1955; Rubinskaya 1974; Pennisi and Lynch 1977; Exxon 1979; Bio/dynamics Inc 1979; Exxon 1987). They can also induce slight to moderate dermal sensitization.

The overall no-effect level (NOEL) for systemic effects is 100 mg/kg-bw per day. This is based on a combined short-term and reproductive/developmental oral toxicity study where male and female Sprague-Dawley rats were administered NAs daily by gavage for 28 days (males; 14 days prior and after mating) or up to 53 days (females; 14 days prior to mating until lactation day 3) at doses of 100, 300 or 900 mg/kg-bw per day (McKee et al. 2014). Histological and organ weight changes observed at 100 mg/kg-bw per day and above were not considered adverse by the authors (i.e., statistically significant findings considered as minimal, within the historical control

data at the testing facility or not considered as being associated with pathological changes by the authors).

In this study, the overall no observed adverse effect level (NOAEL) for reproductive and developmental effects is 100 mg/kg-bw per day. At 300 mg/kg-bw per day and above, a significant reduction in the number of live pups/litter, and a dose-related increase of epididymis and testes relative weights were observed. The developmental effects observed in the study at 300 mg/kg-bw per day were observed in the absence of maternal toxicity. At 900 mg/kg-bw per day, there was a significant reduction in the number of offspring born per litter and in survival (those who survived had significantly lower body weights than those in the control groups). There was also a substance-related decrease in the numbers of *corpora lutea* and implantation sites however changes were not significant. The significant reduction in absolute uterine weight at 100 mg/kg-bw per day and above was considered related to the reduced (not significant) body weight gain and was not associated with any gross, histopathological, or clinical pathology changes. The study authors also noted that there were no apparent treatment-related effects on mating, frequency of mating, time to mate, mating success, or gestational period length (McKee et al. 2014).

Calcium naphthenates

A carcinogenicity study was available (dermal study in mice) however, the study authors noted that tumour formation in the group administered calcium naphthenates may have been influenced by local tissue damage (Shell Research Limited 1986; Shell Oil Co 1987). Calcium naphthenates were not genotoxic in several *in vitro* mutagenicity and clastogenicity assays (i.e., bacterial reverse mutation and gene conversion assays, mouse lymphoma forward mutation test and chromosome aberration assay) (Shell Toxicology Laboratory [Tunstall] 1982; Seifried et al. 2006). In dermal studies, neither systemic toxicity nor adverse effects on reproduction/development (no significant changes in testes weights of exposed males) was observed (Shell Research Limited 1983); calcium naphthenates were found to suppress active sebaceous glands after repeated dermal exposure (Shell Research Limited 1987). Calcium naphthenates are not acutely toxic (oral $LD_{50} \geq 5$ mL/kg in rats) (Rockhold 1955; Shell Toxicology Laboratory [Tunstall] 1977). Calcium naphthenates are not expected to have sensitizing properties.

6.3 Characterization of risk to human health

Exposure of the general population to NAs and calcium naphthenates through environmental media, food, or the use of products available to consumers is expected to be minimal. Accordingly, the potential risk to human health is considered to be low.

6.4 Uncertainties in evaluation of risk to human health

There are some uncertainties in the health effects database due to the lack of toxicological data. However, there is sufficient data to inform on the level of exposure of

NAs and calcium naphthenates to the general population in Canada. Given that exposure to the general population in Canada is expected to be minimal, a qualitative approach to risk characterization is considered appropriate for this assessment.

7. Conclusion

Considering all available lines of evidence presented in this draft screening assessment, there is low risk of harm to the environment from NAs and calcium naphthenates. It is proposed to conclude that NAs and calcium naphthenates 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 information presented in this draft screening assessment, it is proposed to conclude that NAs and calcium naphthenates 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.

It is therefore proposed to conclude that NAs and calcium naphthenates do not meet any of the criteria set out in section 64 of CEPA.

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