



Government
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du Canada

Assessment

Commercial Naphthenic Acids Group

Chemical Abstracts Service Registry Numbers

1338-24-5

61789-36-4

**Environment and Climate Change Canada
Health Canada**

January 2024

Cat. No.: En84-341/2023E-PDF
ISBN: 978-0-660-49147-9

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Synopsis

Pursuant to section 68 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Minister of the Environment and the Minister of Health have conducted an assessment of two substances referred to collectively under the Chemicals Management Plan (CMP) as the Naphthenic Acids and Salts Group, hereinafter referred to as the Commercial Naphthenic Acids Group.

The Chemical Abstracts Service Registry Numbers (CAS RN¹), their *Domestic Substances List* (DSL) names and their common name are listed in the table below.

Substances in the Commercial Naphthenic Acids Group

CAS RN	DSL name	Common name
1338-24-5 ^a	Naphthenic acids	N/A
61789-36-4 ^a	Naphthenic acids, calcium salts	Calcium naphthenates

Abbreviation: N/A, not applicable

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

This assessment addresses two commercial naphthenic acids obtained via the extraction of petroleum distillates: naphthenic acids (CAS RN 1338-24-5), hereinafter referred to by its CAS RN, and naphthenic acids, calcium salts (CAS RN 61789-36-4), hereinafter referred to as calcium naphthenates. Nineteen other commercial naphthenic acids and commercial salts of naphthenic acids have been or are being addressed through various approaches under the Chemicals Management Plan². Commercial naphthenic acids differ from complex mixtures of naphthenic acids present as a by-product in oil sands process-affected water (OSPW) generated from oil sands mining, extraction and processing of bitumen. OSPW naphthenic acids differ in source, composition, properties and use compared to commercial naphthenic acids. OSPW naphthenic acids do not have associated CAS RNs and are not included on the DSL; therefore, they were not subject to categorization of the DSL and are not considered in this assessment. Activities to better understand OSPW naphthenic acids have been initiated under the Canada-Alberta Oil Sands Monitoring program, and are being pursued by Environment and Climate Change Canada, notably targeting the presence and effects of naphthenic acids in tailing ponds' seepage. In addition, Environment and Climate Change Canada has added naphthenic acid fraction compounds (which

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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 assessments; and, assessments of various metal moieties.

includes diverse polar organic compounds present in bitumen and OSPW) and their salts to the National Pollutant Release Inventory, beginning with the 2020 reporting year. This addition does not include naphthenic acids and their salts used solely in the context of commercial mixtures.

In Canada, CAS RN 1338-24-5 and calcium naphthenates were not reported to be manufactured above the reporting threshold in 2011 in response to a survey issued pursuant to section 71 of CEPA. Import quantities reported in the survey were in the range of 100 000 kg to 1 000 000 kg for CAS RN 1338-24-5 and between 1000 kg and 10 000 kg for calcium naphthenates.

In Canada and internationally, CAS RN 1338-24-5 is mainly found in lubricants and greases, and in paints and coatings that are intended for professional/industrial use only. Lubricants and greases containing CAS RN 1338-24-5 are used primarily in the industrial, transportation and aviation sectors while paints and coatings containing CAS RN 1338-24-5 are used in the automotive and industrial sectors. CAS RN 1338-24-5 has 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 CAS RN 1338-24-5 and calcium naphthenates were characterized using the ecological risk classification of organic substances (ERC), which is a risk-based approach that employs multiple metrics for both hazard and exposure, with weighted consideration of multiple lines of evidence for determining risk classification. Hazard profiles are based primarily on metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity. 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. Based on the outcome of the ERC analysis, CAS RN 1338-24-5 and calcium naphthenates are considered unlikely to be causing ecological harm.

Considering all available lines of evidence presented in this assessment, there is low risk of harm to the environment from CAS RN 1338-24-5 and calcium naphthenates. It is concluded that CAS RN 1338-24-5 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.

CAS RN 1338-24-5 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 CAS RN 1338-

24-5 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.

The human health assessment took into consideration those groups of individuals within the Canadian population who, due to greater susceptibility or greater exposure, may be more vulnerable to experiencing adverse health effects. For the commercial naphthenic acids group, these subpopulations were considered; however, exposures were expected to be minimal based on use patterns and therefore were not quantified.

Considering all the information presented in this assessment, it is concluded that CAS RN 1338-24-5 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 concluded that CAS RN 1338-24-5 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 68 of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted an assessment of naphthenic acids (CAS RN³ 1338-24-5), and naphthenic acids, calcium salts (CAS RN 61789-36-4), hereinafter referred to by its CAS RN and calcium naphthenates, respectively, to determine whether these substances present or may present a risk to the environment or to human health. These substances were identified as priorities as they met categorization criteria as described in ECCC, HC (modified 2017). The two substances were referred to collectively under the Chemicals Management Plan as the Naphthenic Acids and Salts Group, and are hereinafter referred to as the Commercial Naphthenic Acids Group.

This assessment addresses two commercial naphthenic acids obtained via the extraction of petroleum distillates. Nineteen other commercial naphthenic acids and commercial salts of naphthenic acid substances that met categorization criteria have been addressed through various approaches, as outlined in Tables 1-1 and 1-2.

Table 1-1. Commercial salts of naphthenic acid substances addressed under other approaches

CAS RN	<i>Domestic Substances List</i> name	Approach under which the substance is addressed
12001-85-3	Naphthenic acids, zinc salts	Zinc and its Compounds screening assessment (ECCC, HC 2019a)(based on the substance contributing to zinc moiety)
1338-02-9	Naphthenic acids, copper salts	Copper and its Compounds screening assessment (ECCC, HC 2019b)(based on the substance contributing to copper moiety)
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)

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CAS RN	<i>Domestic Substances List name</i>	Approach under which the substance is addressed
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	Cobalt and Cobalt-Containing substances screening assessment (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 2-2. Commercial naphthenic acid substances addressed under other approaches

CAS RN	<i>Domestic Substances List name</i>	Approach under which the substance is addressed
61790-54-3	Naphthenic acids, compds. with <i>N</i> -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)

Commercial naphthenic acids differ from complex mixtures of naphthenic acids present as a by-product in oil sands process-affected water (OSPW) generated from oil sands mining, extraction and processing of bitumen. OSPW naphthenic acids differ in composition, properties and use compared to commercial naphthenic acids. One of the primary objectives of the Chemicals Management Plan (CMP) has been to address the existing substances identified as priorities for assessment following the Government of Canada's categorization of the substances on the *Domestic Substances List* (DSL), as required under CEPA. The naphthenic acids on the DSL are refined or commercial naphthenic acids and their salts that have associated CAS RNs. OSPW naphthenic acids do not have associated CAS RNs and are not included on the DSL; therefore, they were not subject to categorization and are not considered further in this assessment. Activities to better understand OSPW naphthenic acids were initiated under the Canada-Alberta Oil Sands Monitoring program⁴, and are being pursued by Environment and Climate Change Canada, which notably targets the presence and effects of naphthenic acids in tailing ponds' seepage. In addition, Environment and Climate Change Canada added naphthenic acid fraction compounds and their salts to the National Pollutant Release Inventory (NPRI), beginning with the 2020 reporting

⁴ More information on the Canada-Alberta Oil Sands Monitoring (OSM) program can be found at ECCC [modified 2020].

year. The addition includes classically-defined naphthenic acids⁵ and diverse polar organic compounds present in bitumen and OSPW, but does not include naphthenic acids and their salts used solely in the context of commercial mixtures.

The ecological risks of CAS RN 1338-24-5 and calcium naphthenates were characterized using the ecological risk classification of organic substances (ERC) approach (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 on the basis of such factors as 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 assessment includes consideration of information on chemical properties, environmental fate, hazards, uses and exposures. Relevant data were identified up to February 2021. Empirical data from key studies as well as some results from models were used to reach conclusions. When available and relevant, information from other jurisdictions was considered.

This 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 subject to an external review as well as a 60-day public comment period. Additionally, the draft of this assessment (published August 18, 2018) was subject to a 60-day public comment period. While external comments were taken into consideration, the final content and outcome of this assessment remain the responsibility of Health Canada and Environment and Climate Change Canada.

Assessments focus on information critical to determining whether a substance meets the criteria as set out in section 64 of CEPA by considering scientific information, including information, if available, on subpopulations who may have greater susceptibility or greater exposure, vulnerable environments and cumulative effects⁶, and

⁵ Classically-defined naphthenic acids are mono-carboxylic acids which include chain compounds and compounds with one or more alicyclic ring structures with the general formula $C_nH_{2n+Z}O_2$, where “n” indicates the carbon number and “Z” is referred to as the “hydrogen deficiency” (the number of hydrogen atoms that are lost as the structures become more compact) and is zero or a negative even integer (from -2 to -12).

⁶ The consideration of cumulative effects under CEPA may involve an analysis, characterization and possible quantification of the combined risks to health or the environment from exposure to multiple chemicals.

incorporating a weight of evidence approach and precaution.⁷ This assessment presents the critical information and considerations on which the conclusions are based.

2. Identity of substances

The CAS RNs and DSL names for CAS RN 1338-24-5 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. A UVCB is not an intentional mixture of discrete substances and is considered a single substance. The complexity and variability of their compositions can make them difficult to fully and consistently characterize.

CAS RN 1338-24-5 is a complex mixture 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).

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

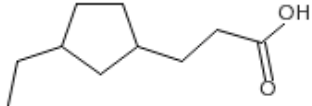
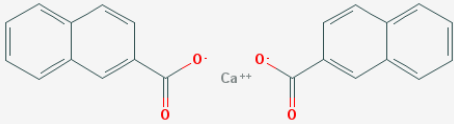
Commercial naphthenic acids, which are obtained via the extraction of petroleum distillates, are distinct from naphthenic acids present as a by-product of OSPW generated from oil sands mining and extraction by their respective differences in composition⁸, properties⁹, and sources and uses in Canada (Brient et al. 2000).

⁷ 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.

⁸ Compositional differences between commercial and OSPW naphthenic acids refer to their number of carbons and their distributions of hydrogen deficiency resulting from ring formation (Clemente et al. 2003). Commercial naphthenic acid mixtures are structurally simple, straight chain oxygen-containing acid species, while all OSPW naphthenic acids have proportionally greater quantities of more complex oxygen-containing species, including aromatic rings (Marentette et al. 2015; Bartlett et al. 2017).

⁹ Commercial naphthenic acids are less resistant to biodegradation than OSPW naphthenic acids (which are more highly alkyl branched) (Han et al. 2008). The few studies comparing commercial and OSPW naphthenic acids toxicity suggest possible differences. For instance, commercial naphthenic acids were shown to reduce the phagocytosis of

Table 2-1. Substances identity

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

Abbreviations: UVCB, unknown or variable composition, complex reaction products or biological materials; 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 (that is, z = 0: acyclic naphthenic acid, z = -2: 1-ring naphthenic acid, z = -4: 2-rings naphthenic acid, etc.).

^a Chemical structures obtained from ChemIDplus (1993-). The chemical structure provided for CAS RN 1338-24-5 is one example of a structure corresponding to a monocyclic naphthenic acid 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 naphthenic acids 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 the physical and chemical properties of CAS RN 1338-24-5 and 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. Additional physical and chemical properties used to develop the substance-specific profiles for CAS RN 1338-24-5 and calcium naphthenates for assessing environmental risk are reported in ECCC (2016b).

macrophages from the peritoneal cavity of exposed mice whereas OSPW naphthenic acids enhanced it (Garcia-Garcia et al. 2011).

CAS RN 1338-24-5 can generally be described as including viscous liquid components with light yellow to dark amber colour; phenolic and sulfur impurities are responsible for their characteristic odour (Brient et al. 2000). These components are weak acids with pKa values of 5 to 6. Their water solubility is low and varies with the pH (that is, 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). CAS RN 1338-24-5 includes components which are completely soluble in organic solvents and oils. With their dual hydrophilic (carboxyl group) and hydrophobic (non-polar aliphatic group) ends, CAS RN 1338-24-5 components are surfactants and will concentrate at aqueous/non-aqueous interfaces (Armstrong 2008). Based on its components with low vapour pressure and boiling point, CAS RN 1338-24-5 may be characterized 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, both substances in the Commercial Naphthenic Acids Group have been included in a survey issued pursuant to section 71 of CEPA. CAS RN 1338-24-5 and calcium naphthenates were not reported 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 CAS RN 1338-24-5 and of 1000 to 10 000 kg for calcium naphthenates (Environment Canada 2013).¹⁰ In the United States, CAS RN 1338-24-5 production quantities were reported to be in the range of 450 000 to 4 500 000 kg in 2016, with no data available for calcium naphthenates (CDAT [modified 2014]). In the European Union, CAS RN 1338-24-5 manufacture and/or import quantities were reported to be in the range of 100 000 to 1 000 000 kg per year, with no data available for calcium naphthenates (ECHA 2016a).

Naphthenic acids occur naturally in crude oil. Commercial naphthenic acids, however, are not extracted from crude petroleum, but rather, they 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 naphthenic acids that can be further refined to produce CAS RN 1338-24-5 (McKee et al. 2014). Commercial naphthenic acids sold by the petroleum industry are available in

¹⁰ Values reflect quantities reported in response to the surveys conducted under section 71 of CEPA (Environment Canada 2013). See surveys for specific inclusions and exclusions (schedules 2 and 3).

various grades of purity and are marketed by acid number, impurity level and colour (Brient et al. 2000; API 2003).

Salts of commercial naphthenic acids, such as calcium naphthenates, do not occur naturally. Calcium naphthenates can be produced either intentionally (through the interaction of calcium with naphthenic acids 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, CAS RN 1338-24-5 is used in lubricants and greases, and as an intermediate (Environment Canada 2013). Material safety data sheets (MSDSs) for products in Canada report CAS RN 1338-24-5 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 (for example, severe vibrations, high temperatures) (MSDS 2005; MSDS 2012a,b; MSDS 2013d; MSDS 2015b,c,d; MSDS 2017c,d). Other MSDSs indicate that CAS RN 1338-24-5 is 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). CAS RN 1338-24-5 may also be present as a component in a mixture or product where it functions as an adhesive or sealant agent (that is, promote bonding between other substances or adhesion to substances) (Environment Canada 2013).

Uses of calcium naphthenates and additional uses of CAS RN 1338-24-5 in Canada are listed in Table 4-1.

Table 4-1. Additional uses in Canada for CAS RN 1338-24-5 and calcium naphthenates

Use	CAS RN 1338-24-5	Calcium naphthenates
Food packaging materials ^a	Y (component in inks)	N
Formulant in pest control products registered in Canada ^b	Y (7 remedial wood preservatives and one insecticide)	Y (antiouling paints)

Abbreviations: Y, yes this use was reported for this substance; N, no this use was not reported for this substance.

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

^b 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 CAS RN 1338-24-5 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

5.1 Characterization of ecological risk

The ecological risks of CAS RN 1338-24-5 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, with 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 (for example, median lethal concentration) for characterization. Since CAS RN 1338-24-5 and calcium naphthenates are UVCB substances and could not be suitably represented by single chemical structures, a manual judgment-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 (for example, classification consistency, margin of exposure) to refine the preliminary classifications of hazard or exposure. However, in the case of CAS RN 1338-24-5 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, analyzing information submitted in response to a CEPA section 71 survey, and making decisions on the basis of consideration of similar substances and/or application of expert judgment.

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 (that is, 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 of 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 modelled acute toxicity values could result in changes in classification of hazard, particularly metrics relying on tissue residue values (that is, mode of toxic action), many of which are predicted values from (Q)SAR models (OECD QSAR Toolbox 2014). 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 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 on the basis of what is estimated to be the current use quantity and may not reflect future trends.

Critical data and considerations used to develop the substance-specific profiles for CAS RN 1338-24-5 and calcium naphthenates and the hazard, exposure, and risk classification results are presented in ECCC (2016b).

The hazard and exposure classifications for CAS RN 1338-24-5 and calcium naphthenates are summarized in Table 5-1.

Table 5-1. Ecological risk classification results for the substances in the Commercial Naphthenic Acids Group

Substance	ERC hazard classification	ERC exposure classification	ERC risk classification
CAS RN 1338-24-5	moderate	low	low
Calcium naphthenates	low	low	low

According to information considered under ERC, CAS RN 1338-24-5 was classified as having a low exposure potential. Although CAS RN 1338-24-5 was 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. Acute aquatic toxicity studies also identified fish and invertebrate species as sensitive to exposure from CAS RN 1338-24-5 (Kinley et al. 2016). In addition, Marentette et al. (2015) determined that CAS RN 1338-24-5 was more hazardous ($EC_{50} = 2$ mg/L, nominal concentration) than naphthenic acid fraction compounds (NAFCs) derived from OSPW ($EC_{50} = 5-12$ mg/L, nominal concentration). Similarly, Bartlett et al. (2017) also reported

that CAS RN 1338-24-5 was 30-, 4-, and 120-fold more hazardous than NAFCs derived from OSPW in *Hyalella azteca* (freshwater amphipod), *Vibrio fischeri* (marine bacterium), and *Lampsilis cardium* (freshwater mussel larvae), respectively. On the basis of low exposure potentials, however, CAS RN 1338-24-5 is unlikely to be resulting in concerns for the environment in Canada.

On the basis of low hazard and low exposure classifications according to ERC, calcium naphthenates were classified as having a low potential for ecological risk. It is therefore unlikely that these substances are resulting 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, and their limited volatility, significant releases of CAS RN 1338-24-5 and 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, CAS RN 1338-24-5 is 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 CAS RN 1338-24-5 from products is not expected.

In Canada, CAS RN 1338-24-5 has 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).

In Canada, calcium naphthenates are used in antifouling paints which are regulated under the *Pest Control Products Act*.

6.2 Health effects assessment

CAS RN 1338-24-5 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 CAS RN 1338-24-5 and calcium naphthenates; no toxicological data is available for the inhalation route. This information is summarized below.

CAS RN 1338-24-5

There are no data available on the carcinogenic potential for CAS RN 1338-24-5, and *in vitro* (that is, bacterial reverse mutation assay) and *in vivo* (that is, micronucleus test) assay results did not indicate genotoxicity (McKee et al. 2014). CAS RN 1338-24-5 is not acutely toxic (oral and dermal LD₅₀ ≥ 3000 mg/kg (Rockhold 1955; Rubinskaya 1974; Pennisi and Lynch 1977; Exxon 1979; Bio/dynamics Inc 1979; Exxon 1987). It 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 CAS RN 1338-24-5 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 (that is, 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).

As part of the registration requirements under REACH, ECHA requested that the Registrant carry out additional toxicity studies on CAS RN 1338-24-5 (ECHA 2016b). As a result, the Registrant carried out a 90-day oral toxicity study in rats (OECD 408), as well as an oral pre-natal developmental toxicity study in rats (OECD 414) and the data were added to the registration dossier in 2019. The results from these studies (Unnamed Study Report 2018a, 2018b as cited in ECHA c2007-2017) were reviewed, and the study authors did not identify effect levels more conservative than the values described above (for example, 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 (that is, 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 LD₅₀ ≥ 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 CAS RN 1338-24-5 and calcium naphthenates through environmental media, food, or the use of products available to consumers is expected to be minimal. As a result of the expected minimal exposure, the potential risk to human health is considered to be low, and a hazard characterization was not considered necessary at this time.

The human health assessment took into consideration those groups of individuals within the Canadian population who, due to greater susceptibility or greater exposure, may be more vulnerable to experiencing adverse health effects. For the commercial naphthenic acids group, these subpopulations were considered; however, exposures were expected to be minimal based on use patterns and therefore were not quantified.

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 CAS RN 1338-24-5 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 assessment, there is low risk of harm to the environment from CAS RN 1338-24-5 and calcium naphthenates. It is concluded that CAS RN 1338-24-5 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.

Considering all the information presented in this assessment, it is concluded that CAS RN 1338-24-5 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 concluded that CAS RN 1338-24-5 and calcium naphthenates do not meet any of the criteria set out in section 64 of CEPA.

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