FORM FOR NOTIFICATION

OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Country: Canada

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	**Chlorinated alkanes that have the molecular formula $C_nH_xCl_{(2n+2-x)}$ in which 10 ≤ n ≤ 13**
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	IUPAC Name: Alkanes, C_{10-13}, chloro
1.3	**Trade names and names of preparations**	**Short-chain chlorinated alkanes (SCCAs)** **Short-chain chlorinated paraffin (SCCPs)** **These two names are considered synonymous in this document and supporting documents.**
1.4	**Code numbers**	
1.4.1	CAS number	Please refer to the Appendix of this notification for a list of indicative (non-exhaustive) CAS numbers covered by this regulatory action.
1.4.2	Harmonized System customs code	

1.4.3 Other numbers (specify the numbering system)

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☒ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☐ This notification replaces all previously submitted notifications on this chemical.

Date of issue of the previous notification: ____________________________

SECTION 2 FINAL REGULATORY ACTION

2.1 The chemical is: ☒ **banned** **OR** ☐ **severely restricted**

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

A person must not manufacture, use, sell, offer for sale or import SCCAs or a product containing them unless the toxic substance is incidentally present.

A person must not manufacture, use, sale, offer for sale or import SCCAs or products containing them unless they are to be used in laboratory for analysis, in scientific research or as a laboratory analytical standard.

A person who manufactures or imports SCCAs listed in Schedule 2, Part 4 or a product containing it whether incidentally or not, above the reporting thresholds must submit an annual report by March 31st of the following year.

A person may use, sell, or offer for sale a product containing SCCAs if the product is manufactured or imported before the day on which these Regulations come into force (March 14, 2013).

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

Prohibition of Certain Toxic Substances Regulations, 2012

Canada Gazette, Part II, Vol. 147, No. 1 — January 2, 2013.

http://www.gazette.gc.ca/rp-pr/p2/2013/2013-01-02/html/sor-dors285-eng.html

2.2.3 Date of entry into force of the final regulatory action

March 14, 2013

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

SCCAs were primarily used in Canada as extreme pressure additives in metalworking fluids. In 2010, the total quantity of SCCAs imported into Canada was estimated to be 33 tonnes. However, companies involved reported that the use of the substances was phased out at the end of that year. Products containing SCCAs, including paints, adhesives, sealants, rubber and plastics, could have been imported into Canada, the volume of such imports was believed to be small.

2.3.2 Final regulatory action has been taken for the category ☒ Industrial

Use or uses prohibited by the final regulatory action

All manufacture, use, sale, offer for sale or import of SCCAs, or a product containing them, is prohibited unless the toxic substance is incidentally present.

Use or uses that remain allowed (only in case of a severe restriction)

N/A

2.3.3 Final regulatory action has been taken for the category ☐ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

N/A

Formulation(s) and use or uses that remain allowed

(only in case of a severe restriction)

N/A

2.4 **Was the final regulatory action based on a risk or hazard evaluation?**

☒ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

Government of Canada. 1993a. Priority Substances List assessment report. Chlorinated paraffins. Minister of Supply and Services, Ottawa, Ontario (ISBN 0-662-20515-4; Catalogue No. En40-215/17E). Government of Canada. 2004. Follow-up Report on a PSL1 Substance for Which There Was Insufficient Information to Conclude Whether the Substance Constitutes a Danger to the Environment. Ottawa, Ontario. Government of Canada. 2004. Follow-up Report on a PSL1 Substance for Which Data Were Insufficient to Conclude Whether the Substance Was “Toxic” to Human Health Chlorinated Paraffins. Ottawa, Ontario. Government of Canada. 2008. Follow-up Report on a PSL1 Assessment for Which Data Were Insufficient to Conclude Whether the Substances Were “Toxic” to the Environment and to the Human Health. Ottawa, Ontario.

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health?

☒ Yes

☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

For SCCAs, critical data relevant to both estimation of exposure of the general population in Canada and assessment of the weight of evidence for the mode of induction of specific tumours were identified following release of the first Priority Substances List (PSL1) assessment and prior to February 2001, although most of this information has been reported in incomplete published summary accounts or abstracts. These data suggest that several tumours observed in carcinogenicity bioassays in rats and mice exposed to SCCAs are induced by modes of action either not relevant to humans (kidney tumours in male rats) or for which humans are likely less sensitive (in rats, liver tumours related to peroxisome proliferation and thyroid tumours related to thyroid–pituitary disruption). Complete documentation of available studies and consideration in additional investigations of the reversibility of precursor lesions in the absence of continued exposure is lacking. However, reported data on mode of induction of tumours in addition to the weight of evidence that SCCAs are not DNA reactive are at least sufficient as a basis for consideration of a Tolerable Daily Intake (TDI) for non-cancer effects as protective for carcinogenicity for observed tumours. Upper-bounding estimates of daily intake of SCCAs approach or exceed the TDI for these compounds, which, on the basis of available information, is likely also protective for potential carcinogenicity.

Expected effect of the final regulatory action

Prevention of potential risks of harm to the Canadian environment and, where applicable, human health by prohibiting the manufacture, use, sale, offer for sale or import of SCCAs as well as products containing these substances.

2.4.2.2 Is the reason for the final regulatory action relevant to the environment?

☒ Yes

☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

The risk evaluation considered all Chlorinated Alkanes (CAs) including SCCAs, Medium-Chain Chlorinated Alkanes (MCCAs) and Long-Chain Chlorinated Alkanes (LCCAs).

There are no known natural sources of CAs. The major sources of release of CAs into the Canadian environment are likely the formulation and manufacturing of products containing CAs, such as polyvinyl chloride (PVC) plastics, and use in metalworking fluids. The possible sources of releases to water from manufacturing include spills, facility wash-down and drum rinsing/disposal. CAs in metalworking/metal cutting fluids may also be released to aquatic environments from drum disposal, carry-off and spent bath. These releases are collected in sewer systems and often ultimately end up in the effluents of sewage treatment plants. When released to the environment, CAs tend to partition primarily to sediment or soil.

SCCAs have been detected in the following environmental samples from Canada: in Arctic air, in sediments from remote northern lakes, in sewage treatment plant effluents from southern Ontario, in surface water, sediments and fish from Lake Ontario and in marine mammals from the Canadian Arctic and the St. Lawrence River. Maximum Canadian concentrations of SCCAs were observed in aquatic biota and sediments from the St. Lawrence River and also in sediments and fish from southwestern Ontario.

Atmospheric half-lives for many CAs are estimated to be greater than 2 days. In addition, SCCAs have been detected in Arctic biota and lake sediments in the absence of significant sources of SCCAs in this region, which suggests that long-range atmospheric transport of SCCAs is occurring. SCCA residues have been detected in Canadian lake sediments dating back over 25 years, suggesting that the half-lives of SCCAs in sediment are greater than 1 year. It is therefore concluded that SCCAs are persistent as defined in the *Persistence and Bioaccumulation Regulations* of the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

Bioaccumulation factors (BAFs) of 16,440–25,650 wet weight (wet wt.) in trout from Lake Ontario indicate that SCCAs are bioaccumulating to a high degree in aquatic biota in Canada. This is supported by very high bioconcentration factors (BCFs) for SCCAs measured in mussels (5,785–138,000 wet wt.).

In cases where appropriate Canadian environmental exposure data were not available, international concentration data were used for the risk quotients. Conservative risk quotients indicate that SCCAs have the potential to harm pelagic and soil organisms, that SCCAs may harm benthic organisms and that SCCAs have the potential to harm fish-eating wildlife through food chain effects.

Based on the information available, it is proposed that SCCAs are entering the environment in quantities or concentrations or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

Expected effect of the final regulatory action

Prevention of potential risks of harm to the Canadian environment and, where applicable, human health by prohibiting the manufacture, use, sale, offer for sale or import of SCCAs as well as products containing these substances with a limited number of exemptions.

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced	N/A	N/A
imported	N/A	N/A
exported	N/A	N/A
used	3000	2001

2.5.2 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

At the time the regulation came into force, SCCAs were not manufactured in Canada. Also, the use of SCCAs was phased out by industry in early 2010. As a result, the Regulations were not expected to result in any incremental costs to industries. However, the Regulations prevent a re-introduction of these substances and of products containing them in the Canadian market, thereby eliminating the risk of release of SCCAs and resulting ecological harm. Furthermore, they serve to reduce any potential transboundary emissions of SCCAs and protect the environment from its risks on a global level, signalling Canada's commitment to take action on SCCAs to its international partners.

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

Considerations for alternatives considered all CAs.

Metalworking Fluids

There are two approaches to minimizing the releases of CAs within the metalworking industry, specifically to: (i) increase the adoption rate of substitutes to CAs among metalworking fluid formulators and end-users; and (ii) increase the adoption of best management practices by end-users of metalworking fluids.

Although substitutes to CAs are available to metalworking fluid formulators, several issues need to be considered in their implementation, as some potential alternatives are:

- not technically suitable for all applications;
- more costly; and
- may also pose environmental and health risks.

<u>Polyvinyl Chloride</u>

In PVC manufacturing, CAs were used primarily in applications where moderate plasticizing and flame retardant properties were required at low cost. Moreover, it was not anticipated that there would be many technical obstacles if CAs had to be replaced with alternative plasticizers and/or flame retardants. Analysis of CA alternatives suggested that, in many cases, the overall technical characteristics of the PVC product such as flexibility and stability would improve with the use of alternatives. Although technically feasible, the use of these alternatives would likely increase the raw material costs for manufacturers and they may also pose environmental and health risks.

<u>Paints and Coatings, Adhesives and Sealants, and Rubber and Elastomers</u>

Very small quantities of CAs are used annually in Canada in the formulation of paints and coatings, adhesives and sealants, and rubber and elastomers relative to metalworking fluids and PVC. Less than 100 tonnes of both MCCAs and LCCAs were reported to Environment Canada for the year 2001. The favorable characteristics provided by CAs include good compatibility with the resin systems where they are used; they are colourless; they are non-volatile and do not add to volatile organic compounds (VOC) content of a coating system; and they have low viscosity.

The use of CAs in the rubber industry has historically involved the utilization of SCCAs to manufacture rubberized conveyor belts for the underground mining industry as well as other technical products such as hoses and gaskets. They were used in these applications because of their superior flame retardant properties, which are often required in order to meet fire standard codes for products.

Technical barriers were been reported for adhesives and sealants substitutes as well; the primary technical issue was that they are more prone to bleeding from the sealant product, thus directly affecting the durability of the sealant and the substrate.

Source: Proposed Risk Management Approach for Chlorinated Paraffins (August 2008).

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

N/A

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

N/A

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

International classification systems e.g. WHO, IARC, etc.	Hazard class

Other classification systems e.g. EU, USEPA	Hazard class

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

SCCAs are mixtures that are viscous, colourless or yellowish dense oils.

SCCAs have the molecular formula $C_nH_xCl_{(2n+2-x)}$ in which $10 \leq n \leq 13$

Vapour pressure (Pa): 2.8×10^{-7} – 0.028 (48 – 71% Cl)
Henry's Law Constant (Pa·m^3/mol): 0.68 – 17.7 (48 – 56% Cl)
Water Solubility (µg/L): 6.4 – 2370 (48 – 71% Cl)
log K_{OW}: 4.39 – 8.69 (48 – 71% Cl)
log K_{OA}: 8.2 – 9.8 (48 – 56% Cl)
log K_{OC}: 4.1 – 5.44

Reference

Government of Canada. 2008. Follow-up Report on a PSL1 Assessment for Which Data Were Insufficient to Conclude Whether the Substances Were "Toxic" to the Environment and to the Human Health. Ottawa, Ontario.

3.2.2 Description of toxicological properties of the chemical

Overall, toxicity studies are few for effects of SCCAs to pelagic biota and mammals.

Mammals

In a 13-week oral (gavage) rat study by International Research and Development Corporation (1984), increases in liver and kidney weight and hypertrophy of the liver and thyroid occurred at doses of 100 mg/kg-bw per day. This value was the most sensitive LOAEL for mammals. Interspecies scaling using data for a typical adult otter was used to extrapolate to a food concentration for this species. This resulted in a CTV of 1,000 mg/kg food.

Reference

Government of Canada. 2008. Follow-up Report on a PSL1 Assessment for Which Data Were Insufficient to Conclude Whether the Substances Were "Toxic" to the Environment and to the Human Health. Ottawa, Ontario.

3.2.3 Description of ecotoxicological properties of the chemical

Lowest-Observed-Effect Concentrations (LOECs) (i.e., survival, reproduction and growth) ranged from 8,900 to 10,000 ng/L for pelagic biota. Effects of SCCAs to benthic and soil-dwelling organisms are not available. More toxicological data are available for MCCAs. In particular, the acute and chronic toxicity of MCCAs has been studied in algae, invertebrates and several species of fish. The range of acute effects is 5,900 ng/L to > 10g/L (10,000,000,000 ng/L). LOECs for pelagic biota ranged from 18,000 to 31,000 ng/L. Contrary to SCCAs, toxicity studies, albeit few, are available for benthic and soil-dwelling organisms. LOECs for sediment dwelling biota ranged from 270 to 410 mg/kg dry weight. A reproductive LOEC for earthworm was reported to be 383 mg/kg dry weight. A limited number of studies is available for effects to pelagic biota. Acute effects were observed at greater than 3,800,000 ng/L.

A- Pelagic aquatic organisms

The lowest toxic effect level identified for a pelagic freshwater aquatic species is 8,900 ng/L, which is the 21-day chronic LOEC for Daphnia magna (Thompson and Madeley 1983a). The effect was for mortality of the offspring. The No-Observed-Effect Concentration (NOEC) is 5,000 ng/L.

B- Benthic organisms

A valid measurement endpoint was not available for a sediment-dwelling invertebrate. As a result, an equilibrium partitioning approach (Di Toro et al. 1991) using the most sensitive chronic measurement endpoint identified for a pelagic freshwater invertebrate aquatic species (8,900 ng/L) was used to estimate the toxicity to benthic organisms. The LOEC benthic was estimated to be 35.5 mg/kg dry wt. for sediment containing 2% organic carbon (Environment Canada, 2008).

C- Soil-dwelling organisms

Bezchlebová et al. (2007) investigated the effects of SCCAs on the survival and reproduction of five species of soil organisms (*Fosomia candida*, *Eisenia fetida*, *Enchytraeus albidus*, *Enchytraeus crypticus*, and *Caenorhabditis elegans*). All tests were performed following international methods, using an Organisation for Economic Co-operation and Development (OECD) artificial soil (70% sand, 20% clay, 10% peat) with an organic carbon content of approximately 2.7%. Folsomia candida (*collembola*) was identified as the most sensitive organism, with a median lethal concentration (LC50) value for adult survival and median effective concentration (EC50) and EC10 values for reproduction of 5,733, 1,230, and 660 mg/kg dry wt. (nominal), respectively. The soil Critical Toxicity Value (CTV) for SCCAs is 660 mg/kg dry wt.

Bioaccumulation

Bioaccumulation factors (BAFs) for SCCAs chain length groups in Lake Ontario plankton, alewife (*Alosa pseudoharengus*), slimy sculpin (*Cottus cognatus*), rainbow smelt (*Osmerus mordax*) and lake trout (*Salvelinus namaycush*) were determined based on a whole organism (wet weight) and filtered water concentrations using data from Houde et al. (2006). SCCAs were found in all components of the food chain and BAFs ranged from 9,900 to 51,200 (wet weight). SCCAs bioaccumulated to the greatest extent in fish, with the highest BAFs (51,200) in sculpin, smelt and trout. Assuming no metabolism, the Modified Gobas BAF model for fish estimated BAF values greater than 5,000 for all possible SCCAs (Arnot and Gobas 2003).

Bioconcentration factors (BCFs) calculated from laboratory studies for SCCAs have been reviewed in Government of Canada (1993b) and were found to vary dramatically among different species. Relatively low BCF values have been determined in freshwater and marine algae (<1–7.6). BCF values of up to 7,816 wet wt. have been measured in rainbow trout (*Oncorhynchus mykiss*) (Madeley and Maddock 1983a,b) and 5,785–138,000 wet wt. in the common mussel (*Mytilus edulis*) (Madeley et al. 1983b, Madeley and Thompson 1983d, Renberg et al. 1986).

Reference

Government of Canada. 2008. Follow-up Report on a PSL1 Assessment for Which Data Were Insufficient to Conclude Whether the Substances Were “Toxic” to the Environment and to the Human Health. Ottawa, Ontario.

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	Environment Canada
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PLEASE RETURN THE COMPLETED FORM TO:

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Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) 'Chemical' means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(d) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.

Appendix: Non-exhaustive list of CAS Registered Numbers for Short-Chain Chlorinated Alkanes (SCCAs)

Chemical name	CAS Registered Numbers
Chlorowax	51990-12-6
Alkanes, chloro	61788-76-9
Paraffin waxes and Hydrocarbon waxes, chloro	63449-39-8
Paraffin waxes and Hydrocarbon waxes, chloro, chlorosulfonated	68188-19-2
Hydrocarbons, C2-6, chloro	68476-48-2
Hydrocarbons, C1-6, chloro	68606-33-7
Alkanes, chloro, sulfurized	68911-63-7
Alkanes, C6-18, chloro	68920-70-7
Paraffin waxes and Hydrocarbon waxes, chloro, reaction products with naphthalene	68938-42-1
Alkanes, C10-18, bromo chloro	68955-41-9
Alkanes, C11-14, 2-chloro	68990-22-7
Alkanes, C12-13, chloro	71011-12-6
Paraffin waxes and Hydrocarbon waxes, chloro, sulfonated, ammonium salts	72854-22-9
Paraffins (petroleum), normal C5-20, chlorosulfonated, ammonium salts	73138-78-0
Alkanes, C10-21, chloro	84082-38-2
Alkanes, C10-32, chloro	84776-06-7
Paraffin oils, chloro	85422-92-0
Alkanes, C10-13, chloro	85535-84-8
Alkanes, C12-14, chloro	85536-22-7
Alkanes, C10-14, chloro	85681-73-8
Paraffins (petroleum), normal C>10, chloro	97553-43-0
Alkanes, C10-26, chloro	97659-46-6
Alkanes, C10-22, chloro	104948-36-9
Alkanes, C10-12, chloro	108171-26-2
1-chlorododecane	112-52-7
1-chlorodecane	1002-69-3
1,10-dichlorodecane	2162-98-3
1,12-dichlorododecane	3922-28-9