Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals

Decision Guidance Document

Short-chain chlorinated paraffins

Secretariat of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

180717

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[1] for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[2] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its eighth meeting, held in Geneva from 24 April to 5 May 2017, the Conference of the Parties agreed to list Short-chain chlorinated paraffins in Annex III of the Convention and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on 15 September 2017, in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III of the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention.
Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

[1] According to the Convention, the term “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.

[2] According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
µm	micrometre
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
CA	chlorinated alkanes
cc	cubic centimetre
cm	centimetre
CP	chlorinated paraffins
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment of the European Commission
CTV	critical toxicity value
DNA	deoxyribose nucleic acid
DT_{50}	dissipation time 50%
EC	European Community
EC_{50}	median effective concentration
ED_{50}	median effective dose
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Chemical Substances
EU	European Union
EUSES	European Union System for the Evaluation of Substances
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
i.m.	intramuscular

STANDARD CORE SET OF ABBREVIATIONS	
i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC_{50}	median inhibitory concentration
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 1000)
kg	kilogram
Koc	soil organic partition coefficient.
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre
LC_{50}	median lethal concentration
LCCP	long-chain chlorinated paraffins
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	lowest-observed-effect level
m	metre
MCCP	medium-chain chlorinated paraffins
m.p.	melting point
mg	milligram
ml	millilitre
mPa	millipascal
MRL	maximum residue limit
MTD	Maximum Tolerated Dose
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
NP	nonylphenol
NPE	nonylphenolethoxylates
OECD	Organisation for Economic Co-operation and Development
OSPAR Convention	Convention for the Protection of the Marine Environment of the North-East Atlantic
PEC	predicted environmental concentration
POPRC	Persistent Organic Pollutants Review Committee
Pow	octanol-water partition coefficient, also referred to as Kow
PPE	personal protective equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RfD	reference dose (for chronic oral exposure; comparable to ADI)
SCCP or SCCPs	short-chain chlorinated paraffins
SMR	standard(ized) mortality ratio
STEL	short-term exposure limit
TDI	tolerable daily intake

STANDARD CORE SET OF ABBREVIATIONS	
TER	toxicity exposure ratio
TLV	threshold limit value
TWA	time-weighted average
UNECE	United Nations Economic Commission for Europe
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VOC	volatile organic compound
w/w	weight for weight
WHO	World Health Organization
wt	weight

1. Identification and uses (see Annex 1 for further details)

Common name	Short-chain chlorinated paraffins (SCCP) with a chlorination degree of more than 48% by weight. Various abbreviations for (short-chain) chlorinated paraffins are used in the underlying documentation for this DGD. For clarification purposes, only the abbreviations SCCP or CP are used in this report.
Chemical name and other names or synonyms	Alkanes, $C_{10\text{-}13}$, chloro; Chlorinated paraffins with a chlorination degree of more than 48% by weight.
Molecular formula	$C_xH_{(2x-y+2)}Cl_y$, where x=10-13 and y=1-13 (European Chemicals Bureau (2000) with a chlorination degree of more than 48% by weight.
CAS-No.(s)	85535-84-8
Harmonized System Customs Code	3824.9
Other numbers	-
Category	Industrial
Regulated category	Industrial chemical
Use(s) in regulated category	**Norway** The notified regulatory action relates to SCCP and the industrial use of the chemical as softeners in paints, plastics, fillers and coatings, as flame inhibitors in rubber, plastics and textiles, and as additives in other chemical substances and products. There has also been limited use in metal working fluids as well as in certain lubricants and car care products. (UNEP/FAO/RC/CRC.10/6 section 1.7.2). **Canada** The regulatory action notified by Canada relates to the use of SCCP as industrial chemicals. The final regulatory action states that all manufacture, use, sale, offer for sale or import of SCCP or products containing them is prohibited, unless SCCP are incidentally present in the product or if they are used in a laboratory for analysis, in scientific research or as a laboratory analytical standard (UNEP/FAO/RC/CRC.10/6 section 2.1, 2.2.1 and 2.2.3).
Trade names	A70 (wax); Chloroflo; Adekacizer E; Chlorparaffin; Arubren; Chlorowax; Cereclor; Cloparin; Chlorcosane; Cloparol; Chlorez; Clorafin; Chlorofin; CW; Derminolfett; Derminolol; EDC-tar; Electrofine; Enpara; Hordaflam; Horda-flex; Hordalub; Hulz; Khp; Meflex; Monocizer; Paroil; Poliks; Tenekil; Toyoparax; Unichlor. *This is an indicative list. It is not intended to be exhaustive.*
Formulation types	Not relevant
Uses in other categories	Canada and Norway No reported use as pesticide.

Basic manufacturers Chlorinated paraffins (CPs) (of various chain lengths) are currently produced in the Russia, India, China, Japan and Brazil. However according to Annex E (2014) information from China, no specific SCCP production data are available since production is related to several chlorinated paraffin products that do not distinguish SCCPs from other chlorinated paraffins. Most abundant are CP-42, CP-52 and CP-70 (other are CP-13, CP-30, CP-40, CP-45, CP55 and CP-60). Very limited information is available on SCCP production in some countries. (POPRC 2015)

This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.

2. Reasons for inclusion in the PIC procedure

SCCP are included in the PIC procedure as industrial chemicals. They are listed on the basis of final regulatory actions notified by Norway and Canada that ban their use as industrial chemicals.

No final regulatory actions relating to pesticidal uses of SCCP have been notified.

2.1 Final regulatory action (see Annex 2 for further details)

Norway

The use of SCCP is banned by the final regulatory action which states that production, import, export, sale and use of SCCP in pure form, in preparations or in products containing > 0.1 % SCCP is prohibited (UNEP/FAO/RC/CRC.10/6 sections 2 and, 2.2.1). Use for research and analytical purposes is still allowed (UNEP/FAO/RC/CRC.10/6 section 2.5.1).

Reason: Environment

Canada

The use of SCCP is banned by the final regulatory action which entered into force on 14 March 2013 which states that after the above mentioned date, all manufacture, use, sale, offering for sale or import of SCCP or products containing them is prohibited, unless incidentally present in a product or if used in a laboratory for analysis, in scientific research or as a laboratory analytical standard (UNEP/FAO/RC/CRC.10/6 sections 2.1, 2.2.1 and 2.2.3).

Reason: Human Health and Environment

2.2 Risk evaluation (see Annex 1 for further details)

Norway

SCCP are very toxic to aquatic organisms, they degrade slowly in the environment and have a high potential for bioaccumulation. These properties, together with the potential for long range transport via air and water, confirmed by monitoring data, give rise to serious concerns for long term effects in the aquatic environment (UNEP/FAO/RC/CRC.10/6 Annex I, section 2.3).

The use of SCCP in metal working fluids and in leather finishing has been found to present a risk to aquatic organisms in surface water due to local exposures. Possible risks to sediment-dwelling organisms were identified as a result of the production of short-chain chlorinated paraffins, formulation and use of metal cutting fluids and formulation and use of leather finishing products and, use in rubber formulations. There is a possible risk to soil-dwelling organisms in agricultural soils at a local level (for metal working fluid formulation and use, and leather finishing formulation and use) and at a regional level due to spreading of sewage sludge. Further information for the soil and sediment compartments could be gathered to clarify the risk. However, risk reduction methods should be considered for metal working since further information (either on exposure or aquatic toxicity) is unlikely to change significantly the PEC/PNEC ratios calculated for aquatic organisms. Based on the available data, a risk to aquatic organisms cannot be excluded for leather finishing applications either and so risk reduction measures should also be considered for that use (UNEP/FAO/RC/CRC.10/INF/10, p. 136).

Canada

On the basis of the available information, the latest assessment report from 2008 concluded that SCCP are entering, or may enter, the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (UNEP/FAO/RC/CRC.10/INF/11, p. 184).

The risk evaluation considered all Chlorinated Alkanes (CA) including SCCP, Medium-Chain Chlorinated Alkanes (MCCA) and Long-Chain Chlorinated Alkanes (LCCA). There are no known natural sources of CA. The major sources of release of CA into the Canadian environment are likely the formulation and manufacturing of products

containing CA, 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. CA 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, CA tend to partition primarily to sediment or soil (UNEP/FAO/RC/CRC.10/6 section 2.4.2.2).

In Canada, SCCP have been detected in the following environmental media: Arctic air, sediments from remote northern lakes, sewage treatment plant effluents from southern Ontario, surface water, sediments and fish from Lake Ontario and marine mammals from the Canadian Arctic and the St. Lawrence River. Maximum Canadian concentrations of SCCP were observed in aquatic biota and sediments from the St. Lawrence River and also in sediments and fish from south-western Ontario. Atmospheric half-lives for many CA are estimated to be greater than 2 days. In addition, SCCP have been detected in Arctic biota and lake sediments in the absence of significant sources of SCCP in this region, which suggests that long-range atmospheric transport of SCCP is occurring. SCCP residues have been detected in Canadian lake sediments dating back over 25 years, suggesting that the half-lives of SCCP in sediment are greater than 1 year. It is therefore concluded that SCCP are persistent as defined in the *Persistence and Bioaccumulation Regulations* of the *Canadian Environmental Protection Act, 1999* (UNEP/FAO/RC/CRC.10/6 section 2.4.2.2).

Based on the information available, it was concluded that SCCP were 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 (UNEP/FAO/RC/CRC.10/6 section 2.4.2.2).

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Norway

The regulatory action notified by Norway bansthe use of SCCP as industrial chemicals. Production, import, export, sale and use of SCCP in pure form, in preparations or in products containing > 0.1 % SCCP is prohibited (UNEP/FAO/RC/CRC.10/6 section 2, 2.2.1). Use for research and analytical purposes is still allowed (UNEP/FAO/RC/CRC.10/6 section 2.5.1).

The regulation entered into force on 1 January 2001. However, stock items imported or produced before 1 January 2001 were allowed to be sold and used until 1 January 2002. As stated in OSPAR decision 95/1, there was a transition period until 1 January 2005 for conveyor belts used in the mining industry and for sealing materials in dams containing SCCP. However, such applications were not relevant in Norway (UNEP/FAO/RC/CRC.10/6 section 2.2.3).

Canada

The regulatory action notified by Canada relates to the use of SCCP as industrial chemicals. All manufacture, use, sale, offer for sale or import of SCCP is banned by the final regulatory action which entered into force on 14 March 2013.

The final regulatory action states that after the above mentioned date, all manufacture, use, sale, offer for sale or import of SCCP or products containing them are prohibited, unless the SCCP are incidentally present in the product, or if they are used in laboratory for analysis, in scientific research or as a laboratory analytical standard (UNEP/FAO/RC/CRC.10/6 section 2.1, 2.2.1 and 2.2.3).

3.2 Other measures to reduce exposure

UNECE LRTAP and OSPAR

In August, 2005, the European Community proposed SCCPs to be added to the UNECE Convention on Long Range Transboundary Air Pollution (LRTAP), Aarhus Protocol on Persistent Organic Pollutants. SCCPs met the criteria of decision 1998/2 of the Executive Body for persistence, potential to cause adverse effects, bioaccumulation and potential for long range transport. Thus SCCPs were added to Annexes I and II of the 1998 Aarhus Protocol in December 2009 at the 27th session of the Executive Body. Annex II restricts SCCP uses to fire retardants in rubber used in conveyor belts in the mining industry and in dam sealants, and states that action to eliminate these uses should occur once suitable alternatives are available (POPRC 2015).

In 1995, OSPAR (Oslo/Paris) Commission for the Protection of Marine Environment of the North-East Atlantic adopted a decision on SCCPs (Decision 95/1). OSPAR Decision 95/1 and subsequent EU measures regulate the main uses of SCCPs and sources. In 2006, OSPAR prepared an overview assessment of the implementation of PARCOM (Paris Commission) Decision 95/1 on SCCPs (OSPAR 2006). The assessment was based on national implementation reports received from nine of 15 Contracting Parties which have been requested to submit, in the 2005/2006 meeting cycle, reports on the national measures taken. All reporting Contracting Parties have taken measures to implement

PARCOM Decision 95/1. Some Contracting Parties reported a full ban of all or certain uses of SCCPs and reductions of other uses. In general, Contracting Party measures have addressed those uses covered by European Directive 2002/45/EC (POPRC 2015).

Similar to OSPAR, the Baltic Marine Environment Protection Commission (HELCOM) has included SCCP in their list of harmful substances. On November 15, 2007, HELCOM included SCCP in the HELCOM Baltic Sea Action Plan. Contracting Parties to HELCOM have agreed, starting in 2008, to work for strict restriction on the use in the whole Baltic Sea catchment area of the Contracting States of several hazardous substances, including SCCP. Hazardous substances are those found to be PBT or vPvB (Annex E 2010 submission from Lithuania) (POPRC, 2015).

3.3 Alternatives

It is essential that before a country considers substituting alternatives, it ensure that the use is relevant to its national needs and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

Further, the POPs Review Committee of the Stockholm Convention will undertake an evaluation of alternatives to SCCP during the Annex F (Risk Management Evaluation) phase of its review of SCCP as a candidate POP. Once adopted, the Risk Management Evaluation should provide valuable information on alternatives to SCCP.

Canada

In determining risk management options, the risks and costs of potential alternative substances and technologies were considered.

Metalworking Fluids

There are two approaches to minimizing the releases of CP within the metalworking industry, specifically to: (i) increase the adoption rate of substitutes to CP 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 CP 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.

Polyvinyl Chloride

In PVC manufacturing, CP 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 CP had to be replaced with alternative plasticizers and/or flame retardants. Analysis of CP alternatives suggests 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.

Paints and Coatings, Adhesives and Sealants, and Rubber and Elastomers

Very small quantities of CP 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 MCCP and LCCP were reported to Environment Canada for the year 2001. The favourable characteristics provided by CP 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 CP in the rubber industry has historically involved the utilization of SCCP to manufacture rubberized conveyor belts for the underground mining industry as well as other technical products such as hoses and gaskets. They are 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 have 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 (Environment Canada, Health Canada, 2008).

OSPAR

MCCP, the medium-chain chlorinated paraffins (C14-17) may have similar uses to SCCP and are used as replacements for SCCP as extreme pressure additives in metalworking fluids, as plasticisers in paint, and as additives in sealants.

The United Kingdom risk assessment on MCCP, in the framework of the Existing Substances Regulation, states that some risk reduction measures are required for uses in the production of PVC, in some process formulations of metal cutting fluids, in emulsifiable metal cutting/working fluids where the spent fluid is discharged to waste water, in leather fat liquors and in carbonless copy paper during recycling. The risk from use in oil-based metal cutting fluids may also be of concern.

LCCP, the long-chain chlorinated paraffins have been used in some demanding applications in metalworking fluids instead of SCCP in Sweden. LCCP are also suggested as a replacement to SCCP in the leather industry as well as in paint and coatings, in sealants and rubber.

Alkyl phosphate esters and sulfonated fatty acid esters may function as replacements for SCCP as extreme pressure additives in metalworking fluids. Natural animal and vegetable oils are also alternatives in the leather industry. In paint and coatings, phthalate esters, polyacrylic esters, diisobutyrate as well as phosphate and boron-containing compounds are suggested as replacements.

Phthalates esters are alternatives for use in sealants. Alternatives as flame retardant in rubber, textiles and PVC are antimony trioxide, aluminium hydroxide, acrylic polymers and phosphate containing compounds. Sweden considers these substances as being less harmful than chlorinated paraffins.

However, there might still be uses for which these alternatives do not fulfil all technical and security demands. In addition, the cost of substitution may not be proportional to health and environmental advantages for all types of applications. Risk reduction measures like closed production and/or further regulation of emission limits, are amongst several measures that could be taken into account.

It was agreed at the OECD Expert Meeting on SCCP and NP/NPEs, hosted by Switzerland on 8 - 10 November 1999, that some form of exchange of information on substitute chemicals and processes is desirable. A password protected web site has been established by the OECD Secretariat (OSPAR, 2009).

3.4 Socio-economic effects

Canada

Socio-economic considerations for CP included a qualitative analysis of costs to industry in terms of switching to alternatives and benefits to the public.

It was determined that the cost of using alternative substances would have a minimal economic effect for most uses. However, where the costs of alternatives are significant there would be an increase in the raw material costs for manufacturers that are currently using CP in their products. This increase, along with other re-formulation costs, could hinder the competitiveness of these products in domestic and foreign markets (Environment Canada, Health Canada, 2008).

At the time the regulation came into force, SCCP were not manufactured in Canada. Also, the use of SCCP 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 SCCP and resulting ecological harm. Furthermore, they serve to reduce any potential transboundary emissions of SCCP and protect the environment from its risks on a global level, signalling Canada's commitment to take action on SCCP to its international partners. (UNEP/FAO/RC/CRC.10/6 section 2.5.3.1).

4. Hazards and Risks to human health and the environment	
4.1 Hazard Classification	
WHO / IPCS	-
IARC	2B – Possible carcinogen to humans
European Community	In accordance to Regulation (EC) No 1272/2008, which implements the UN GHS in the EU: **Hazard Class, Category Code and Hazard Statement Code** Carc. 2; H351 – Suspected of causing cancer Aquatic Acute 1; H400 – Very toxic to aquatic life Aquatic Chronic 1; H410 – Very toxic to aquatic life with long-lasting effects **Pictograms, Signal Word Codes**  Environment GHS09:  Health hazard GHS 08: In accordance with Council Directive 67/548/EEC: **Carc. Cat. 3; R40** – Limited evidence of a carcinogenic effect. **R66** – Repeated exposure may cause skin dryness or cracking. **N** - Dangerous for the environment. **R50-53** – Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
US EPA	SCCPs are persistent, bioaccumulative, and toxic to aquatic organisms at low concentrations. They can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, increasing the probability and duration of exposure. Even relatively small releases of these chemicals from individual manufacturing, processing, or waste management facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on the environment. SCCPs have been measured in a variety of environmental media including air, sediment, surface waters, and wastewater. SCCPs have also been measured in a variety of biota, including freshwater aquatic species, marine mammals, and avian and terrestrial wildlife. In addition, SCCPs have been detected in samples of human breast milk from Canada and the United Kingdom, as well as in a variety of food items from Japan and various regions of Europe. (U.S. EPA Short-Chain chlorinated Paraffins (SCCPs) Action Plan: http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/sccps_ap_2009_1230_final.pdf)

4.2 Exposure limits

IPCS (1996):

On the basis of available data on repeated dose toxicity, **a Tolerable Daily Intake (TDI) for non-neoplastic effects of SCCP for the general population can be developed:**

TDI = 10 mg/kg body weight per day / 100 = 100 µg/kg body weight per day;

where 10 mg/kg body weight per day is the lowest reported no-observed-effect level (increases in liver and kidney weights and hypertrophy of the liver and thyroid at the next highest dose in a 13-week study on rats); and 100 is the uncertainty factor (× 10 for interspecies variation; × 10 for intraspecies variation).

On the basis of multistage modelling of the tumours with highest incidence (hepatocellular adenomas or carcinomas (combined) in male mice) in the carcinogenesis bioassay with SCCP, the estimated dose associated with a 5% increase in tumour incidence is 11 mg/kg body weight per day (amortized for period of administration). After dividing this value by 1000 (uncertainty factor for a non-genotoxic carcinogen), it can be recommended that **daily doses of SCCP for the general population should not exceed 11 µg/kg body weight, on the basis of neoplastic effects**.

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class and Packing Group:	Chlorinated paraffins (C10-C30): Hazard Class: UN: 9 Packing Group: UN: III (United Nations, 2013)
International Maritime Dangerous Goods (IMDG) Code	Chlorinated paraffins (C10-C30): UN 3082 Environmentally hazardous substance, liquid, N.O.S. Class 9 (IMO, 2013)
Transport Emergency Card	Not available

4.4 First aid

4.5 Waste management

Since chlorinated paraffins are bioaccumulative and toxic to environmental organisms and owing to difficulties in monitoring environmental levels, it is recommended that use and disposal of these compounds should be controlled to avoid release to the environment.

Disposal of wastes containing chlorinated paraffins occurs through resource recovery, destructive incineration or landfill, usually on disposal sites for special wastes and in compliance with local regulations. Owing to their thermal instability, chlorinated paraffins are expected to be degraded by incineration at low temperatures and thus would not be expected to volatilize in exhaust gases from an incinerator. However, in a study by Bergman et al. (1984), chlorinated aromatic compounds such as PCBs, naphthalenes and benzenes were formed by pyrolysis of chlorinated paraffins (see section 4.2.1) although the conditions used were not identical to the operation conditions of waste incineration plants. Chlorinated paraffins are not expected to be formed *de novo*. The disposal of chlorinated paraffins in landfills may give rise to leaching into water, but owing to the low water solubility and strong adsorption onto solids the amounts reaching water are likely to be low. (IPCS 1996)

Annexes

Annex 1 **Further information on the substance**

Annex 2 **Details on Final regulatory action**

Annex 3 **Address of designated national authorities**

Annex 4 **References**

Annex 1 Further information on the substance

Introduction

The information presented in the present annex reflects the conclusions of the two notifying Parties, namely Norway and Canada. Where possible, information provided by these two Parties on hazards has been presented together, while the risk assessments, which are specific to the conditions prevailing in the Parties, are presented separately. This information is taken from the documents referenced in the notifications in support of the final regulatory actions banning short-chain chlorinated paraffins.

The notification from Canada was first reported in PIC Circular XXXVIII of December 2013 and the notification from Norway in PIC Circular XV of June 2002.

Further information – short-chain chlorinated paraffins

1.	**Physico-Chemical properties**	
1.1	**Identity**	Short-chain chlorinated paraffins (SCCP) with a chlorination degree of more than 48% by weight. (short-chain) chlorinated paraffins are used in the underlying documentation for this DGD. For clarification purposes, only the abbreviations SCCP or CP are used in this report.
1.2	**Formula**	$C_xH_{(2x-y+2)}Cl_y$, where x=10-13 and y=1-13 (European Chemicals Bureau (2000) with a chlorination degree of more than 48% by weight.
1.3	**Colour and Texture**	clear to yellowish liquid (ECB, 2000)
1.4	**Decomposition temperature**	-
1.6	**Density (g/cm^3)**	-
1.7	**Resistance to acids**	-
1.8	**Resistance to alkalis**	-
1.9	**Tensile strength (10^3 kg/cm^2)**	-
2	**Toxicological properties**	
2.1	**General**	
2.1.1	**Mode of Action**	Narcotic
2.1.2	**Symptoms of poisoning**	-
2.1.3	**Absorption, distribution, excretion and metabolism in mammals**	In general there is very limited information on the toxicokinetics of SCCP and there is no information with respect to differing chain length and degree of chlorination. No information is available on the toxicokinetics of these substances following inhalation or dermal exposure in animals. However the physicochemical properties and information on longer chain chlorinated paraffins indicate that dermal absorption is predicted to be minimal. With respect to oral exposure, only limited studies on SCCP are available. Significant absorption (up to about 60% of the administered dose) does occur following oral administration. One study indicated that absorption is greater for SCCP with lower chlorination states. Absorbed CP have been shown to distribute preferentially to tissues of high metabolic activity and/or high rate of cell proliferation, following oral dosing. No attempts have been made to identify any metabolites of CP, although cytochrome P450 oxidation to CO_2 has been demonstrated. CP and/or their metabolites are excreted via exhaled air, urine and faeces, with up to approximately 60% of the administered dose being excreted in the air and urine in 12 hours. The only information on the toxicokinetics of SCCP in humans is from an in vitro study which demonstrated extremely poor absorption across skin samples (European Communities, 2000).

2.2 Toxicology studies

2.2.1 Acute toxicity

There is no information available on the effects of acute exposure to SCCP in humans. However, the limited information available from animal studies clearly demonstrates that SCCP are of very low acute toxicity, with no toxicity occurring in rats following 1-hour exposure to a vapour or aerosol of 3300 mg/m^3 or with a dermal dose of 2.8 g/kg, and some signs of systemic toxicity with oral doses of up to 13 g/kg in rats and 27 g/kg in mice. A very high, unsubstantiated rabbit dermal LD_{50} of approximately 13 g/kg has been reported. The nature and degree of effects were independent from the degree of chlorination (European Communities, 2000).

The acute toxicity of all CP is considered to be low with oral LD_{50} values for rats and mice being greater than 4 g/kg b.w. (Dover Chemical Corp., 1975; Birtley et al., 1980; Bucher et al., 1987). Signs of toxicity in rats, which were most evident following oral administration of the shorter chain CP (doses greater than 4 g/kg b.w.) included piloerection, muscular incoordination, and urinary and fecal incontinence (Birtley et al., 1980; Government of Canada, 1993).

2.2.2 Short term toxicity

The liver and thyroid were identified as target organs in oral studies in rats and mice, however, the thyroid effects seen in rats and mice are considered unlikely to be relevant to human health. Other signs of toxicity, such as reduction in body weight gain and increase in kidney weight, were observed in several 14- and 90-days studies in rats and mice. NOAELs for effects considered relevant to human health of 100 and 1000 mg/kg bw/day were identified in rats and mice respectively (Norwegian notification).

2.2.3 Genotoxicity (including mutagenicity)

Overall, the data available (and a consideration of the generally unreactive nature of the SCCP), indicate that SCCP as a group are not mutagenic (Norwegian notification).

Available data are limited to the genotoxicity of the short chain CP. Although not mutagenic in bacterial assays in-vitro with or without metabolic activation (Birtley et al., 1980; NTP, 1986a), short chain CP have been clastogenic in in-vitro bioassays in the absence of metabolic activation (Myhr et al., 1990) and have also induced cell transformation in the majority of available in-vitro assays of this endpoint (ICI, 1982a). In two in-vivo studies, the complete reports of which were not available for this assessment, short chain CP did not induce dominant lethal mutations in rats or increase the frequency of chromosomal aberrations in bone marrow cells in rats (Serrone et al., 1987; Government of Canada, 1993).

2.2.4 Long term toxicity and carcinogenicity

In rodent studies the chlorinated paraffins tested produced toxicologically significant, dose-related increases in the incidence of several tumour types, e.g. in the liver, thyroid and kidney.

The substance is classified as carcinogenic in category 3, i.e. substances that cause concern for man owing to possible carcinogenic effects, but in respect of which the available information is not adequate for making a satisfactory assessment (Norwegian notification).

For SCCP, 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 SCCP 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 SCCP 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 SCCP approach or exceed the

TDI for these compounds, which, on the basis of available information, is likely also protective for potential carcinogenicity (UNEP/FAO/RC/CRC.10/6 section 2.4.2.1).

The US National Toxicology Programme (NTP) also conducted studies on SCCPs in both rats and mice. In a 13-weeks study where rats were dosed with SCCPs by gavage, a dose-related increase in relative liver weight was observed starting from the lowest dose of 313 mg/kg/day. According to NTP there was clear evidence for carcinogenicity due to increased incidences of hepatocellular neoplasms (primarily neoplastic nodules) in male and female rats, of adenomas or adenocarcinomas (combined) of the kidney tubular cells in male rats, and of follicular cell adenomas or carcinomas (combined) of the thyroid gland in female rats. Also mononuclear leukemia in male rats had been related to the exposure of SCCPs (NTP, 1986). The NTP also conducted a 13 week and a two year lifetime study on mice (NTP, 1986). In the 13 weeks study, a significantly increased relative liver weight was observed at doses of 250 mg/kg/day and higher. In the 2 years carcinogenicity study, doses of 125 and 250 mg/kg/day produced clinical signs of intoxication (decreased activity, prominent backbones, abnormal breathing) at both dose levels and survival was decreased in top dose females. Other effects included dose-related increases in hepatocellular carcinomas and adenomas, and in thyroid follicular cell carcinomas and adenomas in females (POPRC 2015).

Based on these studies, the International Agency for Research on Cancer determined in 1990 that there is sufficient evidence for the carcinogenicity (possibly carcinogenic – groups 2B) of the commercial chlorinated paraffin product tested, which is described as an average carbon-chain length C12 and average degree of chlorination 60% (IARC 1990). In the 13th report on carcinogens SCCPs (are classified as reasonably anticipated to be human carcinogens. Several mechanistic studies were conducted to understand the mechanisms of these tumours and whether they are relevant for human health (EC 2000). SCCPs are included in the State of California Office of Environmental Health Hazard Assessment proposition 65 list of chemicals known to the state to cause cancer and they were listed in 1999(POPRC 2015).

The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) reviewed a draft of the EU risk assessment for SCCPs. The CSTEE concluded that:

"The liver and thyroid are target organs in repeated dose studies with rats and mice. The liver damage is associated with peroxisome proliferation, whereas the thyroid effects are correlated to altered thyroid hormone status and glucuronyl transferase induction. Humans would be much less sensitive to peroxisome proliferation and thyroid hormone perturbation than rats and mice."

CSTEE who was invited to review the EU Risk Assessment Report (RAR) conclusions on SCCPs stated that the alveolar/bronchiolar carcinomas in male mice should not totally be discounted but acknowledged that "the control animals in this experiment did not show any evidence of lung tumours, whereas the historical control incidence was 5.8%. A dose-related trend was seen with the lowest effective dose of 125 mg/kg/day. The underlying mechanism for this finding is not known, although it should be noted that the chlorinated paraffins are not genotoxic. It was the view of CSTEE that the finding of lung tumours in male mice might be of importance for humans (CSTEE 1998). The final EU risk assessment (EC 2000) noted that although there was an increase in alveolar/bronchiolar carcinomas in mice, the results were within historical control ranges and the controls had a greater incidence of adenomas of the lung than the treated animals. The EU concluded that rodent studies showed dose related increases in adenomas and carcinomas in the liver, thyroid, and kidney. They determined that there was insufficient evidence to conclude that the carcinogenicity observations in the liver and thyroid in mice and the benign tumours in the kidney of male rats were a male rat specific event and consequently the concern for humans could not be ruled out. SCCPs are classified in the EU as a Carcinogen Category 3: R40 – Limited evidence of a carcinogenic effect, and are similarly classified as hazardous in Australia. According to the globalized harmonised system (GHS) which is implemented by the CLP regulation (Commission Regulation (EC) No 1272/2008) in the European Union SSCPs would be classified with Carc Cat 2, H 351: Suspected of causing cancer.

A recent in vitro study with human metabolically competent hepatoma cells (Hep G2) studied the effects of SCCPs on different endpoints. Environmental relevant concentrations of 1µg/l and 10 µg/l lead to significant reduction in cell viability, perturbation of energy production, protein biosynthesis, fatty acid metabolism, ammonia recycling(Geng et al., 2015)(POPRC 2015).

A recent study on the induction of renal tumours in male rats by SCCPs (Warnasuriya et al. 2010, submitted by IPEN as an Annex E 2010 submission) indicates that the mechanism by which renal carcinogenic effects is induced by SCCPs is complex and does not follow the classic profile of male-rat specific alpha-2-urinary globulin (α2u) nephropathy, i.e., accumulation of renal α2u and increase in regenerative cell proliferation. Though SCCPs were found to bind to α2u, exposure to SCCPs resulted in a down-regulation of α2u in the liver leading to no observed accumulation of renal α2u or increase in renal cell proliferation. However, the little α2u that was expressed in the liver appeared to accumulate in the kidney; this, plus the binding of SCCPs to the α2u indicates that α2u nephropathy can not be ruled out. It is hypothesized that peroxisome proliferation in the liver may be responsible for the suppression of α2u expression. As peroxisome proliferation is dose-dependent with SCCPs, lower SCCP doses may result in less α2u expression, thus leading to greater α2u nephropathy and an inverse dose response in renal tumour incidence, as was observed in one study (NTP 1986). Further study is needed to determine the exact mechanism of renal tumour induction by SCCPs before it can be concluded that it is male-rat specific (POPRC 2015).

The most recent assessment of the EU derived a NOAEL of 10 mg/kg/day for subchronic exposure and concluded that the potential toxicological effects of SCCPs on mammals are on the liver, the thyroid hormone system, and the kidneys, e.g., by causing hepatic enzyme induction and thyroid hyperactivity, which in the long-term can lead to carcinogenicity in these organs. Based on the available database, an overall NOAEL of 10 mg/kg/day has been deduced. It has been stated that this NOAEL does not cover chronic exposure situations. No NOAEL can be obtained from the chronic studies (ECHA 2008)(POPRC 2015).

2.2.5 Effects on reproduction

There are no data available on fertility in animals; however, no changes were seen in the reproductive organs in rats and mice treated for 13 weeks with up to 5000 and 2000 mg/kg/day, respectively. In a study in rats chlorinated paraffins produced developmental effects at a dose which also caused maternal toxicity (2000 mg/kg), but no developmental effects at lower doses (500 mg/kg and below). For developmental effects a NOAEL of 500 mg/kg/day has been established (Norwegian notification).

In a series of developmental studies conducted for the Chlorinated Paraffins Manufacturers Toxicology Testing Consortium, the number and location of viable and nonviable fetuses, early and late resorptions, the number of total implantations and corpora lutea, and the incidence of fetal malformations were examined following administration of a short chain CP (C10-13, 58% C1) by gavage in corn oil to pregnant Charles River rats on days 6 to 19 of gestation and pregnant Dutch Belted rabbits on days 6 to 27 of gestation. An increase in the incidence of adactyly and/or shortened digits in the offspring of rats exposed to a maternally toxic dose [2000 mg/kg bw/day by gavage in corn oil] (IRDC, 1982) and embryo- or feto-toxic effects at doses less than those that were toxic to the mothers were observed in rabbits exposed to 30 and 100 mg/kg b.w. (IRDC, 1983a; Government of Canada, 1993).

2.2.6 Neurotoxicity/ delayed neurotoxicity, Special studies where available

Available data are extremely limited on the potential neurotoxicity of short chain chlorinated paraffins. Following oral administration of a single dose (1 mg/kg b.w.) of a short chain CP (polychlorohexadecane) to 10-day-old male and female mice, there was no effect on muscarinic receptors, though it was suggested on the basis of an observed decrease in the Vmax for sodium-dependent choline uptake, that there was a presynaptic effect on the cholinergic system (Eriksson and Nordberg, 1986). There was a dose-related trend to decreased motor capacity in adult NMRI male mice administered a single dose of 30 to 300 mg/kg bw of a short chain CP (C10-13, 49% C1) intraperitoneally, which was statistically significant at the highest dose (Eriksson and Kihlstrom, 1985; Government of Canada, 1993).

2.2.7 Summary of mammalian toxicity and overall evaluation

- Limited information available from animal studies demonstrates that SCCP are of very low acute toxicity.
- For short-term toxicity, the liver and thyroid were identified as target organs in oral studies in rats and mice, however, the thyroid effects seen in rats and mice are considered unlikely to be relevant to human health.
- Regarding mutagenicity, the data available (and a consideration of the generally unreactive nature of the SCCP), indicate that SCCP as a group are not mutagenic.
- SCCP are suspected of causing cancer.
- Developmental effects of SCCP were observed in high dose groups in animal studies (2000 – 5000 mg/kg bw/day).
- Available data are extremely limited on the potential neurotoxicity of SCCP.

3 Human exposure/Risk evaluation

3.1 Food

Table 3.21 Concentration of combines short and intermediate chain length chlorinated paraffins (C_{10-20}) in human foodstuff (Campbell and McConnell, 1980)

Foodstuff class	No of samples analysed	Average concentration of C_{10-20} chlorinated paraffins (µg/kg)
Dairy products	13	300
Vegetable oils and derivatives	6	150
Fruit and vegetables	16	5
Beverages	6	ND

ND = not detected (detection limit = 50 µg/kg)
*Detected in approximately 70% of samples analysed
(European Communities, 2000)

Based on log K_{ow}`s of > 6, accumulation of CP via the food chain (i.e., biomagnification) could be significant (Thomann, 1989). In studies on uptake of various short chain (C10-13) chlorinated paraffins from food using rainbow trout (*Oncorhynchus mykiss*) and bleaks (*Alburnus alburnus*), BAFs ranged from 2 to 41 on a wet weight (w.w.) basis (Lombardo et al., 1975; Bengtsson and Ofstad, 1982), indicating that biomagnification could occur in the environment (Government of Canada, 1993).

In a market basket survey (KAN-DO Office and Pesticides Team, 1995) [3] of 234 ready to-eat foods, which represented approximately 5000 food types in American diets, “Chlorowax 500C” was detected once, in enriched white bread, at a concentration of 0.13 µg/g. Food items were screened by gas or liquid chromatography using ion-selective detectors. Findings were confirmed by unspecified analysis (Government of Canada, 2003).

Upper-bound estimates of intake of SCCP were calculated for the general Canadian population. For each age group in the Canadian population, virtually all of the estimated intake is from food. The upper-bound estimated intake of breast-fed infants was 1.7 µg/kg bw per day, and that of formula-fed infants was 0.01 µg/kg bw per day. For the remaining age groups, intakes ranged from 5.1 µg/kg bw per day for adults over 60 years of age to 26.0 µg/kg bw per day for infants who were not formula fed (i.e., those being introduced to solid foods).

Canadian data incorporated within this estimate include high-confidence values in fish (whole carp determined by GC/ECNI-HRMS) and data on breast milk, for which details of sampling and analysis were not reported. Estimated intake of SCCP in fish represents up to 58% of the total daily intake. The intake from dairy products, which accounts for 89.9% of the intake of infants not formula fed, is based upon limited sampling and analysis — considered semiquantitative only — of dairy products in the United Kingdom, reported in 1980. Probably the most representative estimates of intake are those from cereals, which are based upon data reported in an American

		market basket survey, carried out from 1982 to 1991; however, intake from this foodstuff constitutes <0.1% of total estimated intake, and analytical methods were not specified. Intake of SCCP by a potentially higher-exposure subgroup of Inuit for whom the primary source of food is subsistence hunting and fishing (Kuhnlein, 1989; Kinloch et al., 1992) was also estimated, based on data on concentrations of SCCP in blubber from marine mammals in Canada (Tomy et al. 2000) and less specific data (including both SCCP and MCCP) for terrestrial and marine mammals from Sweden (Jansson et al., 1993). On the basis of these data, the estimated intake of an Inuit adult, namely 1.47 µg/kg bw per day, is well within the range of values estimated above for the general population (see supporting documentation) (Government of Canada, 2003).
3.2	**Air**	Tomy (1997) determined SCCP (C10–13, 60–70% chlorine) in 24-hour air samples collected daily during a 4-month period in the summer of 1990 in Egbert, Ontario, a "rural site northwest of Toronto," by HRGC/ECNI-HRMS (Muir et al., 1999). Concentrations ranged from 65 to 924 pg/m^3. Although a summary statistic of 543 pg/m^3 was reported, it was not specified whether this was a mean or median value. Egbert has also been reported to be near an "industrialized area" (Muir et al., 2000). Lower concentrations of SCCP have been identified at other sites in Canada (Halsall et al., 1998; Stern et al., 1998; Bidleman et al., 1999, 2000, 2001; Muir et al., 2001) (Government of Canada, 2003).
3.3	**Water**	Data on concentrations of SCCP in drinking water in Canada or elsewhere were not identified. The maximum concentration of SCCP (C10–13, 50–70% chlorine) in the Red River, at a site remote from industrialized areas, was 0.05 µg/L (Tomy, 1997) (Government of Canada, 2003).
3.4	**Occupational exposure**	At the exposure levels presented (negligible up to 63 mg/m^3), the only effects that are likely to be of concern are those arising from repeated exposures (doses), i.e. general toxicity, kidney carcinogenicity and developmental effects. When compared to the relevant NOAELs, in all but one case, the margin of safety is considered to be adequate, that is at least two orders of magnitude. While it is important not to read too much into simple ratios, this does suggest that, in general, the use of the substance is appropriately controlled. While certain uses imply a narrower margin of safety, these are not considered to be a cause for concern (European Communities, 2000)
3.5	**Medical data contributing to regulatory decision**	-
3.6	**Public exposure**	The only effects that are likely to be of concern are those arising from repeated exposures (doses), that is general toxicity, kidney carcinogenicity and developmental effects. When compared to the relevant NOAELs, the margins of safety are well over three orders of magnitude and, given the conservative nature of the exposure calculations, in all probability considerably more. While it is important not to read too much into simple ratios, this does suggest that the use of the substance poses no significant risk for consumers (European Communities, 2000).
3.7	**Summary-overall risk evaluation**	The only effects that are likely to be of concern are those arising from repeated exposures (doses), that is general toxicity, kidney carcinogenicity and developmental effects. When compared to the relevant NOAELs, the margins of safety are well over three orders of magnitude and, given the conservative nature of the exposure calculations, in all probability considerably more. While it is important not to read too much into simple ratios, this does suggest that the use of the substance poses no significant risk for both workers and consumers (European Communities, 2000). Available data relevant to consideration of the weight of evidence for proposed modes of induction of liver, kidney and thyroid tumours associated with exposure to SCCP, although limited, are suggestive that tolerable intakes that protect for non-neoplastic precursor effects will likely also be protective for cancer. However, owing

principally to limited investigation of aspects such as recovery and inadequate documentation of relevant studies, there is considerable uncertainty in drawing this conclusion, particularly for the thyroid tumours (Government of Canada, 2008).

4 Environmental fate and effects

4.1 Fate

In the EU risk assessment, it was found that some major characteristics of C10-13 chloroalkanes are relevant for the assessment of exposure to the environment: the C10-13 chloroalkanes are not hydrolysed in water; are not readily or inherently biodegradable; have a high log Kow value (4.4 - 8) and have an estimated atmospheric half-life of 1.9 - 7.2 days. The high log Kow values indicate a high potential for bioaccumulation, strong adsorption to sludge and sediments and very low mobility in soil.

High bioconcentration factors have been reported with a variety of freshwater and marine organisms (ranging from 1000 to 50000 for the whole organism, with higher values for individual tissues) (OSPAR, 2009).

Few data are available on the environmental fate of CP because of the complex nature of the mixtures and difficulties in measuring low levels. Based on general patterns of behaviour of hydrophobic organics in the environment, it is likely that CP are fairly immobile, remain adsorbed onto soil or sediment particles, and are slowly degraded. In the natural environment, CP are generally stable, but degradation is possible by micro-organisms (Madeley and Birtley, 1980). The ability of aerobic micro-organisms to oxidize a range of CP depends on the previous acclimatization of the microbes, the chain length, and the degree of chlorination of the CP. Short and medium chain CP (i.e. C10-20) are degraded most rapidly. The longer the carbon chain and the higher the chlorine content, the less chlorine is released (Omori et al., 1987).

Few data have been identified on the mobility and transport of CP residues from sites of manufacturing, use, or disposal. However, some of the calculated Henry's Law constants for CP are similar to those for chlorinated aliphatic pesticides, such as toxaphene, chlordane, and aldrin (Sunito et al., 1988), which are known to be transported in the atmosphere. Airborne dispersion of CP has been found in the United Kingdom and Sweden where monitoring data indicate widespread levels of low contamination in water, sediments, aquatic and terrestrial biota, and even commercial foods (Campbell and McConnell, 1980; Jansson et al., 1993).

Chlorinated paraffins are generally considered to be persistent. Hydrolysis, oxidation, and photolysis with visible or near ultraviolet radiation are insignificant routes of transformation at ambient temperatures. No experimental data are available on the fate of any CP that volatilize to the atmosphere. However, it may be assumed that any volatilized CP would be subject to attack by hydroxyl radicals in the troposphere. Using the method of Atkinson (1986) for estimating the rate constant for reaction of chlorinated paraffins with hydroxyl radicals, the likely tropospheric half-life is a few days under summer conditions.

While data indicate a potential for bioaccumulation, few bioconcentration factors (BCFs) or biomagnification factors (BAFs) have been experimentally determined. The uptake and accumulation of CP in fish from water and food appear to be inversely proportional to molecular weight, i.e., CP with short chain length and low chlorine content are taken up most rapidly. Similarly, depuration is slowest for highly chlorinated forms. Measurement of BCFs and BAFs is difficult due to the low water solubility of these substances, and subsequent slow uptake rates requiring long exposure periods to achieve steady-state equilibrium. In several of the reviewed tests, it was unclear whether steady-state had been achieved. Reported bioconcentration factors vary dramatically between different CP and between species, ranging from 0.007 to 139000 (Sundstrom and Renberg, 1985). The highest bioconcentration factor, which was observed for mussels (Renberg et al., 1986), was reported at a much lower concentration of chlorinated paraffins in water than that in most other studies. Observations for dioxins and furans have been similar, with Cook et al. (1991) reporting much higher BCFs when aquatic species were exposed to concentrations of pg/L rather than ng/L.

Based on log Kow`s of >6, accumulation of CP via the food chain (i.e., biomagnification) could be significant (Thomann, 1989). In studies on uptake of various short chain (C10-13) chlorinated paraffins from food using rainbow trout (*Oncorhynchus mykiss*) and bleaks (*Alburnus alburnus*), BAFs ranged from 2 to 41 on a wet weight (w.w.) basis (Lombardo et al., 1975; Bengtsson and Ofstad, 1982), indicating that biomagnification could occur in the environment (Government of Canada, 1993).

4.1.1 Soil

Predicted concentrations of short chain length chlorinated paraffins in soil have been calculated using EUSES (see Section 3.1.1.2). The concentrations obtained in the regional model were 11.5 µg/kg wet wt in natural/industrial soil and 10.8 mg/kg wet wt in agricultural soil. Similarly the levels calculated using the continental model were 4.6 µg/kg wet wt in natural/industrial soil and 0.95 mg/kg wet wt in agricultural soil respectively. The high level predicted in agricultural soil is mainly due to the assumption that high levels of chlorinated paraffins will be present in sewage sludge applied to the soil.

Short chain length chlorinated paraffins have been measured at levels of 47-65 mg/kg dry weight in sewage sludge from a waste water treatment plant in Germany that received both industrial and domestic wastewater (see Section 3.1.1.3) (European Communities, 2000).

Concentrations of SCCP in soil in Canada or elsewhere were not identified. The concentrations in surface sediment in harbours in Lake Ontario ranged from 5.9 to 290 ng/g dry weight (Muir et al., 2001). Analyses were by HRGC/ECNI-HRMS (Government of Canada, 2003).

4.1.2 Water

Short chain length chlorinated paraffins are likely to adsorb strongly onto suspended sediments. When interpreting the measured levels of chlorinated paraffins in water it is important to try to distinguish between levels that refer to chlorinated paraffins in the dissolved phase and those that refer to chlorinated paraffin adsorbed onto suspended matter (European Communities, 2000).

Concentrations of SCCP in surface water, sediment, sewage sludge up to 2001

Monitoring data from the EU Risk Assessment Report (1999) and from Organohalogen Compounds, Volume 47 (2000) are summarised here:

Levels of 0.12 - 1.45 µg/L have been measured in surface water in rivers from industrial areas in the United Kingdom in the year 1986;

- Levels of 0.50 - 1.2 µg/L and 0.05 - 0.12 µg/L have been measured in two rivers in Germany in the years 1987 and 1994, respectively. These values include sites downstream from a chlorinated paraffins production plant;
- Levels of 17 - 83 µg/kg dry weight in sediments have been measured in rivers in Germany in 1994. These values also includes sites downstream from a chlorinated paraffins production plant;
- Levels of 47 - 65 µg/g in sewage sludge have been measured near a metal working plant in Germany. Further levels around 0.12 µg/L in the run-off water from the sewage plant into a nearby river, and of 0.08 and 0.07 µg/L in the river water, up and downstream from the metal working plant have been measured in the years 1991 to 1993;
- Levels of 18 - 275 µg/kg dry weight in surface sediments have been measured in three lakes in Canada;
- Levels of 0.0073 - 0.29 µg/g in surface sediment have been measured in harbour areas along Lake Ontario;
- Average levels around 1.8 µg/g have been measured in sediment of the Detroit River at Lake Eire in Canada;
- Levels of 0.06 - 0.448 µg/L have been measured in final effluent from sewage treatment plants in southern Ontario in Canada in 1998;
- Levels of around 0.0045 µg/g dry weight have been measured in sediment in Lake Hazen on Ellesmere Island in the Arctic;

- Estimates of SCCP in waters in non-industrial areas compared to marine waters and industrial areas in the United Kingdom were 0.1 - 0.3, 0.1 - 1 and 0.1 - 2 µg/L, respectively.

These data were estimated from analytical values for all chlorinated paraffins in the range C10-C20 (data published in 1980).

Monitoring data of SCCP in sediments, water, digested sludge and soil published after 2001

- In general, Baltic Sea sediments were more contaminated with Chloroparaffins (CP) than North Sea sediments. The concentrations of SCCP in sediments from the North Sea varied between 5 to 112 ng/g dw and in sediments from the Baltic Sea between 116 to 377 ng/g dw. The samples were collected between August 2001 and May 2003 (Huttig and Oehme, 2005);
- The concentrations of SCCP in surface sediments collected during 1998 in Lake Ontario in North America were on average 49 ng/g dw with the highest concentrations ranging from 147 to 410 ng/g dw (Marvin *et al.* 2003). The highest concentrations were found in the most industrialised areas. Core samples from a polluted site in the Niagara Basin showed a decreasing trend of accumulation of SCCP with the highest peak during the 1970s of about 700 - 800 ng/g dw. However at a background site in Lake Ontario there was still a slight increase in accumulation of SCCP (Marvin *et al.* 2003);
- SCCP and MCCP (medium chain chlorinated paraffins) in samples from the UNITED KINGDOM collected 1983 to 1988 showed concentration levels in sediment of <0.2 - 65.1 mg/kg dw, in water <0.1 - 1.7 µg/L, in digested sewage 1.8 - 93.1 mg/kg dw and in soil <0.1 mg/kg dw (Nicholls *et al.* 2001). These sampling sites were chosen on the basis of target specific industries;
- Sediments in 11 Czech rivers were collected during 2003 and 2004, were analysed for SCCP. Concentrations of SCCP were between 6 to 397 ng/g dw. The highest concentration occurred close to a chemical and electro engineering industry (Pribylová *et al.*, 2006);
- The concentrations of SCCP in sediments from the Czech Republic varied in the Kosetice area between 24 to 46 ng/g dw, in the Zlin area 16 to 181 ng/g dw and in the Beroun area from 5 to 22 ng/g dw (Stejnarova *et al.* 2005). The Kosetice area is considered to be a background area, the Zlin area is a typical industrial region with rubber, tanning and textile industries and the Beroun area represents the cement and machinery industries;
- Sediments from Lake Mälaren in Sweden were collected close to an urban area,
- Stockholm. The concentrations of SCCP in the sediments varied between 170 to
- 3300 ng/g dw in samples collected at sites close to the city and between 8 - 63 ng/g dw at urban background sites (Sternbeck *et al.*, 2003);
- Sediment samples were collected in Norway and analysed for SCCP and the results varies between 5.8 to 1300 ng/g dw. High concentrations were found in *e.g.* Trondheim harbour, while Tromsö harbour showed as low concentrations as 5.8 ng/g dw (Fjeld *et al.*2004) (OSPAR, 2009).

SCCP were detected in surface waters in Canada and the United Kingdom. Low levels of dissolved total (C10-13) SCCP were measured in western Lake Ontario between 1999 and 2004 (Muir et al. 2001, Houde et al. 2006). The concentration of total SCCP was 1.75 ng/L in 1999. Concentrations of total SCCP ranged from 0.606 – 1.935 ng/L over the 2000 – 2004 sampling period. Concentrations were generally greater in western Lake Ontario, likely due to the proximity of large urban areas (Houde et al. 2006). SCCP concentrations of 30 ± 14 ng/L were measured in the Red River in Selkirk, Manitoba, over a 6-month period in 1995 (Tomy 1997) (Government of Canada, 2008).

4.1.3 Air

Predicted concentrations of short chain length chlorinated paraffins in air have been calculated using EUSES for the local, regional and continental scenarios (see Section 3.1.1.2). The estimated regional air concentration is 11.6 ng/m^3. It is thought that direct emissions of chlorinated paraffin vapour to the atmosphere from local sources are likely to be very low (most emissions will be to water), therefore the PEClocal (air) is likely to be very low. The predicted concentrations in air from EUSES are <2.79 ng/m^3 for most local scenarios, which are lower than the regional background concentration of 11.6 ng/m^3. The one exception to this is the leather use (scenario B), where a direct releases to air give an estimated concentration during an emission event of 138 ng/m^3 and an annual average PEClocal (air) of 17.8 ng/m^3. In the regional and continental model, very little direct input into the atmosphere was assumed and so the levels reflect the small, but measurable volatility of the substance (see also Section 3.1.0.7).

No measured data appear to exist on the air levels of short chain length chlorinated paraffins (European Communities, 2000).

SCCP were detected in air in Canada, United Kingdom and Norway. They have also been detected in arctic air and in air of other remote areas (Section 4.2.1). Concentrations of SCCP in air samples collected at Egbert, Ontario, Canada, in 1990 ranged from 65 to 924 pg/m^3 (Tomy 1997; Tomy et. al. 1998a). Concentrations of SCCP over Lake Ontario in 1999 and 2000 ranged from 120 to 1,510 pg/m^3 (Muir et al. 2001).

No atmospheric concentration data are available for MCCP and LCCP, either in

Canada or elsewhere (Government of Canada, 2008).

4.1.4 Bioconcentration

Short chain length chlorinated paraffins have been shown to bioconcentrate to a large extent in fish and molluscs. Bioconcentration factors from various studies ranged from 574-5300 L/kg for fish (whole fish BCF) and from 5785-40900 L/kg for mussel (European Communities, 2000). See also sections 4.1 and 4.2.2

4.1.5 Persistence

Based on general patterns of behaviour of hydrophobic organics in the environment, it is likely that CP are fairly immobile, remain adsorbed onto soil or sediment particles, and are slowly degraded (Government of Canada, 1993). See also section 4.1

SCCPs meet the criterion for persistence for sediment (Annex D, Stockholm Convention). They also are sufficiently persistent in air for long range transport to occur. SCCPs appear to be hydrolytically stable. While there is evidence that low chlorinated SCCPs can readily degrade in water under enhanced conditions, the ecological relevance of the test results is not known. There is insufficient information to conclude on the persistence of higher chlorinated SCCPs in water. There is also insufficient information on their persistence in soil. Overall, SCCPs are considered to meet the Stockholm Convention criteria for persistence (POPRC, 2015).

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

An avian reproduction study using Mallard ducks has been carried out with a C10-12, 58% Cl chlorinated paraffin. The study was a 22 week feeding study, including a 9 week pre-egg-laying period without photostimulation, a 3 week pre-egg-laying period with photostimulation and a 10 week egg laying period with photostimulation. Slight effects on reproduction were seen at 1000 ppm in diet. Therefore the NOAEC is 166 ppm in diet (166 mg/kg food) (European Communities, 2000).

Very limited information is available on SCCP concentrations in tissues of terrestrial wildlife. In Sweden, Jansson et al. (1993) reported CP concentrations (unspecified chain length) in rabbit (Revingeshed, Skåne), moose (Grismsö, Västmanland), reindeer (Ottsjö, Jaämtland) and osprey (from various regions in Sweden) to be 2.9, 4.4, 0.14 and 0.53 mg/kg lipid wt., respectively. Nicholls et al. (2001) reported the concentrations of SCCP and MCCP in earthworms residing in fields on which sludge had been applied ranging from <0.1 to 0.7 mg/kg dry wt. in the United Kingdom in the summer of 1998.

Campbell and McConnell (1980a) determined levels of C10–20 CP in birds in the United Kingdom. The C10–20 levels were likely to be dominated by contributions

from the SCCP and MCCP. Concentrations of C10–20 CP ranged from 0.1 to 1.2 mg/kg weight wt. in liver of birds and from <0.05 to >6 mg/kg in seabird eggs. Concentrations of C20–30 CP ranged from not detected to 1.5 mg/kg weight wt. in liver of birds and from <0.05 to 1 mg/kg in seabird eggs. Reth et al. (2006) quantified SCCP in liver and muscle from the seabirds, little auk (*Alle alle*) and kittiwake (*Rissa tridactyla*) collected at Bear Island (European Arctic). Concentrations between 0.005 and 0.088 mg/kg wet weight were measured. Reth et al. (2006) determined the concentration of C14-15 MCCP in seabirds from the European Arctic. Concentrations ranged from 0.005 to 0.370 mg/kg wet wt (Government of Canada, 2008).

4.2.2 Aquatic species

Fish

Short chain length chlorinated paraffins appear to be of low acute toxicity to fish with 48 and 96 hour LC50s in excess of 100 mg/L. However, it should be noted that such values are well in excess of the solubility of this group of compounds. Chronic toxicity values include a 60 day LC50 at 0.34 mg/L and no observed effect concentrations of <0.040 and 0.28 mg/L for rainbow trout and sheepshead minnow respectively (European Communities, 2000).

Aquatic invertebrates

Twenty four hour EC50s for daphnids range from 0.3 to 11.1 mg/L with acute no observed effect concentrations ranging from 0.06 to 2 mg/L. There appears to be no clear pattern with regard to the effects of the carrier substance or the degree of chlorination on the acute toxicity of short chain length paraffins to *D. magna*. In 21day tests EC50s ranged from 0.101 to 0.228 mg/L; NOECs ranged from 0.005 to 0.05 mg/L.

The NOEC of 0.005 mg/L for the 58% chlorinated short chain length paraffin means that this species is the most sensitive aquatic species tested.

The second instar of the midge *Chironomus tentans* was exposed to a C10-12, 58% chlorinated paraffin at levels ranging from 18 to 162 µg/L for 48 hours. This caused no adverse effects on the test organism. The use of this paraffin over the whole 49 day life cycle at concentrations of 61 to 394 µg/L also gave no significant response except in halting adult emergence at 121 and 394 µg/L. This led to a maximum acceptable toxicant concentration (MATC) for this paraffin of between 78 and 121 µg/L, with a geometric estimated value for the MATC of 97 µg/L. The NOEC for this study is 61 µg/L (E & G Bionomics, 1983).

Thompson and Madeley (1983d) studied the toxicity of a 58% chlorinated short chain length paraffin to the mysid shrimp *Mysidopsis bahia* and found the 96 hour LC50 to be between 14.1 and 15.5 µg/L, with the lowest concentration causing a significant mortality at 13.7 µg/L. The chronic toxicity of this compound was studied in 28 day exposures to concentrations of 0.6, 1.2, 2.4, 3.8 and 7.3 µg/L. Significant mortalities were observed in some of the groups during the test but these were not treatment related. There was no treatment-related effect on reproductive rate (offspring per female) or growth over the 28 day test period. A no effect level was determined as 7.3 µg/L.

Madeley and Thompson (1983) studied the toxicity of the 58% chlorinated short chain length paraffin (C10-14) to the mussel *Mytilus edulis* over a period of 60 days. Tests were carried out at measured concentrations of 0.013, 0.044, 0.071, 0.13 and 0.93 mg/L (nominal concentrations were 0.018, 0.056, 0.1, 0.32 and 3.2 mg/L). There was significant mortality at 0.071, 0.13 and 0.93 mg/L with LT50s of 59.3, 39.7 and 26.7 days for the three exposure concentrations respectively. There was no significant mortality observed at concentrations of 0.013 and 0.044 mg/L; reductions in filtration rate were reported but these were not measured quantitatively. The 60-day LC50 was estimated to be 0.074 mg/L based on measured concentrations.

A further study on mussels *Mytilus edulis* using a 58% chlorinated short chain length chlorinated paraffin has been carried out by Thompson and Shillabeer (1993). The study was carried out as a follow up to a bioaccumulation study and only two exposure concentrations were used.

Groups of 30 mussels were exposed to measured concentrations of 2.3 µg/L or 9.3 µg/L in seawater for 12 weeks in a flow-through system. No mortalities were seen in any of the exposure groups or controls, but growth (as assessed by increase in shell length and tissue weight) was significantly reduced in the group exposed to 9.3 µg/L. No significant effects were seen in the group exposed to 2.3 µg/L (European Communities, 2000).

Algae

Ninety-six hour EC50s range from 0.043 to 3.7 mg/L with the marine alga *Skeletonema costatum* appearing to be more sensitive to short chain length paraffins than the freshwater alga *Selenastrum capricornutum*. A NOEC of 12.1 µg/L was reported in the study on *S. costatum*. It should be noted that the EC50 values given for *Selenastrum* exceeded the highest mean measured concentrations of the test substance; they are, therefore, extrapolated values.

Further, the toxic effects seen with the marine alga were transient, with no effects being seen at any concentration after 7 days exposure (European Communities, 2000).

Microorganisms

Short chain length chlorinated paraffins appear to be of low toxicity to the microorganisms tested. In anaerobic microorganisms, Madeley et al. (1983b) used measurements of gas production and its inhibition to assess the toxicity of a short chain length C10-12, 58% chlorinated paraffin to the anaerobic sludge digestion process. This study showed that significant (>10%) inhibition of gas production occurred when chlorinated paraffin concentrations of 3.2, 5.6 and 10% on digester volatile suspended solids were employed.

These effects were observed on the first 3 to 4 days of the experiment, after which, gas production recovered to normal levels until day 10 when the study was terminated. It was concluded that the compound tested caused transient partial inhibition of gas production with rapid recovery and no longer-term effects (European Communities, 2000).

Concentrations of SCCP in Biota up to 2001

- Mussels were collected up and downstream from a chlorinated paraffin manufacturing site in the United States. Measured levels of SCCP ranged between 7 - 280 µg/kg;
- High levels of SCCP have been measured in different marine mammals in the Arctic, such as seal from Iceland and walrus from Western Greenland. The measured concentrations of SCCP were 526 and 426 µg/kg in blubber, respectively;
- On a lipid basis, average levels of 13 µg/kg of SCCP have been measured in breast milk from Inuit women living in communities on the Hudson Strait in Northern Quebec;
- Levels of SCCP of 370 - 1400 µg/kg have been measured in beluga blubber from the St. Lawrence River in Canada;
- Average levels of SCCP of 630 µg/kg, 200 µg/kg, 320 µg/kg and 460 g/kg have been measured in blubber from male beluga collected in different Arctic places; Hendrickson Island, Arivat (Western Hudson Bay), Sanikiluaq (Belcher Island area in southern Hudson Bay) and in Pangnirtung (south eastern Baffin Island), respectively.
- On a lipid basis, levels of around 1500 µg/kg chlorinated paraffins (C6-C16) have been measured in herring (muscle), in the Bothnian Sea, in the Baltic Sea and in Skagerrak in Sweden in the years 1986 and 1987;
- High concentrations of chlorinated paraffins (C6-C16) have also been measured in rabbit and moose (2900 and 4400 µg/kg, respectively on a lipid basis) in Sweden in 1986;
- On a lipid basis, levels of around 130 and 280 µg/kg chlorinated paraffins (C6-C16), respectively, have been measured in ringed seal blubber from Kongsfjorden, Svalbard in 1981 and in grey seal blubber from the Baltic Sea during 1979 - 85;

- On a lipid basis, levels of chlorinated paraffins (C6-C16) of around 1000 µg/kg and 570 µg/kg, respectively, have been measured in whitefish muscle in Lake Storvindeln, Lapland, in Sweden and in Arctic char muscle in Lake Vättern, central Sweden in 1986 and 1987;
- On a lipid basis, levels of chlorinated paraffins (C6-C16) of around 140 µg/kg and 530 µg/kg, respectively, have been measured in reindeer suet and in osprey muscle in Sweden in 1986;
- Levels of chlorinated paraffins (C10-C20) up to 200 µg/kg in fish, 100 - 12 000 µg/kg in mussels, levels in mussels above 200 µg/kg have been measured in the Wyre Estuary close to a paraffinic production site, 50 - 2000 µg/kg have been found in seabirds (eggs), 100 - 1200 µg/kg in heron and guillemot, 200 - 900 µg/kg in herring gull, 50 - 200 µg/kg in sheep close to a chlorinated paraffin production plant and 40 - 100 µg/kg in grey seal have been found in the United Kingdom (data published in year 1980). All these values were estimated from analytical values for all chlorinated paraffins in the range C10 to C20;
- Stern et al. (1998) noted that the Arctic formula group profiles showed higher proportions of the lower chlorinated congeners (Cl5-Cl7), suggesting that the major source of contamination to the Arctic is via long range atmospheric transport.

Monitoring data of SCCP in Biota published after 2001

- In liver samples of little alks collected in the European Arctic SCCP levels of 5 - 88 ng/g ww were found (Reth et al. 2006). The range for SCCP in cod varied from 11 to 70 ng/g ww, and in Arctic char from 7 to 27 ng/g ww;
- Fish from the North Sea and the Baltic Sea were collected during 2002; cod, flounder and North Sea dab. In the Baltic Sea the concentration levels of SCCP varied between 19 and 221 ng/g ww, and in the North Sea the levels varied between 26 and 286 ng/g ww. The congener patterns in the samples from the Baltic Sea were similar to commercial SCCP mixtures and C13 were the most abundant, while the North Sea samples had a higher abundance of C10 (Reth et al. 2005);
- In ringed seals from Pangnirtung and Eureka in the Canadian Arctic, levels of SCCP of 95 and 527 ng/g ww were found, respectively (Braune et al. 2005);
- The concentrations of SCCP and MCCP in biota samples collected during 1983 to 1988 in UNITED KINGDOM were in fish <0.1 - 5.2 mg/kg ww, in benthos <0.05 - 0.8 mg/kg ww and in earthworms <0.1 - 1.7 mg/kg ww (Nicholls et al. 2001);

  (OSPAR, 2009)

Pelagic aquatic organisms

The lowest toxic effect level identified for a pelagic freshwater aquatic species is 8900 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 NOEC is 5000 ng/L.

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 (8900 ng/L) was used to estimate the toxicity to benthic organisms. The LOECbenthic was estimated to be 35.5 mg/kg dry wt. for sediment containing 2% organic carbon (Environment Canada, 2008)

(Government of Canada, 2008).

4.2.3	**Honeybees and other arthropods**	No data available.
4.2.4	**Earthworms**	Soil-dwelling organisms Bezchlebová et al. (2007) investigated the effects of SCCP 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 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 an LC_{50} value for adult survival and EC_{50} and EC_{10} values for reproduction of 5733, 1230, and 660 mg/kg dry wt. (nominal), respectively. The soil CTV for SCCP is 660 mg/kg dry wt (Government of Canada, 2008). In the EU-RAR, there are no studies available on plants, earthworms or other soil-dwelling organisms. In the absence of any ecotoxicological data for soil-dwelling organisms, the PNEC may provisionally be calculated using the equilibrium partitioning method with the PNEC for aquatic organisms and the soil/water partition coefficient. PNECsoil = Ksoil-water /Psoil · PNECaquatic organisms · 1000 where K soil-water = soil - water partition coefficient = 2736 for a log K_{ow} of 6. Psoil = density of soil = 1700 kg/m^3 However, the ingestion of the soil-bound substance by soil-dwelling organisms may not be sufficiently explained by this relationship for substances with a log Kow greater than 5. The Technical Guidance Document suggests that the PEC/PNEC ratio is increased by a factor of 10 to take account of ingestion. The reported log Kow for short chain length chlorinated paraffins range from 4.39-8.69 and so the equilibrium partitioning method is not really applicable to these substances. However, in the absence of any other data a tentative PNEC for soil can be calculated assuming a K soil-water of 2736 m^3/m^3. This gives a PNEC for soil of 0.80 mg/kg wet weight. It must be borne in mind that data obtained for aquatic organisms cannot replace data for terrestrial organisms because the effects on aquatic species can only be considered as effects on soil-dwelling organisms which are exposed exclusively to the interstitial water of the soil (European Communities, 2000).
4.2.5	**Soil microorganisms**	See section 4.2.4
4.2.6	**Terrestrial plants**	See section 4.2.4

5 Environmental Exposure/Risk Evaluation

5.1	**Terrestrial vertebrates**	In a 13-week oral (gavage) rat study by IRDC (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 critical toxicity value (CTV) of 1000 mg/kg food (Environment Canada, 2008).

5.2 Aquatic species

A PNEC of 0.5 µg/L has been derived for the freshwater aquatic compartment.

The PEClocal for fresh surface water depends on the release source. The worst case ratios are summarised in Table 3.31.

Table 3.31 PEC/PNEC ratios for the aquatic compartment

Scenario	PEC/PNEC ratio
PEC_{local} Production (2 sites)	**< 0.72 – site specific** **< 0.86 – site specific**
PEC_{local} Metal working (formulation)	**8.6**
PEC_{local} Metal working (use)	**2.8 or 10**
PEC_{local} Rubber formulations	**< 0.68**
PEC_{local} Paints and sealing compounds	**Neglible**
PEC_{local} Leather (formulation: scenario A) **PEC_{local} Leather (formulation: scenario B)** **PEC_{local} Leater (use: scenario B)**	**[124]** **154** **154**
PEC_{local} Textile applications	**Negligible**
$PEC_{regional}$	**0.66**
$PEC_{continental}$	**0.066**

The PEC/PNEC ratios indicate a significant risk to freshwater aquatic organisms from some local sources (European Communities, 2000).

5.3 Honey bees

no data

5.4 Earthworms

Based on the calculated PEC/PNEC ratio for soil-dwelling organisms (see section 4.2.4), the following was concluded in the EU-RAR:

For production sites (site specific data), and use in rubber formulations, paints and sealing compounds and textile applications:

ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.

For all other scenarios:

i) There is a need for further information and/or testing

The need for further information and/or testing should be re-evaluated once the outcome of the risk reduction measures recommended for surface water are known (European Communities, 2000).

5.5 Soil microorganisms

5.6 Summary – overall risk evaluation

The use of short chain length chlorinated paraffins in sealants, rubber, back coating of textiles and paints is not thought to present a risk to the environment. Secondary poisoning is not thought to be of concern, except for leather treatment formulation and use and possibly for use in metal finishing. No risks to the function of sewage treatment plants were identified from either production or any use. For the atmospheric compartment, neither biotic nor abiotic effects are considered likely to occur as a result of production or any use. Short chain length chlorinated paraffins have been raised as a possible concern with regard to long range atmospheric transport. This area is currently being discussed within the appropriate international fora.

The use of short chain length chlorinated paraffins in metal working fluids and in leather finishing has been found to present a risk to aquatic organisms in surface water due to local exposures. Possible risks to sediment-dwelling organisms were identified as a result of production of short chain length chlorinated paraffins, formulation and use of metal cutting fluids and formulation and use of leather finishing products, use in rubber formulations, and at a regional level. There is a possible risk to soil-dwelling organisms in agricultural soils at a local level (for metal working fluid formulation and use, and leather finishing formulation and use) and at a regional level due to spreading of sewage sludge. Further information for the soil and sediment compartments could be gathered to clarify the risk. However, risk reduction methods should be considered for metal working since further information

(either exposure or aquatic toxicity) is unlikely to change significantly the PEC/PNEC ratios calculated for aquatic organisms. Based on the available data, a risk to aquatic organisms cannot be excluded for leather finishing applications either and so risk reduction measures should also be considered for this use (European Communities, 2000).

In the EU risk assessment, it was found that some major characteristics of C10-13 chloroalkanes are relevant for the assessment of exposure to the environment: the C10-13 chloroalkanes are not hydrolysed in water; are not readily or inherently biodegradable; have a high log Kow value (4.4 - 8) and have an estimated atmospheric half-life of 1.9 - 7.2 days. The high log Kow values indicate a high potential for bioaccumulation, strong adsorption to sludge and sediments and very low mobility in soil.

High bioconcentration factors have been reported with a variety of freshwater and marine organisms (ranging from 1000 to 50000 for the whole organism, with high values for individual tissues).

SCCP have been raised as a concern with regard to long range transport. This is currently being discussed within the appropriate international forums. High levels of SCCP in biological samples from the Arctic indicate that these chemicals are effectively transported over long distances (CSTEE 1998) and a draft risk profile made for the Stockholm Convention in October 2008 mentions that:

“SCCP are not expected to degrade significantly by hydrolysis in water, and dated sediment cores indicate that they persist in sediment longer than 1 year. SCCP have atmospheric half-lives ranging from 0.81 to 10.5 days, indicating that they are relatively persistent in air. SCCP have been detected in diverse environmental samples (air, sediment, water, wastewater, fish and marine mammals), and in remote areas such as the Arctic, providing evidence of long-range transport.”

Tumours of the liver, thyroid and kidney (male rats only) were observed in a lifetime carcinogenic study in rats carried out in the US (Organohalogen Compounds, Volume 47, 2000).

It can be concluded that all environmental contamination of SCCP is likely to represent a widespread problem. This is due to the persistent, bioaccumulative and toxic (PBT), as well as the carcinogenic properties of SCCP. It can further be concluded that emissions from different, also diffuse sources, have the potential to reach the maritime area. On the basis of the accessibility of data on the amount of discharges, emissions and losses from several sources, it is not always possible to fully estimate the degree of risk to the marine environment. However, the absence of data to quantify emissions from each source should not be an obstacle to observing potential risks. Hence, the absence of quantifiable data does not eliminate a risk as such (OSPAR, 2009).

Potential to cause environmental harm may be estimated quantitatively using risk quotients (RQs). When RQs exceed 1 (i.e., in this case when Estimated Exposure Values (EEVs) exceed Estimated No-Effect Values (ENEVs)) this is an indication of potential for risk.

It is acknowledged, however, that when risks for persistent and bioaccumulative substances - such as SCCP, MCCP, and C18-20 LCCP - are determined using standard methods, the risks may be underestimated. For example, since it can take decades for persistent substances to achieve maximum steady state concentrations in sediment and soil, EEVs based on monitoring data will be too low if steady state concentrations have not been achieved in these media. Similarly, since it can take a long time for persistent and bioaccumulative substances to reach maximum steady state concentrations in the tissues of laboratory organisms, ENEVs based on standard toxicity tests may underestimate effect thresholds if test durations are insufficient to achieve maximum internal organism concentrations. Furthermore, since food consumption is usually the primary route of exposure to persistent and bioaccumulative substances in the field - especially for top predators - ENEVs may underestimate effect thresholds if the food pathway is not considered in key toxicity studies. These factors are exacerbated when available effects and exposure data are limited, as is the case for the chlorinated paraffins.

Risk quotients were calculated for SCCP, MCCP, C18-20 LCCP and C>20 LCCP (Table 7). For each identified class of risk receptors (e.g., pelagic organisms, benthic organisms), an EEV was selected based on empirical data. The maximum reported field concentration which is relevant to the Canadian environment was used as the EEV.

Chemical concentrations from the Canadian environment were preferably used for EEVs; however, data from other regions in the world were used in the absence of suitable Canadian data. Section 8.2 of the supporting document (Environment Canada, 2008) further discusses this point. An ENEV was determined by dividing a Critical Toxicity Value (CTV) by an assessment factor. CTVs, a detailed description is provide in Section 8.0 of the supporting document (Environment Canada, 2008), typically represent the lowest chronic ecotoxicity value from an available and acceptable data set. Assessment factors were used to reduce the CTV to account for extrapolation from a sometimes limited set of effects data for laboratory organisms, to estimates of effect thresholds for sensitive species in the field. Note that an extra assessment factor was not used to account for the tendency for conventional RQs to underestimate potential for harm for persistent and bioaccumulative substances. Results are summarized in Table 7.

Table 7. List of Estimated Exposure Values (EEV), Critical Toxicity Values (CTV), Assessment Factors (AF), and Estimated No Exposure Values (ENEV) used in the calculation of Risk Quotients (RQ) for SCCPs

Organism	EEV	CTV	AF	ENEV	RQ (EEV/ENEV)
Pelagic	**44.8[a] ng/L**	**8900[b] ng/L**	**10 (lab/field)**	**890 ng/L**	**0.05**
Benthic	**0.41[c] mg/kg**	**35.5[d] mg/kg**	**10 (lab/field)**	**3.55 mg/kg**	**0.12**
Soil-dwelling	**0.64[e] mg/kg**	**660[d] mg/kg**	**10 (lab/field)**	**66.0 mg/kg**	**0.01**
Secondary Consumer	**2.63[f] mg/kg**	**1000[g] mg/kg**	**100 (lab/field & species variations)**	**10 mg/kg**	**0.26**

[a] The highest concentration of SCCPs observed in final effluent of sewage treatment plants in southern Ontario was 448 ng/L at the Woodward Avenue sewage treatment plant in Hamilton, Ontario. A dilution factor of 10 was used to calculate the EEV which results in an EEV of 44.8 ng/L.
[b] 21-day LOEC for *Daphnia magna*
[c] Highest concentration in surface sediments observed from Lake Ontario, Niagara (or west) basin, in 1998.
[d] EC_{10} for *F. candida* reproduction.
[e] The maximum allowable rate for sewage biosolid application to agricultural lands is 8 tonnes of solids per hectare per 5 years (MOE 1998). The soil mass is 5000 tonnes/ha (assuming that the biosolids are incorporated into the top 20cm of soil having a dry soil bulk density of 2500 kg/m^3 (EU 2003)). Using a SCCP concentration in sewage sludge of 200 mg/kg dry wt. and assuming that SCCP-containing sludge is applied to the land for 10 years and that no or little biodegradation of the SCCP occurs, a soil concentration of 0.64 mg/kg dry wt is estimated.
[f] Concentratio of total SCCP found in carp from Hamilton Harbour in Lake Ontario.
[g] The LOAEL for the 13-week oral (gavage) rat study is 100 mg/kg bw/day (IRDC 1984). Interspecies scaling using this LOAEL for a typical adult otter (*lutra Canadensis*) (adult body weight of 8 kg and average daily food ingestion rate of 0.8 kg wet wt. per day) was used to extrapolate to a food concentration for this species (CCME 1998). The resulting CTV was 100 mg/kg food wet wt.
(Government of Canada, 2008).

Annex 2 – Details on final regulatory actions reported

Country Name: Norway

1	**Effective date(s) of entry into force of actions**	The regulation entered into force on January 2001. However, stock items imported or produced before January 2001 could be sold and used until January 2002. As stated in OSPAR decision 95/1, there is a transition period until January 2005 for conveyor belts used in the mining industry and for sealing materials in dams containing SCCP. (UNEP/FAO/RC/CRC.10/6 section 2.2.3).
	Reference to the regulatory document	"Regulation Governing Short Chain Chlorinated Paraffins", laid down by Ministry of the Environment 13 December 2000 with a legal basis in ACT no 79 of 11 June 1976 relating to product control, section 4.
2	**Succinct details of the final regulatory action(s)**	The regulatory action notified by Norway relates to the use of SCCP as industrial chemicals. The use of SCCP is banned by the final regulatory action which states that production, import, export, sale and use of SCCP in pure form, in preparations or in products containing > 0.1 % SCCP is prohibited (UNEP/FAO/RC/CRC.10/6 section 2, 2.2.1). Use for research and analytical purposes is still allowed (UNEP/FAO/RC/CRC.10/6 section 2.5.1).
3	**Reasons for action**	Risk for-long term effects to the aquatic environment. SCCP is also classified as category 3 carcinogen, i.e. there is limited evidence of carcinogenic effects. (UNEP/FAO/RC/CRC.10/6 Annex I, section 2.3).
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect the environment. The regulatory action was based on a risk evaluation taking into account the prevailing conditions in Norway.
4.1	**Risk evaluation**	SCCP are very toxic to aquatic organism, especially daphnia. They degrade slowly in the environment and have a high potential for bioaccumulation. Their negative long term effects in the aquatic environment, the risk secondary poisoning of predators through the food chain, and their potential for long range transport via air and water give rise to serious concerns for long-term effects to the aquatic environment. In the Norwegian notification, reference is made to the EU-RAR, which states that the use of short chain length chlorinated paraffins in metal working fluids and in leather finishing has been found to present a risk to aquatic organisms in surface water due to local exposures (European Communities, 2000).
4.2	**Criteria used**	Risk to the environment.
	Relevance to other States and Region	High concentrations of SCCP in environmental media e.g. in the Baltic Sea, are reported. SCCP are recognized to be of possible concern with regard to long range atmospheric transport. It is concluded that similar environmental problems are likely to be encountered in other countries.
5	**Alternatives**	Though no information on alternatives for SCCP for Norway specifically were mentioned, general information on alternatives was included in the Norwegian supporting documentation (UNEP-FAO-RC-CRC.10-INF-10).
6	**Waste management**	The notifying Party did not provide information on waste management of SCCP.
7	**Other**	None

Country Name: Canada		
1	**Effective date(s) of entry into force of actions**	March 14, 2013
	Reference to the regulatory document	*Prohibition of Certain Toxic Substances Regulations, 2012* Canada Gazette, Part II, Vol. 147, No.1- January 2, 2013.
2	**Succinct details of the final regulatory action(s)**	The regulatory action notified by Canada relates to the use of SCCP as industrial chemicals. The final regulatory action states that all manufacture, use, sale, offer for sale or import of SCCP or products containing them is prohibited, unless SCCP are incidentally present in the product or if they are used in a laboratory for analysis, in scientific research or as a laboratory analytical standard (UNEP/FAO/RC/CRC.10/6 section 2.1, 2.2.1 and 2.2.3).
3	**Reasons for action**	The regulatory action was based on concerns related to human health and environment.
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect human health and environment. The regulatory action was based on a risk evaluation taking into account the prevailing conditions in Canada.
4.1	**Risk evaluation**	The risk evaluation considered all Chlorinated Alkanes (CA), including SCCP, Medium-Chain Chlorinated Alkanes (MCCA) and Long-Chain Chlorinated Alkanes (LCCA). For SCCP, 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 SCCP 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 SCCP 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 SCCP approach or exceed the TDI for these compounds, which, on the basis of available information, is likely also protective for potential carcinogenicity (UNEP/FAO/RC/CRC.10/6 section 2.4.2.1). On the basis of the available information, the latest assessment report from 2008 concludes that SCCP are entering, or may enter, the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (UNEP/FAO/RC/CRC.10/INF/11, p. 184).
4.2	**Criteria used**	Risk to human health and environment.
	Relevance to other States and Region	The presence of SCCP in remote Arctic regions suggests that there is long-range atmospheric transport of SCCP. It is concluded that the considerations that led to the final regulatory action are applicable to a wide geographical area and circumstances.
5	**Alternatives**	Some alternatives were included in the supporting documentation (Environment Canada, Health Canada, 2008). for the following uses: metalworking fluids, polyvinyl chloride, paints and coatings, adhesives and sealants, and rubber and elastomers.
6	**Waste management**	The notifying Party did not provide information on waste management of SCCP.
7	**Other**	None

Annex 3 – Addresses of designated national authorities	
Norway	
C	
Norwegian Pollution Corntrol Authority Section for Chemicals and Metallurgical Industry PO Box 8100 Dep N – 0032 Oslo Norway *Bjørg Fjeld* *Senior Advisor*	**Phone** +47 22 57 34 00 **Fax** +47 22 67 67 06 **E-mail** Bjorg.fjeld@sft.no
Canada	
C	
Environment Canada 351 St. Joseph Blvd. Gatineau, Quebec, K1A 0H3 Canada *Ms. Lucie Desforges* *Director, Chemical Production Division*	**Phone** +1 819-938-4209 **Fax** +1 819-938-4218 **E-mail** Lucie.Desforges@ec.gc.ca

C Industrial chemicals

Annex 4 – References

Regulatory actions

Norway

Ministry of the Environment: Forskrift om kortkjedete klorparaffiner (Regulation Governing Short Chain Chlorinated Paraffins), laid down on 13 December 2000 with a legal basis in Act no 79 of 11 June 1976 relating to product control, section 4 (UNEP/FAO/RC/CRC.10/INF/10, p. 529-532)

Canada

Prohibition of Certain Toxic Substances Regulations (2012), Canada Gazette Part II, Vol. 147, No. 1 – January 2, 2013 ((UNEP/FAO/RC/CRC.10/INF/11, p. 3-25). Available at: http://www.gazette.gc.ca/rp-pr/p2/2013/2013-01-02/html/sor-dors285-eng.html)

Supporting documentation provided by Norway

Borgen, A. R., Schlabach, M., Mariussen, E. (2003). Screening of Chlorinated Paraffins in Norway. Organohalogen Compounds, Volume 60, pages 331-334.

European Communities (2000). European Union Risk Assessment Report, alkanes, C10-13, chloro, CAS No.: 85535-84-8, EINECS No.: 287-476. ISBN 92-828-8451-1. .

Norwegian Pollution Control Authority (SFT) (2001). Halogenerte organiske miljøgifter og kvikksølv i norsk ferskvannsfisk, 1995-1999 (Halogenated organic environmental chemicals and mercury in Norwegian freshwater fish, 1995-1999). SFT 4402-01, Rapport 827/01. (In Norwegian only).

Norwegian Pollution Control Authority (SFT) (2002). Kartlegging av bromerte flammehemmere og klorerte parafiner (Screening of brominated flame retardants and chlorinated paraffins). SFT TA-1924/2002, Rapport 866/02. (In Norwegian only).

Norwegian Pollution Control Authority (SFT) (1999). Kortkjedete høyklorerte paraffiner. Materialstrømsanalyse. (Short-chain highly chlorinated paraffins. Material Flow Analysis). SFT TA-1689/99, Rapport 99/24. (A cover page with a summary in English and first 4 pages of the document in Norwegian only).

Norwegian Pollution Control Authority (SFT) (1996). Overvåking av Hvaler-Singlefjorden og munningen av Iddefjorden 1990-1994. Miljøgifter i organismer. (Monitoring of environmental chemicals in organisms in fjord and coastal area 1990-1994, toxicants in organisms). SFT 3443-96, Rapport 651/96. (In Norwegian only).

OSPAR Commission (2009). Background Document on short chain chlorinated paraffins. Hazardous Substances Series.

OSPAR Commission (2001). Draft OSPAR Background Document on Short Chain Chlorinated Paraffins. ASMO 01/6/10 – HSC 01/5/6-E.

Supporting documentation provided by Canada

Government of Canada (2004a). 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 (2004b). 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 (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.

Government of Canada (1993). Priority Substances List assessment report. Chlorinated paraffins. Minister of Supply and Services, Ottawa, Ontario (ISBN 0- 662-20515-4; Catalogue No. En40-215117E).

Government of Canada (2013). Prohibition of Certain Toxic Substances Regulations, 2012 (SOR/2012-285). Canada Gazette, Part II, Vol. 147, No. 1.

Environment Canada, Health Canada (2008). Proposed Risk Management Approach for Chlorinated Paraffins. Government of Canada, Ottawa.

Others

POPRC (2010). Supporting document for the draft risk profile on short-chain chlorinated paraffins. UNEP/POPS/POPRC.6/INF/15.

POPRC (2015). Short-chain chlorinated paraffins. Risk profile. UNEP/POPS/POPRC.11/10/Add.2.

Relevant guidelines and reference documents

IARC (1990). Chlorinated paraffins. In: Some flame retardants and textile chemicals, and exposures in the textile manufacturing industry. Lyon, International Agency for Research on Cancer, pp 55-72 (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 48). Available at: http://monographs.iarc.fr/ENG/Monographs/vol48/mono48-7.pdf

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IPCS (1996): Environmental Health Criteria 181 "Chlorinated Paraffins". Available at: http://www.inchem.org/documents/ehc/ehc/ehc0181.htm

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