Short-Chain Chlorinated Paraffins (SCCPs) and Other Chlorinated Paraffins Action Plan

I. Overview

SCCPs are found world-wide in the environment, wildlife and humans. They are bioaccumulative in wildlife and humans, are persistent and transported globally in the environment, and toxic to aquatic organisms at low concentrations. Based on these factors, as well as the availability of viable substitutes for certain uses of SCCPs, EPA intends to initiate action to address the manufacturing, processing, distribution in commerce, and use of SCCPs.

EPA intends to further evaluate whether the manufacturing, processing, distribution in commerce and/or use of medium chained chlorinated paraffins (MCCPs) and long-chained chlorinated paraffins (LCCPs) should also be addressed.

As part of the Agency's efforts to address SCCPs, EPA also intends to evaluate the potential for disproportionate impact on children and other sub-populations.

II. Introduction

As part of EPA's efforts to enhance the existing chemicals program under the Toxic Substances Control Act (TSCA)[1], the Agency identified an initial list of widely recognized chemicals, including SCCPs, for action plan development based on their presence in humans; persistent, bioaccumulative, and toxic (PBT)[2] characteristics; use in consumer products; production volume; or other similar factors. This Action Plan is based on EPA's initial review of readily available use, exposure, and hazard information on SCCPs. EPA considered which of the various authorities provided under TSCA and other statutes might be appropriate to address potential concerns with SCCPs in developing the Action Plan. The Action Plan is intended to describe the courses of action the Agency plans to pursue in the near term to address its concerns. The Action Plan does not constitute a final Agency determination or other final Agency action. Regulatory proceedings indicated by the Action Plan will include appropriate opportunities for public and stakeholder input, including through notice and comment rulemaking processes.

III. Scope of Review

For the purposes of this action plan, SCCPs include the chlorinated paraffins that meet the following definition:

$C_xH_{(2x-y+2)}Cl_y$
where x = 10-13;
y = 3-12; and

the average chlorine content ranges from approximately 40 to 70 percent with the limiting molecular formulas set at $C_{10}H_{19}Cl_3$ and $C_{13}H_{16}Cl_{12}$. Any individual chemical meeting this definition is considered an SCCP and is covered by this action plan. Furthermore, this action

[1] 15 U.S.C. §2601 *et seq.*
[2] Information on PBT chemicals can be found on the EPA website at http://www.epa.gov/pbt/.

plan covers any chemical substance or mixture that contains a chemical that meets the definition. For example, CAS registry number (CASRN) 63449-39-8 (Paraffin waxes and hydrocarbon waxes, chlorinated) denotes chlorinated paraffin waxes of unspecified carbon chain length and unspecified degree of chlorination. If a portion of that chemical substance falls within the definition of SCCPs then the entire substance would be subject to this action plan. Likewise, CASRN 71011-12-6 named (Alkanes, C_{12-13}, chloro) would only contain chemicals that meet the alkyl range described in the definition and would be subject to the action plan if any of the chlorine content were consistent with the 40 to 70 percent criteria.

Medium chained chlorinated paraffins (MCCP; C_{14-17} alkyl chain) and long-chained chlorinated paraffins (LCCP; generally C_{18-28}) are also discussed in this action plan.

Only four chlorinated fractions are on the TSCA Inventory [Alkanes, C_{6-18}, chloro (CASRN 68920-70-7); Alkanes, C_{12-13}, chloro (CASRN 71011-12-6); Alkanes, chloro (CASRN: 61788-76-9); Paraffin waxes and Hydrocarbon waxes, chloro (CASRN 63449-39-8)] (EPA, 2006). Other CASRNs associated with SCCPs are not on the TSCA Inventory. The CASRNs associated with certain MCCPs and LCCPs are also not on the TSCA Inventory.

IV. Uses and Substitutes Summary

The current use of chlorinated paraffins (SCCP, MCCP, and LCCP) in the United States is on the order of 150 million pounds per year. Production of short-chain and medium-chained chlorinated paraffins (C_9 to C_{17}) was 100 million pounds in 2007. A very small fraction of that number is attributable to import/export business. According to the Chlorinated Paraffins Industry Association, MCCPs represent the largest production and use of chlorinated paraffins in North America while SCCPs is only half that volume (CPIA, 2009). Marketing and use of SCCP has been restricted in the European Union (ECHA 2008a). In Canada, SCCPs are not currently manufactured and use was approximately 3000 metric tons in 2000 and 2001, the latest figures reported (Environment Canada, 2008). In the United States, Dover Chemical Corp. is the sole manufacturer of chlorinated paraffins and several companies import SCCPs (EPA, 2006).

The largest use of SCCPs in the United States is as a component of lubricants and coolants in metal cutting and metal forming operations. The second-largest use is as both a secondary plasticizer and a flame retardant in plastics, especially PVC. Other minor domestic SCCP uses are as a plasticizer and a flame-retardant additive to a variety of products including: rubber formulations, paints and other coatings, and adhesives and sealants (CPIA, 2009). For safety reasons, other countries (those in the European Union and Canada) have allowed SCCPs to be used as a flame retardant in underground mining conveyor belts (rubber formulations) and fire retardants in dam sealants (ECHA 2008a).

MCCPs are alternatives to SCCPs for many applications. Based on their physical-chemical properties, MCCPs are also expected to be persistent in the environment and several field surveys have shown they are present in sediments and biota, demonstrating their release to and persistence in the environment. Field-measured bioaccumulation factors (BAFs) that are greater than 5000 and biomagnification factors (BMF) greater than 1 indicate that MCCPs are bioaccumulative in biota and can biomagnify in food chains (UNEP, 2009). MCCPs have toxicity to sensitive aquatic organisms that is similar to SCCPs. Canada has concluded that MCCPs are "toxic" as defined by the Canadian Environmental Protection Act (CEPA) (Government of Canada 2008). The European Union's 2005 Risk Assessment Report and 2007 draft update conclude that there is a need for limiting the risks posed by certain uses of MCCPs in the production of PVC and metal cutting (EC, 2005, 2007).

LCCPs appear to have been used as alternatives to SCCPs in some of the more demanding metal working applications (HELCOM, 2002). LCCPs also appear to have potential as an alternative in leather, paints and coatings, sealants and rubber applications. LCCPs are expected to be persistent and bioaccumulative in the environment based on their physical-chemical properties and bioaccumulation modeling, respectively. Canada has concluded that LCCPs up to C_{20} are "toxic" as defined by CEPA (Government of Canada 2008).Canada has not made a determination of whether LCCPs greater that C_{20} are toxic.

A number of other potential alternatives, e.g. nitroalkanes, alkyl phosphate and sulfonated fatty acid esters and vegetable oil based products, are available for specific applications. It is stated that these alternatives are considered less harmful than chlorinated paraffins (UNECE, 2006). These non-chlorinated paraffin alternatives are often more expensive and may require special handling. A UK estimated cost for completely converting SCCPs to non-SCCPs in metal working was predicted to be four million £ per year (IRTA, 2004). An analysis of costs conducted in California found that overall metal working processing costs were more expensive for the SCCP alternatives but including other associated costs (clean up and waste removal) made the non-SCCP alternatives competitive (IRTA, 2004).

V. Hazard Identification Summary

Human Health Effects

Acute toxicity of SCCPs (C_{10-13}) is very low (EC, 1999; UNEP, 2009). SCCPs may cause skin and eye irritation upon repeated application, but do not appear to induce skin sensitization (EC, 1999; UNEP, 2009). There was no evidence of developmental effects in prenatal developmental toxicity studies in rats and rabbits (EC, 1999; UNEP, 2009).

The liver, kidney and thyroid are major target organs in repeated-dose studies with rats and mice. When administered by gavage, chlorinated paraffins (C_{12}, 60 percent chlorine) are carcinogenic in rats and mice of both sexes (NTP, 1986a; 2005). The underlying mechanisms for the carcinogenicity of SCCP in rats and mice are not clearly known. SCCPs were not mutagenic to bacteria with or without metabolic activation (NTP 1986a, b). There are some indications that the SCCP-induced kidney tumors in male rats are associated with alpha 2μ-globin accumulation in hyaline droplets, a mode of action unique to male rats and irrelevant to humans, but this could not be confirmed by immunocytochemical techniques. There are also data showing that the liver toxicity/carcinogenicity induced by SCCP is associated with peroxisome proliferation, whereas the thyroid effects are correlated to altered thyroid hormone homeostasis. A number of scientific working groups, including the International Agency for Research on Cancer (IARC), have concluded that liver tumors induced by peroxisome proliferators are not relevant to humans

(IARC, 1990; Klaunig et al., 2003). Humans are expected to be much less sensitive to thyroid hormone perturbation than rats and mice.

There is no experimental evidence using human data that demonstrates the carcinogenicity of SCCPs. In the 11th Report on Carcinogens, NCI lists chlorinated paraffins (C_{12}, 60 percent chlorine) as *reasonably anticipated to be human carcinogens* based on sufficient evidence of carcinogenicity in experimental animals (NTP, 2005). They are classified by the IARC as *Group 2B - possibly carcinogenic to humans* based on sufficient evidence of carcinogenicity in experimental animals and mechanistic considerations (IARC, 1990).

Health Canada and Environment Canada have characterized all chlorinated paraffins (SCCPs, MCCPs and LCCPs) as "toxic" under CEPA (Government of Canada 2008).

A recent compilation of toxicity data indicates the acute toxicity of MCCPs is low and they are not genotoxic. Prenatal developmental toxicity studies in rats and rabbits showed reduced fetal body weight. A reproductive toxicity study also showed postnatal developmental toxicity as demonstrated by reduced pup body weight, as well as reduced pup survival at higher doses; there was no evidence of reproductive toxicity. Repeated-dose studies in rats and dogs showed effects on the liver (ECHA, 2008a).

Environmental Effects

SCCPs are highly toxic to aquatic invertebrates following acute (48-hr EC_{50} = 0.043 to 11 mg/L) and chronic (NOEC = 0.005 to 2 mg/L) exposures. In fish high toxicity is associated with chronic exposures, but not for acute exposures (96-hr LC_{50} = 300 to 10,000 mg/L and NOEC = 0.0096 to 0.05 mg/L). For aquatic plants, there is high toxicity associated with both acute and chronic exposures to SCCPs (96-hr EC_{50}s range from 0.043 to 0.39 mg/L and NOEC ranges from 0.012 to 0.39 mg/L) (UNEP, 2009).

Both Health Canada and Environment Canada have characterized all chlorinated paraffins (SCCPs, MCCPs and LCCPs) as "toxic" under CEPA (Government of Canada 2008).

VI. Physical-Chemical Properties and Fate Characterization Summary

EPA has gathered information on the water solubility, vapor pressure, Henry's Law constant, and partition coefficient (log K_{ow}) data for several different SCCP molecular formulae to characterize the SCCPs category (Environment Canada, 2008; HSDB, 2008; UNEP, 2009). In general, water solubility decreases and Henry's Law Constant and log K_{ow} of SCCPs increase with increasing carbon chain length and increasing chlorine content. Short- and medium- chain length chlorinated paraffins are liquids while longer chain, higher chlorinated paraffins are solids. The SCCPs are viscous liquids at room temperature and normal pressure. Vapor pressure of chlorinated paraffins generally decreases with increasing MW (a function of number of chlorine atoms). All chlorinated paraffins have low to negligible water solubility but the lower molecular weight chlorinated paraffins can be emulsified by adding an organic co-solvent. The octanol-water partition coefficients (log K_{ow}) of chlorinated paraffins range from 4.5 to 12, with SCCPs log K_{ow}s ranging from approximately 4.5 to 7.4. The log K_{ow}s are generally above 5, the criteria used by many national and international authorities to indicate potential for bioaccumulation because it can be readily measured and calculated on the basis of structure (UNEP, 2009).

SCCPs are persistent and bioaccumulative in the environment. The Persistence Organic Pollutant Review Committee (POPRC) of the Stockholm Convention has concluded that SCCPs fulfill the persistence and bioaccumulation criteria put forth in Annex D of the Stockholm Convention on Persistent Organic Pollutants (UNEP, 2009). The EU has concluded that SCCPs meets its criteria for both persistent and bioaccumulative (PB) substance and a very persistent, very bioaccumulative (vPvB) substance (ECHA 2008b). Canada has also concluded SCCPs are persistent and bioaccumulative (Environment Canada 2008).

SCCPs released to the atmosphere are expected to exist in the vapor and particulate phase in the ambient atmosphere given the range of vapor pressures reported for these substances. Vapor phase constituents are degraded in air by reaction with hydroxyl radicals with half-lives of less than one to slightly greater than ten days. A half-life greater than about two days in the atmosphere can be a significant factor in facilitating long-range transport of persistent chemicals.

SCCPs released to water are expected to adsorb to sediment and suspended particulate matter based on log K_{oc} values. They are stable to hydrolysis and photolysis. Volatilization from water is expected to be moderate based on estimated Henry's Law constants of the individual congeners; however, adsorption to suspended solids and sediment in the water column may attenuate the rate of volatilization. No degradation was observed in sediments under anaerobic conditions. Detection of SCCPs in sediment cores dating back to the 1940s provides evidence that SCCPs are persistent (UNEP, 2009).

SCCPs released to soil are expected to have low mobility given their log K_{oc}. Volatilization from moist soil surfaces is expected to be moderate based on estimated Henry's Law constants of the individual congeners; however, adsorption may attenuate the rate of volatilization.

Measured data indicate SCCPs bioaccumulate in biota. High bioconcentration factors (BCFs) have been measured, ranging from 1,000 to 50,000 for whole body and/or individual tissues in a variety of freshwater and marine organisms (Environment Canada, 2008; UNEP, 2009). Field-derived bioaccumulation factors (BAFs) over one million were measured for vertebrate species collected from the Great Lakes and in arctic marine mammals (Environment Canada, 2008; UNEP, 2009).

The Henry's Law constant values for SCCPs imply partitioning from water to air or from moist soils to air, depending on environmental conditions and prevailing concentrations in each compartment. Evidence that SCCPs undergo such transport is provided by findings that they are globally dispersed in the environment and appear in the Arctic (Hüttig, 2005). The Persistent Organic Pollutant Review Committee (POPRC) of the Stockholm Convention on Persistent Organic Pollutants (POPs) concluded that evidence is sufficient to conclude that SCCPs meet the screening criterion on potential for long-range environmental transport (UNEP, 2009). In

December 2009 the Executive Body of the Convention on Long-Range Transboundary Air Pollution will consider adding SCCPs to the POPs Protocol to the Convention (UNECE, 2009).

VII. Exposure Characterization Summary

Releases

SCCPs have the greatest potential for environmental release and exposure of the chlorinated paraffins. The likely sources of releases for SCCPs are identified as manufacturing and lubricant applications. In 2000 and 2001, nearly all usage of SCCPs was reported to be in metalworking applications. Losses from the use of SCCPs in paint and sealants are generally regarded as much lower than those from metalworking. Releases of SCCPs may occur during production, storage, transportation, industrial and consumer use of chlorinated paraffin-containing products, disposal and burning of waste, leaching, runoff or volatilization from landfills, and sewage sludge or other waste disposal sites (Tomy et al., 1998).

Major sources of releases of chlorinated paraffins into the environment are likely the formulation and manufacturing of products containing chlorinated paraffins and use in metalworking fluids as an extreme pressure additive. EPA estimated releases of SCCPs during metalworking fluid use using generic scenario methodology. Releases to wastewater were estimated to be approximately 2,400 kg/site-yr from container cleaning, dragout (fluid that remains on the part after shaping), disposal of filter media and spent metalworking fluid. Releases to landfill and incineration from these same release sources were estimated to be approximately 900 kg/site-yr using the generic site methodology. Incinerators would not be as significant a source.

The possible sources of releases to water from manufacturing include spills, facility wash down and drum rinsing/disposal. Chlorinated paraffins in metalworking/metal cutting fluids may also be released to aquatic environments from drum disposal, carry-off and spent bath. These releases often ultimately end up in the effluents of sewage treatment plants. In comparison to river and lake sediments, concentrations of SCCPs/MCCPs in sewage sludge are much higher, especially from waste water treatment plants serving industrial areas.

Human Exposure

The primary non-occupational routes of exposure to SCCPs include ingestion, both directly and through contaminated food, and dermal contact with products. Chlorinated paraffins have been isolated from human liver, kidneys, adipose tissue and breast milk. Due to their potential for environmental transport, SCCP exposure may occur from sources far from their use and release. For example, SCCPs have been found in breast milk samples taken from Inuit women (UNEP, 2009).

There is potential for inhalation exposure to SCCPs in metalworking fluids from mists generated during metal shaping operations. EPA estimated that potential inhalation exposure ranges from 1.8 to 8.3 mg/day for this scenario. There is also potential inhalation exposure to mists in uses where products containing SCCPs are spray applied such as in paints, adhesives and sealants.

EPA estimated the potential for occupational dermal exposure for various manufacturing, formulation and use scenarios to range up to 1800 mg/day. These exposures could be mitigated by the use of personal protection equipment, such as gloves that have been demonstrated to be effective in preventing permeation by SCCPs and formulations containing SCCPs.

Environmental Exposure

In 1986, EPA/OPPT conducted a monitoring study of Sugar Creek near the Dover Chemical manufacturing facility in Dover, Ohio (Murray et al., 1988). SCCP concentrations of 0.21 µg/L were detected in water at the outfall and 0.3 µg/L in particulates in water upstream from the outfall. Monitoring of a metalworking fluid end-user on Tinkers Creek did not detect chlorinated paraffins in either filtered water or particulates. The report authors thought that this may be due to analytical difficulties. In 1988, a production plant in the same city reported C_{10-13}, 60 percent chlorine SCCP concentrations of <150-3300 ng/L in water from an impoundment drainage ditch that received effluent from chlorinated paraffins (Murray et al., 1988). SCCPs were detected in the Houston Ship Channel in 1978 at levels ranging from less than 1.0 µg/L to 1.5 µg/L. In 1977, near a Diamond Shamrock Facility on the Grand River in Painesville, OH, concentrations as high as 3.0 µg/L were detected upstream and downstream from the plant (EPA, 1993).

As summarized in a draft Risk Profile prepared by the POPs Review Committee of the Stockholm Convention, SCCPs have been measured in a variety of environmental media including air, sediment, surface waters, and wastewater in North America, Europe, Japan, and/or the Arctic (UNEP, 2009).

SCCPs have also been measured in a variety biota, including freshwater aquatic species from North America, Europe and the Arctic, marine mammals from several locations in Canada and the Arctic, and avian and terrestrial wildlife in Europe. 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 (UNEP, 2009).

VIII. Risk Management Considerations

SCCPs continue to be manufactured, imported, processed and used in industrial applications in the United States. SCCPs are persistent, bioaccumulative, and toxic to aquatic organisms at low concentrations. The persistence and bioaccumulative properties of SCCPs increase the probability and duration of exposure such that even relatively small releases from individual facilities that manufacture, import, process or use them or from waste management facilities have the potential to accumulate over time to levels that cause significant adverse impacts on the environment. Thus, a snapshot of industrial and other releases of SCCPs will underestimate the environmental loadings and burden in biota, and thus potential risks. Indeed, SCCPs have been measured in biota and various environmental media, including in terrestrial as well as aquatic organisms.

Other chlorinated paraffins such as MCCPs and LCCPs can be used as substitutes for SCCPs. They are also persistent and bioaccumulative although they have lower water solubilities than SCCPs. They have also been measured in environmental media and biota. The toxicity of MCCPs and LCCPs may appear to be lower based on their lower solubility and bioavailability, however, their toxicity is generally not as well characterized as for the SCCPs.

There are no specific impacts on children associated with chlorinated paraffins.

IX. Next Steps

EPA is addressing the discrepancy between the specific chlorinated paraffins companies are actually manufacturing or importing and those listed on the TSCA Inventory. Only some of the chlorinated paraffin fractions being manufactured or imported are on the TSCA Inventory. EPA intends to require companies to submit Pre-Manufacture Notices for the SCCPs, MCCPs, and LCCPs fractions that are not on the TSCA Inventory. If appropriate, EPA will initiate action under TSCA section 5 to address the risks posed by such SCCPs, and potential risks associated with MCCPs and LCCPs. EPA plans to explore these questions in the near future.

Concurrently, EPA intends to consider initiating action under TSCA section 6(a) to ban or restrict the manufacture, import, processing or distribution in commerce, export, and use of SCCPs based on the persistence, bioaccumulation and toxicity of SCCPs and their presence in the environment. EPA will develop more detailed assessments to support the TSCA section 6(a) "presents or will present an unreasonable risk" findings. If these more detailed assessments indicate that a different approach to risk management is appropriate, EPA will consider additional approaches.

EPA intends to further evaluate whether the manufacturing, processing, distribution in commerce, use and/or disposal of MCCPs and LCCPs should also be addressed under TSCA section 6(a).

As part of the Agency's efforts to address these chemicals of concern, EPA intends to evaluate the potential for disproportionate impact on children and other sub-populations.

X. References

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