American Chemistry Council

March 18, 2016

Via Electronic Mail
Mr. Kenneth Moss
Chemical Control Division (7405M)
Office of Pollution Prevention and Toxics
USEPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Re: Chlorinated Paraffins; Request for Available Information on PMN Risk Assessments

Docket ID: EPA-HQ-OPPT-2015-0789

Dear Mr. Moss:

I am submitting to the docket today the attached Comments of the Adhesive and Sealant Council, American Chemistry Council, American Wire Producers Association, ACC's Center for the Polyurethanes Industry, Chlorinated Paraffins Industry Association, Independent Lubricant Manufacturers Association, Industrial Fasteners Institute, Motor and Equipment Manufacturers Association, and Vinyl Institute (Comments) for EPA's consideration in its evaluation of the draft risk assessments on medium-chain chlorinated paraffins and long-chain chlorinated paraffins.

The Comments have nine attachments. One of the attachments is a spreadsheet that supplements Attachment 4. The spreadsheet will not function properly when in PDF format; therefore, I am uploading as a document separate from the PDF Comments and attachments.

Please contact me should you have any questions.

Sincerely,

Christina Franz

Christina Franz
Senior Director, Regulatory & Technical Affairs

americanchemistry.com®   700 Second St., NE | Washington, DC | 20002 | (202) 249-7000

Comments of the:

Adhesive and Sealant Council
American Chemistry Council
American Wire Producers Association
ACC's Center for the Polyurethanes Industry
Chlorinated Paraffins Industry Association
Independent Lubricant Manufacturers Association
Industrial Fasteners Institute
Motor and Equipment Manufacturers Association
Vinyl Institute

In regard to the U.S. Environmental Protection Agency's Notice:

Chlorinated Paraffins; Request for Available Information on PMN Risk Assessments

Docket ID: EPA–HQ–OPPT–2015–0789

March 18, 2016

Table of Contents

List of Attachments

1. Chlorinated Paraffins Industry Association. March 2015: Existing Evaluations of LCCP/vLCCP Category Assessments for U.S. EPA Review of PMN Submissions.

2. Chlorinated Paraffins Industry Association. May 2015: Evaluation of Environmental Release and Environmental Assessment of Medium Chain Chlorinated Paraffins (C14-C17) and Long Chain Chlorinated Paraffins (C18-C20)

3. Independent Lubricant Manufacturers Association (ILMA). July 24, 2015: letter from Holly Alfano, ILMA Executive Director, to Greg Schweer, EPA.

4. Arnot, Jon. April 28, 2014. Bioaccumulation Assessment of Medium-chain chlorinated paraffins (MCCPs). [Includes text report and spreadsheet supporting assessment.]

5. European Chemicals Bureau. 2007. TC NES Subgroup on Identification of PBT and vPvB Substances: Results of the Evaluation of the PBT/vPvB Properties Paraffin waxes and Hydrocarbon waxes, chloro, EC number 264-150-0, CAS number 63449-39-8; Long-Chain Chlorinated Paraffin. PBT List no. 110. November 9, 2007.

6. American Chemistry Council. February 4, 2016. EPA Options for Addressing Chlorinated Paraffins. Letter to Wendy Cleland-Hamnett.

7. American Chemistry Council. February 25, 2016. Status of Chlorinated Paraffins as a Category Under Section 8(b)(2) of TSCA. Letter to Avi Garbow.

8. American Chemistry Council. October, 30, 2015. Medium-Chain and Long-Chain Chlorinated Paraffins: TSCA Analysis. Submitted to Jim Jones.

9. Chlorinated Paraffins Industry Association. April 11, 2014. Comments to EPA on vLCCP proposed SNUR. EPA-HQ-OPPT-13-0399.

Executive Summary

These comments are submitted by a coalition of trade associations (the Coalition) that represent an array of industries impacted by the Environmental Protection Agency (EPA) actions on medium-chain chlorinated paraffins (MCCPs), C_{14}-C_{17} chloroalkanes, and long-chain chlorinated paraffins (LCCPs), C_{18}-C_{20} chloroalkanes. While the Coalition appreciates the opportunity to submit these comments to EPA, we believe this public comment period does not address the fundamental process concerns with EPA's handling of MCCPs and LCCPs under the Toxic Substances Control Act (TSCA). Here are the facts as the Coalition understands them:

- Forms of MCCPs and LCCPs have been in use in the U.S. for many decades -- long before implementation of TSCA and the compilation of the initial TSCA Inventory in 1979. Manufacturers of these substances timely reported them for the initial Inventory using broad categorical names suggested by EPA on the Candidate List. Therefore, these substances should be regarded as existing chemicals with ongoing uses under TSCA.
- MCCPs, LCCPs and other chlorinated paraffins are highly complex chemicals that contain thousands of possible isomers. As such, they are UVCB[1] substances that cannot be described by a single chemical structure or a specified group of chemical structures. There have been many different chlorinated paraffin commercial products and trade names over the years. Given the close similarities of these products, industry has relied upon generic category descriptions that appear on the TSCA Inventory.
- EPA encouraged companies to report broad categorical names for CPs for the TSCA Inventory by listing these same names on the 1977 Candidate List under what are now CAS No. 61788-76-9 and CAS No. 63449-39-8. See Attachment 8 (TSCA Analysis Paper).
- TSCA section 8(b)(2) and section 26 (c) authorize EPA to identify categories of chemical substances on the TSCA Inventory rather than list individual members of those categories. That is what EPA did with those two categories. See Attachment 7 (Category Paper).
- Between 1977 and 2011, EPA relied on CAS No. 61788-76-9 and CAS No. 63449-39-8 to address MCCPs and LCCPs in numerous regulatory actions. See Attachment 8 (TSCA Analysis Paper).
- The ongoing uses of MCCPs and LCCPs are highly valuable and important to U.S. manufacturing sectors including aerospace, automotive, construction, defense, metallurgy, polymer manufacturing and others. Switching to alternative substances is not possible in all uses and, even when alternatives may exist, reformulation would be a lengthy multi-year process to reformulate that will cost U.S. industry billions of dollars.
- In 2009, after more than three decades of regulating chlorinated paraffins under CAS No. 61788-76-9 and CAS No. 63449-39-8, EPA suddenly decided that <u>none</u> of the currently manufactured or imported chlorinated paraffin products was properly covered by the

---

[1] Chemicals of unknown or variable composition, complex reaction products, and biological materials.

existing category descriptions on the TSCA Inventory and therefore these substances must all be treated as new chemicals and go through the premanufacture notice (PMN) process.

- Since 2012 EPA has received seven PMNs for substances that can be described as MCCPs or LCCPs. In addition, EPA has received PMNs for other substances that include constituents in both the LCCP range (C_{18}-C_{20}) and above ($C_{>20}$) and PMNs for substances just C_{21} and greater, which EPA now refers to as very long-chain chlorinated paraffins (vLCCPs).
- Separately, in 2012 EPA announced its new TSCA Work Plan program to review priority existing substances. EPA identified over 80 priority substances for initial review under this program including MCCPs and LCCPs. This program included a detailed process for assessing priority chemicals, including public comment and expert peer review. In fact, EPA announced it had begun its assessment of MCCPs and LCCPs in 2012 and published a Peer Review Plan for them in 2013. In 2014, EPA updated the TSCA Work Plan program details and priority list; both MCCPs and LCCPs remained on the list of chemicals to go through the program.
- In January 2015, EPA informed the MCCP and LCCP PMN submitters that, based on environmental concerns as detailed in the Risk Assessments that are the subject of this notice,[2] it planned to seek to eliminate the manufacture and import of these substances. At the time EPA indicated a cessation date of May 31, 2016, though subsequent presentations by EPA indicated that it may now be seeking a date may in mid-2017. There has been no public notice regarding these dates. This current notice is the first opportunity for most Coalition members to review and comment upon the underlying Risk Assessments.
- Industry representatives, Coalition members, and even Members of Congress have requested that EPA reconsider its approach of reviewing and regulating these substances under the TSCA section 5 PMN process given their ongoing use in the U.S. TSCA is clear that existing substances such as chlorinated paraffins are subject to regulation under section 6. The TSCA Work Plan program is the appropriate mechanism for review and regulation of these chemicals given their history.
- Given the value of the products produced using MCCPs and LCCPs and the costs associated with replacing them, these Risk Assessments rise to the level of highly influential scientific assessments (HISAs) under guidance issued by the Office of Management and Budget (OMB) and EPA's Peer Review Handbook. As such, these Risk Assessments necessitate peer review under both EPA's and OMB's guidance.

The Coalition believes that the Risk Assessments do not provide an adequate basis to support EPA's key conclusions that MCCPs and LCCPs are expected to be PBT chemicals or that ongoing uses are exceeding Concentrations of Concern (COCs) for aquatic and sediment-

---

[2] 80 Fed. Reg. 79886 (Dec. 23, 2015).

dwelling organisms. On the contrary, applying a weight-of-the-evidence approach, the available data provides an adequate basis for concluding the following:

- The physiochemical properties of MCCPs and LCCPs, such as very low ambient vapor pressure and very low water solubility, limit the potential for the release of significant quantities of these substances to the environment, particularly to surface water or air.

- Information from the manufacturers and downstream users of these substances indicates that there are not the release pathways to water for MCCPs and LCCPs that EPA assumed in the Risk Assessments.

- Use applications are well defined and controlled. Many of the uses are in applications that are water-sensitive and therefore do not present a likely release pathway to water.

- Exceedances of EPA's COCs in environmental surface water or sediment do not appear to be occurring in the U.S. An EPA-led binational effort on chemicals of interest in the Great Lakes has shown levels of CPs in the Great Lakes to be dropping over time in recent years.

- Conclusions regarding the PBT characteristics of MCCPs and LCCPs are overstated in the Risk Assessments and EPA fails to make a weight-of –the-evidence evaluation of the available data.

Overall, the Coalition believes that it is completely unnecessary and a serious overstep for EPA to seek the cessation of the manufacture and import of these MCCP and LCCP PMN substances, and by extension, the processing and use of MCCPs and LCCPs in the U.S. Indeed, the complete review of the scientific evidence suggests that EPA has an insufficient legal basis to propose a ban of these substances. MCCPs and LCCPs have been and can continue be managed by restricting/eliminating existing or future discharge pathways to water using ongoing effective industry practices with discharge restrictions under the existing regulatory framework. Additional research on current levels of MCCPs and LCCPs in the U.S. environment could provide additional information to further refine risk estimates in the Risk Assessments.

Part I. Introduction, Scope of Comments, and Overview of Chlorinated Paraffins Chemistry

A. Introduction and Scope of Comments

These comments respond to EPA's request[3] for comments and information on draft risk assessments (the Risk Assessments) for several medium-chain chlorinated paraffins (MCCPs) and long-chain chlorinated paraffins (LCCPs) that were the subject of premanufacture notices (PMNs). These comments are submitted by a coalition of trade associations throughout the value chain (the Coalition) that would be affected by EPA actions based on the Risk

---

[3] 80 Fed. Reg. 79886 (Dec. 23, 2015).

Assessments. These impacted industries include aerospace, automotive, construction, defense, electronics, and others.

It is highly unusual for a broad array of industries to be impacted by EPA PMN reviews. In this case, however, MCCPs and LCCPs, such as those that are the subject of the Risk Assessments have been in commerce since well before the passage of TSCA in 1976. EPA identified chlorinated paraffins as categories or statutory mixtures on the original TSCA Inventory. During the subsequent three decades, EPA regulated or proposed to regulate chlorinated paraffins, such as these MCCPs and LCCPs, as a category. The Coalition has raised serious procedural concerns with EPA's treatment of these chemicals as new substances, given the significant ongoing and historic use of these substances. While the Coalition is not addressing EPA's prior enforcement actions related to these substances, it is strongly opposed to EPA's stated intent to ban the production in the U.S. and import to the U.S. of MCCPs and LCCPs through TSCA section 5(e), based on the incorrect position that these substances are "new" chemicals when they, in fact, have been in commerce and listed as categories or statutory mixtures on the TSCA Inventory since TSCA was enacted. For more information regarding why MCCPs and LCCPs as a category of chemicals should be considered as listed on the Inventory, see Attachments 7 [categories paper] and 8 [TSCA analysis].

The Coalition strongly urges EPA to review MCCPs and LCCPs under the TSCA Work Plan program, complete with full public comment and independent external peer review. MCCPs and LCCPs are existing chemical substances under TSCA and any regulatory action EPA takes on them will have broad economic impacts across a wide array of industries. Section 2(c) of TSCA states that Congress intended for EPA to consider not only the health and environmental impacts of its actions, but also the social and economic effects of its decisions as well. To date, EPA has ignored the economic repercussions of its intended actions on downstream users of MCCPs and LCCPs as the Agency attempts to evaluate them under TSCA section 5.

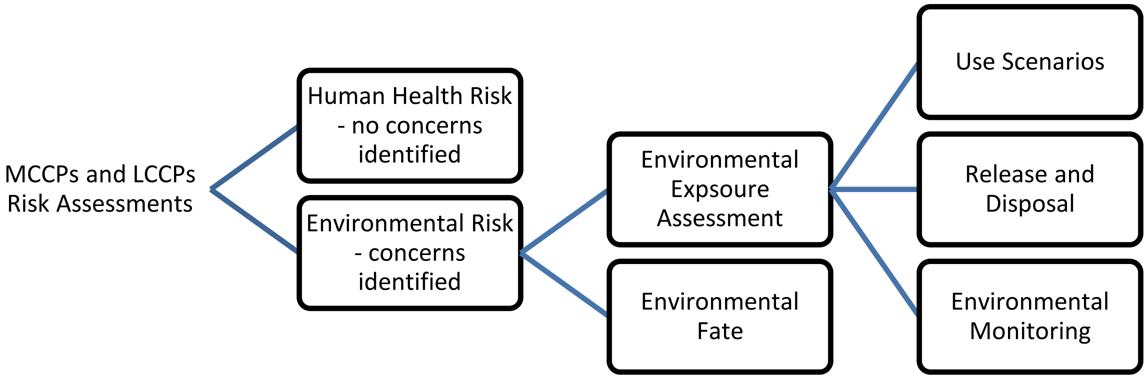
EPA has concluded in these Risk Assessments that:

1) The PMN substances are expected to be persistent, bioaccumulative and toxic (PBT) chemicals; and
2) Releases of the PMN substances may exceed concentrations of concern to aquatic and sediment-dwelling organisms, even without taking into consideration the expected persistence and bioaccumulation of the PMN substances.

EPA has indicated that it does not believe that manufacture of these PMN substances should "commence" (or, in some cases, continue) manufacture absent the development of sufficient information to permit a reasoned evaluation of the environmental effects of the substances based on its preliminary risk determinations under TSCA section 5(e).

EPA has overstated many aspects of the potential risks for these substances in the Risk Assessments, including environmental fate characteristics, levels in the environment, and the potential for release to the water. Moreover, the Coalition believes EPA has several readily available regulatory options that would permit the ongoing responsible use of these substances without a ban of manufacture and import.

The following diagram is an overview of the major components of the Risk Assessments. Importantly, EPA did not identify any human health risks.



These comments will address the findings of EPA's Risk Assessments and EPA's approach to the regulation of MCCPs and LCCPs.

B. Overview of Chlorinated Paraffin Chemistry and PMN Substances

Chlorinated paraffins (or chloroalkanes, depending on the feedstock; these comments refer to them as chlorinated paraffins) are polychlorinated predominantly straight-chain hydrocarbons that have historically been in the range of C_{10} to C_{30+}, with subdivisions based on carbon-chain lengths and chlorination levels. Most chlorinated paraffins have chlorination levels, by weight, in the range between 40% and 60%.[4] The chlorination process substitutes hydrogen atoms on the carbon-chain backbone with chlorine atoms and is largely random,[5] resulting in thousands of possible isomeric arrangements. Chlorinated paraffins are typically manufactured from paraffin or alpha-olefin feedstocks. The chlorination process does not change the carbon-to-carbon bonds – only the carbon-to-hydrogen bonds. As a result, the finished chlorinated paraffins / chloroalkane products will have the same carbon number range as the starting hydrocarbon feedstocks. Historically, these products were divided into three product sub-divisions based on the predominant carbon-chain range of the starting material, those being:

- Short-chain chlorinated paraffins (SCCPs), C_{10-13}
- Medium-chain chlorinated paraffins (MCCPs), C_{14-17}
- Long-Chain chlorinated paraffins (LCCPs), C_{18-30+}

Within the LCCP subdivision, products were further subdivided into:

- C_{18-20} liquid LCCPs

---

[4] The exceptions to this statement are solid LCCPs/vLCCPs, which are approximately 70% chlorination by weight.

[5] Double bonds in the starting hydrocarbon will typically be a chlorination location. There is also some information that suggests that chlorine substitution is more likely to occur on secondary carbons than primary carbons and that the substitution is more also more likely to be spread out along the carbon chain rather than on adjacent carbons or on an alternated chlorinated carbon (Howard, 1975).

- C_{20-30} liquid LCCPs
- C_{20-30} solid LCCPs

This approach was used to categorize LCCPs for the OECD SIDS program, REACH registration, and other prior reviews.

EPA recently created a new subdivision for chlorinated paraffins, which is presented in the Risk Assessments as:

- SCCPs, C_{10-13}
- MCCPs, C_{14-17}
- LCCPs, C_{18-20}
- Very long-chain chlorinated paraffins (vLCCPs, $C_{>20}$)

This change by EPA in how it describes LCCPs is significant because it attempts to create a bright-line at C_{20} to separate these products, whereas historically, there was overlap in the carbon-number ranges of many LCCPs, including both C_{18-20} and $C_{>20}$ constituents. As discussed later in these comments, this distinction is critical to the risk assessment of LCCPs since EPA has chosen to base the risk assessment of LCCPs on MCCP risk values as opposed to basing the assessments on data for LCCPs or LCCPs/vLCCPs.

1. Chlorinated Paraffin PMNs

Since 2012, EPA has received over a dozen PMNs for chlorinated paraffins. For three of these PMNs (P-12-539, P-13-107, and P-13-109, involving vLCCPs), EPA has completed its reviews, issued section 5(e) consent orders, and promulgated final SNURs.[6] The remaining PMNs are still under review, including the seven (below) addressed by the Risk Assessments:

MCCPs:

P-12-0282	Alkanes, C_{14-16}, chloro
P-12-0283	Tetradecane, chloro [C_{14}]
P-12-0453	Alkanes, C_{14-17}, chloro (40-60 weight % chlorine)
P-14-0683	Tetradecane, chloro [C_{14}]
P-14-0684	Alkanes, C_{14-16}, chloro

LCCPs:

P-12-0284	Octadecane, chloro [C_{18}]
P-12-0433	Alkanes, C_{18-20}, chloro (40-55 weight % chlorine)

Other PMNs still under review, but not considered in the Risk Assessments, concern substances that overlap EPA's LCCP and vLCCP subdivisions. These PMNs will be impacted by EPA's assessment of LCCPs, C_{18-20}, because they include constituents in both the C_{18-20} and $C_{>20}$ carbon-chain length ranges.

---

[6] The final SNURs appear at 81 Fed. Reg. 7455 (Feb. 12, 2016).

2. Physicochemical Parameters Important to the Assessments

There are several important physicochemical properties of MCCPs and LCCPs that impact their environmental risk assessment, including their very low water solubilities and the fact that they decompose prior to boiling. The table below presents the physicochemical parameters used by EPA in the Risk Assessments.

Table 1: Summary of Physiochemical Data from Risk Assessments of MCCPs and LCCPs

Substance	Wt %Cl	Melting Point	Boiling Point	Vapor Pressure	Water Solubility	Log K_{OW}
MCCPs	> 40	< 25 °C (pour point)	> 200 °C (decompose)	< 0.036 Pa at 20 °C	27 µg/L at 20 °C	> 5.5 (measured) 8.30 (estimated)
LCCPs	> 40	< 25 °C (pour point)	> 200 °C (decompose)	$< 2.7 \times 10^{-4}$ Pa at 20 °C	5 µg/L at 20 °C	> 10

EPA Sources: EURAR (ECB, 2008); EA (2009)
EPA Notes: Value calculated using the KOWWIN Program (v1.68) available in EPA's Estimation Programs Interface (EPI) Suite. This estimate was generated using a representative MCCP (i.e., $C_{14}H_{24}Cl_{6}$, 52 wt % Cl) with the following SMILES notation: CCC(Cl)CC(Cl)CCCl)CC(Cl)CC(Cl)CC(Cl)C.

The very low water solubility of MCCPs and LCCPs limit their ability to be released via the dissolved fraction in water, which increases efficacy of treatment technologies and limiting the mass released to water.

The relatively low decomposition temperatures of MCCPs and LCCPs, coupled with their very low vapor pressures, will result in negligible air emissions of MCCPs and LCCPs to the environment both during use and disposal.

Part II: EPA Regulatory Approach

A. Concerns with Current Approach Given Ongoing Uses

The Coalition has substantial concerns with EPA's current approach of addressing the future of chlorinated paraffins through the PMN process. These concerns are addressed in detail in Attachment 6, a letter the American Chemistry Council sent to EPA suggesting regulatory options for EPA to consider as alternatives to the current approach. Briefly, the concerns include, among others:

- **The PMN approach fails to provide an opportunity for comment on EPA decision-making that affects thousands of stakeholders.** Unlike the usual PMN situation, in this circumstance there are thousands of stakeholders currently purchasing MCCPs and/or LCCPs directly or indirectly from the PMN submitters because these substances have been in commerce and listed on the TSCA Inventory as a category for decades. The PMN process, which involves discussions between EPA and the submitters exclusively, precludes affected stakeholders from having their views considered. The current opportunity to comment on the Risk Assessments is not a substitute for the opportunity to comment on whether risk management is needed and what restrictions would be appropriate. Further, in light of concerns with the Risk Assessments, revisions to the Risk Assessments and conclusions should be undertaken before EPA proposes any risk management regulations.

- **The PMN approach seeking cessation of manufacture and import is not cost-effective.** EPA has failed to consider alternatives to a total ban on manufacture and import of MCCPs and LCCPs. Such a ban is the most costly regulatory option. Yet, essentially equivalent environmental benefits may be available at a fraction of the cost through other appropriate restrictions, such as disposal restrictions.

- **The PMN approach has a substantial economic impact.** Some 48 million pounds of MCCPs and LCCPs were reported for the 2012 Chemical Data Reporting rule (CDR). Downstream processors and end users have told EPA that for some applications they have no substitutes for MCCPs and LCCPs, and for others more than five years are needed to identify, qualify, and move to a substitute material. The proposed ban on the manufacture and import of MCCPs and LCCPs would result in significant economic disruption.

B. Highly Influential Assessments

EPA must subject these Risk Assessments to rigorous independent scientific peer review, given the highly influential nature of these assessments and EPA's potential future regulation of MCCPs and LCCPs. Failure to do so would be entirely inconsistent with the guidance issued by the OMB and EPA's own peer review policies and practices.[7] Indeed, EPA's Peer Review Handbook specifically states that scientific information that the Agency "reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions" is influential scientific information (ISI).[8] In addition, a subset of ISI that is a scientific assessment that "could have a potential impact of more than $500 million in any year on either the public or private sector" or "is novel, controversial, or precedent-setting, or has significant interagency interest" is considered a highly influential scientific assessment (HISA).[9] "All of the Agency's ISI/HISA should be peer reviewed unless they meet specified exemption criteria . . ."[10]

In July 2015, the Independent Lubricant Manufacturers Association (ILMA) provided EPA with a cost calculation of potential impact on its metalworking fluid (MWF) members (just one downstream sector impacted) if MCCPs and LCCPs were banned by EPA. In its analysis, ILMA

---

[7] OMB, Final Information Quality Bulletin for Peer Review (Dec. 16, 2004), http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf and http://www2.epa.gov/sites/production/files/2015-09/documents/final_epa_peer_review_handbook-_4th_ed_091415_dummy_link.pdf.

[8] EPA, Peer Review Handbook (4th ed. 2015), http://www.epa.gov/sites/production/files/2015-09/documents/final_epa_peer_review_handbook-_4th_ed_091415_dummy_link.pdf.

[9] Id.

[10] Id.

describes the mass-scale reformulation and testing that would be required at both MWF suppliers' facilities and at end-user customers' facilities and then extrapolates that calculation to every application that currently exists in the U.S. that uses MWFs containing MCCPs and/or LCCPs. ILMA calculated the cost at being in excess of $69 billion.[11]

EPA's threatened action exceeds the potential economic impact threshold of $500 million annually to qualify as a HISA under its own Peer Review Handbook. Further, the action is clearly "novel, controversial, and precedent-setting" in that the Agency has adopted a highly unusual approach to threaten a ban of substances (that have been in commerce for decades) under TSCA section 5 in the New Chemicals Program while simultaneously representing to the public on its website and on its Peer Review Agenda as conducting a risk assessment that will be subject to peer review under the TSCA Work Plan program.[12]

C. Regulatory Options Available to EPA

EPA has alternatives to the current approach of addressing MCCPs and LCCPs. These alternatives are described in Attachment 6, a letter from the American Chemistry Council (ACC) to EPA. These alternatives may be summarized as follows:

- **Option 1: Complete the ongoing review of MCCPs and LCCPs under the TSCA Work Plan, obtain peer review and, if scientifically justified, then pursue a section 6 rulemaking.**
    - EPA is already well on its way to completing its review of MCCPs and LCCPs under the TSCA Work Plan. The important remaining steps to conclude the assessment are public comment and peer review, followed by a risk determination and, if appropriate, risk management rulemaking under section 6.
    - The TSCA Work Plan process provides stakeholders with multiple opportunities for public comment -- opportunities lacking in EPA's current approach under section 5.
    - Consistent with OMB guidance and EPA's Peer Review Handbook, "When in doubt about whether a work product merits peer review, decide to peer review it."[13] EPA's process evaluating MCCPs and LCCPs and its threatened ban of the substances has generated significant concerns among the affected regulated industry that it would behoove the Agency to take all appropriate steps to ensure the integrity of whatever regulatory action it may take going forward. External peer review would be an important step in that direction.
    - Disposal restrictions may be the key to a cost-effective regulatory solution. Regardless of their hazards, MCCPs and LCCPs pose essentially no threat to the

---

[11] See July 24, 2015, letter from Holly Alfano of ILMA to EPA's Greg Schweer (Attachment 3).

[12] See EPA, Peer Review Agenda, http://cfpub.epa.gov/si/si_public_pr_agenda.cfm

[13] EPA Peer Review Handbook at p. 42

environment if they are not released, following appropriate disposal restrictions. Currently, RCRA and NPDES restrictions do not apply to MCCPs and LCCPs as such. TSCA section 6 is a powerful tool for restricting disposal more expeditiously than proceeding under either RCRA or the Clean Water Act.

- **Option 2: Complete the ongoing review of MCCPs and LCCPs, obtain peer review of the Risk Assessments and, after opportunity for stakeholder input, promulgate a SNUR imposing appropriate restrictions.**
    - EPA should provide an opportunity for stakeholders to comment both on the Risk Assessments and on proposed appropriate risk management measures.
    - EPA should not use the direct final rule mechanism for adopting a SNUR in this circumstance, since stakeholders will want to comment on its proposed SNUR.
- **Option 3: Obtain peer review of the Risk Assessments and issue a Request for Information on appropriate risk management controls for MCCPs and LCCPs.**
    - EPA is now accepting comments on the Risk Assessments in a public docket. It should also obtain the benefit of peer review on these Risk Assessments. As noted earlier, OMB guidance, EPA's Peer Review Handbook, and EPA's Peer Review Policy encourage the use of peer review for all scientific and technical information that is intended to inform or support agency decisions.[14] This is true irrespective of the TSCA authority EPA relies upon for its regulatory action.
    - A Request for Information on appropriate risk management controls for MCCPs and LCCPs would enable EPA to make a reasoned decision on how to regulate MCCPs and LCCPs should the final Risk Assessments indicate the need for additional risk management.

Part III: Human Health Risk Assessment

Chlorinated paraffins, across all carbon-chain lengths, are well tested for mammalian toxicity, including acute and chronic toxicity studies, reproductive and developmental toxicity studies, and other endpoints. Much of this information was developed at EPA's request under a 1982 voluntary testing agreement.[15] In addition, chronic toxicity data were generated by the National Toxicology Program (NTP), and additional testing on MCCPs was conducted by the European chlorinated paraffins industry to support assessments under the Dangerous Substances Directive and subsequently REACH.

Based on these data, EPA has concluded in the Risk Assessments that MCCPs and LCCPs are "not expected to pose a carcinogenic hazard to humans." Further, the data are sufficient for EPA to establish human health risk levels for MCCPs and LCCPs.

---

[14] Id.

[15] See EPA, Chlorinated Paraffins; Response to the Interagency Testing Committee, 47 Fed. Reg. 1017 (Jan. 8, 1982).

EPA selected the lowest NOAEL of 23 mg/kg-bw/day from a 90-day rat study of MCCP (CXR, 2005) and a lowest LOAEL of 100 mg/kg-bw/day from a 90-day study of a liquid C_{20-30} v/LCCP (43 wt% Cl) to assess occupational and non-occupational (i.e., general population) risk of MCCPs and LCCPs. When applying these risk levels to the exposure estimates, EPA concluded the following on the use of MCCPs and LCCPs:

> 1. Occupational Exposures: given the assumptions, data and scenarios evaluated in this assessment, there were low risks found for workers from either dermal or inhalation exposures.
>
> 2. General Population Exposures (from environmental releases): given the assumptions, data and scenarios evaluated in this assessment, there were low risks found to humans from environmental releases via exposure to drinking water or fish ingestion.

These conclusions are consistent with the Coalition's information that these chemicals do not present a human health risk when properly manufactured and used.

There are studies that demonstrate the extremely low dermal absorption potential of MCCPs and LCCPs. Scott (1989) conducted a 52% Cl (wt.) MCCP product using an *in vitro* human skin cell method and found no absorption of the MCCP product after 54 hours of exposure using 5 different receptor fluids. Yang et al. (1987) tested two ^{14}C-labelled chlorinated paraffins, C_{18}, 50-53% Cl (CP-LH) and C_{28}, 47% Cl (CP-LL) for dermal absorption in rats (5-7 animals of each sex) at a concentration of 66 mg/cm^2, approximately equivalent to 2000 mg/kg body weight. Only 0.7% (males) and 0.6% (females) of the C_{18} dose was absorbed after 96 hours. Only 0.02% of the C_{28} dose was absorbed in males whereas in females the level was not detectable. This indicates that increasing chain length leads to decreased permeability. Scott (1989) noted the Yang (1987) results as being consistent with his since there is evidence that animal skin is more permeable than human skin. Overall, these data indicated that absorption of MCCPs and LCCPs is likely to be well less than the 1% dermal absorption amount EPA used in the Risk Assessments. This adds further confidence to the above conclusions that MCCPs and LCCPs will not present a risk to human health.

Part IV: Environmental Risk Assessment

A. Uses of MCCPs and LCCPs

Based on the PMN submissions, EPA has identified the following uses for MCCPs and LCCPs:

Metalworking Fluids
Polymers, PVC, and Rubber
Adhesives and Sealants
Specialty Coatings
Specialty Automotive Lubricants
Waterproof Textiles

In addition, several of the PMNs describe MCCP and LCCP manufacturing scenarios. Collectively, these uses are consistent with the Coalition's understanding of the manufacture and use of MCCPs and LCCPs.

EPA has developed a series of scenarios for these use applications and estimated the human and environmental exposures from these uses using models. As previously discussed, EPA did not identify any human health risk concerns for the manufacture and use of MCCPs and LCCPs. Therefore, the Coalition's comments on use will focus on the environmental release and environmental exposure assessment of these substances. In particular, the comments focus on the potential for release to water during manufacture and use, as this potential has the greatest impact on EPA's risk conclusions. In addition, EPA specifically requested information regarding "whether there are uses for the PMN chlorinated paraffin substances that do not present the potential for direct or indirect release to water" in its notice.

Several Coalition members have separate submissions to EPA that specifically address their members' uses and how they manage the disposal of MCCP and LCCP wastes. These control programs, which facilitate compliance with federal and other regulations, create a backdrop of responsible use and disposal that which contradicts the release profile presented in the Risk Assessments.

1. Use in the Manufacture of Foam Insulating Sealants

MCCPs and LCCPs are used as plasticizers and flame retardants in moisture-cure, one-component polyurethane foam insulating sealant formulations (OCF sealants). During manufacture, MCCPs and LCCPs are combined with other raw material ingredients in a blending tank to form a pre-polymerized mixture or pre-polymer. (The term "pre-polymer" is used to describe an intermediate stage in the polymerization process). Once in this pre-polymer mixture, MCCPs and LCCPs are bound into the pre-polymer matrix and are not released. Moreover, any exposure to water of the pre-polymer will result in the rapid final curing of polymer. As such, the OCF sealant manufacturing process is highly water-sensitive due to the reactivity of isocyanates used in product formulations. No part of the manufacturing process is in contact with water. Accordingly, this process should not present the potential for water releases of MCCPs and LCCPs.

OCF sealants are sold to the consumer in a single-use can or canister that contains this pre-polymerized material. During use by consumers, the contents of the can or canister are dispelled under pressure as a viscous foam gel that solidifies by reacting quickly with moisture in the atmosphere to form a chemically and physically stable and rigid polymer foam product. The curing times for OCF sealants are typically within minutes of use for the initial cure (tack-free) and then several hours for the final cure (fully cross-linked solid).

2. Use in Adhesive and Sealant Manufacturing

The adhesive and sealant industry utilizes MCCPs and LCCPs in a wide range of products that are utilized in the construction, automotive, and laminating industry. Manufacturers of air and water barrier sealants utilize these materials for their effectiveness as flame retardants and plasticizers. MCCPs also provide hydrophobicity to structural adhesives and enhance the tack of laminating adhesives.

3. Use in Metalworking Fluid Formulation

Both MCCPs and LCCPs are used as extreme-pressure additives in MWFs to enhance lubricity in certain metal forming and machining applications. MCCPs and LCCPs help ensure that machine components and metal parts do not break down or become damaged under the immense pressure necessary to make finished metal parts to required specifications. As detailed in various submissions by ILMA, the Industrial Fasteners Institute, and others, the functionality of MCCPs and LCCPs in certain formulations is very difficult or impossible to replace given the chemical role of these substances in the metalworking application for which the formulation is designed. The formulation process is very precise and generates virtually no waste as all of the ingredients are needed in the finished products at specified levels. Moreover, these ingredients are both commercially valuable and the weight-and-measurement requirements dictate pinpoint accuracy for the final product in its shipping container.

4. Use in Fastener Manufacturing

The fastener industry uses MWFs that contain MCCPs and LCCPs in several applications, such as stainless steel cold fabrication (cold forming, cold heading, and machining); machining threaded bolts; coolants and lubricants in press operations; titanium grinding; and in screw machines, sheet metal forming, and nut-forming operations. These fasteners are used in industries such as aerospace (commercial and military), automotive, transportation, energy, and defense. In particular, the fastener-manufacturing industry uses MCCPs and LCCPs as an extreme-pressure additive in the MWFs used to create fasteners for aircraft and jet engines. These fasteners include nuts, bolts, latch pins, and rivets that are manufactured to withstand extreme temperatures, corrosive environments, and stress encountered in flight, while having the lowest possible weight. To date, no viable alternatives to MCCPs and LCCPs in MWFs have been identified for tapping, deep drawing of stainless steel, or titanium grinding – all processes necessary to manufacture these parts.

B. Evaluation of EPA Exposure Scenarios and Release Pathways for the Manufacture and Use of MCCPs and LCCPs

1. Exposure Assessment of MCCP and LCCP Uses

Two sources of information on MCCP and LCCP levels in the environment are considered in the Risk Assessments, i.e., monitoring data and modeled concentrations. Monitoring data is addressed in the next section. Modeled environmental exposure data are generated using EPA models based on assumptions regarding processing, handling, release, and disposal for the previously mentioned manufacturing and use scenarios. These data can be useful for generating exposure estimates, though the results can vary greatly depending on assumptions regarding release pathways, particularly to water, and disposal practices. This section discusses the release pathways used in EPA's modeling. It explains how updated information from downstream users can inform EPA's Risk Assessments.

In general, the release pathways EPA included in its exposure scenarios defaulted to water releases for most operations, including tank cleaning, process equipment cleaning, and other steps in the use scenario. As a consequence, most of these scenarios estimated large and unrealistic releases to the water. Polymer, PVC, and rubber scenarios had 5-6% of the total MCCPs or LCCPs used released to water. The scenarios for formulation of adhesives, sealants, and coatings estimated 4-5% of the total MCCPs and LCCPs used in the formulation to be released to water, with an additional 14% released to water from the use of the finished products. The scenarios for MWF formulation estimated 2-5% of the total MCCPs and LCCPs used in the formulation to be released to water, with an additional 90-93% of the total mass of MCCPs or LCCPs used released to water during the use of MWFs. EPA estimates that almost all of the MCCPs and LCCPs used in MWFs are released to water either during formulation or use. The Coalition believes that the potential for release to water is grossly overstated and that in most uses there are no releases to water at all. For additional discussion of these points, see Attachment 2 (May 2015 submission by the Chlorinated Paraffins Industry Association (CPIA)).

2. Control of MCCPs and LCCPs During CP Manufacturing

There is currently only one active CP manufacturing facility in the U.S. producing MCCPs and LCCPs, although an additional facility could also begin manufacture if the PMNs that are the subject of these Risk Assessments are approved. At the currently active facility, there are a variety of controls to prevent discharge of MCCPs and LCCPs into the water. First, the manufacturing process of these substances does not involve water. Second, cooling water used for process cooling is applied via a non-contact closed system which isolates cooling water from process reactants. Third, for maintenance operations where vessel, tank, or pipeline equipment is purged or cleaned, entrained MCCPs and LCCPs are captured and placed into containers for disposal to avoid wastewater discharge. Fourth, the facility monitors the effluent discharge for chlorinated paraffin concentrations and reports the monitoring results monthly in a Discharge Monitoring Report to the Ohio Environmental Protection Agency (EPA).

As described above, because no water is used as a component of the CP manufacturing process, no process wastewater stream is generated. Where process maintenance is performed, if water is used as a cleaning medium, the potential for contaminated wastewater generation exists. The schedule of cleaning is infrequent. The water volume used is minimal. The resulting contaminated wastewater is managed as a waste via an outside approved TSD facility, not through the facility wastewater system.

As the cooling water is physically isolated from direct contact with the CP manufacturing process, the potential for CP contamination is minimized. The process equipment separating the CP manufacturing process from the cooling water (reactor cooling jackets and exchanger systems) is inspected and monitored to ensure the operational integrity needed to maintain physical isolation.

Finally, the facility wastewater effluent is monitored under a very rigorous and extensive testing protocol to assure proper control and compliance with a comprehensive NPDES permit. Results of this monitoring are provided to Ohio EPA on a monthly basis. The facility has been reporting CP effluent concentrations under its NPDES permit since 1993.

3. Control of MCCPs and LCCPs Used in the Manufacture of Foam Insulating Sealants

The blending and manufacturing processes for OCF sealants are designed to minimize any potential for environmental releases of all chemicals used, including MCCPs and LCCPs. The chemicals are pumped directly from bulk storage tanks or intermediate containers and are added to dedicated-blending tanks. Like other raw material ingredients for OCF sealants, MCCPs or LCCPs are added to the blending tank in precise amounts to ensure product quality and performance. They are fully consumed in the manufacturing process, leaving no excess or residual material.

The manufacturing process for OCF sealants is highly water-sensitive due to the reactivity of isocyanates used in product formulations. Therefore, no part of the manufacturing process is in contact with water. Additionally, manufacturers use solvents to conduct any required equipment or storage tank cleaning. It is important to note that tank cleaning is rare because all materials in the dedicated blending tanks are consumed in the manufacturing process and cleaning is not necessary. Any solvents used for cleaning are handled as hazardous waste as required by applicable regulations and disposed of accordingly. See the ACC Center for Polyurethanes Industry comments for more detail.

OCF manufacturers conduct quality control inspections of formulations during processing and final product packaging. Any material that fails quality inspection may be reworked to allow it to be used in the manufacturing process. In the event that the final product is rejected, the off-specification product is handled as hazardous waste due to the presence of other chemical components that are under pressure in the can or canister. All material declared hazardous waste is handled and disposed of according to applicable regulations, such as 40 C.F.R. Part 262 – Standards Applicable to Generators of Hazardous Waste. Water release would not occur during off-specification waste disposal, as the materials are highly incompatible with water.

4. Control of MCCPs and LCCPs During Adhesive and Sealant Manufacturing

Manufacturers using MCCPs and LCCPs in adhesive and sealant applications address disposal of waste material containing these substances by various methods. For water-based products, approaches include cleaning of mixing vessels and collecting waste in large totes and subsequently reusing this wash water and material in the next production cycle. For products and processes that are water-sensitive (i.e., cannot come in contact with water), excess MCCP- or LCCP-containing materials are typically collected in drums and sent off-site to be solidified and shipped to an approved landfill. Organic solvents used to clean residual MCCP- or LCCP-containing material from process equipment is sent for solvent recycling or disposed of as hazardous waste. Empty drums, totes, tank trucks, and rail cars used for shipping MCCPs or LCCPs are either returned to the manufacturer or sent to an approved facility for cleaning and recycling or disposal. Those facilities must have approved permits for their operations and are closely monitored.

5. Control of MCCPs and LCCPs During MWF Formulation

Due to economic incentives and EPA rules, MCCP and LCCP raw materials that arrive at a formulator's facility leave in the form of a final, finished product. Inbound raw materials are received at the formulator's facility in drums, totes or tank wagons using established procedures to control unloading and to inspect raw materials to ensure that the accurate contractual quantity was delivered and that there is no issue with the quality of the product. MCCPs and LCCPs are rarely lost during the unloading process from tank wagons or other bulk containers. For the negligible amount that may not go into the storage tank, that lost raw material is recovered and sent to a reclamation facility. After receipt, MCCPs and LCCPs are generally blended into the formulation either using hard-piping and dedicated mixing tank equipment or directly transferred from drum or tote to the mixing vessel. In all formulation facilities, after final blending and quality-control sampling, finished MWFs are pumped from the blending tank to the drumming area for final packaging and shipment. Empty drums or totes in which MCCPs or LCCPs had been received are sent either to drum recyclers or back to the MCCP or LCCP producer. Because of the product's economic value and the expense of waste disposal, formulators have every incentive to ensure that no finished product is lost during the manufacturing process.

6. Control of MCCPs and LCCPs Used in MWFs

There are specific disposal practices used in fastener and metal-part manufacturing to control wastes and eliminate discharge to water. MWFs are recycled in-house as long as they continue to perform. When they can no longer be used, they are disposed in one of two ways: 1) in accordance with the plant's NPDES permit, which reflects state and federal discharge limits, or 2) through a certified third-party hazardous waste removal company. In the case where a facility hires a hazardous waste company, the MWFs are routinely taken off-site by that company for appropriate hazardous waste treatment of fluids, usually as incineration for fuel, and always in accordance of all applicable state and federal environmental regulations.

C. Evaluation of MCCP and LCCP Environmental Monitoring Data

Environmental monitoring data represent an important information source that EPA typically does not have when conducting a PMN review. These monitoring data should be the focus of EPA's environmental exposure assessment as they have the benefit of being "real world" data that integrate all actual sources of chemical release, including both current and past releases. While these data can be limited in the locations of the samples or by the methods used in sampling and analysis, they are still much more likely to be representative than modeled data.

The Risk Assessments summarized available literature on measured MCCP and LCCP concentrations between 1980 and 2013. This review considered research where the chlorinated paraffin congeners were identified both from the United States and internationally. The Risk Assessments identified three selection criteria:

- defined chain length;
- use of "modern analytical techniques"; and
- "at a minimum, general information on sampling location."

EPA concluded that the data "provide some evidence that MCCPs and LCCPs are released into the environment" at discrete locations and times. The Risk Assessments concluded that measured concentrations reported in the literature may indicate a risk of acute or chronic injury to aquatic organisms, and a risk of chronic injury to sediment-dwelling organisms. The Risk Assessments identified a concentration of concern (COC) for surface water of 1 μg/L (1 ppb) (acute and chronic). The Risk Assessments identified an acute sediment COC of 374 mg/kg d.w. and a chronic sediment COC of 18.7 mg/kg d.w.

A review of the complete set of data considered by EPA does not support an interpretation that exceedances of these COCs will occur in the environment. Furthermore, a comparison of the measured surface water data to the results of EPA modeling demonstrates opportunities for refinement of the EPA modeling inputs to better reflect environmentally plausible surface water concentrations. It is important to note that much of the data were collected outside the United States, where historical discharge and pre-treatment standards may have been less comprehensive than in the U.S. Some of the data reflect impacts not representative of current exposure scenarios in the United States, such as a chlorinated paraffin manufacturing facility surface impoundment lagoon, and surface water ponds impacted by uncontrolled electronic waste recovery operations. As explained below, the available analysis methods are subject to interferences which may result in a positive bias (i.e., overestimation) of actual MCCP and LCCP concentrations. The weight of the evidence indicates that the MCCP-load in the environment can be well managed by eliminating discharge pathways to water, which is reflective of current practices in the United States.

General Limitations of the Measured Data

The Risk Assessments note that it is unknown whether the data summarized is representative of the overall distribution of MCCPs and LCCPs in the environment. EPA also acknowledged that quantification of MCCPs and LCCPs by "modern techniques" can be positively biased by "detection of low chlorination congeners in samples." The EPA summary also noted that a round-robin study of SCCPs has shown appreciable inter-laboratory variation, and that poor selection of calibration standards may cause errors of up to an order of magnitude. The Risk Assessments specifically discussed electron capture negative ion mass spectrometry (ECNI-MS) as an example of a method capable of detecting specific congeners, but where difficulties with data reliability still persist. Literature reviews of ECNI-MS generally indicate that use of low resolution mass spectrometry (LRMS) "increases the risk of interferences, which have to be controlled or eliminated" (Kassim and Barcelo, 2009). The use of high resolution mass spectrometry (HRMS) may address some of these interferences by offering a more selective detection method, but typically is not used for routine analyses.

1. Surface Water

EPA identified nine references with at least one reported MCCP surface water concentration. Fifteen concentrations (some of which represent mean or maximum values) were converted to uniform units by EPA and are presented in Appendix D of the Risk Assessments.

Review of Surface Water Data

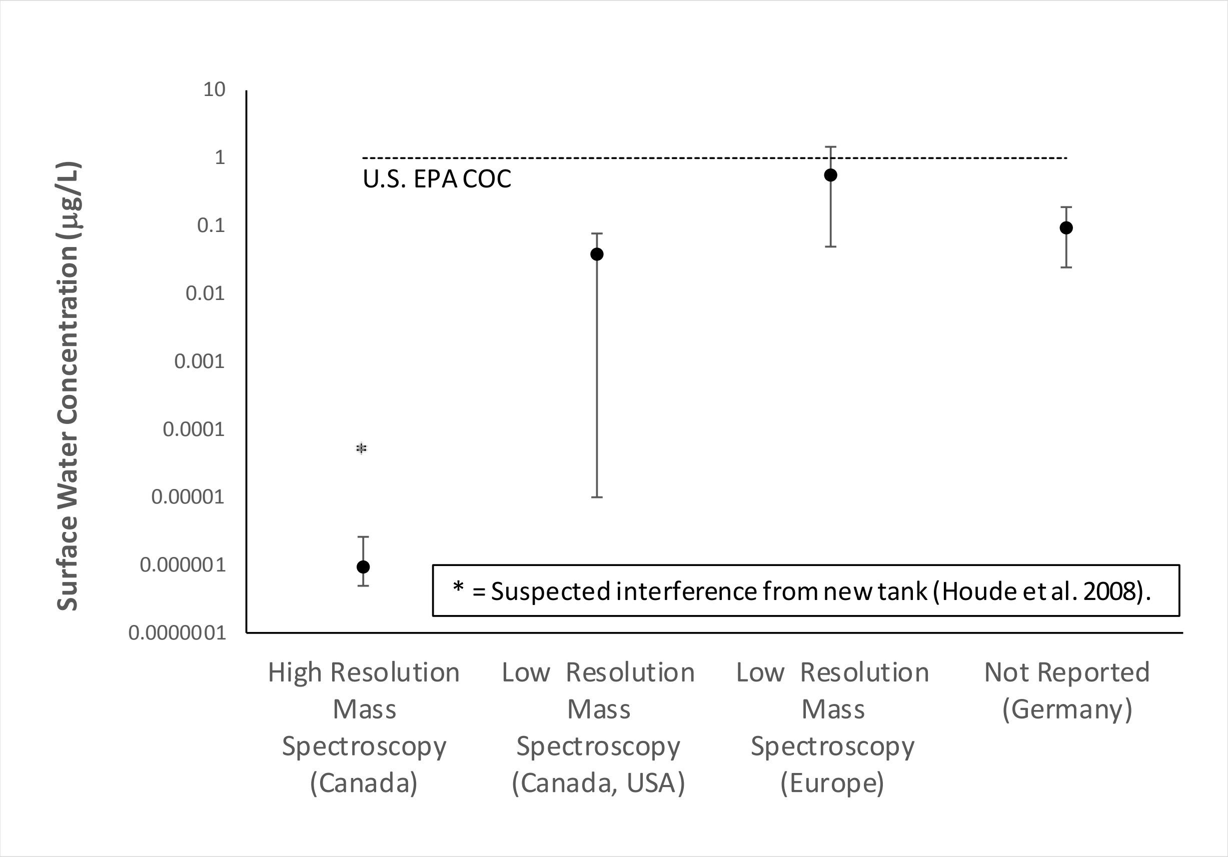
Of the nine studies identified by EPA, only one study (discussed in more detail below) reported a surface water concentration exceeding the EPA COC of 1 ppb. The 15 concentrations considered by EPA are summarized in Figure 2 below. The error bars represent the range of concentrations shown in Appendix D, and the circle indicates the mean of the concentrations summarized by EPA in Appendix D for each group. As acknowledged by EPA, the data are insufficient to determine the distribution of MCCPs in the United States. However, three important trends are apparent:

- Lower MCCP concentrations in Canada or the United States as compared to Europe, which suggests that European data is less likely to be relevant to the U.S.;
- Lower MCCP concentration for analyses based on HRMS as compared to LRMS, which suggests that the reported concentrations based on the less-accurate analytical method may not be reliable; and
- Appreciable fraction of the data representing surface water concentrations below the EPA COC, which suggests that discharges to surface waters are capable of being managed.

It is important to note that there are additional reasons to be cautious in relying on the reported data. For example, in an analysis of Lake Ontario water, Houde et al. 2008 reported an outlier "possibly related to the first use of the tank system during the cruise", which "illustrate[d] the potential for field contamination." As described in more detail below, it is unknown whether the single result of 1.49 µg/L reported by Peterson et al. (2006) may have been impacted by sample contamination, because information regarding the general sampling location and materials used to collect the sample were not provided.

In summary, the data do not indicate the likelihood that MCCP concentrations in surface water exceed the acute or chronic COC for aquatic species, particularly when the higher resolution method is used, and when data from the U.S. is segregated from data in Europe. The HRMS data suggest that the MCCP concentrations may be as much as five to six orders of magnitude less the EPA COC for surface water.

Figure 2: Summary of Surface Water Data Considered by EPA by Region and Analytical Method



Limitations of Key Study Identified by EPA

In its risk characterizations, EPA chose to focus on the maximum surface water concentration from Petersen et al. (2006) collected in Norway from an undisclosed location of 1.49 µg/L. The Risk Assessments note that for surface water, "EPA/OPPT based the aquatic risk findings for MCCPs and LCCPs on the highest concentration reported by Peterson et al. (2006)."[16] This study was the only one reviewed by EPA to report a surface water concentration exceeding the COC of 1 µg/L (1 ppb).

This study has several limitations, however, which call into question whether it should have been considered in the Risk Assessments at all. First, no general location of the sample (other than the country of origin) was reported. Therefore, this study did not meet one of the three selection criteria identified by EPA, and the conditions and release scenario that this sample result represents are unknown. Second, while this study did include steps to remove organo-chlorine interferences like PCBs, quantification was by LRMS, which may have confounded the analysis of SCCPs and MCCPs in the sample. Third, there was a significant difference between the two

---

[16] EPA TSCA New Chemicals Review Program Standard Review Risk Assessment on Medium-Chain Chlorinated Paraffins (PMN P-12-0282, P-12-0283) and Long-Chain Chlorinated Paraffins (PMN P-12-0284) at 30.

water sample results reported in the study, with one MCCP result of 1.49 μg/L, and a second MCCP result that appears to be less than 0.05 μg/L, based on the figure presented in the paper. The authors do not offer an explanation for such a significant difference, and it is not possible to rule out that there may have been sample contamination affecting the first sample. No details were provided regarding the sampling locations, sampling equipment, and sampling methods, which are essential attributes to assess the likelihood of unintended sample contamination. This work was presented at the 2006 annual Dioxin Symposium in Oslo and, therefore, was subject to a more cursory peer review as compared to a peer-reviewed publication. Taking into account the serious limitations of this study, as well as the results of the remaining studies indicating surface water concentrations less than the EPA COC, there appears to be a very low likelihood that environmental surface water concentrations in the United States exceed the EPA COC.

Comparison of Measured Concentrations to EPA Model Results

EPA indicated in its summary of the risk findings that the measured data "were used as supporting information to inform the relevant pathways for estimating potential releases from relevant use categories for the PMN substances." A comparison of the EPA modeling results to measured surface water concentrations shows significant disagreement between the modeling results and the available surface water data. Figures 3a, 3b, and 3c below compare the predicted EPA surface water concentrations to measured data from the U.S. for the metrics 7Q10 (10th percentile), harmonic mean (10th percentile) and harmonic mean (50th percentile). Irrespective of the surface water concentration metric selected from the EPA modeling, the measured surface water concentration data reviewed by EPA indicate that the modeled concentrations are not environmentally plausible. Furthermore, as noted in the Risk Assessments, the water solubility of MCCPs and LCCPs is very low, less than 5 to 27 μg/L. In contrast, the EPA model results reflect maximum predicted surface water concentrations in some cases exceeding 500 μg/L (7Q10 – 10th percentile).

In summary, considering either water solubility or the available measured concentrations of MCCPs, it is clear that there is systematic bias in the EPA modeling assumptions reflecting the implausible assumption of pervasive down-the-drain discharge of MCCPs and LCCPs among industrial and commercial facilities. These assumptions of a down-the-drain pathway to municipal treatment and subsequent discharge to surface waters for wastes generated in cleaning and equipment transfers do not reflect current waste management practices in the United States. As described previously, the local and federal regulatory framework in the United States prohibits down-the-drain disposal of oil-contaminated cleaning wastes or spent fluids such as MWFs. Taking into account the very low solubility of MCCPs and LCCPs, as well as pathway elimination in accordance with current regulations, it is clear that the modeled surface water concentrations presented in the Risk Assessments overstate true environmental surface water concentrations by at least five orders of magnitude, if not more.

Figure 3a: Comparison of Modeled Results to Measured Data (7Q10 – 10th Percentile)

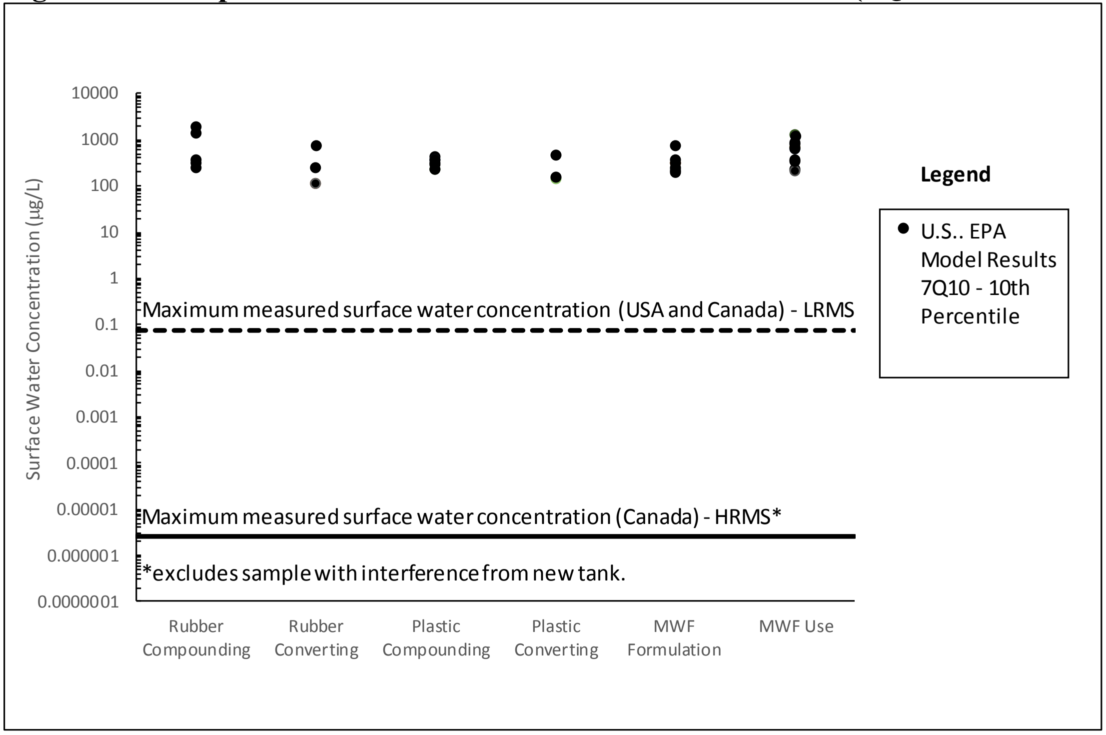


Figure 3b: Comparison of Model Results to Measured Data (Harmonic Mean – 10th Percentile)

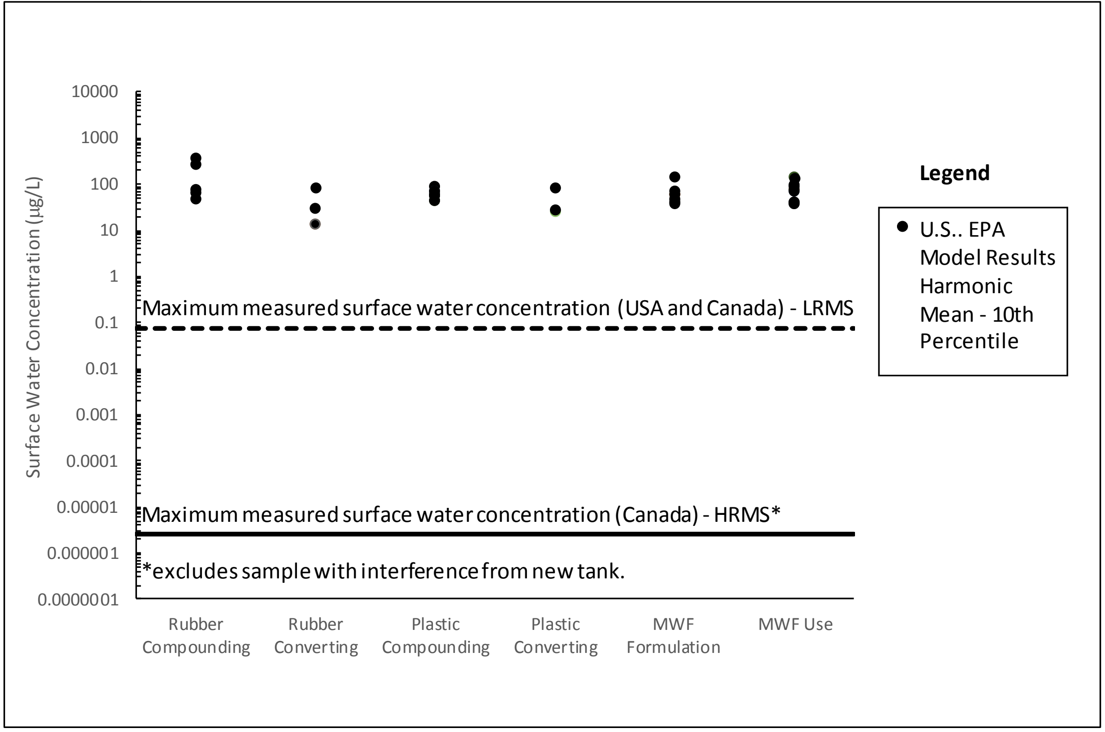
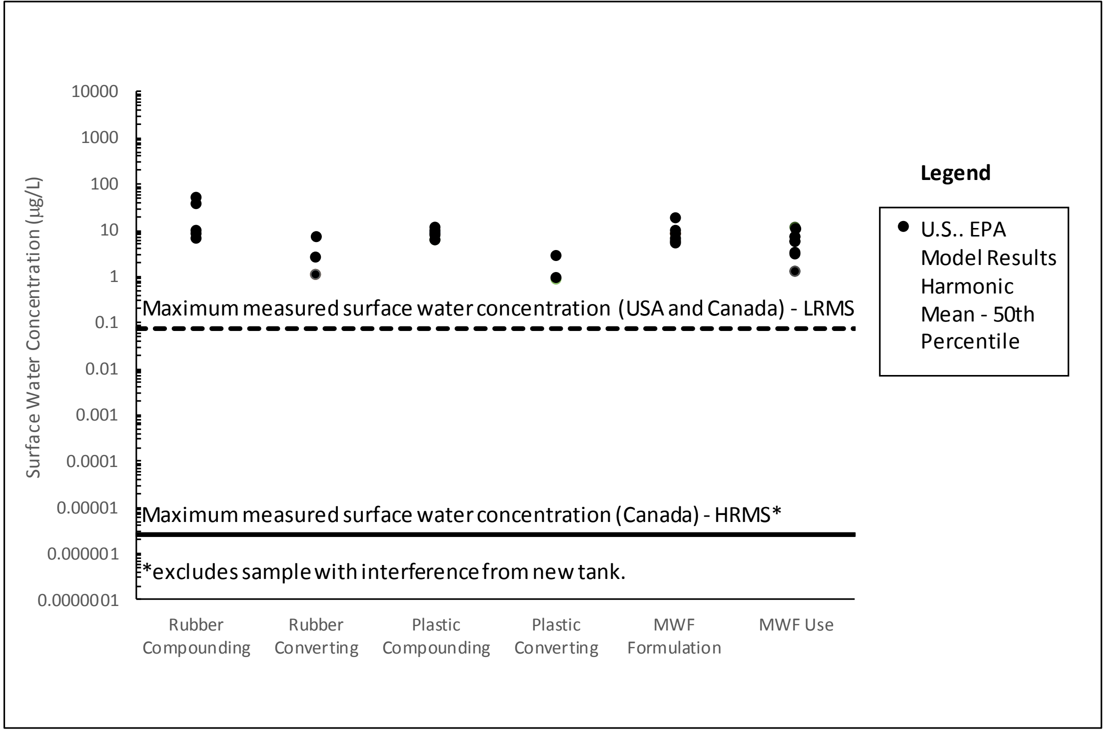


Figure 3c: Comparison of Model Results to Measured Data (Harmonic Mean – 50th Percentile)



2. Sediment

EPA identified 17 studies with reported MCCP sediment concentrations. A total of 139 concentrations (some of which represent mean values, maximum values, or duplicates) were converted to uniform units by EPA and presented in Appendix D of the Risk Assessments. Of the 139 samples, one result appeared to be an instrument detection limit (from Pribylova et al. (2006), and the same result of 0.068 mg/kg d.w. appears to have been associated with Tomy et al. (2009) and Tomy and Stein (2009). Therefore, 137 converted concentrations from Appendix D of the risk assessments are discussed below.

Review of Sediment Data

Of the 17 studies identified by EPA with MCCP data, only three studies reported a sediment concentration greater than the EPA COC of 18.7 mg/kg d.w. Figures 4a and 4b below present the frequency of concentrations categorized by marine and non-marine locations. Figures 5a and 5b present the concentrations categorized by method and region. Of the 137 concentrations listed by EPA, approximately 90% were below the EPA COC, indicating that exceedances of the COC are not common. As explained in more detail below, the three studies with detected concentrations greater than EPA's COC are not reflective of current environmental practices in the United States. Those locations consisted of pond sediment samples from China at an electronic waste facility where chlorinated paraffin release is unregulated (Chen et al., 2011); sediment samples from the United Kingdom at locations with extensive polychlorinated n-alkanes (PCAs) use and discharges to industrial wastewater (Nicholls et al., 2001), and a historical surface impoundment at a chlorinated paraffin manufacturer in the United States (USEPA, 1988), from data collected 30 years ago (in 1986). The LCCP data reviewed by EPA was limited to marine sediment, with a maximum concentration of 0.431 mg/kg d.w.

Several general trends are apparent in Figures 4a, 4b, 5a, and 5b, including:

- MCCPs are not accumulating in marine sediments at levels exceeding the EPA COC for sediment;
- MCCPs detected above the EPA COC are associated with specific discharges to industrial wastewaters (already restricted in the United States) rather than indirect sources;
- Many of the samples were quantified by low resolution mass spectrometry methods, which may be impacted by interferences from other PCAs or chlorinated compounds; and
- The sampling results based on HRMS were below the EPA COC. The two HRMS results that were greater than 1 mg/kg d.w. (but less than the EPA COC) were collected from "landfill sediment."

In summary, the environmental sediment data summarized by EPA suggest that exceedances of the COC are uncommon, and when they have occurred, they appear to be associated with facility-related surface impoundments or discharges of significant amounts of MCCPs to industrial wastewaters. These releases to surface impoundments or industrial wastewaters are restricted by current discharge regulations and waste management practices in the United States.

Figure 4a: Distribution of Marine Concentrations Summarized by EPA

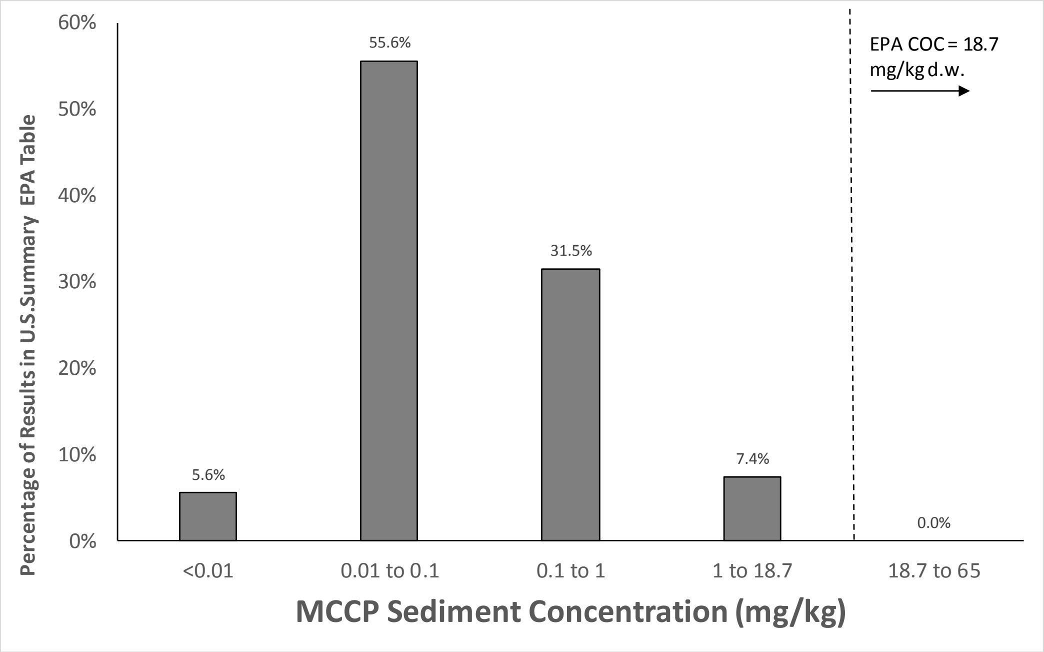


Figure 4b: Distribution of Non-Marine Concentrations Summarized by EPA

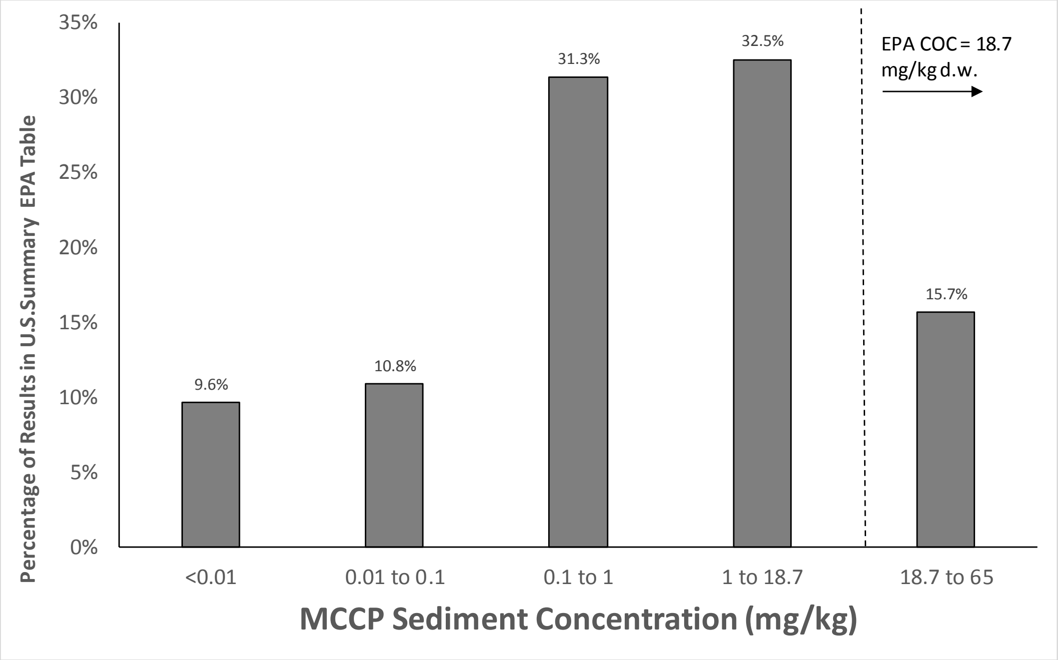


Figure 5a: Summary of Marine Sediment Data Considered by EPA by Region and Analytical Method

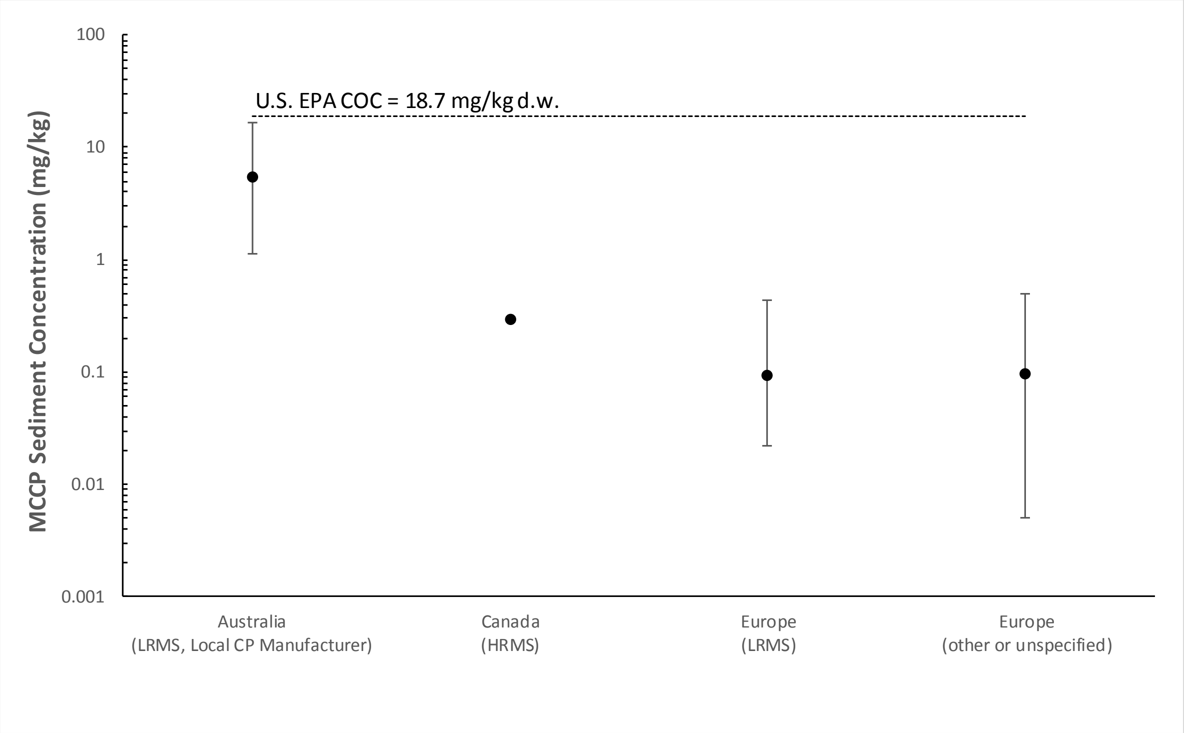
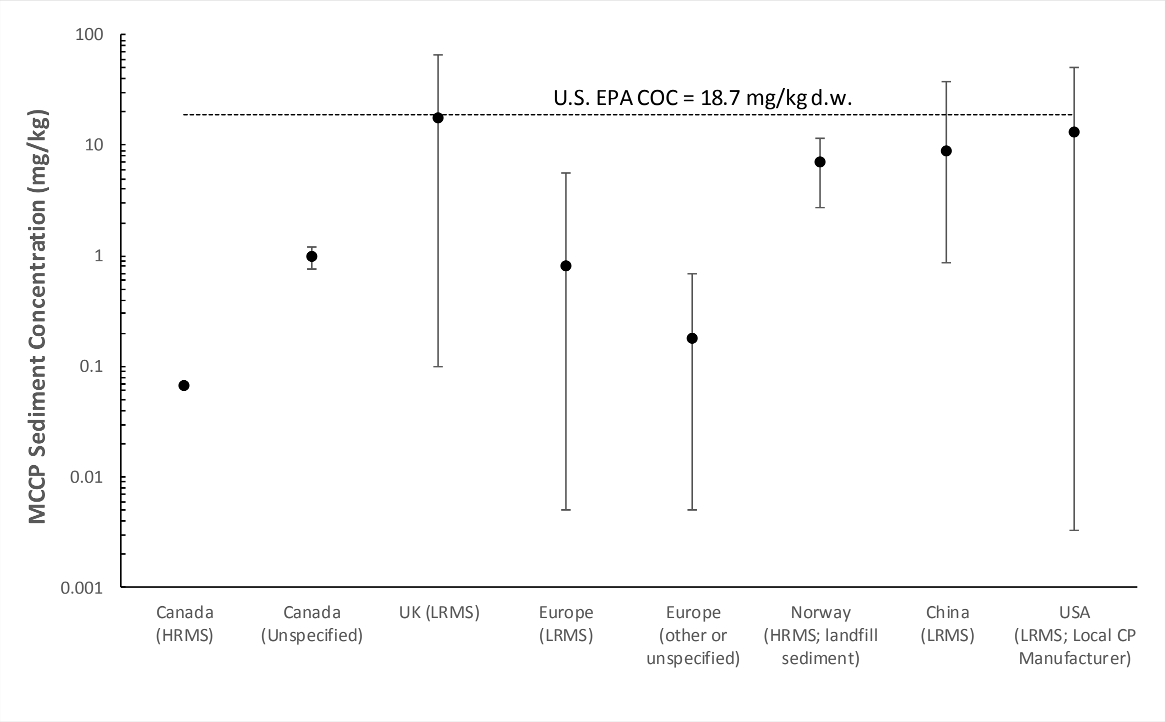


Figure 5b: Summary of Non-Marine Sediment Data Considered by EPA by Region and Analytical Method



Limitations of Studies Reporting Elevated Concentrations

EPA identified three studies with reported concentrations exceeding the COC of 18.7 mg/kg d.w. EPA considered the study conducted in the United Kingdom by Nichollis et al. (2001) to be the most relevant, but it generally considered the studies with at least one risk quotient greater than 1 as supporting the conclusion that MCCP concentrations in sediment may present a chronic risk to aquatic species. Of the three studies considered by EPA with concentrations greater than the EPA COC:

- One study was performed in South China, where use of CPs, including SCCPs, is not regulated (Chen et al. 2011). The mean and maximum MCCP concentrations of 21 and 38 m/kg d.w. cited by EPA were observed in the pond sediment of an electronic waste recycling facility there. Despite the lack of regulation and controls in China, the mean MCCP concentrations in industrialized areas of 3.9 mg/kg d.w. were less than the EPA COC.

- A second study with reported eight of 29 concentrations exceeding the EPA sediment COC was performed in the United Kingdom, including sampling sites targeted for "industries known to employ significant quantities of polychlorinated alkanes (PCAs)" in manufacturing or production (Nicholls et al. 2001). Samples were analyzed by a low resolution mass spectrometry method (GC-NICI-MS). The elevated concentrations in this study appear to reflect down-the-drain disposal of PCAs to industrial effluents, with less restrictive pre-treatment or on-site treatment standards than those in the United States today. In addition, a low resolution mass spectrometry method was used; therefore, it is unclear whether the pervasive PCA use in the areas sampled may have positively biased the reported MCCP concentrations.

- The third and final study with concentrations exceeding the EPA COC (USEPA, 1988) was a field study completed in the United States near a chlorinated paraffin manufacturing facility. Of the eight sample results summarized by EPA, only three results exceeded the COC. These three samples were not representative of environmental sediment, but rather were collected from the surface impoundment lagoon located at the chlorinated paraffin manufacturing facility.

3. Conclusion on Monitoring Data

Based on a review of the environmental measurements summarized by the EPA, the weight of the evidence does not suggest that exceedances of the EPA COC for surface water or sediment are likely. While limited in geographical and temporal coverage, a conclusion of frequent or likely exceedances of the EPA COCs is not supported by the available data.

Information regarding general sample location was not available for the sole surface water result exceeding the EPA COC, though the study appears to have been conducted in Norway. Two of the studies characterized areas with obvious impacts, including a surface impoundment at a CP manufacturing location in the United States 30 years ago, and a pond at an electronic waste facility in China. Sediment data collected in the United Kingdom appears to reflect significant discharge of PCAs to industrial wastewater, a scenario which is not applicable to the current regulatory framework in the United States. The available data support the conclusion that environmental concentrations of MCCPs and LCCPs are effectively managed by controlling discharges to water.

D. Evaluation of the PBT Characteristics of MCCPs

EPA's conclusion that MCCPs are "expected" to be PBT chemicals is profoundly important to this assessment. It is the primary reason why EPA is threatening a ban of MCCPs rather than considering other risk management approaches (see Part VI for more discussion on these). Given the significance of these conclusions, EPA should provide a more transparent presentation of the specific data that led EPA to its conclusion, complete with discussion as to why it believes the data are more representative of the PBT characteristics of MCCPs than other data that do not support a PBT conclusion. Instead, the Risk Assessments rely primarily on statements from select reviews of MCCPs by other governments, some of which are outdated and written before much of the more relevant environmental fate data on MCCPs was developed. EPA's overall conclusion that "some MCCP congener groups present in the products are both [emphasis added] very persistent and very bioaccumulative" cannot be substantiated by the data presented.

The Risk Assessments do not:

- Provide a clear and transparent review of the PBT data against EPA's PBT criteria;
- Define what the congener group is in the context of this assessment and explain how the congeners are relevant to the assessment of the MCCP PMN substances;
- Demonstrate that the same congener groups are both persistent and bioaccumulative or very persistent and very bioaccumulative;
- Conduct a weight-of-the-evidence review that addresses the considerable results that are below EPA's criteria for persistence and bioaccumulation.

To draw the conclusion that some MCCP "congener groups in the products" are both very persistent and very bioaccumulative without actually citing specific study data and explaining why those data were selected over other data that do not support these conclusions is unacceptable in a highly influential scientific assessment of this import and magnitude (see Part II:B on highly influential/influential assessments).

1. MCCP Persistence Data

EPA has stated that its conclusion of persistence for MCCPs is based on "lines of evidence" that include "sediment core studies, environmental fate studies, and associated calculations" and that these data "indicate transformation half-lives of months to years, depending on the environmental media." As stated above, it is not possible to determine from the Risk Assessments to which data EPA is referring or how those data substantiate these conclusions.

While EPA cites sediment core studies in the Risk Assessments, these data are presented only in Appendix D, Environmental Monitoring Data, and there is no mention of how these data can be used to interpret half-lives of MCCPs in sediment. Based on the Coalition's review of these data, they provide a level of MCCPs in the sediment at a single point in time without any indication of transformation rates or half-lives. Further, as discussed in the review of the sediment monitoring data (see Part IV.C), most of these sediment samples are at concentrations well below the sediment COC. The few measurements above the COC were from highly polluted sites in China and United Kingdom, where U.S. controls are not in place, and within a settlement pond at a CP manufacturing facility from 30 years ago that was not outside of the facility's boundaries or in the native environment. The mere detection of MCCPs in the sediment, particularly if there are ongoing and uncontrolled discharges, does not provide an adequate basis to conclude persistence or very persistent. More importantly, the fact that MCCPs have been used for decades and sediment samples, particularly in the U.S., are generally below the COC indicates that MCCPs are not accumulating in sediments at levels that present a risk to the environment in the U.S.

There are 12 MCCP-related biodegradation studies identified in Appendix A. This appears to be a comprehensive review of the available study data. The more reliable of these studies are the series of experiments conducted by van Ginkel, which were conducted recently (2010-2014) using current guidelines and protocols. These data indicate that most MCCP test materials in the lower- to mid-chlorination levels, approximately 40-52% chlorination by weight, are either readily biodegradable or inherently biodegradable. While the higher chlorinated test materials, 55-63% chlorination by weight, were not readily or inherently biodegradable, they did demonstrate significant oxygen consumption, which indicates that partial biodegradation of components occurred. The trend lines showed that degradation of these higher chlorinated test materials was continuing until the study was halted, suggesting that these materials would have continued to biodegrade over time. Poor biodegradation in earlier studies is likely due to the reduced bioavailability of the test materials in test systems that were not well designed for hydrophobic materials like MCCPs.

The Risk Assessments also cited conclusions from reviews by other governments in their persistence reviews. This practice is not ideal because it requires the reviewer to evaluate separately the underlying data in those assessments. Moreover, if EPA is going to cite other governmental reviews, it needs to cite the most recent conclusions from those governments. For example, in the main text of the Risk Assessments, EPA quotes a 2005 European Chemicals Bureau (ECB) review that states there are "no standard ready or inherent biodegradation test results" for MCCPs. This statement is no longer accurate because its own Risk Assessments reference several recent MCCP ready and inherent biodegradation test results in Appendix A-1, in which EPA states:

> EPA/OPPT concurs with the EU's conclusions that under these modified test conditions, C14 41.3 % by wt. Cl and a C14 45.5% by wt. Cl substances are readily biodegradable. C 15 51% by wt. Cl were found to be inherently degradable and possibly readily degradable in modified OECD 301 and 301D tests. This suggests that CPs with these chain lengths and shorter, and this degree of chlorination and lower, are inherently degradable.

Two of five MCCP PMNs under review are for an exclusively C_{14} chloroalkane substance. EPA has concluded that this substance is readily biodegradable at 45% chlorination by weight and therefore not a PBT. In addition, EPA concludes that C_{14} and C_{15} up to 51% chlorination are inherently degradable and likewise are not PBTs. C_{14} and C_{15} are the most common chain lengths in full range MCCPs, C_{14-17}, and thus these data and conclusions are also highly relevant to that substance. These data are, in fact, what led the European Chemicals Agency to conclude that MCCPs up to 50% chlorination are readily biodegradable and therefore do not meet the criteria for Annex XIII of REACH, i.e., they are not PBT or vPvB substances (ECHA 2014).

2. MCCP Bioaccumulation Data

EPA's conclusion in the December 23 Federal Register notice on the bioaccumulation potential of MCCPs is that the available data "indicate that these substances have bioconcentration factors (BCFs) and bioaccumulation factors (BAFs) that exceed 1,000 or 5,000 liters per kilogram wet weight of tissue (L/kg ww). Therefore, the PMN substances are expected to be very bioaccumulative." The Risk Assessments state that this conclusion is based on select data for just some MCCP materials: "available evidence for MCCP congener groups with intermediate chain lengths and chlorination suggests that some may have BCFs or BAFs greater than 1000 or 5000 (EC, 2008b; ECB, 2008). This suggests that some congener groups in MCCP products may be bioaccumulative or very bioaccumulative." [Emphasis added].

However, it is these same congener groups with intermediate chain length and chlorination that EPA found to be readily or inherently biodegradable. Accordingly, EPA's own conclusions undermine its determination that "some MCCP congener groups present in the products are both very persistent and very bioaccumulative" (emphasis added), because those select MCCP test materials with lower carbon number ranges and chlorination levels cannot be both very persistent and very bioaccumulative.

Further, EPA has based key conclusions on previous reviews by Environment Canada and the ECB, the citation for this is actually a draft report by the ECB, rather than more appropriately reviewing the source data already included in the Risk Assessments.

EPA also cites Houde (2008) as evidence for bioaccumulation of MCCPs in field-derived log BAFs and BMFs derived for food chains in Lake Ontario and Lake Michigan. The data from Houde (2008) were reviewed independently by several experts, Thompson and Vaughan (2014) and Arnot (2014) (Attachment 4), and these scientific reviews reached very different conclusions than EPA did.

Arnot (2014) reviewed 97 measured data points, including those from Houde (2008) and Fisk (1996, 1998, and 2000). Of these 97 measured data points, 90 (92.8%) were lower than the threshold criterion of a biomagnification factor (BMF) of 1. The median BMF value (central tendency) was 0.27, well below the biomagnification criterion. In addition, this assessment demonstrated that all of the measured trophic magnification factors (TMFs) for MCCP constituents were < 1. In this review, the lipid normalized BAFs were divided by the substance K_{OW} to convert BAFs to fugacity ratios using the methods outlined in Burkhard et al. 2012. This conversion allows all of the data (BCFs, BAFs, BMFs, TMFs) to be placed into a framework for assessing biomagnification potential under equal terms in a weight-of-the-evidence approach.

Such an approach was determined to be the most appropriate approach by the SETAC POP/PBT expert workshop (Gobas et al., 2009), which concluded that a TMF >1 represented the most conclusive evidence of the bioaccumulative nature of a chemical. In this case, the data indicate that MCCPs are not bioaccumulating in the environment since the normalized BAF, BMF, and TMF data are largely below the common B criterion of 1.

The following figure is from Dr. Arnot's report. It shows that the vast majority of the data, including all of the TMF data, are below 1 and thus do not support a bioaccumulation conclusion for MCCPs. Further, as most of these are field data that include all chlorination levels, it should provide additional confidence that all MCCPs, even those with lower chlorination levels, are not bioaccumulating in the environment.

Figure 1 from Arnot 2014: Bioaccumulation Assessment of MCCPs

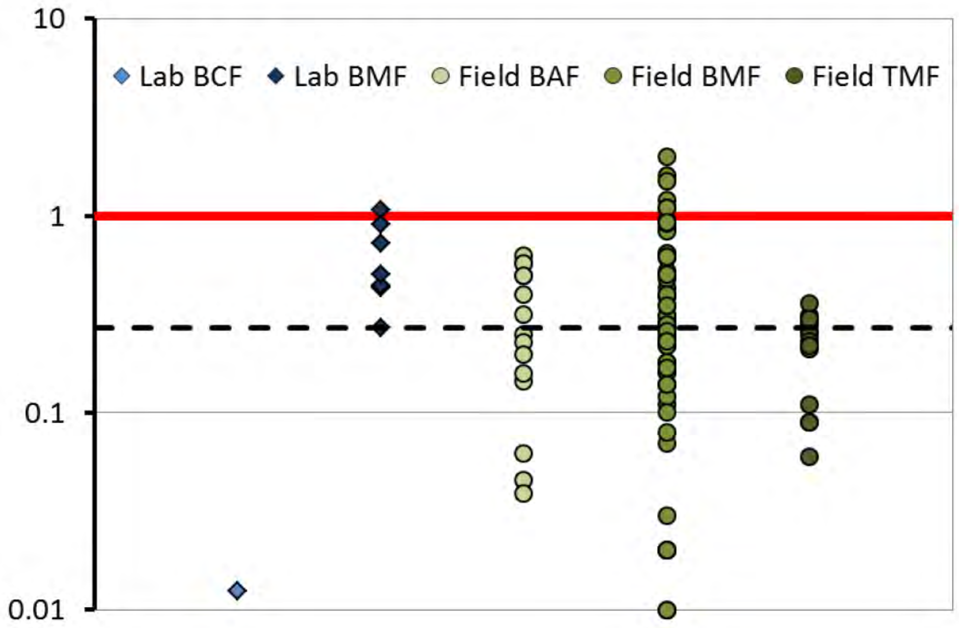


Figure 1. Fugacity ratios calculated using the recommended methods [6] for available relevant and reliable bioaccumulation data for MCCP constituents. Values > 1 (red line) indicate biomagnification (bioaccumulation) hazard. 93% of the data points are < 1 and the median value = 0.27.

Thompson and Vaughan (2014) likewise cited laboratory-derived BMFs (expressed on a whole-fish basis) ranging from 0.1 to 0.96 (with a mean of 0.38) for juvenile rainbow trout fed diets containing one of four C_{14} CPs (ranging from 42 to 55% chlorination) or two C_{16} CPs (34 and 69% chlorination). Again, these values do not fulfill the bioaccumulation criteria (i.e., BMF > 1). Similarly, based on field data, Thompson and Vaughan (2014) concluded that there is no convincing evidence for BMFs of > 1 for C_{14}, C_{15} and C_{16} CPs (and the mean of the three) derived between trout and three species of potential prey fish caught in Lake Ontario and Lake

Michigan. These values are lipid-normalized, which is standard for field data. In regard to the TMF data, Thompson and Vaughan stated:

> Trophic magnification factors, considered the most convincing evidence for bioaccumulative properties by Gobas et al. (2009) and the Gold Standard measure, were observed to be less than the criterion of 1, with a maximum of 0.29 for individual chain lengths and a value of 0.22 for total C14–17 chlorinated alkanes in Lake Ontario. Trophic magnification factors could not be calculated for Lake Michigan due to nondetected values in numerous species (although the TMF data again suffers from the same issues of small sample size with high variability discussed above), the present of nondetected values in numerous species is pertinent when considering that MCCPs have been used for many years and thus could be considered to have reached steady-state in the environment.

Overall, it appears that a weight-of-the-evidence evaluation of the environmental fate data demonstrate that there are no circumstances where MCCP congeners or products are both simultaneously persistent and bioaccumulative or very persistent and very bioaccumulative. This assessment is supported by the existing monitoring data that do not reveal high levels (above the COCs) in the environment in the U.S. and the fact that many of the field samples were reported as non-detectable. As discussed in Part V.B, there is the possibility of collecting additional monitoring data to address any lingering uncertainties EPA may have with its risk assessment of MCCPs. This would be a more direct and effective way of evaluating the environmental risks of MCCPs.

E. Evaluation of the PBT Characteristics of LCCPs

A particular concern with EPA's evaluation of the PBT characteristics of LCCPs, C_{18-20}, is that the Risk Assessments, after presenting relevant data on LCCPs, chose to read down to MCCP data and conclusions rather than draw independent conclusions for LCCPs. This is particularly troubling because there are no data in the Risk Assessments that indicate specific environmental hazard concerns with C_{18-20} chloroalkanes. For example, for aquatic acute concern for LCCPs, EPA concluded "Aquatic Acute Concern Concentration = NES," meaning that there are no effects at saturation, but the quantitative assessment deriving COCs used all MCCP data.

The conclusion that LCCPs are NES is consistent with other EPA guidance for both acute and chronic toxicity, given the very high log K_{OW}s for LCCPs:

> In general, where the log K_{OW} is less than or equal to 5.0 for fish and daphnid, or 6.4 for green algae, ECOSAR provides reliable quantitative (numeric) toxicity estimates for acute effects. If the log K_{OW} exceeds those general limits, empirical data indicate that the decreased solubility of these lipophilic chemicals results in "no effects at saturation" during a 48-hour to 96-hour test. For chronic exposures, the applicable log K_{OW} range to derive reliable quantitative (numeric) results is extended up to log K_{OW} 8.0. If the log K_{OW} of the chemical exceeds 8.0 which generally indicate a poorly soluble chemical, "no

> effects at saturation" are expected in saturated solutions even with long-term exposures (Tolls et al. 2009).[17]

EPA's summary of how it ultimately addressed the LCCPs environmental hazard assessment is included below. EPA called this "a very conservative approach" and that it "may not inherently characterize toxicity to LCCPs directly."

> Specifically for the chronic and acute aquatic invertebrate, aquatic sediment, avian, and terrestrial plant endpoints for LCCPs, other analog data provided was acceptable using compounds with chlorination percentage of 52 wt % and carbon chain lengths of $C_{14\text{-}17}$ which is defined as a MCCP material. These data are used in this assessment to fill data gaps for the $C_{18\text{-}20}$ LCCPs as this would be a conservative approach to charactering hazard in the absence of data. Concern concentrations based on these data are again a very conservative approach in the absence of data for the LCCP materials themselves and therefore may not inherently characterize toxicity to LCCPs directly.

While EPA has referenced other ECB reports, it does not appear that EPA considered the report by the ECB Technical Committee for New and Existing Substances (TC NES) Subgroup on Identification of PBT and vPvB Substances report on LCCPs (ECB 2007) (Attachment 5). In this report, the PBT expert group under the ECB concluded that LCCPs, which they describe as $C_{18\text{-}32}$ chloroalkanes, are not PBT substances, and are not vPvB substances. The report states:

> Summary: paraffin waxes and hydrocarbon waxes, chloro [LCCP] is not likely to fulfil the B criterion. The substance may meet the P/vP criteria according to the screening data. Concerning the T criterion, the substances (esp. shorter chain constituents) may be regarded as a borderline case. It is concluded that these substances are not considered as PBT substances.

As discussed below, the Coalition believes the ECB's comment on the T criterion are too equivocal given that there are no aquatic toxicity results at or below the water solubility limit of the LCCP test substance in the study. In addition, the ECB (2007) PBT review of LCCPs, along with all other previous international and governmental reviews, supports treatment of LCCPs and vLCCPs in same category. Recent reviews of the LCCP/vLCCP category by the OECD clearly include C_{20} in the longer-chain (i.e., vLCCPs) sub-category, which they call $C_{20\text{-}30}$, and note that that there may be minor constituents outside this range (see CPIA March 2015, Attachment 1).

1. LCCP Aquatic Toxicity

There are no toxicity results seen in aquatic endpoint studies run on LCCPs and vLCCPs at or below the water solubility of the LCCP/vLCCP test material. See Table 3 below (previously submitted to EPA in the CPIA April 11, 2014, comments on the proposed SNUR for three vLCCP substances). These data include key studies on test materials with a variety of carbon number ranges, including constituents in the $C_{18\text{-}20}$ range (e.g., $C_{18\text{-}26}$, and $C_{20\text{-}30}$).

---

[17] EPA, Methodology Document for the ECOlogical Structure-Activity Relationship Model (ECOSAR) Class Program (May 2012), at 16-17.

Some of these studies, such as many of the fish acute studies, were conducted at test concentrations many times greater than the water solubility of the LCCP test material. Other studies report levels that are seemingly quite low; however, that is due to very low water solubility level of LCCPs as determined in that study. For example, the Hooftman (1993) chronic daphnia study reported no statistically significant effects on daphnia reproduction over the 21-day test period at 2 µg/L (the no observable effect concentration – NOEC). While this is a very low NOEC, this is driven by the very low water solubility of the LCCP test material in that study, not by a specific toxicological concern. The value reported for this study - 2 µg/L - is simply the water solubility limited determined for that study for the test material use. It is worth noting that the Hooftman results provided in the report were difficult to interpret, so a detailed statistical analysis of the actual study results was developed by Dr. Roy Thompson (see Attachment9, CPIA April 2014 comments to EPA).

Table 3: Summary of LCCP Aquatic Toxicity Results in REACH Dossier February 2014

IUCLID Section	Endpoint	Reference	Key Study	Test Material	Result	Study Reliability (Klimisch) Rating
Acute Fish Studies						
6.1.1	Fish: Acute	Howard 1975		C_{18-20}, 39% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Johnson and Finley 1980		C_{18-20}, 39% Cl	>300 mg/L	3
6.1.1	Fish: Acute	Hoechst 1976		C_{18-20}, 35% Cl	400 mg/L	2
6.1.1	Fish: Acute	Hoechst 1976		C_{18-20}, 35% Cl	400 mg/L	3
6.1.1	Fish: Acute	Hoechst 1976		C_{18-20}, 44% Cl	500 mg/L	3
6.1.1	Fish: Acute	HRC/ICI 1982		C_{18-20}, 44% Cl	500 mg/L	3
6.1.1	Fish: Acute	Hoechst 1976		C_{18-20}, 49% Cl	>500 mg/L	2
6.1.1	Fish: Acute	Hoechst 1976		C_{18-20}, 49% Cl	>500 mg/L	3
6.1.1	Fish: Acute	Hoechst 1977		C_{18-20}, 52% Cl	>500 mg/L	2
6.1.1	Fish: Acute	Mayer 1986		$C_{>20}$, 38-47% Cl	>300 mg/L	4
6.1.1	Fish: Acute	Mayer 1986		$C_{>20}$, 38-47% Cl	>300 mg/L	4
6.1.1	Fish: Acute	Howard 1975		C_{20-30}, 40% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Howard 1975		C_{20-30}, 40% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Madeley 1980		C_{20-30}, 42% Cl	>770 mg/L	2
6.1.1	Fish: Acute	Linden 1979		C_{22-26}, 42% Cl	>5000 mg/L	2
6.1.1	Fish: Acute	Howard 1975		C_{22-26}, 48-50% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Howard 1975		C_{22-26}, 48-50% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Johnson and Finley 1980		C_{22-26}, 70% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Howard 1975		C_{22-26}, 70% Cl	>300 mg/L	2
Chronic Fish Studies						
6.1.2	Fish: Chronic	Bentsson 1979	Key Study	C_{18-26}, 49% Cl	>0.125 mg/L	2

6.1.2	Fish: Chronic	Zitko 1974		C_{20-30}, 42% Cl	N/A	3
6.1.2	Fish: Chronic	Madeley 1983	Key Study	C22-26, 43% Cl	>=4 mg/L	2
6.1.2	Fish: Chronic	Madeley 1983	Key Study	C_{20-30}, 70% Cl	>=3.8 mg/L	2
Acute Aquatic Invertebrate Studies						
6.1.3	Invert: Acute	Frank 1993	Key Study	C_{18-20}, 52% Cl	EC0 = 0.36 mg/L	2
6.1.3	Invert: Acute	Frank 1994		C_{18-20}, 52% Cl	EC0 >0.026-0.877 mg/L	2
6.1.3	Invert: Acute	Thompson 2005	Key Study	C_{20-30}, 43% Cl	EC0 = 5.1 mg/L	2
6.1.3	Invert: Acute	Hoechst 1984		C_{18-27}, 60% Cl	NOEC=23 mg/L	3
6.1.3	Invert: Acute	Hoechst 1984		C_{18-27}, 60% Cl	NOEC=45 mg/L	3
6.1.3	Invert: Acute	Hoechst 1984		C_{18-27}, 60% Cl	NOEC=100 mg/L	3
6.1.3	Invert: Acute	Hoechst 1984		C_{18-27}, 60% Cl	NOEC=100 mg/L	3
Chronic Aquatic Invertebrate Studies						
6.1.4	Invert: Chronic	Frank 1993-1994		C_{18-20}, 52% Cl	NOEC = 29-33 µg/L	2
6.1.4	Invert: Chronic	Hooftman 1993		C_{18-20}, 52-56% Cl	NOEC = 2 µg/L	2
6.1.4	Invert: Chronic	Hoechst 1984		C_{18-27}, 60% Cl	NOEC = 4.2 mg/L	4
6.1.4	Invert: Chronic	Sharpe 2007	Key Study	$C_{>20}$, 43% Cl	55 µg/L	1
6.1.4	Invert: Chronic	Madeley 1983	Key Study	C_{22-26}, 43% Cl	NOEC = 2.18 mg/L	2
6.1.4	Invert: Chronic	Madeley 1983	Key Study	C_{20-30}, 70% Cl	NOEC = 1.33 mg/L	2
Aquatic Algae Studies						
6.1.5	Algae	Craigie 1975		C_{20-30}, 50% Cl		3
6.1.5	Algae	Thompson 1997	Key Study	MCCP; 52% Cl	NOEC - 0.1 mg/L; LOEC = 0.18 mg/L	1

2. LCCP Bioaccumulation

Given the very low water solubility levels, high molecular weights, and difficulty analyzing LCCPs in environmental and laboratory test samples, modeled estimates of theoretical constituents of LCCPs for bioaccumulation were favored in most assessments (ECB 2007, OECD 2009, EA 2009). BCFs in fish were modeled based on representative log K_{OW} values and using the approaches detailed in the EU Technical Guidance Document (ECB 2007, OECD 2009, EA 2009). The results for each subgroup were reported as:

$C_{18\ 20}$ liquid LCCP	BCF = 1,096 L/kg (based on log K_{OW} 9.7)
$C_{20\text{-}30}$ liquid LCCP	BCF = 192 L/kg (based on log K_{OW} 10.3)
$C_{20\text{-}30}$ solid LCCP	BCF < 1 L/kg (based on log K_{OW} 17)

EPA quotes the United Kingdom Environment Agency assessment (EA, 2009) in the LCCPs bioaccumulation assessment. It is unclear how this assessment, which presents the above BCF calculations, supports EPA's conclusions that LCCPs are bioaccumulative to very bioaccumulative, especially since the EA (2009) report clearly states:

> Thus it is concluded that LCCPs are unlikely to meet the B or vB (very bioaccumulative) criteria.

If EPA intends to rely upon this review to support its assessment, it should also present the conclusions of this assessment for the endpoint in question.

Modeling results of various theoretical LCCP category constituents using EPA's EPISUITE, BCFBAF v 3.00, model are also available (included in Attachment 1). These modeling results show BCF values are low to very low for the constituents in this category and that the values, like estimates from the OECD/EA evaluation, decrease significantly with increasing carbon-number and chlorination level:

$C_{18\text{-}20}$ liquid LCCP	BCF values 56.4 - 104 L/kg
$C_{20\text{-}30}$ liquid LCCP	BCF values 3.16 – 34.3 L/kg
$C_{20\text{-}30}$ solid LCCP	BCF 3.16 – 9.59 L/kg

EPA ordinarily uses the EPISUITE model extensively to evaluate chemicals in the PMN process. Accordingly, EPA does not explain why – given the limited measured data available on LCCP bioaccumulation – it has chosen not to rely primarily upon its own models in the Risk Assessments.

F. Complexity of Substances and Environmental Fate and Effects Dataset Establishes Need for Expert Peer Review

As noted above, this is not the usual PMN situation. Thousands of processors and users of MCCPs and LCCPs would be affected by risk management actions taken by EPA based on the results of the Risk Assessments. Accordingly, it is important that EPA use the best available science and base its decisions on the weight of the evidence.

The Risk Assessments show that there are many different studies that present a wide range of results for environmental fate endpoints. However, EPA has chosen to rely upon selective results and statements by other reviewers that support EPA's conclusions on environmental fate and effects, even when there are recent and reliable data and reviews that establish:

- MCCPs under 50% chlorination are readily biodegradable based on test data;
- MCCPs up to 51% chlorination are inherently biodegradable based on test data;
- MCCP field biomagnification and trophic magnification data show a clear pattern of MCCPs not bioaccumulating in the environmental food web;
- LCCPs are not toxic to aquatic organisms at or below their upper water solubility limit;
- LCCPs are not predicted to be bioaccumulative using EPA models;
- LCCPs were determined to be "unlikely to meet the B or vB (very bioaccumulative) criteria" by the U.K. Environment Agency – a reference EPA used extensively in developing its conclusions.

Under a weight-of-the-evidence approach, these data and results would have led EPA to conclude that MCCPs and LCCPs are not PBT substances. This is particularly true given weight-of-the-evidence considerations for endpoints such as bioaccumulation and the fact that monitoring data in the U.S. does not show a pattern of these substances being in the environment at levels above the COCs. Given the wide range of results and the very significant economic consequences of ban of MCCPs and LCCPs, it is essential that EPA subject these endpoints to external expert peer review. That peer review should evaluate whether EPA applied a weight-of-the-evidence approach in its assessment of all available data, and consider whether additional data could be developed to resolve any uncertainties in the expert review.

Further, it is well established that MCCPs and LCCPs are UVCB substances that will contain thousands-to-tens-of-thousands of possible isomers as chlorination substitution on the carbon-chain backbone is non-specific and difficult to control in the manufacturing process. The complexity of these substances can complicate their review, which is yet another reason why external expert peer review is so necessary.

Part V: Future Research

A. EPA Testing Approach Concerns

EPA has developed a three-phased approach to testing MCCPs and LCCPs that is based on a total of nine separate test materials, including C_{14}, C_{16}, and C_{18} each separately chlorinated to average chlorine levels, by weight, of 30%, 56% and >70%. The Coalition notes that CPIA has specifically addressed this testing plan in its comments, so we will not repeat all of those points here except to note that any testing program for MCCPs and LCCPs should focus on addressing specific areas of uncertainty or data gaps in the Risk Assessments. For example, EPA has chosen to read across the environmental endpoints of concern and COCs from MCCPs to LCCPs in the Risk Assessments due to uncertainties/gaps in the LCCP database. However, there are no specific tests in this program to develop data to support the derivation of COCs for LCCPs. Rather this testing program is focused entirely on evaluating the potential for transformation in the environment and the toxicity of the transformation chemicals rather than on MCCPs and LCCPs themselves.

B. Alternative Testing and Research Options

EPA should consider developing new environmental monitoring data in the U.S. as was suggested in the 2015 report on CPs by U.S. and Canada Identification Task Team (ITT), of which EPA was a member, on Chemicals of Mutual Concern in the Great Lakes instead of the additional laboratory fate testing it has proposed.

The ITT 2015 report concluded that there are "insufficient data and/or information available to effectively apply the Binational Considerations" and, therefore it made a designation of "No Determination" for all CPs - SCCPs (C_{10-13}), MCCPs (C_{14-17}) and LCCPs ($> C_{18}$).

The ITT specifically recommended "continued targeted monitoring in top predator fish across the Great Lakes, including in the near-shore environment, in order to confirm recent trends continue to show decreases for SCCPs and definitely establish whether downward trend exists for MCCPs." The ITT also recommended "targeted sediment monitoring … in the near shore environment and tributaries, to establish trends and evaluate loadings of these chemicals to the lakes." It noted that "this monitoring work will provide some of the information necessary to evaluate the performance of existing and forthcoming risk management and control activities."

Importantly, the ITT report found that the trend data for CPs in the Great Lakes showed a drop in levels of SCCPs and MCCPs in the biota based on the work by Ismail et al. (2009) and Sarborido-Basconcillo et al. (2015). Given the enhanced review of the monitoring data in this report, collecting new water and sediment data using high-resolution methods could provide a confirmation that these substances are not presenting an unreasonable risk to the environment. Such an approach could also confirm the apparent downward trends and eliminate any concerns that these substances are accumulating in the environment.

Part VI: Risk Management Approaches

While EPA has only asked for comment on its Risk Assessments, EPA evidently plans to use the final risk assessments as a basis for risk management. The only kind of risk management that EPA is apparently considering today is a complete ban on manufacture or import of the PMN substances after a phase-out period. As noted earlier, EPA has not established the necessary scientific foundation to support its proposed action, raising significant questions about the legality of a ban.

After EPA issues its final risk assessment following external peer review, EPA should provide a public comment period regarding the appropriate risk management measures to address any identified concerns. For example, appropriate disposal restrictions for MCCPs and LCCPs may be cost-effective in preventing environmental release, and thus adequately control any environmental risk. Such disposal restrictions may cost far less than would a ban of MCCPs and LCCPs. Disposal restrictions would allow uses lacking effective substitutes to continue rather than trigger the need to develop a crash program to identify, develop, and implement substitutes for many applications.

The Coalition strongly urges EPA to address risk management under TSCA section 6, not TSCA section 5. It is unprecedented for EPA to take risk management action under TSCA section 5 on chemicals that are currently in ongoing uses under TSCA. EPA's threatened action to ban the manufacture and import of MCCPs and LCCPs would adversely impact thousands of downstream users, not just the PMN submitters. Downstream users of MCCPs and LCCPs were not parties to or aware of the consent order negotiations that occurred between 2009 and 2012, but they will be manifestly prejudiced if EPA proceeds under section 5 to eliminate the availability of these chemicals in the U.S.

Downstream users and processors of MCCPs and LCCPs will be denied due process if EPA takes risk management action to ban the manufacture and import of these substances under TSCA section 5. Under either section of TSCA, however, the result of risk management would be that downstream processors and users of the PMN substances would be directly impacted. Again, this is not the usual PMN situation, where a PMN substance is not yet in commerce and processors and users are not yet dependent on the PMN substance. Because of these highly unusual circumstances, EPA must provide an opportunity for public comment on any risk management measures under consideration.

Part VII: Conclusions

The Risk Assessments do not provide an adequate basis to support the key conclusions that MCCPs and LCCPs are expected to be PBT chemicals or that ongoing uses are exceeding COCs for aquatic and sediment-dwelling organisms. On the contrary, applying a weight-of-the-evidence approach, the available data provide an adequate basis for concluding the following:

- MCCPs and LCCPs do not present a human health risk.
- The physiochemical properties of MCCPs and LCCPs, such as very low ambient vapor pressure and very low water solubility, limit the potential for the release of significant quantities of these substances to the environment, particularly via surface water or air.
- Information from the manufacturers and downstream users of these substances indicates that there are not the release pathways to water for MCCPs and LCCPs that EPA assumed in the Risk Assessments.
- Use applications are well defined and controlled. Many of the uses are in applications that are water sensitive and therefore do not present a likely release pathway to water.
- Exceedances of EPA's COCs in environmental surface water or sediment have not been shown to be occurring in the U.S. A U.S. EPA lead binational effort on chemicals of interest in the Great Lakes has shown levels of CPs in the Great Lakes to be dropping over time in recent years and has proposed the collection of additional monitoring data to confirm this trend.
- Conclusions regarding the PBT characteristics on MCCPs and LCCPs are overstated in the Risk Assessments based on the data showing that:

  - MCCPs under 50% chlorination are readily biodegradable based on test data;
  - MCCPs up to 51% chlorination are inherently biodegradable based on test data;
  - MCCP field biomagnification and trophic magnification data show a clear pattern of MCCPs not bioaccumulating in the environmental food web;
  - LCCPs are not toxic to aquatic organisms at or below their upper water solubility limit;
  - LCCPs are not predicted to be bioaccumulative using EPA models;
  - LCCPs were determined to be "unlikely to meet the B or vB (very bioaccumulative) criteria" by the United Kingdom Environment Agency – a reference EPA used extensively in developing its conclusions.

- MCCPs and LCCPs can be effectively managed by eliminating discharge pathways to water using existing U.S. industry practices and the regulatory framework.

- EPA has not established a scientific foundation sufficient to support a ban of MCCPs and LCCPs.

References:

Arnot, Jon. 2014. Bioaccumulation Assessment of Medium-chain chlorinated paraffins (MCCPs). April 28, 2014. Unpublished reported provided in Section 13 of the MCCP REACH dossier.

Gobas, F.;W. de Wolf, L. Burkhard, E. Verbruggen, and K. Plotzke. (2009). Revisiting Bioaccumulation Criteria for POPs and PBT Assessments. Integrated Environmental Assessment and Management, Volume 5, Number 4, pp. 624–637.

Chen, M. Y., X. J. Luo, X. L. Zhang, M. J. He, S. J. Chen, and B. X. Mai. 2011. Chlorinated Paraffins in Sediments from the Pearl River Delta, South China: Spatial and Temporal Distributions and Implication for Processes. Environmental Science and Technology, 45(23), 9936-9943.

Environment Agency (EA) of England and Wales. (2009) Environmental Risk Evaluation Report: Long-Chain Chlorinated Paraffins. January 2009.

EPA. 1997. Exposure Factors Handbook 1997 Edition (Final). U.S. Environmental Protection Agency. Washington, DC. EPA/600/P-95/002F a-c.

EPA. 2011. Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency. Washington, DC. EPA/600/R-09/052F.

Howard, P., J. Santodonato, J. Saxena. 1975. Investigation of Selected Potential Environmental Contaminants: Chlorinated Paraffins. EPA Report No. 560/2-75-007. November 1975.

Houde, M., D. C. Muir, G. T. Tomy, D. M. Whittle, C. Teixeira, and S. Moore. 2008. Bioaccumulation and Trophic Magnification of Short- and Medium-Chain Chlorinated Paraffins in Food Webs from Lake Ontario and Lake Michigan. Environmental Science & Technology, 42(10), 3893-3899.

Identification Task Team (ITT) for Chemicals of Mutual Concern (CMCs) in the Great Lakes. 2015. Binational Summary Report: Chlorinated Paraffins.

Ismail, N., S.B. Gewurtz, K. Pleskach,† D.M. Whittle, P.A. Helm, C.H. Marvin, and G.T. Tomy. 2009. Brominated and Chlorinated Flame Retardants in Lake Ontario, Canada, Lake Trout (Salvelinus namaycush) Between 1979 and 2004 and Possible Influences on Food-Web Changes. Environmental Toxicology and Chemistry, Vol. 28, No. 5, pp. 910–920.

Kassim, Tarek A., and Damià Barceló, eds. Contaminated sediments. Vol. 5. Springer Science & Business Media, 2009.

McGoldrick, D.J., E.W. Murphy. 2015. Concentration and distribution of contaminants in lake trout and walleye from the Laurentian Great Lakes (2008-2012). Environmental Pollution 2015: 12.019.

Nicholls, C. R., C. R. Allchin, and R. J. Law. 2001. Levels of Short and Medium Chain Length Polychlorinated N-Alkanes in Environmental Samples from Selected Industrial Areas in England and Wales. Environmental Pollution, 114(3), 415-430.

Petersen, M., P. Bussmann, R. Grumping, and G. Liek. 2006. Analysis of Short-Chain (C10-C13) and Medium-Chain Chlorinated Paraffins (C14-C17) in Norwegian Sediment and Water Samples by Gc/Ecni-Ms. Organohalogen Compounds, 68, 2101-2104.

Sarborido-Basconcillo, L. S.; S.M. Backus, D.J. McGoldrick, D. Zaruk, E. Sverko, D.C.G. Muir. 2015. Current status of short- and medium chain polychlorinated n-alkanes in top predatory fish across Canada. Chemosphere 127: 93-100.

Scott, Robert. 1989. In vitro absorption of some chlorinated paraffins through human skin. Archives of Toxicology. 63: 425-426.

Thompson, Roy and Martin Vaugh. 2014. Medium-chain chlorinated paraffins (MCCPs): A review of bioaccumulation potential in the aquatic environment. Integrated Environmental Assessment and Management. Volume 10, Issue 1, pages 78–86, January 2014.

Yang, J.J., T.A. Roy, W. Neil, A.J. Krueger, C.R. Mackerer. 1987. Percutaneous and Oral Absorption of Chlorinated Paraffins in the Rat. Toxicology and Industrial Health. Vol. 3 No. 3 405-412.

Chlorinated Paraffins Industry Association

Existing Evaluations of LCCP/vLCCP Category Assessments for U.S. EPA Review of PMN Submissions

March 2015

Long-Chain Chlorinate Paraffins (LCCP) Category

Long-Chain Chlorinated Paraffins (LCCP) is a category of chloroalkane substances predominately greater than C_{18}. The carbon-chain range has been reported as C_{18} to C_{30} (OECD 2009) and C_{18} to C_{38} (EC/HC 2012). It has often been considered in 3 subcategories based on the main commercial LCCP products (OECD, 2009, EA 2009):

- C_{18}-C_{20} LCCP, liquid (ca. 40 – 52% Cl by wt.)
- C_{20}-C_{30} LCCP, liquid (ca. 40 – 54% Cl by wt.)
- C_{20}-C_{30} LCCP, solid (ca. 70% Cl by wt.)

Recently, the U.S. EPA began referring to the two longer chain length subcategories, C_{20}-C_{30}, liquid and solid, as very Long-Chain Chlorinated Paraffin (vLCCP) (EPA 2013, 2014).

It should be noted that the carbon-chain lengths mentioned for each sub-category are for the predominant chain-lengths present for substances in these in these categories. Depending on the starting hydrocarbon material, these products may contain small amounts of constituents either above or below the predominant range (OECD 2009, EA 2009). Most of the paraffin or wax starting materials used for LCCP/vLCCP production are not manufactured to carbon-chain length specifications. Alpha-olefin starting materials are more commonly manufactured to specific carbon-chain ranges; these materials will generally only contain even-numbered constituents because they are derived from the oligomerization of ethylene (C_2H_4). The chlorination process does not change the chain-lengths of the starting hydrocarbon material.

The most recent global assessment of the LCCP category was done under the Organization for Economic Cooperation and Development's (OECD) Screening Information Dataset (SIDS) program in 2009. Recent national assessments on LCCP/vLCCP have also been conducted by the U.K.'s Environment Agency (EA), by Health Canada and Environment Canada, and under the EU's Registration, Evaluation and Authorization of Chemicals (REACH) regulation.

EPA was an active participant in the international review of the LCCP category under the OECD's SIDS Program. EPA reviewed the draft dosser and assessment report and provided its written comments to the OECD on September 16, 2009. EPA's overall comment was:

> *We agree with the characterizations of the data and conclusions in the SIAR and SIAP for physicochemical properties, fate and aquatic toxicity. Some comments regarding mammalian toxicity are addressed below.*

EPA's comments (provided as Attachment A) were relatively minor and were addressed in the final dossier, SIAR, and SIAP. The final SIDS SIAR and Dossier are now available from the OECD.

LCCP Physicochemical Properties

All of the substances in the LCCP category have very high molecular weights, are not volatile, have high octanol-water coefficients (K_{ow}) and are essentially not soluble in water. The molecular weight and K_{ow} properties will increase with increasing carbon-chain length and chlorination levels, while the water solubility will decrease. Like all chlorinated paraffins, LCCPs will decompose prior to boiling/volatilizing.

The following are key conclusions on the physicochemical properties of LCCP from various assessments:

> *Estimated octanol-water partition coefficients (log K_{ow}) range from 7.5 – 11.5 for C_{18-20}, from 7.6 -17.5 for liquid C_{20-30} and from 16.9 – 20.1 for solid C_{20-30} LCCPs.* (OECD 2009)
>
> *The estimated water solubility ranges from 1.6×10^{-11} to 6.6 µg/L at 20 °C for LCCPs.* (OECD 2009)
>
> *[vLCCP] will not occur in dissolved form in the water column, rather the Agency expects [vLCCP] to be present in the water column when exposures occur by adsorption to suspended solids or sediments.* (EPA 2013)

LCCP Environmental Fate and Toxicity

The very high K_{ow} values and very low water solubility of LCCP are the driving characteristics for these substances' environmental fate and toxicity. LCCPs are expected to show a strong affinity for organic media (soil and sediment) over the aqueous compartment and are not expected to be mobile in the environment. These characteristics, along with their high molecular weights, will result in LCCP/vLCCP having low bioavailability (ECB 2007) to environmental organisms and thus limiting its biodegradation, bioaccumulation, and toxicity.

Persistence

Existing data indicate some potential for biodegradation of LCCPs, though none of the tests achieved ready biodegradable results. LCCP biodegradation appears to increase with decreasing chlorine content. There is also information to suggest that the biodegradation of LCCPs may occur under anaerobic conditions. LCCPs do not appear to be toxic to microorganisms in the available study data (OECD 2009).

Bioaccumulation

Given the very low water solubility levels, high molecular weights, and difficulty analyzing LCCPs in environmental and laboratory test samples, modeled estimates of theoretical constituents of LCCP for bioaccumulation were favored in most assessments (ECB 2007, OECD 2009, EA 2009). BCFs in fish were modeled based on representative log K_{ow} values and using the EU Technical Guidance Document parabolic equation: log BCF = -0.2 x(log Kow)2 + (2.74

x log Kow – 4.72)) (ECB 2007, OECD 2009, EA 2009). The results for each subgroup were reported as:

C18 20 liquid LCCP	BCF = 1,096 L/kg (based on log Kow 9.7)
C20-30 liquid LCCP	BCF = 192 L/kg (based on log Kow 10.3)
C20-30 solid LCCP	BCF <1 L/kg (based on log Kow 17)

Modeling results of various theoretical LCCP category constituents using EPA's EPISUITE, BCFBAF v 3.00, model are also available (Attachment B). These modeling results show BCF values are low to very low for the constituents in this category and that the values, like estimates from the OECD/EA evaluation, decrease significantly with increasing carbon-number and chlorination level:

C18 20 liquid LCCP	BCF values 56.4- 104 L/kg
C20-30 liquid LCCP	BCF values 3.16 – 34.3 L/kg
C20-30 solid LCCP	BCF 3.16 – 9.59 L/kg

It is worth noting that these modeling results would be the same as those obtained using the PBT Profiler as the Profiler uses the same bioaccumulation model.

In a separate evaluation, the European Chemicals Bureau concluded that LCCP, C_{18}-C_{32}, did not meet the criteria for bioaccumulation (or for toxicity) and is, therefore, not considered a PBT substance in the EU (ECB 2007).

Environmental Toxicity

There is a number of aquatic toxicity data available for LCCPs, though given the very low water solubility of LCCPs these studies have generally been run at nominal concentrations well in excess of the water solubility limit. Regardless, many of these studies were run using best available practices for generating water accommodated fractions and their results can be used to demonstrate that LCCP substances are not expected to be toxic to aquatic organism at the water saturation limit. The following are key conclusions regarding the aquatic toxicity of these substances.

> *The substances in the [LCCP] category generally show little or no toxicity at concentrations well in excess of their water solubility in acute tests.* (OECD 2009)
>
> *C20-30 liquid and solid LCCPs are of low concern for the environment based on their low hazard profile.* (OECD 2009)
>
> *EPA expects that exposure and uptake for all of the [vLCCP] PMN substances will be very limited from the aqueous phase.* (EPA 2013)
>
> *The available experimental studies on vLCCPs indicate that the acute toxicity to aquatic organisms is No Effects at Saturation (NES) - that is, all of the PMN substances are not expected to cause acute toxicity to aquatic organisms up to their solubility limit.* (EPA 2013)

In addition to these EPA and OECD conclusions, the LCCP REACH Consortium recently completed a comprehensive evaluation of the acute and chronic aquatic toxicity of LCCP/vLCCP in response to an inquiry regarding the aquatic classification of LCCP in the EU. This report was provided to EPA in the CPIA April 2014 comments (CPIA 2014) and showed that there are reliable acute and chronic aquatic toxicity data on LCCP/vLCCP and that these data do not indicate toxicity at concentrations up to the maximum water solubility limit of the test substance. The report concluded that LCCP/vLCCP is appropriately not classified as hazardous to the environment.

The CPIA (2014) comments also included the basis under which the sediment toxicity endpoint was addressed by the Environment Agency in its review of LCCP (EA 2009). LCCPs were predicted to have very low sediment toxicity risk using the equilibrium partitioning method that extrapolates from aquatic toxicity data to sediment toxicity considering the portioning of the substance between the organic and the aqueous media.

Human Health and Toxicity

All reviews of LCCP/vLCCP have consistently concluded that this category of substances does not present a risk to human health (OECD 2009, EA 2009, EC/HC 2012, EPA 2013). Existing data are available to demonstrate that LCCP/vLCCP substances have low toxicity hazards. Under the GHS system they are not classified as hazardous to human health or the environment. Exposures should be very limited given their lack of volatility and extremely low water solubilities. Additionally, the ECB review concluded that LCCP would not be expected to biomagnify in the food chain (ECB 2007).

References

Chlorinated Paraffins Industry Association (CPIA). (2014). Comments on the Proposed Significant New Use Rule for CAS 1417900-96-9 (P-12-539), 1401947-24-0 (P-13-107), and 1402738-52-6 (P-13-109). April 11, 2014.

Environment Agency (EA) of England and Wales. (2009) Environmental Risk Evaluation Report: Long-Chain Chlorinated Paraffins. January 2009.

Environment Canada and Health Canada (EC/HC).(2012) Canada Gazette Part 1: 1307-1309. May 12, 2012. Publication of results of investigations and recommendations for substances — long-chain chlorinated alkanes that have the molecular formula $C_nH_xCl_{(2n+2-x)}$ in which $18 \leq n \leq 38$ — specified on the Domestic Substances List (paragraphs 68(b) and (c) of the Canadian Environmental Protection Act, 1999) — chlorinated alkanes (previously identified as chlorinated paraffins).

Environmental Protection Agency (EPA). (2013) Consent Order and Determinations Supporting Consent Order for PMN submissions P-12-0539, P-13-0107, and P-13-0109. March 19, 2013.

Environmental Protection Agency (EPA). (2014). 79 Federal Register 7621. Proposed Significant New Use Rule on Certain Chemical Substances.

European Chemicals Bureau (ECB) PBT Working Group. 2007. Results of the Evaluation of the PBT/vPvB Properties of Paraffin waxes and Hydrocarbon waxes, chlor; EC number 264-150-0; CAS number 63449-39-8. PBT List No. 110. September 11, 2007.

Organization for Economic Cooperation and Develop (OECD). (2009) SIDS Initial Assessment Report (SIAR) an Dossier on Long Chain Chlorinated Paraffins. Discussed at SIAM-29, October 2009.

COMMENTS POSTED ON EDG

CHEMICAL: Long Chain Chlorinated Paraffins

CAS No: 63449-39-8; 85535-86-0; 85422-92-0

SPONSOR COUNTRY:

DOCUMENTS LODGED ON EDG SITE:

COUNTRY: USA DATE: 09-16-2009

GENERAL ISSUES

Comment from	Action	Details of Comments
USA		We agree with the characterizations of the data and conclusions in the SIAR and SIAP for physicochemical properties, fate and aquatic toxicity. Some comments regarding mammalian toxicity are addressed below.

PHYSICAL-CHEMICAL DATA

Comment from	Action	Details of Comments
USA		A more complete description of CAS numbers would be helpful, in order to see the connection between the subgroups of this category to CAS numbers. In particular, the CAS No. 85422-92-0 is listed as “Paraffin oils, chloro” in both SIAP and SIAR; any additional information would be helpful because this description is not very specific.
USA		Please add the purity information from the SIAR to the IUCLID.
USA		The molecular weight and general formula should be included with the chlorine content information listed on the top of page 7 of the SIAR.
USA		**SIAR, Henry’s Law constants, Page 16, Table 3**: There are no units provided for the Henry’s law constants. There are also no units listed in the SIDS Dossier and the experimental value adjustment estimation method is not explained.

ENVIRONMENTAL FATE AND PATHWAYS

Comment from	Action	Details of Comments
USA		**SIAR, Section 2.2.6, Bioaccumulation:** If possible, add details for the BCF equation used on page20.
USA		**SIAP, Bioaccumulation:** A sentence regarding the BCF is needed in the SIAP.

ECOTOXICITY

Comment from	Action	Details of Comments
USA		**Toxicity to Algae:** Can we use algal data from the MCCP category as a read-across and include it in the SIAP? We agree that filling this data gap is not critical for environmental assessment, if LCCP are considered together with SCCP and MCCP. However, as a stand

		alone category, we think that the algal endpoint needs to be addressed.

MAMMALIAN TOXICITY

Comment from	**Action**	**Details of Comments**
USA		**Acute Oral Toxicity – Dossier, Section 5.1.1:** Reference 8 – If possible, please convert the value of 10 ml/kg to X mg/kg.
USA		**Sensitisation – Dossier, Section 5.3:** Reference 83 **–** If possible, add details from this study to help determine why this result differs from the results of the other two sensitisation studies.
USA		**Repeated-Dose Toxicity – Dossier, Section 5.4:** Reference 58 – It would help to know at which doses the 10 deaths occurred.
USA		**Repeated-Dose Toxicity – Dossier, Section 5.4:** Reference 45 – Incidence of nephrolithiasis should be stated as well as statistical significance of the effect, in order to judge the statement that the effect was coincidental. The increased CYP 450 might be treatment-related since this occurred in females that exhibited liver toxicity in the 13-week study. It is not clear that such effects would be considered adverse (although it may be some indication that adverse liver effects may occur after longer exposures, as seen in females in the 13-week study).
USA		**Genotoxicity – Dossier, Section 5.5:** Reference 30 – The results of the cell transformation assay may be valid even though it doesn't address any SIDS endpoints. Thus, you may wish to reclassify the Klimisch code (e.g., note that limited details are available if that is true). A remark could be included in the summary that states that the test doesn't satisfy the SIDS endpoints for genotoxicity.
USA		**Carcinogenicity – Dossier, Section 5.7:** Reference 70/6 – (1) The conclusion from the NTP summary was that there was no evidence of carcinogenicity in male rats; equivocal evidence in female rats; clear evidence in male mice; and equivocal evidence in female mice. Therefore, the NOAELs/LOAEL don't appear to correspond with the carcinogenic effects (e.g., > 5000 mg/kg for mice). If non-neoplastic NOAELs and LOAELs are of interest, they could be included in a robust summary in the 'Repeated-Dose Toxicity' section of the Dossier. **NTP Reference:** http://ntp-apps.niehs.nih.gov/ntp_tox/index.cfm?fuseaction=abstracts.abstract&chemical_name=Chlorinated%20paraffins%3A%20C23%2C%2043%25%20chlorine&cas_no=108171-27-3&study_no=C53543&study_length=2%20Years&abstract_url=07079D30-013A-54B2-183343A92F831886&next=longtermbioassaydata.datasearch (2) The summary information from NTP regarding Reference 70/6 notes that CAS No. 63449-39-8 (as noted in the original 1986 report) has been replaced with CAS No. 108171-27-3. The corrected CAS No. should be added to the robust summary in the LCCP Dossier. (3) Although the NTP data on the paraffin with average chain length of 23 and chlorine content of 43% are described by IARC, this compound isn't currently classified by IARC: http://monographs.iarc.fr/ENG/Classification/index.php Further, the IARC Monograph (Volume 48) notes that although there is limited evidence of carcinogenicity for C23/ 43% chlorine, there is no overall conclusion in the evaluation section of the report. http://monographs.iarc.fr/ENG/Monographs/vol48/volume48.pdf Therefore, the IARC entry in the Dossier should be corrected.

USA		**Developmental Toxicity/Teratogenicity** – **Dossier, Section 5.8.2**: (1) Reference 49 - A LOAEL for developmental toxicity (probably 2000 mg/kg-bw) should be listed. (2) Reference 50 - A LOAEL for developmental toxicity (1000 mg/kg-bw?) should be listed.
USA		**Exposure Experience- Dossier, Section 5.10** and **Additional Remarks – Dossier, Section 5.11 –** The references (#61 and #29) are repeated in both sections but should be listed only once (e.g., in Section 5.10).

USE/EXPOSURE

Comment from	**Action**	**Details of Comments**
USA		The consumer exposure section could be expanded – even though the LCCPs are not marketed directly to consumers, they appear to be used in consumer products.
USA		**CAS No. 63449-39-8:** 2006 IUR information reports production and import volume in the United States of between 10 to < 50 million lbs (http://www.epa.gov/iur/tools/data/index.htm).

Attachment B: BCF Modeling of LCCP Using EPISUITE

BCF EPISUITE Modeling (BCFBAF v3.00) Results for LCCP Constituents

Overview

Theoretical[1] chloroalkane constituents of LCCP were modeled using the EPA EPISUITE software. Constituents were selected that represent the lower and upper end of carbon number and chlorination level for the 3 subcategories of LCCP:

- C_{18}-C_{20} LCCP, liquid (ca. 40 – 52% Cl by wt.)
- C_{20}-C_{30} LCCP, liquid (ca. 40 – 54% Cl by wt.)
- C_{20}-C_{30} LCCP, solid (ca. 70% Cl by wt.)

C18 LCCP Constituents

C18, Cl5 LCCP, 41% Cl (wt.)

```
SMILES : CCC(CL)CCC(CL)CCCCC(CL)CC(CL)CCCC(CL)C
CHEM   :
MOL FOR: C18 H33 CL5
MOL WT : 426.73
-------------------------------- BCFBAF v3.00 --------------------------------
Summary Results:
  Log BCF (regression-based estimate):  2.02  (BCF = 104 L/kg wet-wt)
  Biotransformation Half-Life (days) :  118  (normalized to 10 g fish)
  Log BAF (Arnot-Gobas upper trophic):  4.59  (BAF = 3.89e+004 L/kg wet-wt)

Log Kow (experimental):  not available from database
Log Kow used by BCF estimates:  10.08

Equation Used to Make BCF estimate:
   Log BCF = -0.49 log Kow + 7.554 + Correction

      Correction(s):                    Value
       Alkyl chains (8+ -CH2- groups)  -0.596

   Estimated Log BCF =  2.016  (BCF = 103.9 L/kg wet-wt)

===========================================================
Whole Body Primary Biotransformation Rate Estimate for Fish:
===========================================================
------+-----+------------------------------------------+---------+---------
 TYPE | NUM | LOG BIOTRANSFORMATION FRAGMENT DESCRIPTION |  COEFF  |  VALUE
------+-----+------------------------------------------+---------+---------
 Frag |  5  |  Aliphatic chloride   [-CL]              | 0.3608 |  1.8038
 Frag |  2  |  Methyl  [-CH3]                          | 0.2451 |  0.4902
```

---

[1] It is chemically impossible to identify individual chemical constituents of LCCP. Selected constituents were identified based on carbon-chain length, approximate chlorination level by weight. Chlorine substitution on the chain was selected by excluding the terminal carbons, which are thought to be less reactive, placing only one chlorine per carbon atom, as already substituted carbons will be less reactive, and spacing out the chlorine substitutions to the extent possible due to the size of the chlorine atom.

```
 Frag | 11  |  -CH2-  [linear]                    |  0.0242 |  0.2661
 Frag |  5  |  -CH-   [linear]                    | -0.1912 | -0.9562
 L Kow|  *  |  Log Kow =  10.08 (KowWin estimate)       |  0.3073 |  3.0991
 MolWt|  *  |  Molecular Weight Parameter              |         | -1.0943
 Const|  *  |  Equation Constant                       |         | -1.5058
============+============================================+=========+=========
   RESULT   |       LOG Bio Half-Life (days)           |         |  2.0717
   RESULT   |           Bio Half-Life (days)           |         |    118
   NOTE     |  Bio Half-Life Normalized to 10 g fish at 15 deg C   |
============+============================================+=========+=========

Biotransformation Rate Constant:
 kM (Rate Constant):  0.005876 /day (10 gram fish)
 kM (Rate Constant):  0.003305 /day (100 gram fish)
 kM (Rate Constant):  0.001858 /day (1 kg fish)
 kM (Rate Constant):  0.001045 /day (10 kg fish)

Arnot-Gobas BCF & BAF Methods (including biotransformation rate estimates):
   Estimated Log BCF (upper trophic) =  1.205  (BCF = 16.01 L/kg wet-wt)
   Estimated Log BAF (upper trophic) =  4.590  (BAF = 3.886e+004 L/kg wet-wt)
   Estimated Log BCF (mid trophic)   =  1.346  (BCF = 22.18 L/kg wet-wt)
   Estimated Log BAF (mid trophic)   =  4.323  (BAF = 2.106e+004 L/kg wet-wt)
   Estimated Log BCF (lower trophic) =  1.390  (BCF = 24.52 L/kg wet-wt)
   Estimated Log BAF (lower trophic) =  4.137  (BAF = 1.369e+004 L/kg wet-wt)

Arnot-Gobas BCF & BAF Methods (assuming a biotransformation rate of zero):
   Estimated Log BCF (upper trophic) =  1.845  (BCF = 69.98 L/kg wet-wt)
   Estimated Log BAF (upper trophic) =  5.544  (BAF = 3.501e+005 L/kg wet-wt)
```

C18, Cl8 LCCP, 53% Cl (wt.)

```
BCFBAF Program (v3.00) Results:
==============================
SMILES : CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CCC(CL)C
CHEM   :
MOL FOR: C18 H30 CL8
MOL WT : 530.06
--------------------------------- BCFBAF v3.00 --------------------------------
Summary Results:
  Log BCF (regression-based estimate):  1.75  (BCF = 56.4 L/kg wet-wt)
  Biotransformation Half-Life (days) :  257  (normalized to 10 g fish)
  Log BAF (Arnot-Gobas upper trophic):  4.44  (BAF = 2.73e+004 L/kg wet-wt)

Log Kow (experimental):  not available from database
Log Kow used by BCF estimates:  10.63

Equation Used to Make BCF estimate:
   Log BCF = -0.49 log Kow + 7.554 + Correction
```

```
   Correction(s):                  Value
    Alkyl chains (8+ -CH2- groups)  -0.596

  Estimated Log BCF =  1.751  (BCF = 56.38 L/kg wet-wt)

=========================================================
Whole Body Primary Biotransformation Rate Estimate for Fish:
=========================================================
------+-----+------------------------------------------+---------+---------
 TYPE | NUM | LOG BIOTRANSFORMATION FRAGMENT DESCRIPTION |  COEFF  |  VALUE
------+-----+------------------------------------------+---------+---------
 Frag |  8  |  Aliphatic chloride   [-CL]              |  0.3608 |  2.8861
 Frag |  2  |  Methyl  [-CH3]                          |  0.2451 |  0.4902
 Frag |  8  |  -CH2-  [linear]                         |  0.0242 |  0.1935
 Frag |  8  |  -CH-   [linear]                         | -0.1912 | -1.5299
 L Kow|  *  |  Log Kow =  10.63 (KowWin estimate)      |  0.3073 |  3.2656
 MolWt|  *  |  Molecular Weight Parameter              |         | -1.3593
 Const|  *  |  Equation Constant                       |         | -1.5058
============+============================================+=========+=========
  RESULT   |       LOG Bio Half-Life (days)            |         |  2.4092
  RESULT   |           Bio Half-Life (days)            |         |   256.6
  NOTE     |  Bio Half-Life Normalized to 10 g fish at 15 deg C   |
============+============================================+=========+=========

Biotransformation Rate Constant:
 kM (Rate Constant):  0.002702 /day (10 gram fish)
 kM (Rate Constant):  0.001519 /day (100 gram fish)
 kM (Rate Constant):  0.0008544 /day (1 kg fish)
 kM (Rate Constant):  0.0004804 /day (10 kg fish)

Arnot-Gobas BCF & BAF Methods (including biotransformation rate estimates):
  Estimated Log BCF (upper trophic) =  0.927  (BCF = 8.445 L/kg wet-wt)
  Estimated Log BAF (upper trophic) =  4.436  (BAF = 2.728e+004 L/kg wet-wt)
  Estimated Log BCF (mid trophic)   =  1.069  (BCF = 11.72 L/kg wet-wt)
  Estimated Log BAF (mid trophic)   =  4.109  (BAF = 1.286e+004 L/kg wet-wt)
  Estimated Log BCF (lower trophic) =  1.113  (BCF = 12.97 L/kg wet-wt)
  Estimated Log BAF (lower trophic) =  3.871  (BAF = 7429 L/kg wet-wt)

Arnot-Gobas BCF & BAF Methods (assuming a biotransformation rate of zero):
  Estimated Log BCF (upper trophic) =  1.322  (BCF = 20.97 L/kg wet-wt)
  Estimated Log BAF (upper trophic) =  5.009  (BAF = 1.02e+005 L/kg wet-wt)
```

Attachment B: BCF Modeling of LCCP Using EPISUITE

C20 LCCP Constituents

C20, Cl5 LCCP, 39% Cl (wt.)

```
BCFBAF Program (v3.00) Results:
==============================
SMILES : CCCC(CL)CCC(CL)CCCCC(CL)CCC(CL)CCCC(CL)C
CHEM   :
MOL FOR: C20 H37 CL5
MOL WT : 454.78
-------------------------------- BCFBAF v3.00 --------------------------------
Summary Results:
  Log BCF (regression-based estimate):  1.54  (BCF = 34.3 L/kg wet-wt)
  Biotransformation Half-Life (days) :  224  (normalized to 10 g fish)
  Log BAF (Arnot-Gobas upper trophic):  3.94  (BAF = 8.68e+003 L/kg wet-wt)

Log Kow (experimental):  not available from database
Log Kow used by BCF estimates:  11.07

Equation Used to Make BCF estimate:
   Log BCF = -0.49 log Kow + 7.554 + Correction

      Correction(s):                  Value
       Alkyl chains (8+ -CH2- groups)  -0.596

   Estimated Log BCF =  1.535  (BCF = 34.29 L/kg wet-wt)

===========================================================
Whole Body Primary Biotransformation Rate Estimate for Fish:
===========================================================
------+-----+--------------------------------------------+---------+---------
 TYPE | NUM | LOG BIOTRANSFORMATION FRAGMENT DESCRIPTION |  COEFF  |  VALUE
------+-----+--------------------------------------------+---------+---------
 Frag |  5  |  Aliphatic chloride   [-CL]                |  0.3608 |  1.8038
 Frag |  2  |  Methyl  [-CH3]                            |  0.2451 |  0.4902
 Frag | 13  |  -CH2-  [linear]                           |  0.0242 |  0.3144
 Frag |  5  |  -CH-   [linear]                           | -0.1912 | -0.9562
 L Kow|  *  |  Log Kow =  11.07 (KowWin estimate)        |  0.3073 |  3.4010
 MolWt|  *  |  Molecular Weight Parameter                |         | -1.1662
 Const|  *  |  Equation Constant                         |         | -1.5058
============+============================================+=========+=========
   RESULT   |       LOG Bio Half-Life (days)             |         |  2.3500
   RESULT   |           Bio Half-Life (days)             |         |  223.9
   NOTE     |  Bio Half-Life Normalized to 10 g fish at 15 deg C   |
============+============================================+=========+=========

Biotransformation Rate Constant:
 kM (Rate Constant):  0.003096 /day (10 gram fish)
 kM (Rate Constant):  0.001741 /day (100 gram fish)
```

```
 kM (Rate Constant):  0.000979 /day (1 kg fish)
 kM (Rate Constant):  0.0005506 /day (10 kg fish)

Arnot-Gobas BCF & BAF Methods (including biotransformation rate estimates):
   Estimated Log BCF (upper trophic) =  0.532  (BCF = 3.405 L/kg wet-wt)
   Estimated Log BAF (upper trophic) =  3.938  (BAF = 8677 L/kg wet-wt)
   Estimated Log BCF (mid trophic)   =  0.654  (BCF = 4.506 L/kg wet-wt)
   Estimated Log BAF (mid trophic)   =  3.619  (BAF = 4161 L/kg wet-wt)
   Estimated Log BCF (lower trophic) =  0.692  (BCF = 4.922 L/kg wet-wt)
   Estimated Log BAF (lower trophic) =  3.388  (BAF = 2443 L/kg wet-wt)

Arnot-Gobas BCF & BAF Methods (assuming a biotransformation rate of zero):
   Estimated Log BCF (upper trophic) =  0.913  (BCF = 8.193 L/kg wet-wt)
   Estimated Log BAF (upper trophic) =  4.569  (BAF = 3.71e+004 L/kg wet-wt)
```

C20, Cl9 LCCP, 54% Cl (wt.)

```
BCFBAF Program (v3.00) Results:
==============================
SMILES : CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CCC(CL)C
CHEM   :
MOL FOR: C20 H33 CL9
MOL WT : 592.56
-------------------------------- BCFBAF v3.00 -------------------------------
Summary Results:
  Log BCF (regression-based estimate):  1.18  (BCF = 15.2 L/kg wet-wt)
  Biotransformation Half-Life (days) :  631  (normalized to 10 g fish)
  Log BAF (Arnot-Gobas upper trophic):  3.56  (BAF = 3.63e+003 L/kg wet-wt)

Log Kow (experimental):  not available from database
Log Kow used by BCF estimates:  11.79

Equation Used to Make BCF estimate:
   Log BCF = -0.49 log Kow + 7.554 + Correction

      Correction(s):                  Value
       Alkyl chains (8+ -CH2- groups)  -0.596

   Estimated Log BCF =  1.181  (BCF = 15.19 L/kg wet-wt)

===========================================================
Whole Body Primary Biotransformation Rate Estimate for Fish:
===========================================================
------+-----+------------------------------------------+---------+---------
 TYPE | NUM | LOG BIOTRANSFORMATION FRAGMENT DESCRIPTION |  COEFF  |  VALUE
------+-----+------------------------------------------+---------+---------
 Frag |  9  |  Aliphatic chloride   [-CL]              | 0.3608 |  3.2468
 Frag |  2  |  Methyl  [-CH3]                          | 0.2451 |  0.4902
```

```
 Frag |  9  |  -CH2-  [linear]                      |  0.0242 |  0.2177
 Frag |  9  |  -CH-   [linear]                      | -0.1912 | -1.7211
 L Kow|  *  |  Log Kow =  11.79 (KowWin estimate)   |  0.3073 |  3.6229
 MolWt|  *  |  Molecular Weight Parameter           |         | -1.5195
 Const|  *  |  Equation Constant                    |         | -1.5058
============+============================================+=========+=========
   RESULT   |       LOG Bio Half-Life (days)         |         |  2.8000
   RESULT   |           Bio Half-Life (days)         |         |  630.9
   NOTE     |  Bio Half-Life Normalized to 10 g fish at 15 deg C   |
============+============================================+=========+=========

Biotransformation Rate Constant:
 kM (Rate Constant):  0.001099 /day (10 gram fish)
 kM (Rate Constant):  0.0006178 /day (100 gram fish)
 kM (Rate Constant):  0.0003474 /day (1 kg fish)
 kM (Rate Constant):  0.0001954 /day (10 kg fish)

Arnot-Gobas BCF & BAF Methods (including biotransformation rate estimates):
   Estimated Log BCF (upper trophic) =  0.235  (BCF = 1.72 L/kg wet-wt)
   Estimated Log BAF (upper trophic) =  3.560  (BAF = 3633 L/kg wet-wt)
   Estimated Log BCF (mid trophic)   =  0.330  (BCF = 2.14 L/kg wet-wt)
   Estimated Log BAF (mid trophic)   =  3.205  (BAF = 1604 L/kg wet-wt)
   Estimated Log BCF (lower trophic) =  0.361  (BCF = 2.297 L/kg wet-wt)
   Estimated Log BAF (lower trophic) =  2.938  (BAF = 867.5 L/kg wet-wt)

Arnot-Gobas BCF & BAF Methods (assuming a biotransformation rate of zero):
   Estimated Log BCF (upper trophic) =  0.358  (BCF = 2.279 L/kg wet-wt)
   Estimated Log BAF (upper trophic) =  3.848  (BAF = 7048 L/kg wet-wt)
```

C20, Cl18 LCCP, 71% Cl (wt.)

```
BCFBAF Program (v3.00) Results:
==============================
SMILES : CC(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(C
         L)C(CL)C(CL)C(CL)C(CL)C
CHEM   :
MOL FOR: C20 H24 CL18
MOL WT : 902.57
-------------------------------- BCFBAF v3.00 --------------------------------
Summary Results:
  Log BCF (regression-based estimate):  0.98  (BCF = 9.59 L/kg wet-wt)
  Biotransformation Half-Life (days) :  6.49e+003  (normalized to 10 g fish)
  Log BAF (Arnot-Gobas upper trophic):  2.19  (BAF = 156 L/kg wet-wt)

Log Kow (experimental):  not available from database
Log Kow used by BCF estimates:  13.41

Equation Used to Make BCF estimate:
```

Attachment B: BCF Modeling of LCCP Using EPISUITE

```
  Log BCF = -0.49 log Kow + 7.554 + Correction

    Correction(s):                  Value
     No Applicable Correction Factors

  Estimated Log BCF =  0.982  (BCF = 9.592 L/kg wet-wt)

===========================================================
Whole Body Primary Biotransformation Rate Estimate for Fish:
===========================================================
------+-----+--------------------------------------------+---------+---------
 TYPE | NUM | LOG BIOTRANSFORMATION FRAGMENT DESCRIPTION |  COEFF  |  VALUE
------+-----+--------------------------------------------+---------+---------
 Frag | 18  |  Aliphatic chloride   [-CL]                |  0.3608 |  6.4937
 Frag |  2  |  Methyl  [-CH3]                            |  0.2451 |  0.4902
 Frag | 18  |  -CH-   [linear]                           | -0.1912 | -3.4422
 L Kow|  *  |  Log Kow =  13.41 (KowWin estimate)        |  0.3073 |  4.1222
 MolWt|  *  |  Molecular Weight Parameter                |         | -2.3145
 Const|  *  |  Equation Constant                         |         | -1.5058
============+============================================+=========+=========
  RESULT   |       LOG Bio Half-Life (days)              |         |  3.8124
  RESULT   |           Bio Half-Life (days)              |         |    6492
  NOTE     |  Bio Half-Life Normalized to 10 g fish at 15 deg C  |
============+============================================+=========+=========

Biotransformation Rate Constant:
 kM (Rate Constant):  0.0001068 /day (10 gram fish)
 kM (Rate Constant):  6.004e-005 /day (100 gram fish)
 kM (Rate Constant):  3.376e-005 /day (1 kg fish)
 kM (Rate Constant):  1.899e-005 /day (10 kg fish)

Arnot-Gobas BCF & BAF Methods (including biotransformation rate estimates):
  Estimated Log BCF (upper trophic) =  -0.034  (BCF = 0.9239 L/kg wet-wt)
  Estimated Log BAF (upper trophic) =  2.192  (BAF = 155.6 L/kg wet-wt)
  Estimated Log BCF (mid trophic)   =  -0.010  (BCF = 0.9784 L/kg wet-wt)
  Estimated Log BAF (mid trophic)   =  1.831  (BAF = 67.77 L/kg wet-wt)
  Estimated Log BCF (lower trophic) =  -0.003  (BCF = 0.9935 L/kg wet-wt)
  Estimated Log BAF (lower trophic) =  1.553  (BAF = 35.69 L/kg wet-wt)

Arnot-Gobas BCF & BAF Methods (assuming a biotransformation rate of zero):
  Estimated Log BCF (upper trophic) =  -0.033  (BCF = 0.9259 L/kg wet-wt)
  Estimated Log BAF (upper trophic) =  2.226  (BAF = 168.3 L/kg wet-wt)
```

Attachment B: BCF Modeling of LCCP Using EPISUITE

C30 LCCP Constituents

C30, Cl8 LCCP, 41% Cl (wt.)

```
BCFBAF Program (v3.00) Results:
==============================
SMILES : CC(CL)CCCC(CL)CCCC(CL)CCCC(CL)CCCC(CL)CCCC(CL)CCCC(CL)CCC(CL)C
CHEM   :
MOL FOR: C30 H54 CL8
MOL WT : 698.39
-------------------------------- BCFBAF v3.00 --------------------------------
Summary Results:
  Log BCF (regression-based estimate):  0.50  (BCF = 3.16 L/kg wet-wt)
  Biotransformation Half-Life (days) :  1.2e+004  (normalized to 10 g fish)
  Log BAF (Arnot-Gobas upper trophic):  0.01  (BAF = 1.02 L/kg wet-wt)

Log Kow (experimental):  not available from database
Log Kow used by BCF estimates:  16.52

Equation Used to Make BCF estimate:
   Log BCF = -0.49 log Kow + 7.554 + Correction

      Correction(s):                  Value
       No Applicable Correction Factors
       Minimum Log BCF of 0.50 applied when Log Kow > 7

   Estimated Log BCF =  0.500  (BCF = 3.162 L/kg wet-wt)

===========================================================
Whole Body Primary Biotransformation Rate Estimate for Fish:
===========================================================
------+-----+------------------------------------------+---------+---------
 TYPE | NUM | LOG BIOTRANSFORMATION FRAGMENT DESCRIPTION |  COEFF  |  VALUE
------+-----+------------------------------------------+---------+---------
 Frag |  8  |  Aliphatic chloride   [-CL]              |  0.3608 |  2.8861
 Frag |  2  |  Methyl  [-CH3]                          |  0.2451 |  0.4902
 Frag | 20  |  -CH2-  [linear]                         |  0.0242 |  0.4837
 Frag |  8  |  -CH-   [linear]                         | -0.1912 | -1.5299
 L Kow|  *  |  Log Kow =  16.52 (KowWin estimate)      |  0.3073 |  5.0768
 MolWt|  *  |  Molecular Weight Parameter              |         | -1.7909
 Const|  *  |  Equation Constant                       |         | -1.5058
============+============================================+=========+=========
   RESULT   |       LOG Bio Half-Life (days)             |         |  4.0790
   RESULT   |           Bio Half-Life (days)             |         |1.2e+004
   NOTE     |  Bio Half-Life Normalized to 10 g fish at 15 deg C   |
============+============================================+=========+=========

Biotransformation Rate Constant:
 kM (Rate Constant):  5.778e-005 /day (10 gram fish)
```

```
 kM (Rate Constant):  3.249e-005 /day (100 gram fish)
 kM (Rate Constant):  1.827e-005 /day (1 kg fish)
 kM (Rate Constant):  1.028e-005 /day (10 kg fish)

Arnot-Gobas BCF & BAF Methods (including biotransformation rate estimates):
   Estimated Log BCF (upper trophic) =  -0.049  (BCF = 0.893 L/kg wet-wt)
   Estimated Log BAF (upper trophic) =  0.008  (BAF = 1.019 L/kg wet-wt)
   Estimated Log BCF (mid trophic)   =  -0.031  (BCF = 0.9315 L/kg wet-wt)
   Estimated Log BAF (mid trophic)   =  -0.006  (BAF = 0.9858 L/kg wet-wt)
   Estimated Log BCF (lower trophic) =  -0.027  (BCF = 0.9402 L/kg wet-wt)
   Estimated Log BAF (lower trophic) =  -0.014  (BAF = 0.9684 L/kg wet-wt)

Arnot-Gobas BCF & BAF Methods (assuming a biotransformation rate of zero):
   Estimated Log BCF (upper trophic) =  -0.049  (BCF = 0.893 L/kg wet-wt)
   Estimated Log BAF (upper trophic) =  0.010  (BAF = 1.024 L/kg wet-wt)
```

C30, Cl13 LCCP, 53% Cl (wt.)

```
BCFBAF Program (v3.00) Results:
==============================
SMILES : CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CC(CL)CCC
         C(CL)CCC(CL)C
CHEM   :
MOL FOR: C30 H49 CL13
MOL WT : 870.61
-------------------------------- BCFBAF v3.00 --------------------------------
Summary Results:
  Log BCF (regression-based estimate):  0.50  (BCF = 3.16 L/kg wet-wt)
  Biotransformation Half-Life (days) :  4.38e+004  (normalized to 10 g fish)
  Log BAF (Arnot-Gobas upper trophic):  -0.04  (BAF = 0.909 L/kg wet-wt)

Log Kow (experimental):  not available from database
Log Kow used by BCF estimates:  17.42

Equation Used to Make BCF estimate:
   Log BCF = -0.49 log Kow + 7.554 + Correction

      Correction(s):                    Value
       No Applicable Correction Factors
       Minimum Log BCF of 0.50 applied when Log Kow > 7

   Estimated Log BCF =  0.500  (BCF = 3.162 L/kg wet-wt)

===========================================================
Whole Body Primary Biotransformation Rate Estimate for Fish:
===========================================================
------+-----+------------------------------------------+---------+---------
 TYPE | NUM | LOG BIOTRANSFORMATION FRAGMENT DESCRIPTION |  COEFF  |  VALUE
------+-----+------------------------------------------+---------+---------
```

```
 Frag | 13  |  Aliphatic chloride   [-CL]              |  0.3608 |  4.6899
 Frag |  2  |  Methyl  [-CH3]                          |  0.2451 |  0.4902
 Frag | 15  |  -CH2-  [linear]                         |  0.0242 |  0.3628
 Frag | 13  |  -CH-   [linear]                         | -0.1912 | -2.4860
 L Kow|  *  |  Log Kow =  17.42 (KowWin estimate)       |  0.3073 |  5.3542
 MolWt|  *  |  Molecular Weight Parameter              |         | -2.2325
 Const|  *  |  Equation Constant                       |         | -1.5058
============+============================================+=========+=========
   RESULT   |       LOG Bio Half-Life (days)           |         |  4.6415
   RESULT   |           Bio Half-Life (days)           |         |4.38e+004
   NOTE     |  Bio Half-Life Normalized to 10 g fish at 15 deg C   |
============+============================================+=========+=========

Biotransformation Rate Constant:
 kM (Rate Constant):  1.583e-005 /day (10 gram fish)
 kM (Rate Constant):  8.899e-006 /day (100 gram fish)
 kM (Rate Constant):  5.005e-006 /day (1 kg fish)
 kM (Rate Constant):  2.814e-006 /day (10 kg fish)

Arnot-Gobas BCF & BAF Methods (including biotransformation rate estimates):
   Estimated Log BCF (upper trophic) =  -0.049  (BCF = 0.893 L/kg wet-wt)
   Estimated Log BAF (upper trophic) =  -0.041  (BAF = 0.9092 L/kg wet-wt)
   Estimated Log BCF (mid trophic)   =  -0.031  (BCF = 0.9315 L/kg wet-wt)
   Estimated Log BAF (mid trophic)   =  -0.028  (BAF = 0.9385 L/kg wet-wt)
   Estimated Log BCF (lower trophic) =  -0.027  (BCF = 0.9402 L/kg wet-wt)
   Estimated Log BAF (lower trophic) =  -0.025  (BAF = 0.9438 L/kg wet-wt)

Arnot-Gobas BCF & BAF Methods (assuming a biotransformation rate of zero):
   Estimated Log BCF (upper trophic) =  -0.049  (BCF = 0.893 L/kg wet-wt)
   Estimated Log BAF (upper trophic) =  -0.041  (BAF = 0.9094 L/kg wet-wt)
```

C30, Cl26 LCCP, 70% Cl (wt.)

```
BCFBAF Program (v3.00) Results:
==============================
SMILES : CC(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)CC(CL)C(CL)C(CL)C(CL)C(
         CL)C(CL)C(CL)CC(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C(CL)C
CHEM   :
MOL FOR: C30 H36 CL26
MOL WT : 1318.40
--------------------------------- BCFBAF v3.00 --------------------------------
Summary Results:
  Log BCF (regression-based estimate):  0.50  (BCF = 3.16 L/kg wet-wt)
  Biotransformation Half-Life (days) :  1.27e+006  (normalized to 10 g fish)
  Log BAF (Arnot-Gobas upper trophic):  -0.05  (BAF = 0.893 L/kg wet-wt)

Log Kow (experimental):  not available from database
Log Kow used by BCF estimates:  19.77
```

Attachment B: BCF Modeling of LCCP Using EPISUITE

```
Equation Used to Make BCF estimate:
  Log BCF = -0.49 log Kow + 7.554 + Correction

     Correction(s):                 Value
      No Applicable Correction Factors
      Minimum Log BCF of 0.50 applied when Log Kow > 7

  Estimated Log BCF =  0.500  (BCF = 3.162 L/kg wet-wt)

=====================================================================
Whole Body Primary Biotransformation Rate Estimate for Fish:
=====================================================================
------+-----+--------------------------------------------+---------+---------
 TYPE | NUM | LOG BIOTRANSFORMATION FRAGMENT DESCRIPTION |  COEFF  |  VALUE
------+-----+--------------------------------------------+---------+---------
 Frag | 26  |  Aliphatic chloride   [-CL]                | 0.3608 |  9.3798
 Frag |  2  |  Methyl  [-CH3]                            | 0.2451 |  0.4902
 Frag |  2  |  -CH2-  [linear]                           | 0.0242 |  0.0484
 Frag | 26  |  -CH-   [linear]                           | -0.1912 | -4.9720
 L Kow|  *  |  Log Kow =  19.77 (KowWin estimate)        | 0.3073 |  6.0754
 MolWt|  *  |  Molecular Weight Parameter                |         | -3.3808
 Const|  *  |  Equation Constant                         |         | -1.5058
============+============================================+=========+=========
  RESULT   |       LOG Bio Half-Life (days)          |        | 6.1038
  RESULT   |           Bio Half-Life (days)          |        |1.27e+006
  NOTE     |  Bio Half-Life Normalized to 10 g fish at 15 deg C   |
============+============================================+=========+=========

Biotransformation Rate Constant:
 kM (Rate Constant):  5.458e-007 /day (10 gram fish)
 kM (Rate Constant):  3.069e-007 /day (100 gram fish)
 kM (Rate Constant):  1.726e-007 /day (1 kg fish)
 kM (Rate Constant):  9.705e-008 /day (10 kg fish)

Arnot-Gobas BCF & BAF Methods (including biotransformation rate estimates):
  Estimated Log BCF (upper trophic) =  -0.049  (BCF = 0.893 L/kg wet-wt)
  Estimated Log BAF (upper trophic) =  -0.049  (BAF = 0.8931 L/kg wet-wt)
  Estimated Log BCF (mid trophic)   =  -0.031  (BCF = 0.9315 L/kg wet-wt)
  Estimated Log BAF (mid trophic)   =  -0.031  (BAF = 0.9315 L/kg wet-wt)
  Estimated Log BCF (lower trophic) =  -0.027  (BCF = 0.9402 L/kg wet-wt)
  Estimated Log BAF (lower trophic) =  -0.027  (BAF = 0.9402 L/kg wet-wt)

Arnot-Gobas BCF & BAF Methods (assuming a biotransformation rate of zero):
  Estimated Log BCF (upper trophic) =  -0.049  (BCF = 0.893 L/kg wet-wt)
  Estimated Log BAF (upper trophic) =  -0.049  (BAF = 0.8931 L/kg wet-wt)
```

Chlorinated Paraffins Industry Association

Evaluation of Environmental Release and Environmental Assessment of Medium Chain Chlorinated Paraffins (C14-C17) and Long Chain Chlorinated Paraffins (C18-C20)

Executive Summary

The Environmental Protection Agency's (EPA) Draft Standard Review Risk Assessments of Medium Chain Chlorinated Paraffins (MCCP) (C14-C17) and Long Chain Chlorinated Paraffins (LCCP) (C18-C20) indicated that these substances may present an unreasonable risk to the environment because of concerns that they are released into the environment, particularly to the water, in amounts that could result in levels in excess of the concentrations of concern (CoC). Additionally, EPA has also concluded that these substances are expected to be persistence, bioaccumulative, and toxic (PBT). EPA specifically notes that its concerns are based upon:

- Release of both MCCP and LCCP to water during processing and use.
- Estimated environmental concentrations of MCCP and LCCP;
- Measured concentrations of MCCP in the environment;

With these concerns in mind, the Chlorinated Paraffins Industry Association (CPIA) conducted an evaluation of the environmental release pathways associated with the use, waste generation, and waste handling of MCCP and LCCP for the following industrial use segments:

- Rubber - Compounding and Converting
- PVC and Plastic - Compounding and Converting
- Coatings, Adhesives, Sealants – Formulation and Use

Additionally, the Independent Lubricant Manufacturers Association (ILMA) is working to develop similar information on use, waste generation and waste handling for metalworking fluids (MWF) formulation and use.

There are only a few companies that use the majority of the total MCCP and LCCP volume going into rubber, PVC, plastic, coating, adhesives and sealant applications. For example, only 3 companies represent approximately 80% of the total MCCP and LCCP volume used in rubber, PVC and plastics. The largest users in the above industries were surveyed for information regarding their use practices. All of the respondents confirmed that they do not have any water releases from the processes involving MCCP or LCCP. None of the rubber, PVC or plastic applications use water in their processes or cleaning at all. The coating, adhesive and sealant manufacturers use water for process equipment cleaning; however, this cleaning water is either recycled into the products (some of which are water-based) or sent to landfill for disposal. Based on this information, CPIA believes that any water release pathways can be completely eliminated for these uses. Eliminating these release pathways will have the effect of eliminating the specific concerns identified by EPA for these applications, namely releases to water and estimated environmental concentrations above the CoCs.

CPIA also hired an exposure expert to review the MCCP environmental monitoring data considered by EPA in its risk assessment. EPA concluded these data helped to support a conclusion of unreasonable risk to the environment for these substances. However, the weight of the evidence presented by these data does not suggest that exceedances of the EPA COC for surface water or sediment are likely. For example, the only exceedance of the aquatic CoC noted in these data is from a study in Norway using a lower resolution analytical method. All of the water samples in the U.S. and North America are below the water CoC and, in particular, those samples developed using higher resolution analytical methods were well below the CoC. Likewise the vast majority of sediment samples are below the CoC and the only U.S. samples above the CoC are from a surface impoundment at a CP manufacturing location, not from the native environment. These monitoring data are also significant because they represent the cumulative impact of all release sources in the environment and also appear to indicate that even after decades of use levels of MCCP in the environment are not accumulating to levels above the CoC.

1. Introduction

This evaluation is intended to inform the U.S. Environmental Protection Agency's (EPA) review of Medium Chain Chlorinated Paraffins (C14-C17) and Long Chain Chlorinated Paraffins (C18-C20) for a series of PMNs that EPA received on these substances from CPIA members[1].

EPA's Draft Standard Review Risk Assessments of MCCP and LCCP indicated that these substances may present an unreasonable risk to the environment. In particular EPA concluded that these substances are: 1) expected to be persistent, bioaccumulative, and toxic (PBT), and 2) released into the environment in amounts that may lead to exceedances in the concentrations of concern (CoC) for aquatic and sediment-dwelling organisms.

In regards to concern #2, EPA specifically notes that its concerns are based upon:

- Estimated environmental concentrations of MCCP and LCCP.
- Measured concentrations of MCCP.
- Release of both MCCP and LCCP to water during processing and use.

This document considers the release pathways for MCCP and LCCP identified by EPA in its risk assessment of the downstream uses. A summary of these release pathways is provided followed by recent information collected from downstream users regarding waste generation and handling practices and the potential for water release. The survey results are considered in an assessment of the relevance of EPA's initially identified release pathways. Finally, a detailed analysis of the available monitoring data is provided to better assess the current understanding of environmental concentrations in the U.S. and the impact sampling location and analytical methods have on those data.

---

[1] CPIA members are Dover Chemical, INEOS Chlorvinyls, and Qualice LCC.

2. Physicochemical Parameters Important to the Assessment

The table below presents the physicochemical parameters used by EPA in its assessment of MCCP and LCCP. There are several important physicochemical properties of MCCP and LCCP that impact their environmental risk assessment, including their very low water solubilities and the fact that these substances decompose prior to boiling.

Table 1: Summary of Physiochemical Data EPA used in its Assessment of MCCPs and LCCPs

Substance	%Cl (wt.)	Melting Point	Boiling Point	Vapor Pressure	Water Solubility	Log K_{OW}
MCCPs	> 40	< 25 °C (pour point)	> 200 °C (dec)	< 0.036 Pa at 20 °C	27 µg/L at 20 °C	> 5.5 (measured) 8.30 (estimated)
LCCPs	> 40	< 25 °C (pour point)	> 200 °C (dec)	$< 2.7 \times 10^{-4}$ Pa at 20 °C	5 µg/L at 20 °C	> 10

EPA Sources: EURAR (ECB, 2008); EA (2009)
EPA Notes: Value calculated using the KOWWIN Program (v1.68) available in EPA's Estimation Programs Interface (EPI) Suite TM. This estimate was generated using a representative MCCP (*i.e.*, $C_{14}H_{24}Cl_6$, 52 wt % Cl) with the following SMILES notation: CCC(Cl)CC(Cl)CCCl)CC(Cl)CC(Cl)CC(Cl)C. The EURAR (ECB, 2008) cited Renberg's liquid chromatography to measure a log KOW between 5.5 and 8.2 and then chose to use log KOW = 7 as a representative log KOW for MCCP 45 – 52 wt % Cl.

The very low water solubilities noted by EPA for MCCP and LCCP will limit their ability to be released via the dissolved fraction in water, will increase the efficacy of treatment technologies, and will limit the overall mass released to water. As discussed in Section 8, the very low water solubilities of these substances also complicate aquatic testing and the evaluation of aquatic toxicity results.

Furthermore, the decomposition of MCCP and LCCP coupled with their very low vapor pressure will limit any air emissions of MCCP and LCCP. This decomposition is a consideration in high pressure/temperature applications such as found in metalworking, where the substance will de-chlorinate and degrade during use. This de-chlorination is, in fact, the desired chemical phenomenon during high pressure metalworking as the free chloride ions react with the metal surface to reduce friction.

3. Environmental Critical Release Pathways in Draft Standard Review Risk Assessments

The following is a summary of the critical release pathways for the main downstream uses of MCCP and LCCP from EPA's Draft Standard Review Risk Assessment. Sections 4 and 5 review how these release pathways have been evaluated for this report by collecting information from downstream users and how these release pathways can be modified based on this information. The critical pathways summarized below focus on the assumed releases to water, although it should be noted that in many cases EPA assumed a release could occur to water or incineration or landfill. The E-FAST predicted surface water concentrations are based on the release to water.

A) Rubber - Compounding and Converting

The following tables provide the release parameters that EPA assumed for facilities using MCCP or LCCP in the compounding and converting of rubber. These emissions factors assumed that approximately 2 to 3% of the total MCCP or LCCP mass used at a rubber compounding facility is discharged to water mostly from cleaning operations such as equipment cleaning, tank/drum cleaning. Similarly, EPA assumed approximately up to 5 to 6% of the total MCCP or LCCP mass used in already compounded rubber used at subsequent manufacturing locations (rubber converting) to be discharged to the water in one PMN assessment. In both cases, these water discharges do not assume any on-site treatment. It is worth noting that in one of the PMN assessments, EPA assumed most of the release pathways for rubber converting went to landfill and/or incineration not water. There is also a smaller component that is assumed to be released via fugitive emissions, also without onsite treatment.

Table 2: EPA Model Inputs – Rubber Compounding

Source	**Apparent U.S. EPA Emission Factor Used in E-FAST (critical release)**	**Frequency**	**U.S. EPA Basis**
Fugitive emissions	0.025% or 0.001% (Water)	94 or 250 days/year	OECD Emission Scenario Document for Plastic Compounding; 50% to water
Cleaning liquid residuals from drums used to transport raw material	0.7% (Water)	0 or 96 days/year	EPA/OPPT Drum Residual Model
Cleaning liquid residuals from tank or rail cars	0.2% (Water)	33 or 250 days/year	EPA/OPPT Bulk Transport Residual Model
Equipment cleaning losses from multiple vessels	2% (Water)	96 or 250 days/year	EPA/OPPT Multiple Vessel Residual Model
Spillage during raw material handing	0.01% (Water)	96 or 250 days/year	OECD Emission Scenario Document for Plastic Compounding; 0.01% to water

Table 3: EPA Model Inputs – Rubber Converting

Source	**Apparent U.S. EPA Emission Factor Used in E-FAST (critical release)**	**Frequency**	**U.S. EPA Basis**
Fugitive emissions	0.025% or 0.125% (Water)	250 days/year	OECD Emission Scenario Document for Plastic Converting; 50% to water
Dust generation from converting	0.01% (Water)	0 or 250 days/year	OECD Emission Scenario Document
Cleaning solid or powder residuals from containers used to transport raw material	1% (Water or Landfill/Incineration)[a]	250 days/year	EPA/OPPT Solid Residuals in Transport Containers Model
Scrap material	2.5% (Water or Landfill/Incineration)[a]	250 days/year	OECD Emission Scenario Document

Equipment cleaning losses from multiple vessels	2% (Water or Landfill/Incineration)[a]	250 days/year	EPA/OPPT Multiple Vessel Residual Model
Spillage during raw material handing	0.01% (Water)	250 days/year	OECD Emission Scenario Document for Plastic Compounding; 0.01% to water

[a]Water was excluded as a pathway in one EPA assessment for these sources, and water was included in a pathway in a second EPA assessment.

B) PVC/Plastic - Compounding and Converting

The following are release parameters that EPA assumed for facilities using MCCP or LCCP in the compounding and converting of PVC and plastics. These emissions factors assume that approximately 3 to 6% of the total MCCP or LCCP used during the compounding of PVC and plastics is discharged to water, mostly from cleaning operations such as equipment cleaning, tank/drum cleaning. Similarly, EPA assumed approximately 5 to 6% of the total MCCP or LCCP mass used in already compounded PVC/plastic used at subsequent manufacturing locations (PVC/plastic converting) to be discharged to the water. These water discharges do not assume any on-site treatment. There is also a smaller component that is assumed to be released via fugitive emissions.

Table 4: EPA Model Inputs – PVC/Plastic Compounding

Source	**Apparent U.S. EPA Emission Factor Used in E-FAST (critical release)**	**Frequency**	**U.S. EPA Basis**
Fugitive emissions	0.001% (Water)	126 or 288 days/year	OECD Emission Scenario Document for Plastic Compounding; 50% to water
Equipment cleaning losses of liquids from compounding equipment	2% or 3% (Water)	126 or 288 days/year	OECD Emission Scenario Document for Plastic Compounding
Cleaning liquid residuals from drums used to transport raw material	2% or 3% (Water)	126 or 174 days/year	EPA/OPPT Drum Residual Model
Cleaning liquid residuals from rail cars, tank trucks and totes	1% (Water)	0 or 58 days/year	EPA/OPPT Bulk Transport Residual Model; PMN Submission (landfill)
Spillage during raw material handing	0.01% (Water)	126 or 288 days/year	OECD Emission Scenario Document for Plastic Compounding; 0.01% to water

Table 5: EPA Model Inputs – PVC/Plastic Converting

Source	Apparent U.S. EPA Emission Factor Used in E-FAST (critical release)	Frequency	U.S. EPA Basis
Fugitive emissions	0.075% (Water)	250 days/year	OECD Emission Scenario Document for Plastic Converting; 50% to water
Spillage during raw material handing	0.01% (Water)	250 days/year	OECD Emission Scenario Document for Plastic Converting;
Cleaning powders residuals from containers used to transport raw material	1% (Water)	250 days/year	EPA/OPPT Model for Solid Residuals
Equipment cleaning losses from multiple vessels	2% (Water)	250 days/year	EPA/OPPT Multiple Vessel Residual Model
Scrap material	2.5% (Water)	250 days/year	EPA assessment of SCCP (1992)

C) Coatings, Adhesives, Sealants – Formulation and Use

The following are release parameters that EPA assumed for facilities using MCCP or LCCP in the formulation and use of coatings, adhesives and sealants. These emissions factors generally assume that approximately 4 to 5% of the total MCCP or LCCP used in the formulation of coatings, adhesives and sealants is discharged to water, mostly from cleaning operations such as equipment cleaning, tank/drum cleaning. These factors also assume that up to 14% of the total mass of MCCP and LCCP in finished coatings, adhesives and sealants is discharged to the water. These water discharges do not assume any on-site treatment.

Table 6: EPA Model Inputs – Formulation of Coatings, Adhesives, Sealants

Source	Apparent U.S. EPA Emission Factor Used in E-FAST (critical release)	Frequency	U.S. EPA Basis
Spills during raw material transfer	0.01% (Water)	0 or 2 days/year	RM-2 SCCP Assessment (1992)
Equipment cleaning losses of liquids from a blending tank or mixing vessel	2.5% or 4% (Water)	2 or 200 days/year	EPA/OPPT Single Vessel Residual Model or OECD Emission Scenario Document for Adhesives
Cleaning liquid residuals from drums used to transport raw material	2.% or 6% (Water)	1 or 200 days year	EPA/OPPT Drum Residual Model
Discharge of off-specification material	100% (Water)[a]	0 or 4 days/year	OECD Emission Scenario Document for Adhesives

[a] 100% of daily use on days with off-specification material.

Table 7: EPA Model Inputs – Use of Coatings, Adhesives, Sealants

Source	**Apparent U.S. EPA Emission Factor Used in E-FAST (critical release)**	**Frequency**	**U.S. EPA Basis**
Cleaning liquid residuals from drums used to transport raw material	0.9% or 12% (water)	66 or 177 days/year	EPA/OPPT Small Container or Drum Residual Model
Equipment cleaning losses from multiple vessels	2% (water)	250 or 251 days/year	EPA/OPPT Multiple Process Vessel Residual Model

D) Metal Working Fluids Formulation

The following are release parameters that EPA assumed for facilities using MCCP or LCCP in the formulation of metal working fluids. In total these emissions factors assume that approximately 2 to 5% of the total MCCP or LCCP used at the facility is discharged to water mostly from cleaning operations such as equipment cleaning, tank/drum cleaning. These water discharges do not assume any on-site treatment.

Table 8: EPA Model Inputs

Source	**Apparent U.S. EPA Emission Factor Used in E-FAST (critical release)**	**Frequency**	**U.S. EPA Basis**
Equipment cleaning losses of liquids from a mixing tank	2 to 3% (Water)	38 to 240 days/year	EPA/OPPT Single or Multiple Process Vessel Residual Model
Cleaning liquid residuals from drums, totes or tank trucks used to transport raw material	0.2 to 2% (Water)	1 to 89 days/year	EPA/OPPT Drum Residual or Bulk Transport Model

E) Metalworking Fluid Use

The following are release parameters that EPA assumed for facilities using MCCP and LCCP containing metalworking fluids. In total these emissions factors assume that approximately 90% to 93% of the total MCCP or LCCP contained in these metalworking fluids are discharged to water, including mass contained on filter media and cleaning losses. These water discharges do not assume any on-site treatment.

Table 9: EPA Model Inputs

Source	Apparent U.S. EPA Emission Factor Used in E-FAST	Frequency	U.S. EPA Basis
Dragout Losses	11% (water)	247 days/year	Emission scenario document for MWF (2011)
Cleaning liquid residuals from drums used to transport raw material	3% (water)	18 or 218 days/year	EPA/OPPT Drum Residual Model
Filter media and other recycling waste	35% (water)	247 days/year	OECD Emission Scenario document for MWF (2011)
Spent metal working fluid	45% (water)	247 days/year	OECD Emission Scenario Document for MWF (2011)

4. Information Collection Activities from Downstream Users on Release Pathways, and Waste Handling

As detailed in Section 3, for most uses of MCCP and LCCP there are a few key release pathways, almost all to water, that result in the predicted surface water concentrations of these substances used by EPA in Draft Standard Review Risk Assessments. In order to evaluate the appropriateness of these release pathways, information was collected directly from MCCP and LCCP users regarding their use, cleaning and waste handling practices. Surveys were conducted both by the PMN submitters for non-metalworking applications and by the Independent Lubricant Manufacturers Association (ILMA) for metalworking formulators.

A) Information on Releases for Rubber Uses

Rubber compounding and converting were assessed as two separate uses in the Draft Standard Review Risk Assessment, though it appears that these activities may be combined at a single facility where the raw ingredients of the rubber are combined (i.e., compounding) and then the rubber extruded into an article (e.g. belt) as part of the same operation. It should also be noted that releases of MCCP or LCCP in post-compounding use applications are not expected to result in free MCCP or LCCP that could be released since the substances are bound in the polymer matrix.

There are relatively few operations in the U.S. using MCCP or LCCP in rubber applications. A single company uses approximately 70% of the total volume going into rubber applications. Below are the responses from that user to the release pathways

Table 10: Survey of Rubber Compounding and Converting User

Source	Critical Release Media Assumed by EPA	User 1 Response	Release Pathway Results
Fugitive emissions	Air to Water	1 of 2 U.S. plants has thermal oxidizer.	Minor pathway not a significant source of release.
Cleaning liquid residuals from drums used to transport raw material	Water	No delivery via drums. Totes are not cleaned on site.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.
Cleaning liquid residuals from rail cars	Water	No delivery via rail cars. Trucks are dedicated and not cleaned onsite.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.
Equipment cleaning losses from multiple vessels	Water	Process equipment are not cleaned with water.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.
Spillage during raw material handing	Water	No discharge to water. Spills are sent for waste treatment.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.
Cleaning powders residuals from containers used to transport raw material	Water	Activity does not occur.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.
Scrap material	Water	Wastes not sent to water.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.

B) Information on Releases for PVC and Plastic Uses

PVC or plastic compounding and converting were assessed as two separate uses in the Draft Standard Review Risk Assessment, though it appears that these activities may be combined at a single facility where both the raw ingredients of the PVC/plastic are combined (i.e., compounding) and then the compounded polymer extruded into an article (e.g. flooring) as part of the same operation. It should also be noted that releases of MCCP or LCCP in post-compounding use applications are not expected to result in free MCCP or LCCP that could be released as the substances are bound in the polymer matrix.

There are relatively few operations in the U.S. using MCCP or LCCP in PVC and plastic applications. The three companies that have responded to the survey, to date, represent the majority, approximately 80%, of MCCP and LCCP used in PVC, plastic and polymer applications. Their collective responses to the pathways identified by EPA are presented in the table below.

Table 11: Survey of PVC/Polymer Compounding and Converting Users

Source	**Critical Release Media Assumed**	**User 1 Response**	**User 2 Response**	**User 3 Response**	**Release Pathway Results**
Fugitive emissions	Air to Water	No air emissions controls	Reciprocal thermal oxidizer used for air emissions control.	Scrubber system used for air emissions control.	Minor pathway; completely eliminated with thermal oxidizer at one facility and scrubber system at another facility.
Cleaning liquid residuals from drums used to transport raw material	Water	No delivery via drums or totes.	No delivery via drums or totes.	Totes are not cleaned on-site but sent to waste handler.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.
Cleaning liquid residuals from rail cars	Water	No delivery via rail cars. Trucks are dedicated and not cleaned onsite.	No delivery via rail cars. Trucks are dedicated and not cleaned onsite.	No delivery via rail cars. Trucks are dedicated and not cleaned onsite.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.
Equipment cleaning losses from multiple vessels	Water	No water is used in the process nor in the cleaning of process equipment.	No	No use of water in cleaning operations or in the process itself.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.
Spillage during raw material handing	Water	No discharge to water. Spills are sent for waste treatment.	Any wastes are sent to waste handler, not to water.	Spills are sent for waste treatment. No discharge to water.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.
Cleaning powders residuals from containers used to transport raw material	Water	N/A. Activity does not occur.	Any wastes are sent to waste handler, not to water.	Integrated facility, no transport of compound polymer from one site to another.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.
Scrap material	Water	Wastes not sent to water.	Not addressed, but finished product are solids, flooring and industrial vinyls.	Not addressed, but finished product is solid.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation.

C) Information on Releases for Coating, Adhesive and Sealant Uses

MCCP and LCCP are used is specialized coatings, adhesives and sealants. EPA identified water releases from several pathways during the formulation of these substances. Two of the largest users of these substances in coatings, adhesives, and sealants have responded to the survey, they represent approximately 75% of the total MCCP and LCCP volume going into PVC applications.

Table 12: Survey Coatings, Adhesives, Sealants Formulators

Source	Critical Release Media Assumed	User 1 Response	User 2 Response	Release Pathway Results
Spills during raw material transfer	Water	No discharge to water. Spills are sent for waste treatment.	No discharge to water. Spills are sent for waste treatment.	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation
Cleaning liquid residuals from drums used to transport raw material	Water	Empty drums are not cleaned on site. The vast majority of product comes via dedicated tank trucks, which are also not cleaned on site.	All product comes via dedicated tank truck. No onsite cleaning on site	Pathway not relevant to actual user. Could be eliminated/restricted for future evaluation/regulation
Equipment cleaning losses of liquids from a mixing vessel	Water	Water is used in cleaning process equipment. The waste water is not released. It is either recycled into making future batches or sent to a permitted deep well injection.	Water is used in cleaning process equipment. Waste water and paint wastes from cleaning operations are stored in totes and solidified for disposal at local landfill.	Pathway does not involve release to surface water or POTW. Pathway could be eliminated/restricted for future regulation

D) Survey by ILMA of Metalworking Formulators

ILMA has conducted a survey of its members using MCCP and LCCP[2] in metalworking fluid (MWF) formulations. Details of this survey will be provided to EPA directly from ILMA, but ILMA shared the preliminary results of this survey with CPIA.

Key results from the ILMA survey include:

- Survey responses were received from 30 companies representing over 65% of the MCCP and LCCP containing MWF in the U.S. (in 2014).

- MCCP use is much larger in MWFs than LCCP: 7.94 million pounds of MCCP were used in MWFs in 2014 compared to 1.66 million pounds of LCCP (though this includes both C_{18}-C_{20} and C_{20}+ LCCP products).

- There is minimal waste generation of MCCP and LCCP, by all routes, in the formulation of MWFs.

---

[2] The ILMA survey did not differentiate C18-20 LCCP from C20+ LCCP, as such the results for LCCP from the survey are not representative of just the C18-20 sub-class of LCCP.

- Those companies that receive shipments of MCCP and LCCP in drums send the empty drums to a waste handler or recycler. None of the survey respondents cleaned their drums with water and released the waste water.

- Out of the more than 9.6 million pounds of MCCP and LCCP used in MWF formulations in 2014, the total water release to POTWs was 750 pounds; these releases were from just two companies.

- Most operations, 28 out of the 30, have no (zero) release to water.

E) Information on Releases from MWF Users

Additional information on the waste generation and handling practices of MWF users is being sought. As CPIA previously indicated in its April 27, 2015 regulatory review, all of these facilities are subject to waste regulations and water discharge restrictions. Recent informal communications with several large metalworking operations indicate that these facilities generally do not discharge waste oils/fluids to surface water or to POTW but rather use regulated hazardous waste handlers to dispose of these wastes. Confirming information is being sought on these practices.

One important information gap on the use MCCP and LCCP in MWFs is how much of the MCCP and LCCP are consumed (i.e. de-chlorinated) by the metalworking process. Based on the chemistry of the process, it appears likely that some portion of the MCCP and LCCP no longer remain at the stage of spent fluid removal.

5. Release Modifications/Pathway Elimination

Considering the responses from MCCP and LCCP users regarding their waste generation and handling practices, CPIA believes that there is sufficient basis to revise the release pathways identified by EPA (summarized in Section 3).

EPA should be able to eliminate the various release pathways to water for rubber, PVC, plastic applications (both compounding and converting) and also the formulation of coatings, adhesives and sealants. With a majority of the total volume of MCCP and LCCP used in these applications having been covered in recent survey questionnaires, there is no indication of water releases from these users. With the elimination of these release pathways to water, CPIA believes that EPA's initial concerns regarding unreasonable risk to the environment from the release of MCCP and LCCP to water should be eliminated for these applications. Further, as these facilities are already avoiding releases to water, it should be feasible for EPA to craft use restrictions to ensure this practice continues. See Section 7 below for additional discussion on this point. It should also be noted that these U.S. rubber, PVC, and plastic manufacturing operations, who appear to be operating in an environmentally responsible manner, compete directly with foreign manufactured rubber, PVC and plastic goods which will not be held to the same requirements regarding the use of MCCP and LCCP in their manufacturing operations and finished products.

In regards to metalworking formulation and use, it appears that the water releases assumed by EPA for these applications are likely much, much lower than originally estimated. Additional follow-up research and coordination with that industry should help eliminate any remaining discharges or release pathways that might results in excess levels of MCCP and LCCP in the environment.

An enhanced review of the environmental monitoring data in the next section appears to support the conclusion that releases of MCCP to the environment are low. These monitoring results show levels of MCCP in the aquatic environment are largely below the CoCs. Further, these monitoring data capture both current releases and any background levels of the substance demonstrating that even after decades of use levels in the environment remain low.

6. Evaluation of MCCP and LCCP Environmental Monitoring Data

The EPA Draft Standard Review Risk Assessments summarized available literature on measured MCCP and LCCP concentrations between 1980 and 2013. This review considered research where the CP congeners were identified both from the United States and internationally. The EPA draft risk assessments identified three selection criteria, including:

- defined chain length;
- use of "modern analytical techniques"; and
- "at a minimum, general information on sampling location."

The EPA concluded that the data "provide some evidence that MCCPs and LCCPs are released into the environment" at discrete locations and times. The risk assessments for MCCPs and LCCPs concluded that measured concentrations reported in the literature may indicate a risk of acute or chronic injury to aquatic organisms, and a risk of chronic injury to sediment-dwelling organisms. The EPA concentration of concern (COC) for surface water is 1 μg/L (acute and chronic). The acute sediment COC is 374 mg/kg d.w. and the chronic sediment COC is 18.7 mg/kg d.w.

As described below, a review of the complete set of data considered by the EPA does not indicate any systematic exceedance of the COCs in the environment. Furthermore, a comparison of the measured surface water data to the results of EPA modeling demonstrate opportunities for refinement of the EPA modeling inputs to better reflect environmentally plausible surface water concentrations. It is important to note that much of the data were collected outside North America, where historical discharge and pre-treatment standards may be less comprehensive than in the United States. Some of the data reflect impacts not representative of current exposure scenarios in the United States, such as a CP manufacturing facility surface impoundment lagoon, and surface water ponds impacted by uncontrolled electronic waste recovery operations. As explained below, the available analysis methods are subject to interferences which may result in a positive bias (i.e. overestimate) of actual MCCP and LCCP concentrations. The weight of the evidence indicates that the MCCP load in the environment can be well managed by eliminating discharge pathways to water, which is reflective of current practices in the United States.

General Limitations of the Measured Data

The EPA draft reports noted that it is unknown whether the data summarized is representative of the overall distribution of MCCP and LCCP in the environment. EPA also acknowledged that quantification of MCCP and LCCP by "modern techniques" can be positively biased by "detection of low chlorination congeners in samples." The EPA summary also notes that a round-robin study of SCCPs has shown appreciable inter-laboratory variation, and that poor selection of calibration standards may cause errors of up to an order of magnitude. The EPA specifically discussed electron capture negative ion mass spectroscopy (ECNI-MS) as an example of a method capable of detecting specific congeners, but where difficulties with data reliability still persist. Literature reviews of ECNI-MS generally indicate that use of low resolution mass spectroscopy (LRMS) "increases the risk of interferences, which have to be controlled or eliminated" (Kassim and Barcelo, 2009). The use of high resolution mass spectroscopy (HRMS) may address some of these interferences by offering a more selective detection method, but is typically not used for routine analyses.

Surface Water

EPA identified nine references with at least one reported MCCP surface water concentration. A total of 15 concentrations (some of which represent mean or maximum values) were converted to uniform units by EPA and presented in Appendix D of the reports.

Review of Surface Water Data

Of the nine studies identified by EPA, only one study (discussed in more detail below) reported a surface water concentration exceeding the EPA COC of 1 μg/L. The 15 concentrations considered by EPA are summarized in Figure 1 below. The error bars represent the range of concentrations shown in Appendix D, and the circle indicates the mean of the concentrations summarized by EPA in Appendix D for each group. As acknowledged by EPA, the data are insufficient to determine the distribution of MCCPs in the United States. However, three important trends are apparent, including:

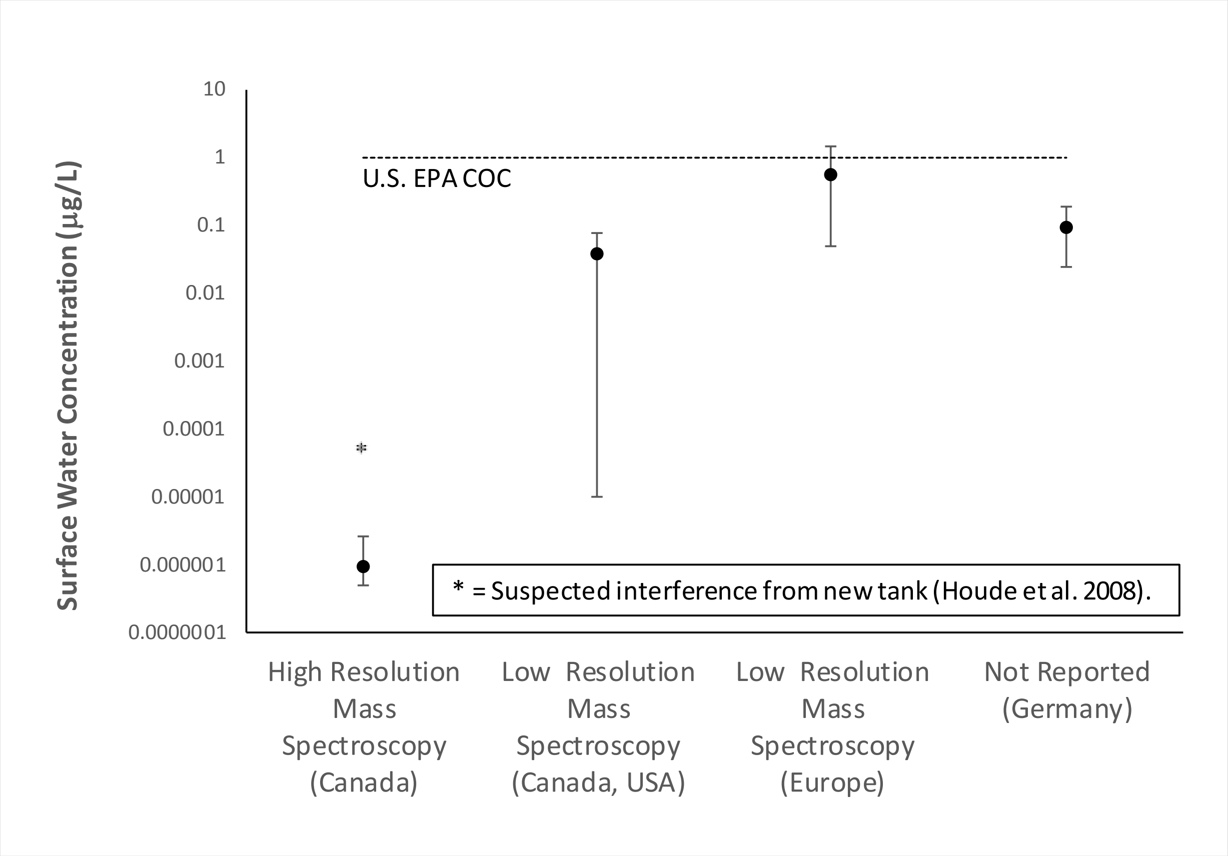
- Lower MCCP concentrations in Canada or the United States as compared to Europe;
- Lower MCCP concentration for analyses based on HRMS as compared to LRMS; and
- Appreciable fraction of the data representing surface water concentrations below the EPA COC.

It is important to note that an example of sample contamination was reported in one of the papers reviewed by the EPA. In an analysis of Lake Ontario water, Houde et al. 2008 reported an outlier "possibly related to the first use of the tank system during the cruise" which "illustrate[d] the potential for field contamination." As described in more detail below, it is unknown whether the single result of 1.49 μg/L reported by Peterson et al. (2006) may have been impacted by sample contamination, because information regarding the general sampling location and materials used to collect the sample were not provided.

In summary, the data do not appear to indicate a high likelihood that MCCP concentrations in surface water exceed the acute or chronic COC for aquatic species, particularly when the higher resolution method is used, and when data from North America is segregated from data in Europe.

The HRMS data suggest that the MCCP concentration may be as much as 5 to 6 orders of magnitude less the EPA COC for surface water.

Figure 1: Summary of Surface Water Data Considered by EPA by Region and Analytical Method



Limitations of Key Study Identified by EPA

In the risk characterizations, EPA choose to focus on the maximum surface water concentration from Petersen et al. (2006) collected in Norway from an undisclosed location of 1.49 µg/L. The draft risk assessments note that for surface water, "…EPA based the aquatic risk findings for MCCPs and LCCPs on the highest concentration reported by Peterson et al. (2006)." This study was the only one reviewed by EPA to report a surface water concentration exceeding the COC of 1 µg/L. This study has several limitations, which call into question whether it should have been considered in the EPA assessment. Most importantly, a general location of the sample (other than the country of origin) was not reported. Therefore, this study did not meet one of the three selection criteria identified by EPA, and the conditions and release scenario that this sample result represents are unknown. Second, while this study did include steps to remove organo-chlorine interferences like PCBS, quantification was by LRMS, which may have confounded the analysis of SCCP and MCCPs in the sample. Third, there was a significant difference between the two water sample results reported in the study, with one MCCP result of 1.49 µg/L, and a second MCCP result that appears to be less than 0.05 µg/L based on the figure presented in the paper. The authors do not offer an explanation for such a significant difference, and it is not possible to rule out that there may have been sample contamination affecting the first sample. As mentioned above, details were not provided regarding the sampling locations, sampling equipment and sampling methods, which are essential attributes necessary for assessing the likelihood of unintended sample contamination. Finally, this work was presented at the 2006 annual Dioxin Symposia in Oslo and, therefore, was subject to a more cursory peer review as compared to a peer-reviewed publication. Taking into account the limitations of this study, as well as the results of the remaining studies indicating surface water concentrations less than the EPA COC, there appears to be a very low likelihood that environmental surface water concentrations in the United States exceed the EPA COC.

Comparison of Measured Concentrations to EPA Model Results

EPA indicated in its summary of the risk findings that the measured data "…were used as supporting information to inform the relevant pathways for estimating potential releases from relevant use categories…" A comparison of the EPA modeling results to measured surface water concentrations indicates significant disagreement between the modeling results and the available surface water data. Figures 2a, 2b and 2c compare the predicted EPA surface water concentrations to measured data from North America for the metrics 7Q10 (10th percentile), harmonic mean (10th percentile) and harmonic mean (50th percentile). Irrespective of the surface water concentration metric selected from the EPA modeling, the measured surface water concentration data reviewed by EPA indicate that the modeled concentrations are not environmental plausible. Furthermore, as noted in the EPA draft risk assessment reports, the water solubility of MCCPs and LCCPs is very low, and less than 5 to 27 μg/L. In contrast, the EPA model results reflect maximum predicted surface water concentrations in some cases exceeding 500 μg/L (7Q10 – 10th percentile).

In summary, considering either water solubility or the available measured concentrations of MCCPs, it is clear that there is systematic bias in the EPA modeling assumptions reflecting the implausible assumption of pervasive down-the-drain discharge of MCCP and LCCP among industrial and commercial facilities. These assumptions of a down-the-drain pathway to municipal treatment and subsequent discharge surface waters for wastes generated in cleaning and equipment transfers do not reflect current waste management practices in the United States. As described previously, the local and federal regulatory framework in the United States prohibits down-the-drain disposal of oil contaminated cleaning wastes or spent fluids. Taking into account MCCP and LCCP solubility, as well as pathway elimination in accordance with current regulations, it is clear that the modeled surface water concentrations presented in the draft risk assessments overstate true environmental surface water concentrations by at least five orders of magnitude, if not more.

Figure 2a: Comparison of Model Result to Measure Data (7Q10 – 10th Percentile)

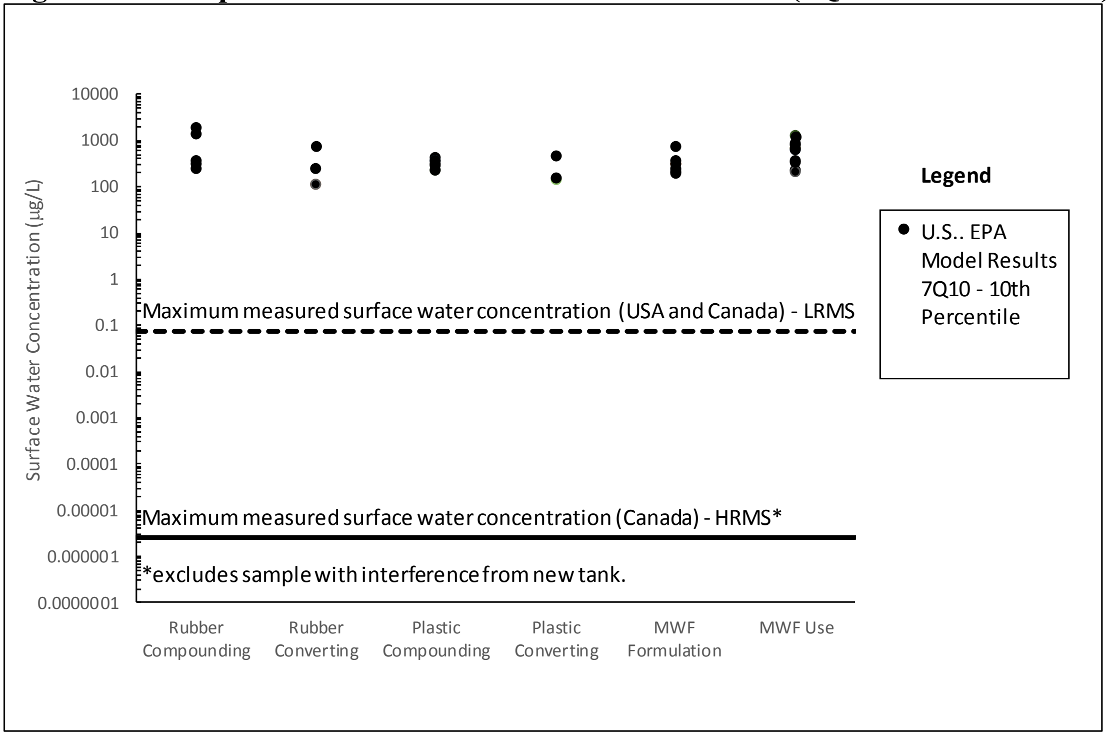


Figure 2b: Comparison of Model Result to Measure Data (Harmonic Mean – 10th Percentile)

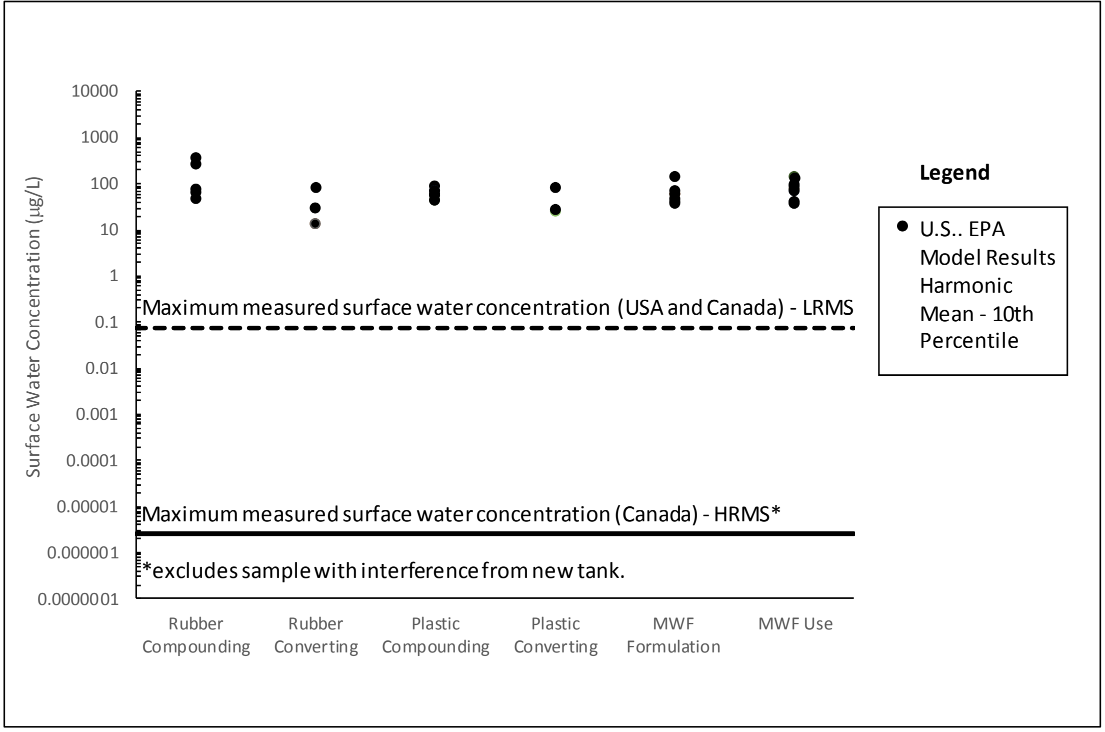
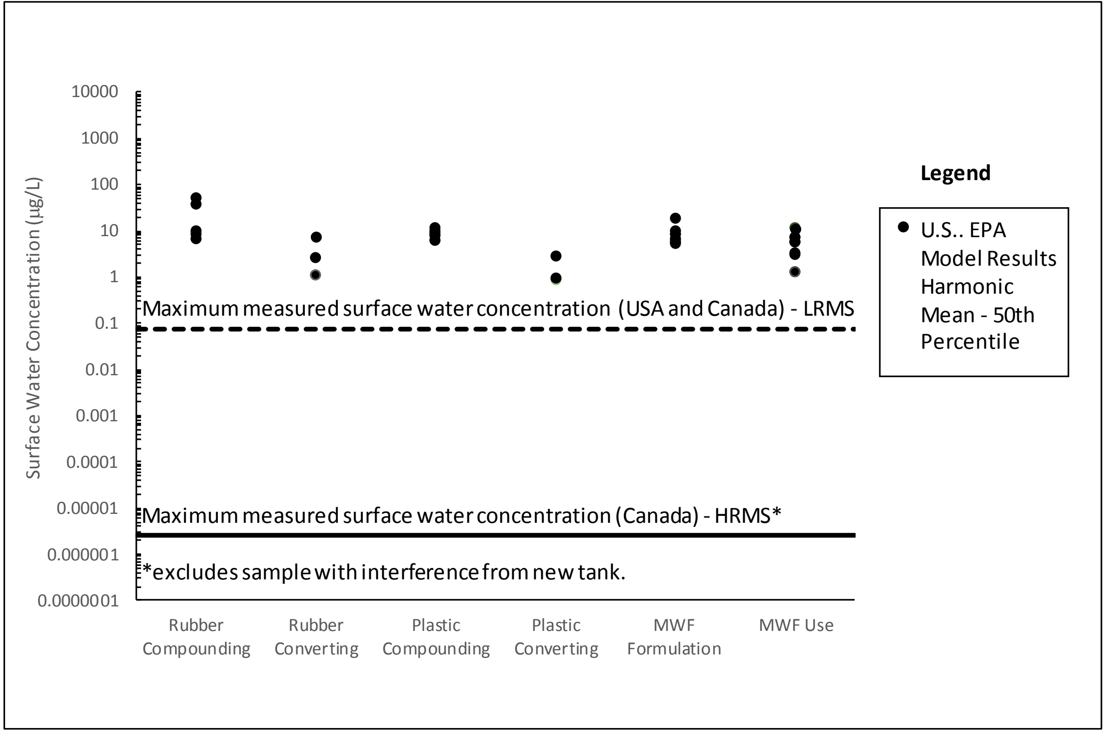


Figure 2c: Comparison of Model Result to Measure Data (Harmonic Mean – 50th Percentile)



Sediment

EPA identified 17 studies with reported MCCP sediment concentrations. A total of 139 concentrations (some of which represent mean values, maximum values or duplicates) were converted to uniform units by EPA and presented in Appendix D of the reports. Of the 139 samples, one result appeared to be an instrument detection limit (from Pribylova et al. (2006), and the same result of 0.068 mg/kg d.w. appears to have been associated with Tomy et al. (2009) and Tomy and Stein (2009). Therefore, 137 converted concentrations from Appendix D of the risk assessments are considered below.

Review of Sediment Data

Of the 17 studies identified by EPA with MCCP data, there were only three studies that reported a sediment concentration greater than the EPA COC of 18.7 mg/kg d.w. Figures 3a and 3b present the frequency of concentrations provided by categorized by marine and non-marine locations. Figures 4a and 4b present the concentrations categorized by method and region. Of the 137 concentrations listed by EPA, approximately 90% were less than the EPA COC, indicating that exceedances of the COC are not common. As explained in more detail below, the three studies with exceedances of the EPA COC are not reflective of current environmental practices in the United States. The locations with concentrations exceeding the COC consisted of pond sediment samples from China at an electronic waste facility where CP release is unregulated (Chen et al., 2011), sediment samples from the United Kingdom at locations with extensive PCA use and discharges to industrial wastewater (Nicholls et al., 2001), and a historical surface impoundment at a U.S. CP manufacturer in the United States (EPA, 1988). The LCCP data

reviewed by EPA was limited to marine sediment, with a maximum concentration of 0.431 mg/kg d.w.
Several general trends are apparent in Figures 4a and 4b, including:

- MCCPs are not accumulating in marine sediments at levels exceeding the EPA COC for sediment;

- MCCPs detected above the EPA COC are associated with specific discharges to industrial wastewaters (already restricted in the United States) rather than indirect sources;

- Many of the samples were quantified by low resolution mass spectroscopy methods, which may be impacted by interferences from other PCAs or chlorinated compounds; and

- The sampling results based on HRMS were below the EPA COC. The two HRMS results that were greater than 1 mg/kg d.w. (but less than the EPA COC were collected from "landfill sediment".

In summary, the environmental sediment data summarized by EPA suggests that exceedances of the COC are uncommon, and when they have occurred appear to be associated with facility-related surface impounds or discharges of significant amounts of MCCPs to industrial wastewaters. These releases to surface impoundments or industrial wastewaters are restricted by current discharge regulations and waste management practices in the United States.

Figure 3a: Distribution of Marine Concentrations Summarized by EPA

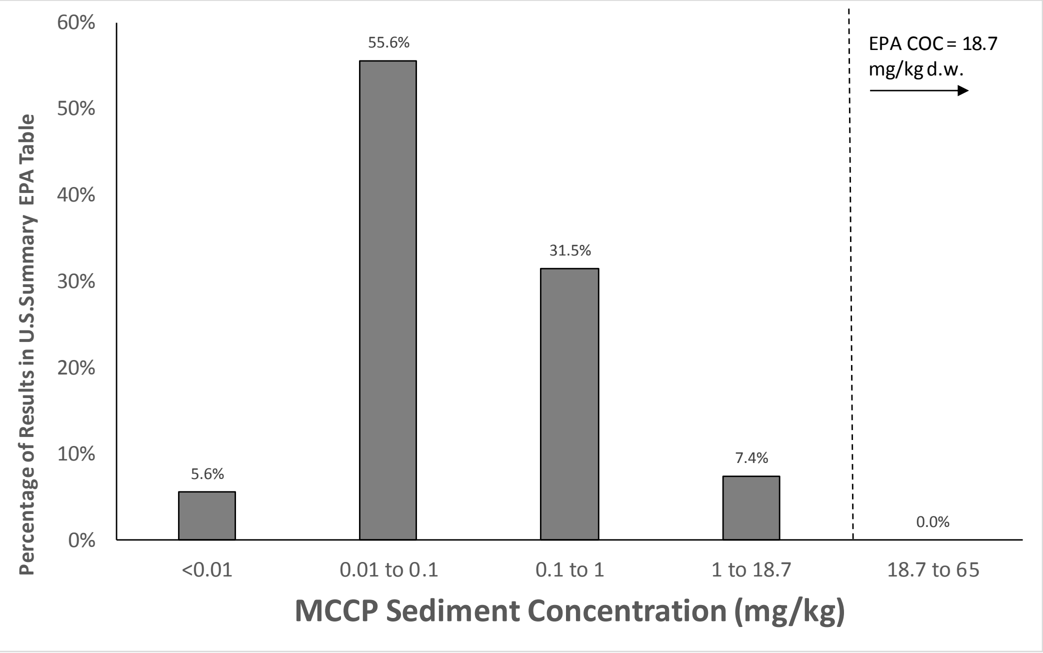


Figure 3b: Distribution of Non-Marine Concentrations Summarized by EPA

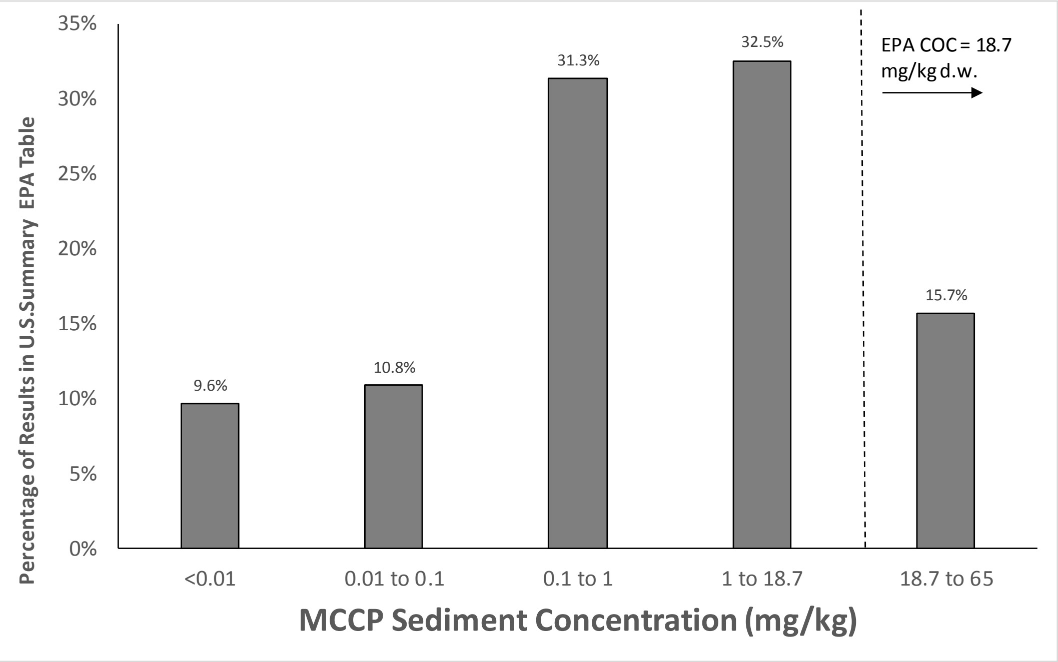


Figure 4a: Summary of Marine Surface Water Data Considered by EPA by Region and Analytical Method

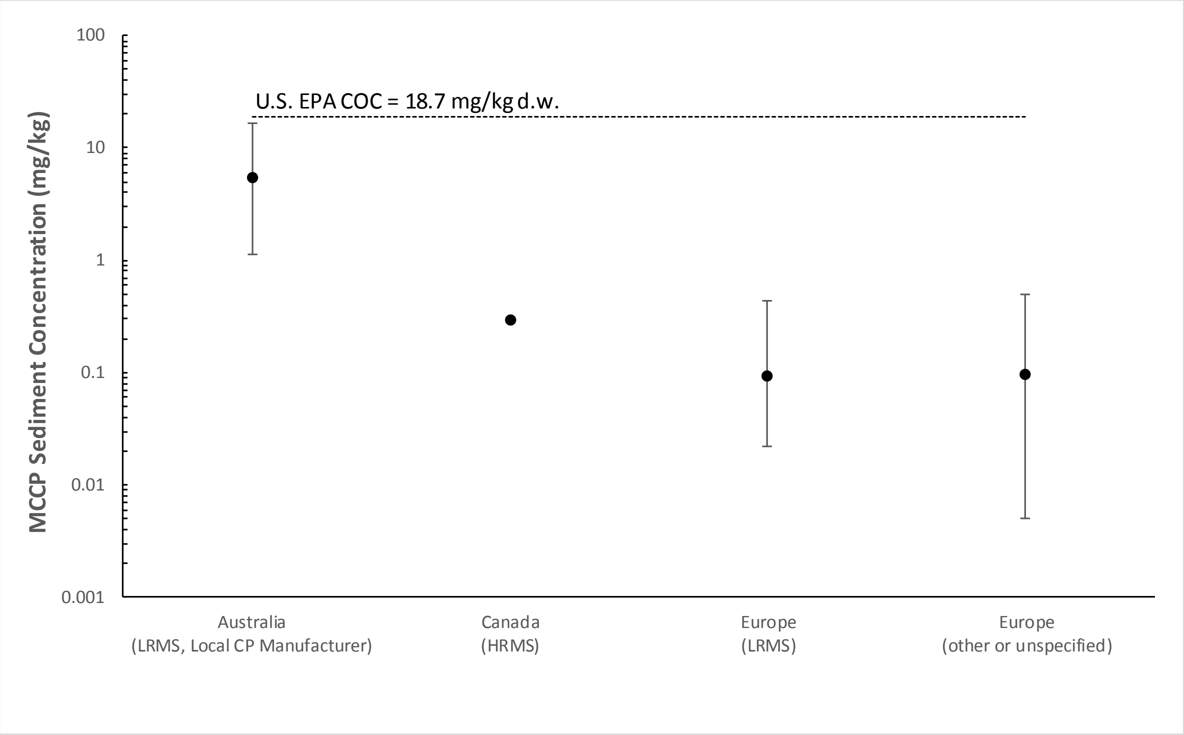
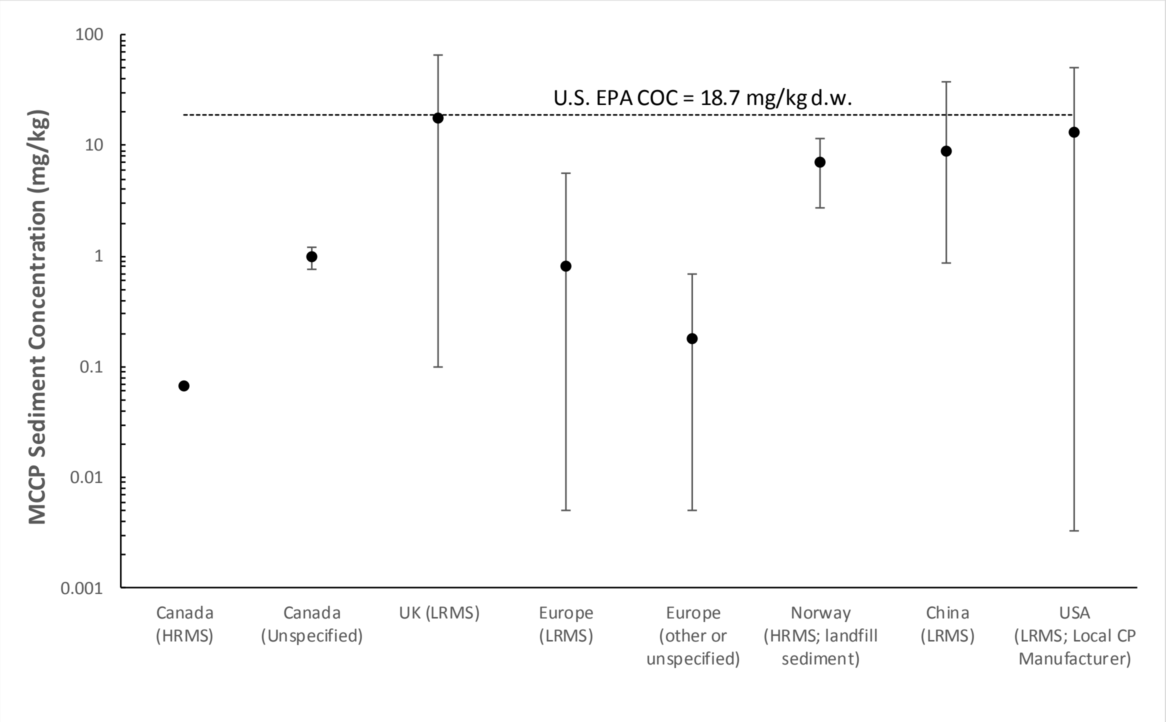


Figure 4b: Summary of Non-Marine Surface Water Data Considered by EPA by Region and Analytical Method



Limitations of Studies Reporting Elevated Concentrations

EPA identified the three studies with reported concentrations exceeding the COC of 18.7 mg/kg d.w. The study conducted in the UK by Nichollis et al. (2001) was considered by EPA to be the most relevant, but EPA generally considered the studies with at least one RQ greater than 1 as supporting the conclusion that MCCP concentrations in sediment may present a chronic risk to aquatic species. Of the three studies considered by EPA with concentrations greater than the EPA COC:

- One study was performed in South China, where usage of CPs, including SCCPs, is not regulated (Chen et al. 2011). The mean and maximum MCCP concentrations of 21 and 38 m/kg d.w. cited by EPA were observed in the pond sediment of an electronic waste recycling facility. Despite the lack of regulation and controls in China, the mean MCCP concentrations in industrialized areas of 3.9 mg/kg d.w. were less than the EPA COC.

- A second study with reported 8 of 29 concentrations exceeding the EPA sediment COC was performed in the United Kingdom, including sampling sites targeted for "industries known to employ significant quantities of PCAs" in manufacturing or production (Nicholls et al. 2001). Samples were analyzed by a low resolution MS method (GC-NICI-MS). The elevated concentrations in this study appear to reflect down-the-drain disposal of PCAs to industrial effluents, with less restrictive pre-treatment or on-site treatment standards than currently enforced in the United States. Because a low resolution mass spectroscopy method was used, it is unclear whether the pervasive PCA use in the areas sampled may have positively biased the reported MCCP concentrations.

- The third and final study with concentrations exceeding the EPA COC (EPA, 1998) was a field study completed in the United States near a chlorinated paraffin manufacturing facility. Of the 8 sample results summarized by EPA, only three results exceeded the COC. These three samples were not representative of environmental sediment, but rather were collected from the surface impoundment lagoon located at the chlorinated paraffin manufacturing facility.

Conclusion on Measured Data

Based on a review of the environmental measurements summarized by the EPA, the weight of evidence does not suggest that exceedances of the EPA COC for surface water or sediment are likely. While limited in geographical and temporal coverage, a conclusion of frequent or likely exceedances of the EPA COCs does not appear to be supported by the available data.

Information regarding general sample location was not available for the sole surface water result exceeding the EPA COC, though the study appears to have been conducted in Norway. With regard to the sediment data, two of the studies characterized areas with obvious impacts, including a historical surface impoundment at a CP manufacturing location in the United States, and a pond at an electronic waste facility in China. Sediment data collected in the United Kingdom appears to reflect significant discharge of PCA to industrial wastewater, a scenario which is not applicable to the current regulatory framework in the United States. The available data suggest that environmental concentrations of MCCPs and LCCPs may be effectively managed by eliminating discharge pathways to water.

7. Conclusions and Reducing Uncertainties in Risk Assessments

In its Draft Standard Review Risk Assessments and subsequent letters[3] to the PMN submitters, EPA identified concerns with MCCP and LCCP, including the potential for release to water during processing and use, estimated environmental concentrations above the CoCs, and measured environmental concentrations above the CoCs. CPIA believes that this submission establishes that for most uses of MCCP and LCCP there are not releases to water and that for those use applications with releases to water, the total mass is very low and well controlled by existing water discharge practices and regulations. Eliminating the release pathways to water eliminates the estimated environmental concerns above the CoC. Additionally, a detailed review of the monitoring data used by EPA does not a support a conclusion of high levels in the environment. Data most relevant to the PMN assessments, based on location and higher resolution analytical methods, in fact supports the conclusion that releases are low and resulting concentrations in the environment are below EPA's concentrations of concern.

Overall, the conclusions from this assessment are:

- The physiochemical properties of MCCP and LCCP, such as very low ambient vapor pressure, decomposition at elevated temperatures, and very low water solubility, limit the ability to release significant quantities of these substances the environment, particularly via the water or air.

---

[3] January 21, 2015 letters from Greg Schweer to each MCCP and LCCP PMN submitter.

- Information from users indicates that there are not the release pathways to water for MCCP and LCCP that EPA assumed in it Draft Standard Review Risk Assessment.

- Exceedances of EPA's COC in environmental surface water or sediment are not expected to occur.

- Finally, that these data support that MCCP and LCCP can be effectively managed by eliminating discharge pathways to water using existing U.S. industry practices and th regulatory framework.

CPIA believes that there is sufficient information for EPA to reconsider its risk conclusions and also to propose alternative actions to those presented in the Agency's January 21, 2015, letters to the PMN submitters. To the extent that EPA still has concerns about uncertainties in the risk assessments for these substances, CPIA believes there are actions short of elimination from the market or extensive additional laboratory studies that could be undertaken reduce these uncertainties.

Perhaps the main follow-up activity that EPA should consider for these substances is new environmental monitoring data in the U.S. along the lines of what was suggested in the 2015 report on chlorinated paraffins by U.S. and Canada Identification Task Team (ITT) on Chemicals of Mutual Concern in the Great Lakes. The ITT 2015 report concluded that there are "insufficient data and/or information available to effectively apply the Binational Considerations" and, therefore it made a designation of "No Determination" for all CPs - SCCPs (C10-C13), MCCPs (C14-C17) and LCCPs (> C18). The ITT specifically recommended "continued targeted monitoring in top predator fish across the Great Lakes, including in the near-shore environment, in order to confirm recent trends continue to show decreases for SCCPs and definitely establish whether downward trend exists for MCCPs." The ITT also recommended "targeted sediment monitoring… in the near shore environment and tributaries, to establish trends and evaluate loadings of these chemicals to the lakes." The ITT noted that "this monitoring work will provide some of the information necessary to evaluate the performance of existing and forthcoming risk management and control activities." It is worth noting that the ITT report had already found that what trend data did exist for CPs in the Great Lakes showed a drop in levels of SCCP and MCCP in the biota based on the work by Ismail et al. (2009). Based on the enhanced review of the monitoring data in this report, CPIA believe that collecting new water and sediment data using high resolution methods could provide a confirmation that these substances are not presenting an unreasonable risk to the environment. Such an approach could also confirm initially identified downward trends and eliminate any concerns that these substances are accumulating in the environment.

CPIA has separately provided EPA information regarding the environmental fate and aquatic toxicity of these substances that CPIA believes supports a conclusion that these substances are not PBTs. These data include analysis of the bioaccumulation potential of MCCP in the environment demonstrating that MCCP is not bioaccumulating in environmental organisms. While CPIA believes these data are sufficient to demonstrate a lack of bioaccumulation, additional sampling could also be done on organism as a part of the monitoring efforts mentioned above.

References

Chen, M. Y., X. J. Luo, X. L. Zhang, M. J. He, S. J. Chen, and B. X. Mai. 2011. Chlorinated Paraffins in Sediments from the Pearl River Delta, South China: Spatial and Temporal Distributions and Implication for Processes. Environmental Science and Technology, 45(23), 9936-9943.

Identification Task Team (ITT) for Chemicals of Mutual Concern (CMCs) in the Great Lakes. 2015. Binational Summary Report: Chlorinated Paraffins.

Ismail, N., S.B. Gewurtz, K. Pleskach,† D.M. Whittle, P.A. Helm, C.H. MARVIN, and G.T. Tomy. 2009. BROMINATED AND CHLORINATED FLAME RETARDANTS IN LAKE ONTARIO, CANADA, LAKE TROUT (SALVELINUS NAMAYCUSH) BETWEEN 1979 AND 2004 AND POSSIBLE INFLUENCES OF FOOD-WEB CHANGES. Environmental Toxicology and Chemistry, Vol. 28, No. 5, pp. 910–920.

Nicholls, C. R., C. R. Allchin, and R. J. Law. 2001. Levels of Short and Medium Chain Length Polychlorinated N-Alkanes in Environmental Samples from Selected Industrial Areas in England and Wales. Environmental Pollution, 114(3), 415-430.

Petersen, M., P. Bussmann, R. Grumping, and G. Liek. 2006. Analysis of Short-Chain (C10-C13) and Medium-Chain Chlorinated Paraffins (C14-C17) in Norwegian Sediment and Water Samples by Gc/Ecni-Ms. Organohalogen Compounds, 68, 2101-2104.

Houde, M., D. C. Muir, G. T. Tomy, D. M. Whittle, C. Teixeira, and S. Moore. 2008. Bioaccumulation and Trophic Magnification of Short- and Medium-Chain Chlorinated Paraffins in Food Webs from Lake Ontario and Lake Michigan. Environmental Science & Technology, 42(10), 3893-3899.

Kassim, Tarek A., and Damià Barceló, eds. Contaminated sediments. Vol. 5. Springer Science & Business Media, 2009.

Attachment 3

ilma

Independent Lubricant Manufacturers Association

400 N. Columbus Street, Suite 201, Alexandria, VA 22314 • p 703.684.5574 • f 703.836.8503 • www.ilma.org • ilma@ilma.org

July 24, 2015

By Overnight Delivery & Electronic Mail

Mr. Greg Schweer, Chief
New Chemicals Notice Management Branch
Office of Pollution Prevention and Toxics
Environmental Protection Agency
Room 4133-A; (MC- 7405M)
1200 Pennsylvania Avenue, N.W.
Washington D.C. 20460

Re: Reasonable Timeline and Cost Considerations for Replacement of Medium-Chain Chlorinated Alkanes and Long-Chain Chlorinated Alkanes

Dear Mr. Schweer:

The Independent Lubricant Manufacturers Association ("ILMA" or "Association") offers these additional comments on the Environmental Protection Agency's ("EPA" or "Agency") pending review of the Pre-Manufacture Notices ("PMNs") for medium-chain chlorinated alkanes ("MCCAs") (C_{14}-C-$_{17}$) and long-chain chlorinated alkanes ("LCCAs")(C_{18}-C_{20}). These comments supplement ILMA's June 10, 2015 letter and the matters discussed during our June 3, 2015 meeting. Specifically, ILMA would like to expand upon the "Realistic Timing Considerations" section in its June 10 letter.

The metalworking fluids ("MWFs") industry and downstream end-users remain very concerned with EPA's pending deadline of May 31, 2016 to eliminate the production and import of MCCAs and LCCAs. There is no practicable way to transition away from MWFs containing MCCAs and LCCAs by May 31, 2016, even if an alternative fluid currently exists for each specific application.

In our June 3 meeting, ILMA noted the amount of manpower needed to develop, test, and fully incorporate alternative fluids into manufacturing processes. The MWF industry is a relatively small community, but the subset of the industry that actually formulates MWFs and then tests the fluids is even smaller. Changing out a MWF in a manufacturing process is more than the simple removal of one fluid and immediate replacement with another MWF. It is a time and labor-intensive activity with relatively few individuals trained to do the required work.

There is a Lack of Manpower

There are a limited number of MWF suppliers in the United States with chemists that develop the thousands of MWF formulations in laboratories for use in the expansive array of domestic manufacturing applications and processes. ILMA, through its internal surveys, believes its Manufacturing Members account for approximately 80% of the MWFs sold annually in the United States. Of ILMA's 317 member companies, there are 125 companies that manufacture and blend lubricants. Of these 125 Manufacturing Members, ILMA believes 62 companies manufacture and sell MWFs. These 62 member companies each employ between one and five chemists who formulate MWFs. Assuming an average number of three chemists per company, and further assuming non-ILMA members who account for the remaining 20% of the MWF volume employ a similar number, the total number of chemists in the United States that formulate MWFs is 232[1].

Next, we then turn to the total number of MWF technicians. These are the individuals employed by the MWF suppliers, including ILMA members, that possess the technical expertise to go into customers' manufacturing facilities and machine shops and work directly with these customers to test and re-test the various fluid formulations developed by the chemists. MWF technicians are also inclusive of the individuals in end-user customers' facilities that similarly possess the requisite expertise and knowledge to implement alternative MWFs. ILMA estimates that there are 2,500 total MWF technicians employed by both suppliers and end-users.

ILMA arrived at its MWF technician estimate based on the average attendance at the Society of Tribologists and Lubrication Engineers' ("STLE") Annual Meeting. STLE is a premier educational resource for professionals in the lubricants industry and is attended annually by the majority of MWF technicians.[2] There were 1,500 industry professionals at STLE's May 2015 conference in Dallas. It is ILMA's assessment that 60% of the MWF technicians attend the STLE Annual Meeting. In order to account for the remaining 40% of the market that may not attend the STLE Annual Meeting, and provide EPA with a reasonable estimate, ILMA added an additional 1,000 technicians for a total of 2,500 individuals.

There are a Significant Number of Sites and Applications

Using the Organization for Economic Co-operation and Development's Emission Scenario Document ("ESD") for MWFs, the Association conservatively projects there are 30,000 end-user sites. ILMA arrived at this number from EPA's estimate that "approximately 89,000 MP&M (metal products and machinery industry) sites operate in the United States," its recent member survey on MCCAs and LCCAs, census data, and conversations with industry experts. ILMA believes that the estimate of 30,000 sites that use MWFs containing MCCAs or LCCAs is reasonable.

---

[1] While ILMA understands that EPA may be reluctant to accept some of ILMA's assumptions and estimates, the Association's data are well respected as reliable industry information. ILMA-supplied data are widely cited in the Organization for Economic Co-operation and Development's Metalworking Fluid Emission Scenario Document.

[2] STLE's mission statement is "[t]o advance the science of tribology and the practice of lubrication engineering in order to foster innovation, improve the performance of equipment and products, conserve resources and protect the environment."

From discussions with ILMA members, the Association's assessment is that there are 10,000 critical applications/uses of MWFs containing MCCAs or LCCAs spread out over these 30,000 sites. Stated differently, there are approximately 0.33 critical uses at every end-user facility in the United States, if the total applications are spread evenly across all facilities. "Critical use" encompasses a specific use for which the lack of alternatives acceptable to the customer would result in a significant market disruption, as well as where there are no technically or economically feasible alternatives or substitutes available to the user from the standpoint of the environment and/or human health. For these critical uses, it simply may not be possible to find alternative chlorine-free formulations, but the number is included in the calculation to illustrate the universe of manufacturing operations that utilize MWFs containing MCCAs or LCCAs.

In addition to the 10,000 "critical use" applications in the United States, there are approximately 375,000 non-critical uses of MWFs containing MCCAs or LCCAs at customers' sites. This number takes into account the practical realities that, in any given end-user facility, there are multiple applications that use MWFs that contain MCCAs or LCCAs. ILMA estimates that each of these 30,000 sites has approximately 10-15 applications or operations that utilize a MWF containing MCCAs or LCCAs. Taking the average of 12.5 applications spread across 30,000 facilities yields 375,000 non-critical uses in the United States. ILMA concedes that chlorine-free alternatives likely can be implemented for these non-critical uses; however, the substitution requires a considerable amount of time from a limited number of skilled chemists and technicians.

At Least Five Years are Necessary to Transition to Alternative Fluids

ILMA calculates from discussions with its Manufacturing Members that at least 72 hours is needed to make a fluid change, per operation or per application. This best-case estimate is based on the fact that each fluid needs to be separately formulated, tested, and fully incorporated into the manufacturing process for each use or application. The 72 hours[3] is needed in the United States, in part, because of the various standards and regulations that have to be met.

MWF changes are a time and labor-intensive process. Each fluid has to be specially formulated and tested for use in individual machines. Even similar processes (*e.g.* fabrication and formation of high nickel alloy tubing) require multiple tests and augmentations depending upon the type of machine used for the process. Even the same machine that manufactures the same part that is a few years older requires a specifically-tailored fluid that may or may not work in the newer machines.[4] Further, customers have to give final approval for the performance of the fluid to ensure the manufactured part is the same finished quality. As a result, fluid changes are an extensive trial-and-error process that takes a considerable amount of time. Therefore, the 72 hours is an exceedingly low, best-case approximation of the true amount of time that is actually needed to fully test and incorporate a new MWF in a manufacturing process.

---

[3] This does not account for the fact that a fluid change triggers a re-approval or re-certification process that can take several months to years to complete.

[4] ILMA members have anecdotally shared the difficulties in changing out different fluids in manufacturing processes and the considerable variation on the time needed to complete the process. One member conveyed he personally had tried to change out a fluid in an application for over three years and still has not completed the transition.

In summary, the total applications, both critical and non-critical, that utilize MWFs containing MCCAs or LCCAs are 385,000. If one takes the total number of applications (385,000) and multiplies it by ILMA's best-case estimate of 72 hours to formulate, test, and fully incorporate a new fluid, then 27,720,000 hours are needed to fully complete the substitution process. If one takes this total number of hours needed (27,720,000) and divides it by the number of capable technicians (2,500), then 277 weeks (presuming a 40-hour work week) or 5.31 years of working non-stop are needed to transition fully away from MWFs with MCCAs and LCCAs to alternative fluids. This calculation is predicated upon chemists and technicians working exclusively on reformulating MCCA or LCCA containing MWFs and nothing else. In reality, these individuals have an array of responsibilities that would not allow their attention to be solely directed to the replacement of MCCAs and LCCAs in MWFs.

Based on the foregoing, good-faith estimates and calculations, it is simply not possible for the industry to reformulate and replace MWFs containing MCCAs and LCCAs by May 31, 2016.

Reformulation will Cost Billions of Dollars

The time needed to formulate away from MWFs containing MCCAs or LCCAs will also come at an immense cost to MWF suppliers and end-user customers. Section 2(c) of the *Toxic Substances Control Act* ("TSCA") instructs EPA to carry out the act in a "reasonable and prudent manner" and that "the Administrator shall consider the environmental, *economic*, and social impact of any action . . ." ILMA and its customers are concerned about the significant cost associated with a ban of MCCAs and LCCAs. EPA should give careful consideration to the financial burden of a ban, in part, because many ILMA members and their customers are small businesses.

Of the 232 chemists, salaries range from $47,000-$280,000 depending upon the individual's education, experience and the size of the company for which the individual works, according to a 2014 survey done by Lubes 'N' Greases Magazine. Taking a lower-end salary of $75,000 for illustration purposes, and multiplying that by the total number of chemists (232), then the annual sum spent on chemist's salaries is $17,400,000.

Salaries range from $30,000-$380,000 for sales managers or MWF technicians according to the same survey. Again, taking a very low salary of $80,000 for illustration purposes and multiplying it by the total number of technicians (2,500), then $200,000,000 was spent on MWF technician's salaries in 2014.

Based on the timing analysis above, which assumes these chemists and MWF technicians do nothing but work on MCCA and LCCA reformulation over the next 5.31 years, the salary costs alone to the industry for the reformulation are $1.15 billion[5].

---

[5] ($17,400,000 + $200,000,000) x 5.31 years = $ 1,154,394,000

Beyond salaries for the individuals that formulate and test the MWFs, a considerable amount of money is spent during the trial-and-error process to develop functional, alternative fluids. This takes into account the cost to the MWF suppliers that have to allocate the time for the tests and the amount of personnel that must be supplied to monitor the tests. Additionally, there is a significant cost associated with the lost production at the MWF supplier's facility because an economically-viable fluid cannot be produced if space and time are allocated to test a potential alternative.To be sure, research and development ("R&D") are part and parcel to every economic sector, but those activities generally occur on a smaller scale and not to the detriment of other portions of a production facility.

Further, there is a considerable cost associated with testing for the customer. If tests are being run on a machine that usually outputs 1,000 finished products an hour, then there is a significant amount of money lost while machines are undergoing tests and can produce no economically viable items. Given the extent to which MWFs containing MCCAs and LCCAs are used in the United States, there would be a mass-scale reformulation and testing period at both the MWF suppliers' facilities and at the end-user customers' facilities that would require significantly more resources than traditional R&D testing.

The true cost of lost production and the accompanying scrap that results is difficult to quantify in dollars; however, a simple model is useful for illustrative purposes. For example, a machine outputs 500 finished parts per hour and those parts sell for $5.00 each. If that particular machine must be taken off-line to reformulate a fluid, then $2,500 is lost each hour that the machine is not operational. If one takes that lost production over the best-case estimate of 72 hours to reformulate (*e.g.,* when the machine will be inoperable), then $180,000 is lost over the course of the reformulation trial period for that particular application.

If this number is taken ($180,000) and applied to every application that exists in the United States (585,000) that use MWFs containing MCCAs and LCCAs then $69.3 billion will be lost due to reformulation at end-user customers' sites.[6] Additionally, if the cost of salaries for both chemists and MWF technicians are factored in ($1,154,394,000), then the expenditure increases to over $70 billion. This is a significant amount of money that will have to be allocated solely for the purpose of finding alternatives to MWFs containing MCCAs and LCCAs and nothing else.

Accordingly, the overall process to formulate away from MWFs containing MCCAs and LCCAs will not only require a significant amount of time, but it will also come with an immense cost to the MWF industry and its customers. This calculation is not intended to be a detailed economic analysis, but it is illustrative of the scope of the problem. Even if EPA adjusted this cost estimate downward by several orders of magnitude, it is clear that the regulatory ban will be an extraordinary financial burden for the MWF industry and U.S. manufacturers.

---

[6] Further, if the lost production at MWF supplier's facilities were included this number would be higher by several orders of magnitude.

EPA should initiate a formal comment process to allow stakeholders to weigh in on the financial considerations of a MCCA and LCCA ban. Further, ILMA would encourage EPA to hire an independent economist to review more closely the likely financial impact of the removal of MCCAs and LCCAs from commerce next May.

Conclusion

ILMA respectfully requests that EPA allow a minimum of a five-year transition if the Agency rejects the PMNs for MCCAs and LCCAs. Even a five-year transition will be problematic and will come at an immense cost to the MWF industry and its customers. Further, a public comment period on the economic impact of the costs to develop and implement substitute chemistries is warranted.

Sincerely,

Holly Alfano

Holly Alfano
Executive Director

cc: Ken Moss, Team Leader, Notice and Regulations Management Teams
ILMA Board of Directors
ILMA SHERA and Metalworking Fluids Committee
Andrew Jaques, Executive Director, Chlorinated Paraffins Industry Association
John K. Howell, Ph.D.
Jeffrey L. Leiter, Esq.
Daniel T. Bryant, Esq.

Attachment 4

Bioaccumulation Assessment of Medium Chain Chlorinated Paraffins (MCCPs)

Prepared for The Regulatory Network Inc.

Summary Report

Prepared by:
Jon Arnot, Ph.D.

April 28, 2014

Arnot Research & Consulting

Summary

This document provides summary information for the bioaccumulation (B) assessment of medium chain chlorinated paraffins (MCCPs) including (i) a review key B terminology and concepts, (ii) current scientific methods recommended for B hazard assessment, and (iii) the application of these methods using available relevant and acceptable quality B data for MCCP constituents.

Substances are generally considered B hazards because concentrations in higher trophic level organisms (at or near the top of food webs) may become high, even though concentrations in the environment are comparatively low. It has been recommended that the overarching objective of B assessment is to identify chemicals that biomagnify in food webs. Chemicals that biomagnify are those that increase in concentration with increasing trophic levels, i.e., chemical concentrations in an organism are greater than chemical concentrations in its diet.

There are various B assessment measurements (data) and criteria. Some B measurements are from laboratory models and some data are obtained from the environment. Academic, government and industry scientists have developed a weight of evidence B assessment framework for interpreting the seemingly disparate sources of B data to identify chemicals that biomagnify in the environment. In this framework different sources of B data are converted into a "common currency" and compared against a single criterion (a value of "1") to answer the question "Does the chemical biomagnify?". Data points greater than 1 indicate biomagnification and bioaccumulation in the environment.

This B assessment framework was applied for MCCP constituents using relevant and reliable (acceptable) quality B data included in the REACH substance evaluation (SEV) document and the peer-reviewed literature. A total of 97 measured data points are compared against the B assessment criterion; 92% of these data are highly relevant because they are measured from the environment. Of the 97 measured data points, 7 (7.2%) met or exceeded the threshold criterion of 1 and 90 (92.8%) were lower than the threshold criterion. The median value (estimate of central tendency) is 0.27. The current weight of evidence indicates that MCCP constituents are not likely to biomagnify in fish and in aquatic food webs.

Previous analyses have shown that the key determinant in assessing the B potential of MCCP constituents is the metabolic biotransformation rate constant. These analyses showed that estimates of the biotransformation rate constants are approximately the same for a range of MCCP constituents. Thus additional animal testing is not expected to provide value added information for the B hazard assessment of MCCP constituents.

Introduction

This document provides summary information regarding the bioaccumulation (B) hazard assessment of medium chain chlorinated paraffins (MCCPs). MCCPs are a mixture of chemicals, considered a UVCB substance (unknown or variable composition, complex reaction products or biological materials), registered for evaluation under a single CAS No (85535-85-9). The range of chemical properties for the MCCP constituents is large. For example, measurements and predictions for the octanol-water partition coefficient (K_{OW}) for MCCP constituents span a few orders of magnitude (log K_{OW}s from ~7 to >9.0 [1] or ~5.5 to 8.2 [2]). The very high K_{OW}s reflect the fact that these chemicals are very hydrophobic ("water-hating") and hence partition from water to biological phases. This summary includes (i) a review of key bioaccumulation terminology and concepts and (ii) current scientific methods recommended for B hazard assessment, and (iii) the application of these methods using available relevant and acceptable quality bioaccumulation data for MCCP constituents. The data used include data in the REACH substance evaluation (SEV) document and associated studies including recent peer-reviewed literature related to the B assessment of MCCP constituents.

Terminology and key concepts

Bioaccumulation is broadly defined as a process by which the concentration of a chemical in an organism exceeds that in the respiratory medium (e.g., water for fish, air for mammals), or in the diet, or both [3]. Bioaccumulation is the net result of competing rates of chemical uptake and elimination in an organism under a defined set of exposure conditions [3-5]. Fish are commonly used as a model organism for B assessment. In the environment fish are exposed to chemical in the water and food. Key routes of chemical elimination include gill elimination, fecal egestion and biotransformation (metabolism). Bioaccumulation is the result of bioconcentration (exposure from the surrounding environment, i.e., water) and biomagnification (exposure from food). Biomagnification is fundamentally different from the bioconcentration process in that it involves chemical transport against the thermodynamic gradient (i.e., from a low fugacity in the prey to a higher fugacity in the predator), whereas bioconcentration involves equilibrium partitioning in which the fugacity in the organism can at the most achieve that in the water [3, 6]. For chemicals with log $K_{OW} > \sim 4.5$ the biotransformation rate constant is a critical parameter determining whether or not a chemical bioaccumulates and biomagnifies [7-10].

Bioaccumulation hazard assessment metrics include K_{OW}, the bioconcentration factor (BCF; L/kg), the bioaccumulation factor (BAF; L/kg), the biomagnification factor (BMF; kg-lipid/kg-lipid) and the trophic magnification factor (TMF) [3, 6]. By definition, K_{OW}, BCF, BAF, BMF and TMF are steady-state metrics, i.e., there are no significant changes in chemical concentrations over time. K_{OW} is used as a surrogate for lipid-water equilibrium partitioning and has recognized limitations for B assessment, primarily because it is only a chemical property and ignores biological processes such as biomagnification and biotransformation [7, 9, 11]. The BCF is the ratio of the chemical concentration in a fish to the chemical concentration in the water following chemical exposure from the water only. The BCF is measured under controlled laboratory conditions; there is no dietary exposure. The BAF is the ratio of the chemical concentration in a fish to the chemical concentration in the water as a result of all routes of exposure (i.e. water and food). The BMF is the ratio of the chemical concentration in an organism to the chemical concentration in its diet. The BMF can be determined through laboratory (model) testing *or* field measurements. Field BMFs include all routes of exposure, whereas laboratory BMFs only include dietary exposures under controlled conditions in which there is no exposure to chemical in the water. The TMF is the average factor by which the chemical concentration in biota of a food web increases per trophic level and is determined from environmental monitoring data, i.e., organisms are exposed to chemical from the environment and diet. Obtaining accurate BCFs and BAFs for very hydrophobic chemicals like MCCP constituents is challenging because of technical difficulties and a general lack of extensive scientific knowledge on the actual dissolved (bioavailable) chemical concentration in the water for such hydrophobic ("water-hating") chemicals. Rationales for lipid correction (normalizing) for neutral organic chemicals and growth correction of the measured data are provided elsewhere [3, 6, 10, 12-14]. It is noted that growth correction methods have not historically been applied in B assessments, i.e., pre-2012. Thus hydrophobic chemicals being evaluated now are not being evaluated to the same historical standards.

Bioaccumulation assessment

Most regulations define persistent, bioaccumulative and toxic (PBT) chemicals and persistent organic pollutants (POPs) in terms of fairly strict bright-line or "pass/fail" criteria based on the state of the science in the late 1970s and early 1980s [15, 16]. The science of environmental chemistry and toxicology has evolved and produced new insights and an assortment of new methods to identify PBT chemicals. Regulatory programs and criteria strive to evolve with this pace; however, this is typically not the case. As a result, current scientific guidance on PBT and POPs criteria is limited and sometimes out of date [15, 16]. To address these issues workshops are commonly organized to bring together experts from academia, industry, and government to reach consensus on current scientific understanding and to promote the best available scientific methods for regulatory decision-making. Two recent and notable workshops related to B assessment and consensus building were (i) the "Science-Based Guidance and Framework for the Evaluation and Identification of PBTs and POPs" (Jan 28–Feb 1, 2008) Pellston Workshop organized by the Society of Environmental Toxicology and Chemistry (SETAC) and (ii) the "Laboratory–Field Bioaccumulation Workshop'' (November 18–19, 2009) sponsored by the International Life Sciences Institute, Health and Environmental Sciences Institute (ILSI-HESI), US EPA, and SETAC. These, and other similar workshops, have led to the publication of "state of the science" papers and guidance for PBT assessment including some cited in this summary.

The general objective of B hazard-based screening assessment is to identify chemicals with a high potential to accumulate in organisms. Bioaccumulative substances are considered hazardous because concentrations in higher trophic level organisms (at or near the top of food webs) may become high, even though concentrations in the environment are comparatively low. Regulatory frameworks for B screening include criteria to identify bioaccumulative substances but do not contain a definition for a bioaccumulative substance [3]. This anomaly contributes to inconsistencies in chemical evaluations between countries and limits the use of high-quality scientific data in assessments [16, 17]. To address the absence of a recognized definition, experts at the SETAC PBT/POP Workshop have defined a B substance as one that biomagnifies in the food-web, that is, increases in normalized concentration (or fugacity) with increasing trophic position [3]. While there is still some debate, the growing consensus in the scientific community is that the overarching objective of B screening is to identify chemicals that biomagnify in food webs [3, 6]. The most relevant metrics for assessing biomagnification are the TMF and the BMF in aquatic (water-breathing, i.e., fish) and terrestrial (air-breathing) species. Chemicals with TMFs > 1 are considered "confirmed B" and chemicals with BMFs > 1 are considered "probable B" [3]. The BCF and K_{OW} are not directly relevant because they do not explicitly include dietary exposures, and hence cannot explicitly quantify chemical biomagnification, although BCF data can be used to model (predict) BMFs, BAFs and TMFs [18]. Chemicals with BCFs or BAFs > 5,000 are considered "possible B" and chemicals with log K_{OW} > 4 are considered "potential B" [3]. Comprehensive reviews further detail the limitations and uncertainties in using BCF and K_{OW} data for B assessment [3, 5, 19-21].

To a first approximation, exposure via the water and diet for a typical fish in the environment is about equal when log K_{OW} ~ 5.6 [18]. When log K_{OW} is lower, exposure from the water (bioconcentration) dominates and when log K_{OW} is higher exposure from the diet (biomagnification) dominates [18]. Relative dietary exposure increases as K_{OW} increases accounting for approximately 85% of the body burden for very hydrophobic chemicals, i.e., log K_{OW} ~8 [22]. The key point is that environmental exposures to MCCP constituents (log K_{OW} > 5.5) are predominantly from the diet (food), not from the water. Hence the most appropriate B metrics are those that address and include dietary exposure pathways such as the BMF, BAF and TMF and not the BCF because it does not include dietary exposures.

Weight of evidence for MCCP B assessment

Following the bioaccumulation expert workshop co-sponsored by the US EPA, SETAC and ILSI-HESI, Burkhard and colleagues [6] proposed a framework to assess bioaccumulation and biomagnification in food webs using a weight of evidence approach that maximizes the application of various available B assessment metrics (i.e., BCFs, BAFs, BMFs, TMFs). Briefly, the approach converts measurements of laboratory and field B assessment metrics (i.e., BCFs, BAFs, BMFs, TMFs) into a “common currency” (fugacity ratios) enabling direct comparisons of different data for B assessment [6]. In this manner the data can be compared against a single B-hazard criterion of 1. Data points > 1 indicate biomagnification, data points < 1 indicate no biomagnification. The additional benefit of the approach is that it can be conveniently displayed in a picture. It is important to recognize that all B data are uncertain due to errors and practical limitations to measurements. Therefore the weight of evidence approach also provides some indication of error in the data in terms of the frequency of data points above or below the threshold criterion of 1.

Figure 1 illustrates the application of this B assessment framework with available measured B data for MCCP constituents from various aquatic species (plankton, invertebrates, fish) from laboratory testing (BCF, BMF) and environmental monitoring (BMF, BAF, TMF). A total of 97 measured data points are compared against the B assessment criterion of 1 (red horizontal line). Data derived from field studies, and in particular TMF values, are considered to be the ultimate indicator of a compound’s potential to bioaccumulate in the natural environment [3]. 93% of the data in Figure 1 are from environmental (field) studies and are thus considered highly relevant (“real world”) B assessment data. Of these 97 measured data points, 7 (7.2%) met or exceeded the threshold criterion and 93 (92.8%) were lower than the threshold criterion. The median value (central tendency) is 0.27 (black dashed line). The SETAC POP/PBT expert workshop experts considered that a TMF >1 represented the most conclusive evidence of the bioaccumulative nature of a chemical [3]. Figure 1 shows that all of the TMFs for the MCCP constituents < 1. The current weight of evidence indicates that MCCP constituents are not likely to biomagnify in fish and in aquatic food webs.

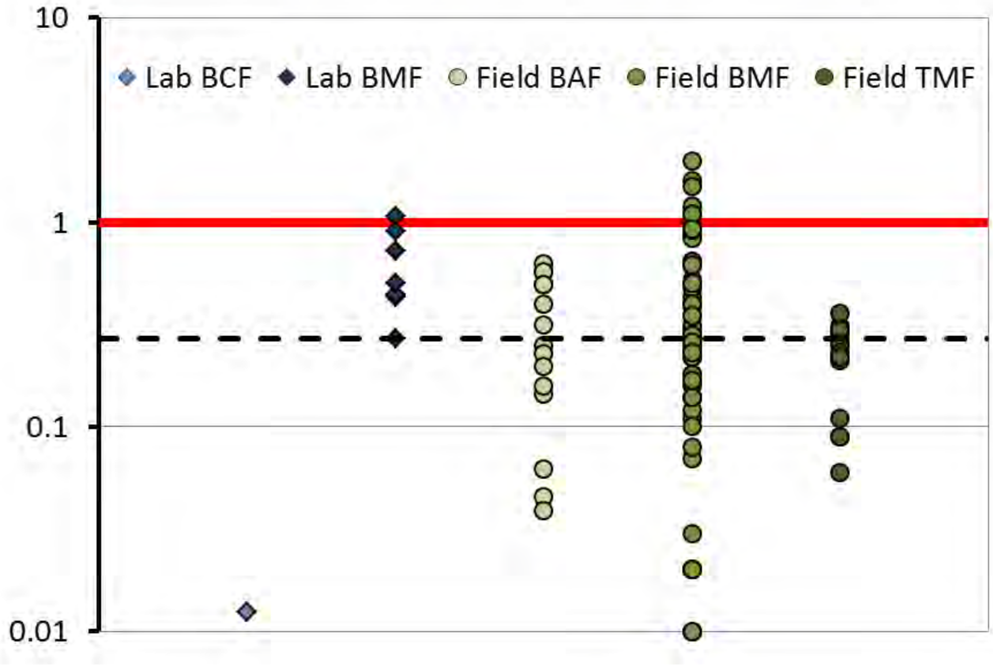


Figure 1. Fugacity ratios calculated using the recommended methods [6] for available relevant and reliable bioaccumulation data for MCCP constituents. Values > 1 (red line) indicate biomagnification (bioaccumulation) hazard. 93% of the data points are < 1 and the median value = 0.27.

The data displayed in Figure 1 are the same data included in the SEV, except as follows:

- A data quality evaluation conducted earlier highlighted that the BCF data from Thompson (2000) are more uncertain (less reliable) than the BCF data from Hurd and Vaughn (2010); therefore, the better quality BCF data were used. The better quality BCF is higher (more conservative) then the poorer quality BCF. The laboratory BCF and BMF tests were conducted with radiolabelled test chemical and hence in this context are considered "conservative" B estimates [5, 23]. The BCF cannot in and of itself be used to assess biomagnification potential because the laboratory test model does not include dietary exposure (required for biomagnification to occur); however, it is included here to combine to the weight of evidence.
- Of note, the laboratory BMFs in Table 26 of the SEV are growth corrected and lipid (corrected) normalized as indicated in the original papers by Fisk and colleagues; however, B data for predominantly SCCPs and LCCPs are not considered relevant and not included here.
- Toxicity testing considered conducted by Cooley et al. (2001) used in the SEV B assessment are less relevant (i.e., not B testing) and also more uncertain than specific laboratory testing that targeted dietary B assessment endpoints (Fisk et al. 1996; Fisk et al. 2000). When existing, reliable quality bioaccumulation (relevant) data exist it does not seem necessary to use data from other types of tests (i.e., toxicity) such as the Cooley et al. (2001) test;

however, it is worth mentioning that all of the BMF data derived from the Cooley et al. (2001) toxicity testing are < 1, thus supporting the general findings of this B assessment.

- Dietary bioaccumulation testing data for terminal Cl-substituted chlorinated alkanes (Fisk et al. 1998) are not considered representative of MCCP constituents and were not included.
- Field BMFs calculated from 1 dietary sample (i.e., some Sculpin-Diporeia data) are considered highly uncertain (as discussed elsewhere [24, 25]) and not included here.

Uncertainty and data gaps

A previous report [10] highlighted the key role of the metabolic biotransformation rate constant for MCCP constituent B assessment. The previous analyses [10] showed that in vivo estimates of the biotransformation rate constants calculated from the existing laboratory BCF and BMF testing data are approximately the same for the range of MCCP constituents tested. Thus additional animal testing is not expected to provide value added information for the B hazard assessment of MCCP constituents. As discussed in the B expert workshops and related publications, e.g., [3], data from a range of species and trophic positions should be considered for B assessment. The current analysis presented in Figure 1 includes a range of aquatic species (plankton, invertebrates and various species and trophic levels of fish) from two different lakes (ecosystems). Data gaps in the overall B analysis include limited (no) information for terrestrial and air-breathing species. If desirable, available measured data could be used to parameterize models to predict BMFs and TMFs for representative terrestrial and air-breathing species if this data gap is considered relevant and until it can be addressed with reliable quality measured data.

References

[1] U.S. EPA. 2011. Estimation Programs Interface (EPI) Suite™ for Microsoft® Windows, Ver. 4.1., Released October, 2011 ed. U. S. Environmental Protection Agency, Washington, D.C.

[2] EU. 2005. European Union Risk Assessment Report: Alkanes, C14-17, chloro (MCCP). 3rd Priority List, Vol 58. European Commission Joint Research Centre.

[3] Gobas FAPC, de Wolf W, Burkhard LP, Verbruggen E, Plotzke K. 2009. Revisiting bioaccumulation criteria for POPs and PBT assessments. *Integr Environ Assess Manage* 5:624 - 637.

[4] Mackay D, Fraser A. 2000. Bioaccumulation of Persistent Organic Chemicals: Mechanisms and Models. *Environ Pollut* 110:375-391.

[5] Arnot JA, Gobas FAPC. 2006. A review of bioconcentration factor (BCF) and bioaccumulation factor (BAF) assessments for organic chemicals in aquatic organisms. *Environ Rev* 14:257-297.

[6] Burkhard LP, Arnot JA, Embry MR, Farley KJ, Hoke RA, Kitano M, Leslie HA, Lotufo GR, Parkerton TF, Sappington KG, Tomy GT, Woodburn KB. 2012. Comparing laboratory and field measured bioaccumulation endpoints. *Integr Environ Assess Manage* 8:17–31.

[7] Arnot JA, Mackay D, Bonnell M. 2008. Estimating metabolic biotransformation rates in fish from laboratory data. *Environ Toxicol Chem* 27:341-351.

[8] Burkhard LP. 2003. Factors influencing the design of bioaccumulation factor and biota-sediment accumulation factor field studies. *Environ Toxicol Chem* 22:351-360.

[9] Nichols JW, Fitzsimmons PN, Burkhard LP. 2007. In vitro-in vivo extrapolation of quantitative hepatic biotransformation data for fish. II. Modeled effects on chemical bioaccumulation. *Environ Toxicol Chem* 26:1304-1319.

[10] Arnot J. 2013. Comments on Preliminary Bioaccumulation Assessment of Medium Chain Chlorinated Paraffins (MCCPs). ARC Arnot Research & Consulting Inc., Toronto, ON.

[11] Arnot JA, Gobas FAPC. 2003. A Generic QSAR for Assessing the Bioaccumulation Potential of Organic Chemicals in Aquatic Food Webs. *QSAR and Combinatorial Science* 22:337-345.

[12] Connolly JP, Pedersen CG. 1988. A Thermodynamic-Based Evaluation of Organic Chemical Accumulation in Aquatic Organisms. *Environ Sci Technol* 22:99-103.

[13] Mackay D. 1982. Correlation of Bioconcentration Factors. *Environ Sci Technol* 16:274-278.

[14] OECD. 2012. OECD Guidelines for Testing Chemicals. Test No. 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure. Organization for Economic Co-operation and Development, Paris.

[15] Klečka GM, Muir DC, Dohmen P, Eisenreich SJ, Gobas FAPC, Jones KC, Mackay D, Tarazona JV, van Wijk D. 2009. Introduction to special series: science-based guidance and framework for the evaluation and identification of PBTs and POPs. *Integr Environ Assess Manage* 5:535-538.

[16] Abelkop ADK, Bergkamp L, Brooks BW, Gergely A, Graham JD, Gray G, van Leeuwen K, Marchant GE, Mueller ML, Royer TV, Vighi M. 2013. Scientific and Policy Analysis of Persistent, Bioaccumulative, and Toxic Chemicals: A Comparison of Practices in Asia, Europe, and North America. The Report of a Consensus Panel.

[17] Moermond CT, Janssen MP, de Knecht JA, Montforts MH, Peijnenburg WJ, Zweers PG, Sijm DT. 2012. PBT assessment using the revised annex XIII of REACH: a comparison with other regulatory frameworks. *Integr Environ Assess Manage* 8:359-371.

[18] Mackay D, Arnot JA, Gobas FAPC, Powell DE. 2013. Mathematical relationships between metrics of chemical bioaccumulation in fish. *Environ Toxicol Chem* 32:1459–1466.

[19] Kelly BC, Ikonomou MG, Blair JD, Morin AE, Gobas FAPC. 2007. Food Web-Specific Biomagnification of Persistent Organic Pollutants. *Science* 317:236-239.

[20] Conder JM, Gobas FAPC, Borgå K, Muir DCG, Powell DE. 2012. Use of trophic magnification factors and related measures to characterize bioaccumulation potential of chemicals. *Integr Environ Assess Manage* 8:85-97.

[21] Swackhamer DL, Needham LL, Powell DE, Muir DCG. 2009. Use of measurement data in evaluating exposure of humans and wildlife to POPs/PBTs. *Integr Environ Assess Manage* 5:638–661.

[22] Qiao P, Gobas FAPC, Farrell AP. 2000. Relative Contributions of Aqueous and Dietary Uptake of Hydrophobic Chemicals to the Body Burden in Juvenile Rainbow Trout. *Arch Environ Contam Toxicol* 39:369-377.

[23] Parkerton TF, Arnot JA, Weisbrod AV, Russom C, Hoke RA, Woodburn K, Traas T, Bonnell M, Burkhard LP, Lampi MA. 2008. Guidance for Evaluating in-vivo Fish Bioaccumulation Data. *Integr Environ Assess Manage* 4:139-155.

[24] Houde M, Muir DCG, Tomy G, Whittle M, Teixeira C, Moore S. 2008. Bioaccumulation and trophic magnification of short- and medium-chain chlorinated paraffins in food webs from Lake Ontario and Lake Michigan. *Environ Sci Technol* 42:3893-3899.

[25] Thompson R, Vaughan M. 2013. Medium-chain chlorinated paraffins (MCCPs): A review of bioaccumulation potential in the aquatic environment. *Integr Environ Assess Manage*: 10: 78-86.

Attachment 4

This Workbook contains the summary data used to make the Figure in the following report

Bioaccumulation Assessment of Medium Chain Chlorinated Paraffins (MCCPs)
Prepared for The Regulatory Network Inc.
Prepared by ARC Arnot Research and Consulting Inc. (Jon Arnot)
28-Apr-14

MCCP
Report_April28_2014

TC NES SUBGROUP ON IDENTIFICATION OF PBT AND VPVB SUBSTANCES

RESULTS OF THE EVALUATION OF THE PBT/VPVB PROPERTIES OF:

Substance name: Paraffin waxes and Hydrocarbon waxes, chloro

EC number: 264-150-0

CAS number: 63449-39-8

Molecular formula: not applicable

Structural formula: not applicable

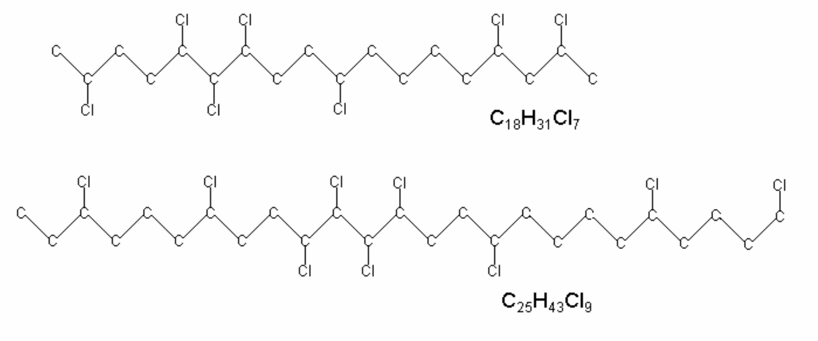
Summary of the evaluation:

Paraffin waxes and hydrocarbon waxes, chloro is not considered as a PBT substance. It is not likely to meet the B criterion. The T criterion is not met as a borderline case. The substance may meet the P/vP criteria according to the available experimental data.

JUSTIFICATION

1 IDENTIFICATION OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

Name:	Paraffin waxes and Hydrocarbon waxes, chloro
EC Number:	264-150-0
CAS Number:	63449-39-8
IUPAC Name:	
Molecular Formula:	$C_nH_{2n+2-y}Cl_y$, where n=18 to 32 and y = ~4 to ~30
Structural Formula:	Not applicable. Two structure examples of this multi-constituent substance are provided below.



(Environment Agency, 2006)

Molecular Weight:	Not applicable
Synonyms:	Hydrocarbon waxes, chlorinated; chloroparaffin; chlorinated paraffins; Alkanes, C_{18-30}, chloro; ; long-chain chlorinated paraffins; LCCP (abbreviation). For more synonyms, see Environment Agency (2006)

1.1 Purity/impurities/additives

The substance belongs to a group of long-chain chlorinated paraffins (LCCPs), which are also sold under other CAS numbers (e.g. CAS 85422-92-0). The substance contains chlorinated alkanes with a chain length C18 to C50. The products in liquid form consist of C18-C20 alkyl chains with chlorine content of 40-50% w/w whereas the solid products mainly contain > C20 alkyl chains with a chlorination content of approximatley 70% w/w (source: confidential IUCLID, company specific data sets) . According to Environment Agency (2006), chlorinated alkyl chains with a length of C16, C19 and C20 are expected to be present in LCCPs in a concentration of < 1%, 0% and < 0.2%, respectively. A typical concentration of 17% (with a possible range of 10-20%) is reported for C17-constituents.

1.2 Physico-chemical properties

Table 1 Summary of physico-chemical properties of the constituents groups. For details and references, see Environment Agency (2006).

REACH ref Annex, §	Property	C_{18-20} liquids	$C_{>20}$ liquids	$C_{>20}$ solids	Comments
V, 5.1	Physical state at 20 C and 101.3 Kpa	Liquid	Liquid	Solid	
V, 5.2	Melting / freezing point	-30°C [a] 0°C [b]	-30°C [a] 0°C [b]	100°C [c]	
V, 5.3	Boiling point	> 210°C (decomp.)	> 210°C (decomp.)	> 210°C (decomp.)	
V, 5.5	Vapour pressure	2.5×10^{-4} Pa (at 25°C)	2.5×10^{-5} Pa (at 25°C)	1.5×10^{-14} Pa (at 25°C)	
V, 5.7	Water solubility	5 µg l^{-1} (at ca. 20°C)	5 µg l^{-1} (at ca. 20°C)	5 µg l^{-1} (at ca. 20°C)	
V, 5.8	Partition coefficient n-octanol/water (log value)	9.7	10.3	17	
VII, 5.19	Dissociation constant	-	-	-	

a) For products with chlorine contents of 42-48% by weight.

b) For products with chlorine contents of 50-52% by weight.

c) For products with chlorine contents of around 70% by weight.

2 MANUFACTURE AND USES

Eleven companies have notified the substance under Regulation 93/793/EEC. According to European Commission (2000), production and import volume is 10,000-50,000 tpa. Environment Agency (2006) estimated, that approximately 5,000 – 10,000 tons of long-chain chlorinated paraffins were used in the EU annually between 1998 and 2004.

A variety of uses has been reported by Environment Agency (2006) and European Commission (2000). These included, i.a., use as plasticiser in PVC, as flame retardant in rubber and textiles, as well as the use as plasticiser, binder and flame retardant in paints, coatings and sealants. LCCPs are also used in metalworking fluids and in fat liquors for leather treatment.

3 CLASSIFICATION AND LABELLING

The substance is not classified under Directive 67/548/EEC.

4 ENVIRONMENTAL FATE PROPERTIES

4.1 Degradation (P)

4.1.1 Abiotic degradation

Indirect photochemical degradation in the atmosphere has been calculated for several constituents from $C_{18}H_{33}Cl_5$ to $C_{30}H_{35}Cl_{27}$ by Environment Agency (2006). Half-lives between 30 and 112 hours were obtained for the reaction with OH-radicals using AOP v1.91 (24 h day^{-1}; $5*10^5$ OH^- cm^{-3}).

Long-chain chlorinated alkylchains are not expected to undergo abiotic degradation in aqueous media.

4.1.2 Biotic degradation

No standard ready or inherent biodegradation test results are available for the substance. The available biodegradation data has been evaluated by Environment Agency (2006). A brief overview of the reviewed information is provided below.

There is evidence that some microorganisms may be capable of degrading LCCPs in the environment in acclimatised or co-metabolic systems. In a 25-day biochemical oxygen demand (BOD) test, acclimatised microorganisms showed approximately 23% biodegradation of a C_{20-30} (42% chlorinated) product, compared with 7.5% biodegradation using a non-acclimatised inoculum (Madeley and Birtley, 1980). The same authors also showed 11% mineralisation ($^{14}CO_2$ evolution) of centrally labelled ^{14}C-pentacosane (42% chlorinated), mixed with the same C_{20-30} product, by non-acclimatised microorganisms after 8 weeks. Under anaerobic conditions, using several bacterial species isolated from soil, chlorinated $C_{24.5}$ (average) products showed up to 33% degradation, as measured by chloride release, after 36 or 48 hours incubation (Omori et al., 1987). The highest level of degradation was obtained for a 40.5% chlorinated substance in the presence of n-hexadecane as a co-metabolite. Other studies have shown, the potential for biodegradation appeared to decrease with increasing chlorine content, although up to 15% degradation was observed for a 70% chlorinated product. Allpress and Gowland (1999) isolated a bacterium (*Rhodococcus* sp.) from stream water that was able to utilise various chlorinated paraffins as the sole source of carbon and energy, with up to 14% degradation (measured as released chloride) after 71 days for a $C_{>20}$ (42% chlorinated) product.

It is not possible to derive rate constants for biodegradation in soil, surface water, marine water or sediment systems from the available data.

4.1.3 Other information [1]

No data available.

---

[1] For example, half life from field studies or monitoring data

4.1.4 Summary and discussion of persistence

No standard ready or inherent biodegradation test results are available for long-chain chlorinated paraffins. From the available data, long-chain chlorinated paraffins can be considered to be not biodegradable in such systems. A biodegradation rate constant of 0 day^{-1} has been used for all types of long-chain chlorinated paraffins in the risk assessment of Environment Agency (2006).

4.2 Environmental distribution

Data not reviewed for this report.

4.2.1 Adsorption

4.2.2 Volatilisation

4.2.3 Long-range environmental transport

4.3 Bioaccumulation (B)

4.3.1 Screening data

LogKow values as summarised by Environment Agency (2006) in **Table 1** are 9.7-17. The alkyl chain length has the most impact on the logKow -value.

4.3.2 Measured bioaccumulation data

The available studies on bioconcentration and dietary accumulation cited below have been evaluated in detail by Environment Agency (2006).

A bioconcentration factor (BCF) of 8 to 16 was obtained for a C_{18-26} (49% chlorinated) substance after a 14-day exposure of bleak (*Alburnus alburnus*) to a concentration of 0.125 mg l^{-1} in brackish water (7% salinity) (Bengtsson et al., 1979). In rainbow trout (*Oncorhynchus mykiss*), a maximum BCF of 9 (measured as parent compound) was observed after 60 days exposure to a C_{22-26} (43% chlorinated) material, mixed with similarly chlorinated n-pentacosane-13-^{14}C; the corresponding BCF based on radiolabel measurement was 38, suggesting some metabolism within the fish tissues (Madeley and Maddock, 1983a). The measured exposure concentrations in water were 0.97 and 4.0 mg l^{-1}. For a $C_{>20}$ (70% chlorinated) material, mixed with 70% chlorinated n-pentacosane-13-^{14}C, the maximum BCFs were 43 and 54, based on parent compound and radiolabel measurements, respectively (Madeley and Maddock, 1983b). The measured exposure concentrations in water were 0.84, 1.9 and 3.8 mg l^{-1}. Although the exposure concentrations used for both of these LCCPs were above the solubility limit, in each case the highest BCFs were obtained at the highest exposure levels, suggesting that adsorption of undissolved material to the external surfaces of the fish may have contributed to the measured body burdens.

The same two substances, with corresponding radiolabels, as used for the rainbow trout studies above, were also tested in 60-day exposures to marine mussels (*Mytilus edulis*) (Madeley and

Thompson, 1983a and 1983b). The maximum BCFs obtained, by parent compound analysis, were 1,000 and 157 for the 40.5% and 70% chlorinated materials, respectively; by radiolabel the corresponding BCFs were 1158 and 341. It is possible that the filter feeding activity of the mussels may have resulted in the ingestion of particles of undissolved test substance, which may account for the higher BCFs than observed for fish.

Although the measured fish BCFs (above) were obtained using exposure concentrations in excess of the water solubility of the substances, they are consistent with the results of reliable studies for short-chain and medium-chain chlorinated paraffins that were obtained by testing below the solubility limit. BCFs of 7,816 and 1,087 were determined for short-chain (^{14}C-C_{11}) and medium-chain (^{14}C-C_{15}) chlorinated paraffins, respectively (Madeley and Maddock, 1983c; Thompson et al, 2000). Thus, based on a comparison with the available data for other chlorinated paraffins, the fish BCF for long-chain chlorinated paraffins would be expected to further reduce with increasing carbon chain length.

This trend of declining BCF with increasing chain length is further confirmed by QSAR estimation based on the octanol-water partition coefficient (Kow). Using a QSAR for substances of log Kow > 6 (EU Technical Guidance Document, 2003), the estimated BCFs in fish for the three types of LCCP are as follows:

$C_{18\text{-}20}$ liquid LCCP	BCF = 1,096
$C_{>20}$ liquid LCCP	BCF = 192
$C_{>20}$ solid LCCP	BCF <1

There is evidence from feeding studies that LCCPs can be taken up via the diet. The accumulation of a C_{18}, 49% chlorinated paraffin has been studied in juvenile rainbow trout (*Oncorhynchus mykiss*) by Fisk et al. (2000). The uptake and accumulation of a $C_{20\text{-}30}$, 42% chlorinated product has been investigated using both rainbow trout (*Oncorhynchus mykiss*) and mussel (*Mytilus edulis*) (Madeley and Birtley, 1980). Zitko (1974) looked at the uptake of two long-chain chlorinated paraffins in the diet of juvenile Atlantic salmon (*Salmo salar*) over 181 days. A further feeding study with fish has been carried out by Bengtsson and Baumann Ofstad (1982). In this experiment, bleak (*Alburnus alburnus*) were exposed to a $C_{18\text{-}26}$, 49% chlorinated product via food for 91 days, followed by a 316-day depuration period. Dietary uptake in rats has been reviewed in BUA (1992) and WHO (1996). In all dietary studies the concentrations reached in the animals were less than those in the diet. This indicates that although uptake of the substance can occur via the food, the levels do not increase through the food chain.

4.3.3 Other supporting information[2]

No data available.

---

[2] For example, measured concentrations in biota

4.3.4 Summary and discussion of bioaccumulation

Environment Agency (2006) summarises the data on bioaccumulation as follows:

the available bioconcentration results on long-chain chlorinated paraffins are not reliable as much of the data were obtained using exposure concentrations well in excess of the water solubility of the substance and it is generally not clear if the length of the studies was sufficient for steady state to be reached. Therefore, although these studies show that uptake does occur, it is not possible to obtain a reliable BCF value from them. As a result, the estimated data for the fish bioconcentration factor will be considered in the assessment as a precautionary approach. The following values will be used for the fish bioconcentration factor.

C_{18-20} liquid	BCF = 1,096
$C_{>20}$ liquid	BCF = 192
$C_{>20}$ solid	BCF <1

For the marine environment, there are data available on the accumulation of long-chain chlorinated paraffins by mussels in salt water and fish in brackish water. These show similar patterns of uptake as found for freshwater species. Again, no reliable BCF can be derived from the data, and so the estimated BCFs are considered the most relevant for the marine environment as a precautionary approach.

In addition to bioconcentration, the TGD also provides methods to take into account biomagnification in the assessment of secondary poisoning. The method requires a biomagnification factor (BMF) for fish, preferably expressed on a lipid normalised basis. According to the TGD, an appropriate BMF for long chain chlorinated paraffins would be 1 for all three types considered based on the fish BCF being < 2,000 and the log Kow being > 9.

There is evidence from feeding studies that the long-chain chlorinated paraffins can be taken up via the diet, but in all cases the concentrations reached in the animals were less than those in the diet. This indicates that although uptake of the substance can occur via the food, the levels should not increase through the food chain. These findings support the default BMF of 1 determined above. Uptake via diet or the undissolved phase may also explain some of the uptake seen in the available bioconcentration studies.

5 HUMAN HEALTH HAZARD ASSESSMENT

Data not reviewed for this report.

6 ENVIRONMENTAL HAZARD ASSESSMENT

6.1 Aquatic compartment (including sediment)

The ecotoxicity data cited below have been evaluated in more detail by Environment Agency (2006).

6.1.1 Toxicity test results

6.1.1.1 Fish

Acute toxicity

For fish, numerous 96-hour LC_{50} studies show no mortality at the highest concentrations tested, in many cases giving 96-hour LC_{50} values >300 mg l^{-1} (see e.g., European Commission, 2000).

Long-term toxicity

No mortalities or other symptoms of toxicity have been observed in the long-term exposures of fish in the bioaccumulation studies. These provide the following NOEC values, all showing no effects at concentrations well in excess of the solubility level of ≤ 0.005 mg l^{-1}:

Species	Substance	Duration (days)	NOEC (mg l^{-1})
Alburnus alburnus	C_{18-26}, 49% Cl	14	≥0.125
Oncorhynchus mykiss	C_{22-26}, 43% Cl	60	≥4
Oncorhynchus mykiss	$C_{>20}$, 70% Cl	60	≥3.8

6.1.1.2 Aquatic invertebrates

Acute toxicity

For the marine crustacean, *Nitocra spinipes*, for both a C_{22-26}, 42% chlorinated substance and a C_{18-26}, 49% chlorinated substance, the 96-hour LC_{50}s were greater than the highest concentrations tested, which were 1,000 and 10,000 mg l^{-1}, respectively (Tarkpea et al., 1981).

Acute toxicity to *Daphnia magna* has been determined for a C_{18-27} (60% chlorinated) product, with and without stabiliser, using both acetone and an emulsifier to prepare the test solutions (BUA, 1992). All the 24-hour EC_{50} values obtained were above 100 mg l^{-1}.

The 48-hour EC_{50} to *Daphnia magna* of a C_{18-20}, 52% chlorinated material was found to be greater than the maximum solubility achieved as a “water-accomodated fraction” (WAF) (Frank, 1993 and Frank and Steinhauser, 1994).

Long-term toxicity

For invertebrates, there were no mortalities in the long-term mussel (*Mytilus edulis*) bioaccumulation studies available (see Section 4.3). Effects were observed on the particle filtration rate at the higher exposure level for each substance but these effects were attributed to the physical effects of undissolved test substance. No such effects were seen at the lower exposure concentrations, which provide 60-day NOECs of 0.12 and 0.46 mg l^{-1} for the C_{22-26}, 43% Cl and $C_{>20}$, 70% Cl substances, respectively, both in excess of solubility.

The effects of C_{18-27} (60% chlorinated) on *Daphnia* reproduction were also determined, with a 21-day NOEC of 4.2 mg l^{-1}, well in excess of solubility. Inhibition observed above this level were most probably due to the physical effects of undissolved material interfering with the organisms filter-feeding activity (BUA, 1992).

Frank (1993) and Frank and Steinhauser (1994) found no effects of the substance on survival and growth of *Daphnia* over 21 days at a nominal concentration of 1 mg l^{-1}, but reported effects of various dilutions of a WAF prepared at a loading rate of 10,000 mg l^{-1}. However, there are a number of reasons to doubt the validity of this result (Environment Agency, 2001). These include a failure of the temperature control system and a serious error in the statistical analysis that are not apparent from the published papers. The use of such a high loading when preparing the WAF is also likely to have preferentially dissolved any toxic impurities in the test substance that were more soluble than the LCCP. This may account for the apparent measured concentration of approximately 0.5 mg l^{-1} in the filtered WAF, well in excess of LCCP solubility, since the analytical method was non-specific (adsorbable organic halogen determination). If these procedural problems are ignored, but correcting the statistical analysis, the 21-day NOEC from this study was 0.029 mg l^{-1}.

6.1.1.3 Algae and aquatic plants

No data are available on the toxicity of LCCPs to freshwater algae. Craigie and Hutzinger (1975) investigated the toxicity of a $C_{>20}$ (50% chlorinated) product to three species of marine algae (*Dunaliella tertiolecta, Olisthodiscus* sp. *and Thalassiosira fluviatilis*). The substance was added to the test flasks as a solution in acetone to give nominal concentrations of 1 mg l^{-1} and 100 mg l^{-1} (in duplicate) and the acetone evaporated to dryness. A natural seawater medium was added to the flasks which were then sterilised by autoclaving and inoculated with the algae. No effects on algal biomass were seen in any of the exposed populations after 6 days growth at 20°C (within 96-105% of the control values). Although no analytical measurements of the exposure concentrations were carried out, it is likely that, at least at the higher nominal concentration, there was sufficient excess material present to ensure that the dissolved concentration was at or near the solubility limit. Therefore, although a precise NOEC cannot be determined, the results strongly indicate that the substance was not toxic to these algal species.

6.1.2 Sediment organisms

No data available.

6.1.3 Other aquatic organisms

Data not evaluated for this report.

6.2 Terrestrial compartment

No data available.

6.3 Atmospheric compartment

No data available.

7 PBT AND vPvB

7.1 PBT, vPvB assessment

Persistence: based on the laboratory studies and other data available, long-chain chlorinated paraffins are considered to be unlikely readily or inherently biodegradable. Although there is some evidence that long-chain chlorinated paraffins may biodegrade in the environment it is considered likely that the rate will be sufficiently slow that long-chain chlorinated paraffins may meet the P/vP criteria.

Bioaccumulation: although the bioconcentration of long-chain chlorinated paraffins has been investigated in laboratory studies, none of the available data are considered sufficiently robust to allow a reliable BCF to be determined for long-chain chlorinated paraffins. Based on estimates of BCF (calculated using the available logKow –values), and consideration of the known accumulation properties of structurally similar substances (short and medium chain chlorinated paraffins), the BCF for long-chain chlorinated paraffins is considered to be < 2,000. In addition, the results of dietary uptake studies provide evidences that no accumulation in the food chain is expected. Thus it is concluded that long-chain chlorinated paraffins are unlikely to meet the B criterion.

Toxicity: the majority of acute and chronic aquatic toxicity studies with LCCPs show that no lethal or sublethal effects are observed up to and substantially above the solubility limit, other than probable physical effects of undissolved material at concentrations two or more orders of magnitude in excess of solubility. This absence of aquatic toxicity is consistent with the evidence of low bioaccumulation potential indicating low bioavailability. Only one study, on the chronic toxicity of a C_{18-20}, 52% chlorinated material to *Daphnia magna*, reports any toxic effects at levels potentially close to the solubility level (NOEC 0.029 mg l^{-1}). Based on the experimental data, long-chain chlorinated paraffins do not meet the toxicity criterion/are considered as not to fulfil the T criterion as a borderline case.

Summary: paraffin waxes and hydrocarbon waxes, chloro is not likely to fulfil the B criterion. The substance may meet the P/vP criteria according to the screening data. Concerning the T criterion, the substances (esp. shorter chain constituents) may be regarded as a borderline case. It is concluded that these substances are not considered as PBT substances.

.

INFORMATION ON USE AND EXPOSURE

Not relevant as the substance is not identified as a PBT.

OTHER INFORMATION

The information and references used in this report were taken from the following sources:

BUA (1992) Chlorinated Paraffins. GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance (BUA). BUA Report 93, June 1992.

Environment Agency (2006) Environmental Risk Evaluation Report: long-chain chlorinated paraffins. Authors: Brooke, D.N. and Crookes, M.J.

European Commission (2000). IUCLID Dataset, Paraffin waxes and Hydrocarbon waxes, chloro, CAS 63449-39-8, 18.2.2000.

WHO (1996) Environmental Health Criteria 181. Chlorinated Paraffins. International Programme on Chemical Safety (IPCS).

Attachment 6

http://acc.ftpstream.com/261361/c2e364000fd675a9871bc2ec9ed3caed/EPA%2bOptions%2bfor%2bAddressing%2bChlorinated%2bParaffins%2bwith%2bAttachments%2b-%2b2-4-16.PDF

American Chemistry Council

February 25, 2016

Avi Garbow (2310A)
General Counsel
Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: <u>Status of Chlorinated Paraffins as a Category Under Sections 8(b)(2) and 26(c) of TSCA</u>

Dear Mr. Garbow:

The American Chemistry Council (ACC) provides the enclosed memorandum as follow-up to our meeting in December 2015 with you and representatives of OGC, OECA, and OPPT about the process EPA should use to address chlorinated paraffins going forward. The memorandum addresses an important issue raised, but not fully explained at the December meeting, i.e., why EPA may properly regard chlorinated paraffins as existing chemicals under TSCA for purposes of determining the appropriate path forward.

At that meeting, we reiterated our position that EPA should consider regulatory options for medium-chain chlorinated paraffins (MCCPs) and long-chain chlorinated paraffins (LCCPs) under section 6 of TSCA rather than under section 5. Section 5 relates to new chemical substances and new uses of existing chemical substances. Section 6 relates to existing chemical substances. For over 30 years, EPA considered MCCPs and LCCPs to be existing chemical substances. Beginning in 2009, however, EPA took the position in two enforcement actions against two manufacturers that MCCPs and LCCPs are new chemical substances. The two manufacturers agreed to sign consent decrees that required them to submit premanufacture notices (PMNs) on the MCCPs and LCCPs. Those consent decrees also permitted the manufacturers to continue manufacturing and distributing MCCPs and LCCPs in commerce while EPA reviewed the PMN submissions. Those enforcement matters are fully resolved, and ACC does not seek to reopen them.

However, for purposes of possible future EPA actions on MCCPs and LCCPs, EPA should reconsider its position that these chlorinated paraffins are strictly new chemical substances. Section 3(9) of TSCA defines a new chemical substance as one that is not on the TSCA Inventory. Two broad entries for chlorinated paraffins <u>are</u> on the Inventory:

- Alkanes, chloro, CAS No. 61788-76-9
- Paraffin waxes and Hydrocarbon waxes, chloro, CAS No. 63449-39-8

These Inventory entries are not specific to MCCPs or LCCPs with particular carbon number ranges, such as those that were the subject of PMNs submitted following entry of the consent decrees. However, EPA should acknowledge that those broad Inventory entries represent categories of chlorinated paraffins, including individual MCCPs and LCCPs. Under section 8(b)(2) and section 26(c) of TSCA, EPA may list a category of related chemicals rather than list individual members of that category. Listing a category has the effect of including all members of the category on the Inventory.

EPA included several categories on the initial TSCA Inventory first compiled in 1979, including these two listed above as pertaining to chlorinated paraffins. Indeed, EPA specifically recommended that these two CAS numbers (or a predecessor CAS number) be reported for the initial Inventory.

The attached memorandum explains the category concept in greater detail. Briefly, it states that at the time EPA added these two CAS numbers to the initial Inventory in 1979, it regarded chlorinated paraffins as a category of related chemicals. EPA recognized that chlorinated paraffins are extremely complex mixtures, with varying compositions, such that it would be burdensome for manufacturers to report each individual combination. EPA knew of no health or environmental basis (other than, perhaps, degree of chlorination) on which to differentiate between individual members of the category. While recognizing that there were individual products with particular carbon length ranges, EPA nevertheless considered them all as essentially undifferentiated for purposes of potential regulation. Accordingly, EPA did not insist on listing individual members of the category and used a category approach instead for purposes of the Inventory.

The memorandum also explains this situation was similar to that of PCBs. At that time EPA regarded PCBs as a category and chose not to add individual PCB congeners to the Inventory. Instead, it relied on a single, non-specific, category name.

EPA has also treated chlorinated paraffins as categories under other provisions of TSCA. Its actions include rulemaking under section 4, section 8(a), and section 8(d), in each case citing either “chlorinated paraffins” or one or both of the category CAS numbers.

As a result, EPA is now in a position to approach future actions involving MCCPs and LCCPs under section 6 of TSCA, since all members of those categories may be considered to be existing chemicals on the TSCA Inventory.

I look forward to discussing the paper with you and your staff. I will contact you shortly to arrange for a meeting.

Sincerely,

Christina Franz

Christina Franz
Senior Director, Regulatory & Technical Affairs

Enclosure
Cc: Wendy Cleland-Hamnett
Maria Doa

Status of Chlorinated Paraffins as a Category Under Sections 8(b)(2) and 26(c) of TSCA

Of Counsel:
Mark N. Duvall
Beveridge & Diamond, P.C.
1350 I Street, N.W.
Washington, DC 20005
(202) 789-6090
mduvall@bdlaw.com

Christina Franz
Senior Director, Regulatory & Technical Affairs
American Chemistry Council
700 Second Street, N.E.
Washington, DC 20002
(202) 249-6406
christina_franz@americanchemistry.com

February 25, 2016

TABLE OF CONTENTS

EXECUTIVE SUMMARY

EPA is seeking to ban future manufacture and import of medium-chain chlorinated paraffins (MCCPs) and long-chain chlorinated paraffins (LCCPs) through the premanufacture notice (PMN) process under section 5 of TSCA. This approach is based on the position that MCCPs and LCCPs are new chemical substances. However, individual MCCPs and LCCPs should be regarded as currently on the TSCA Inventory, since they are members of two categories that do appear on the Inventory.

TSCA section 8(b)(2) and section 26(c) allow EPA to identify categories of chemical substances on the TSCA Inventory rather than list individual members of those categories. EPA did so with MCCPs and LCCPs by listing the following categories on the initial Inventory compiled in 1979:

- Alkanes, chloro, CAS No. 61788-76-9
- Paraffin waxes and Hydrocarbon waxes, chloro, CAS No. 63449-39-8

As a result, individual members of those categories are considered to be on the Inventory.

This situation is similar to that of the 209 individual PCB congeners, virtually none of which are listed individually on the Inventory. Instead, all PCB congeners are considered to be on the Inventory under the categorical listing of 1,1'-Biphenyl, chloro derivs., CAS No. 1336-36-3, i.e., chlorinated biphenyl.

EPA's actions regarding these chlorinated paraffin categories during the period that it assembled the TSCA Inventory strongly supports ACC's position that EPA regarded these particular listings as encompassing all members of the categories.

Similarly, EPA's actions during the three decades after it issued the 1979 initial Inventory demonstrates that it regarded those categorical Inventory entries as encompassing all members of those categories.

In summary, EPA has a clear basis for addressing future actions on MCCPs and LCCPs under section 6 of TSCA.

DISCUSSION

1. Section 8(b)(2) and Section 26(c) Authorize EPA to List Categories of Chemical Substances on the Inventory Rather Than List Individual Members of Those Categories

Section 8(b)(1) of TSCA directs EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States." However, section 8(b)(2) modifies section 8(b)(1). It provides:

> To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

TSCA's legislative history explains that the purpose of section 8(b)(2) was to avoid the need to require persons to report individual members of a category for the Inventory through the PMN process:

> By listing a category of chemical substances, minor modifications or variations in the formulation or structure of a chemical substance which would have insignificant health or environmental consequences would not automatically be subject to the notification requirements of section 5 ….
>
> The Committee recognizes that many chemical companies, particularly small ones, are able to compete in the chemical industry only by continually reformulating or making slight changes in existing chemical substances. It would be extremely burdensome on them as well as on the Administrator if every insignificant change were subject to the premarket notification requirements of section 5. By using categories in the inventory, the Administrator will be able to minimize such burdens.[1]

The legislative history recognizes one limitation on the use of categories:

> However, the Committee also realizes that minor modifications of innocuous compounds may produce highly toxic chemicals. Thus, the use of categories should be limited to areas where the effects of such minor modifications are well understood to have insignificant health and environmental consequences.

The authority in section 8(b)(2) is just one aspect of EPA's broader authority under section 26(c) to take actions on categories of chemical substances rather than on individual chemical substances. Section 26(c) provides:

> Action with respect to categories
>
> **(1)** Any action authorized or required to be taken by the Administrator under any provision of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.
>
> **(2)** For purposes of paragraph (1):
>
> (A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical,

---

[1] House Rep. No. 94-1341 (1976) at 44, in Legislative History of the Toxic Substances Control Act (1976) (Legis. Hist.) at 451. In a colloquy, Senator James Broyhill referred to section 8(b)(2) as "an extremely important leeway to the Administrator." Legis. Hist. at 523.

> chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.
>
> (B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act.

Chlorinated paraffins are "similar in molecular structure" and in the other aspects noted in section 26(c)(2).

The legislative history of this provision refers specifically to EPA adding categories to the Inventory in lieu of individual chemical substances:

> Subsection (c) authorizes the Administrator to take action with respect to categories of chemical substances or mixtures as well as individual chemical substances or mixtures ... Thus, for example, categories might be appropriately used for purposes of compiling the inventory of section 8(b) so that every variation in the distribution of a polymer chain length would not be automatically subject to the premarket notification requirement.[2]

Categories listed on the Inventory pursuant to section 8(b)(2) encompass all members of those categories.[3] Accordingly, for Inventory purposes, when a category is listed on the Inventory, it does not matter whether a manufacturer knew of a more precise description of the category member that it manufactured at Inventory reporting time, or whether subsequently it began manufacture of a different category member. In both cases, the category members are considered to be on the Inventory because the category itself is on the Inventory.

---

[2] Sen. Rep. No. 94-698 (1976) at 30-31, Legis. Hist. at 186-87.

[3] See, for example, EPA, Toxic Substances Control Act (TSCA) PL 94-469 Candidate List of Chemical Substances Addendum III, Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (1978), http://nepis.epa.gov/Exe/ZyNET.exe/20015VKF.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1976+Thru+1980&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C76thru80%5CTxt%5C00000009%5C20015VKF.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=p%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL#, at 1 ("this addendum defines certain categories which encompass the individual chemical substances manufactured in the production of these mixtures.").

2. EPA Listed Several Categories on the Initial Inventory

EPA sometimes refers to categories on the Inventory as "statutory mixtures," as noted in 1995 Inventory nomenclature guidance.[4] That guidance provided the following explanation of six such categories in terms relevant to the legislative history of section 8(b)(2):

> Inorganic glasses, ceramics, frits and cements, including Portland cements, are considered to be statutory mixtures under TSCA. Manufacturers of these products are not required to report them. **When the initial Inventory was being developed, both EPA and industry recognized that the individual substances comprising these mixtures are complex solids and would be very difficult to identify.** Therefore, instead of requiring industry to identify and report every such substance for the Inventory, several special categories were created to include the various substances formed when cement, glass, frit or ceramic are produced. These categories were reported during the initial Inventory reporting period and are currently listed on the TSCA Inventory. Each category contains a definition that describes the various components of that category in terms of the elements and the various types of chemical substances that may be formed with these elements. These categories of substances are:
>
> Cement, Portland, Chemicals [65997-15-1*]
> Cement, Alumina, Chemicals [65997-16-2*]
> Glass, Oxide, Chemicals [65997-17-3*]
> Frits, Chemicals [65997-18-4*]
> Steel Manufacture, Chemicals [65997-19-5*]
> Ceramic Materials and Wares, Chemicals [66402-68-4*]
>
> For example, a category such as Ceramic Material and Wares, Chemicals includes any combination of the elements listed in the Inventory definition, as oxides, borides, carbides, etc., in multiple oxidation states, or in more complex compounds. The listed elements included in the definition of each of these categories are not intended to be inclusive.

These are not the only categories listed on the Inventory, however. For example, EPA considers zeolites to be statutory mixtures:

> As previously stated in IC-2984, it is EPA's position that Zeolites, as a class of crystalline aluminosilicates, fall into the category of statutory mixtures that are excluded from TSCA Inventory and PMN reporting requirements. EPA's position on the reportability of Zeolites is consistent with the policy that applies to other complex combinations of inorganic substances such as alloys, glasses, and ceramics.[5]

---

[4] EPA, Toxic Substances Control Act Inventory Representation for Products Containing Two or More Substances Formulated and Statutory Mixtures (1995), http://www.epa.gov/sites/production/files/2015-05/documents/mixtures.pdf, § III.B.1 (emphasis added).

[5] Letter from Joseph J. Merenda, Acting Deputy Director, Office of Toxic Substances, EPA, to Robert L. Smith, Ethyl Corporation (Mar. 22, 1990) (IC-2984 Follow-up).

Another example, PCBs, serves as a useful reference point for evaluating the Inventory status of chlorinated paraffins. As noted in the 1975 report on chlorinated paraffins, EPA recognized that chlorinated paraffins were even more complex than PCBs. EPA took the same approach to PCBs for purposes of the Inventory as it took for chlorinated paraffins, though: it made PCBs a category on the Inventory.

PCBs have 209 congeners. Of those 209 congeners, only one appears on the TSCA Inventory.[6] Effectively, EPA decided to refer to PCBs for Inventory purposes solely on the basis of a categorical listing, CAS No. 1336-36-3, 1,1'-Biphenyl, chloro derivs., with chlorinated biphenyl being a synonym. EPA's list of the 209 congeners is headed by that CAS number with the name "Polychlorinated biphenyl (PCB)" and the word "category."[7]

EPA also decided to restrict PCBs as a category. The detailed regulations in 40 C.F.R. Part 761 address PCBs of all kinds in exactly the same manner, without regard to particular congener.

EPA's category approach for chlorinated paraffins and PCBs may be contrasted with its approach for chlorinated naphthalenes. There are 75 possible chlorinated naphthalenes. In 1975, EPA found that the higher chlorinated naphthalenes have generally higher toxicity than do the lower species.[8] Perhaps for that reason, EPA did not add a categorical listing for chlorinated naphthalenes to the TSCA Inventory as it did for chlorinated paraffins and for PCBs. A few years later, EPA adopted a rule under section 8(a) for a "category" of 19 chlorinated naphthalenes that consisted of all of the chlorinated naphthalenes listed individually on the TSCA Inventory.[9] Without a categorical listing for chlorinated naphthalenes on the Inventory, EPA had to refer to individual CAS numbers. This is in contrast to how EPA has addressed PCBs using the "category" Inventory listing for CAS No. 1336-36-3. It also contrasts with how EPA addressed chlorinated paraffins by using category listings, as explained in the rest of this paper.

3. <u>EPA Included Chlorinated Paraffins as a Category on the Initial Inventory</u>

Two categorical entries for chlorinated paraffins were listed on the original TSCA Inventory.

- Alkanes, chloro, CAS No. 61788-76-9
- Paraffin waxes and Hydrocarbon waxes, chloro, CAS No. 63449-39-8

Some individual chlorinated paraffins were also listed there, including:

- Alkanes, C_{6-18}, chloro, CAS No. 68920-70-7

---

[6] That one is CAS No. 15968-05-5, 1,1'-Biphenyl, 2,2',6,6'-tetrachloro-.

[7] See EPA, Table of PCB Species by Congener Number (revised as of Nov. 2003), Table of PCB Species by Congener Number (rev. Nov. 2003), http://www3.epa.gov/epawaste/hazard/tsd/pcbs/pubs/congenertable.pdf.

[8] EPA, Environmental Hazard Assessment Report: Chlorinated Naphthalenes, EPA-560/8-75-001 (Dec. 1975), http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=9100ARI9.txt.

[9] EPA, Reporting and Recordkeeping Requirements Category of Chemical Substances Known as Chlorinated Naphthalenes; Submission of Notice of Manufacture or Import, 49 Fed. Reg. 33649 (Aug. 24, 1984)..

- Alkanes, $C_{11\text{-}14}$, 2-chloro, 68990-22-7

EPA encouraged companies to report the two categories of chlorinated paraffins for the original compilation of the TSCA Inventory, i.e., EPA listed CAS No. 61788-76-9 on the 1977 Candidate List of Chemical Substances,[10] and it listed the predecessor CAS number for CAS No. 63449-39-8 on the Candidate List as well.[11] EPA explained that:

> If a given chemical substance appears in the Candidate List, the information required for reporting that chemical substance to EPA is contained in the Candidate List. Therefore, **persons are strongly encouraged to use the information contained in the Candidate List to the greatest extent possible**. Otherwise, a great deal of effort may be expended needlessly.[12]

In issuing the Candidate List, EPA recognized that it was suggesting some chemical names that were quite broad:

> EPA recognizes that some of the chemical substances listed in the Candidate List could be more precisely described …. EPA intends to revise any category on the inventory as appropriate based on information obtained through Section 8 of TSCA or other sources.[13]

EPA has never revised the chlorinated paraffins categories on the Inventory, however, as both CAS numbers remain there, unrevised 39 years after EPA included them in the Candidate List (other than the replacement of CAS No. 8029-39-8 by CAS No. 63449-39-8 and modernization of the names).

4. <u>EPA Regarded Chlorinated Paraffins as a Category When Compiling the Initial Inventory</u>

In addition to the fact that EPA listed two broad categorical names for chlorinated paraffins on the Inventory, there is other evidence that EPA considered that qualified chlorinated paraffins to be treated as a category. Shortly before passage of TSCA in 1976, EPA was investigating both

---

[10] The Candidate List referred to CAS No. 61788-76-9 as “Alkanes, chlorinated.” The current CAS name is “Alkanes, chloro.”

[11] See EPA, Toxic Substances Control Act (TSCA) PL 94-469 Candidate List of Chemical Substances (Apr. 1977), Vol. 3, p. 439 (listing CAS No. 61788-76-9, “Alkanes, chlorinated,”); Volume II, p. 968, listing CAS No. 8029-39-8, “Paraffin chlorinated.” Subsequently, CAS No. 8029-39-8 was replaced by CAS No. 63449-39-8. See EPA’s Substance Registry Services entry for CAS No. 63449-39-8, http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=331603 (identifying CAS No. 8029-39-8 as a former CAS number replaced by CAS No. 63449-39-8).

[12] EPA, General Provisions and Inventory Reporting Requirements; Supplemental Notice, 42 Fed. Reg. 19298 (Apr. 12, 1977) (emphasis added).

[13] EPA, Toxic Substances Control Act (TSCA) PL 94-469 Candidate List of Chemical Substances (Apr. 1977), Vol. I, p. ii.

chlorinated paraffins and PCBs. A 1975 report on chlorinated paraffins commissioned by EPA[14] compared them to PCBs:

> However, from the available data, it can be concluded that chlorinated paraffins are (1) produced in larger quantities than PCB's, (2) are likely to be released to the environment, (3) are less mobile and persistent than PCB's, and (4) are less acutely toxic.[15]

For purposes of this memorandum, the report is important for how it characterizes chlorinated paraffins in ways consistent with the TSCA legislative history's discussion of section 8(b)(2). The report referred to the complex composition of chlorinated paraffins (suggesting that, as with the statutory mixtures discussed above, it would be very burdensome for persons to report individual members of the categories):

> In terms of the number of isomers, these formulations exceed such complicated commercial mixtures as polychlorinated biphenyls (PCB's) and chlorinated naphthalenes. This is due to the mixture of parent paraffinic hydrocarbons (usually various chain lengths) which are used commercially in the chlorination process. In contrast, only one parent hydrocarbon, i.e., biphenyl or naphthalene, is used with polychlorinated biphenyls and chlorinated naphthalenes, respectively.[16]
>
> Commercial chlorinated paraffins are extremely complex mixtures of isomers and analogs of compounds formed when mixtures of n-paraffins ($C_{10} – C_{30}$) are chlorinated to varying percentages of chlorine (usually 40-70% by weight).[17]

The report offers a possible basis for EPA later listing two categories of chlorinated paraffins on the Inventory, one of which refers to waxes and one of which does not:

> In the United Kingdom, a distinction is made between chlorinated paraffins that are derived from liquid paraffins as opposed to those made from solid parent material, the latter being referred to as chlorinated-paraffin waxes (Hardie, 1964). In America, the term chlorinated paraffins refers to "chlorinated, mainly straight-chain, saturated hydrocarbons for the $C_{10} – C_{30}$ range" (Hardie, 1964). The broader American term will be used in this review.[18]
>
> Both liquid products (40-64% chlorine) and solid resins (~70% chlorine) are commercially available.[19]

Summarizing the information then known about chlorinated paraffins, the report indicated that, in the words of the legislative history, the various chlorinated paraffins "would have insignificant

---

[14] Syracuse University Research Corporation, Investigation of Selected Potential Environmental Contaminants: Chlorinated Paraffins, EPA-560/2-75-007 (Nov. 1975), http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=2000ZD84.txt.

[15] Id. at x.

[16] Id. at 1.

[17] Id. at 97.

[18] Id. at 1.

[19] Id. at 97.

health or environmental consequences" as compared with each other. The section on health and environmental effects makes no statements differentiating chlorinated paraffins based on chain length. Instead, they are referred to simply as "chlorinated paraffins" or differentiated based on degree of chlorination. For example:

> Chlorinated paraffins placed in the environment may degrade by one of the following processes ….[20]
>
> Thus, it would appear that these compounds are fairly chemically stable under environmental conditions ….[21]
>
> Considering the low solubility of normal $C_{10} – C_{30}$ paraffins in water, and the increasing hydrophobic effect of chlorine substitution, it appears likely that chlorinated paraffins are insoluble in water and adsorb readily on suspended particles.[22]
>
> In view of the high molecular weight of chlorinated paraffins, their bioaccumulation potential appears to be limited. The ability of chlorinated paraffins to strongly adsorb to suspended particulates in water will further reduce their availability to food chain organisms.[23]
>
> The inability of chlorinated paraffins to accumulate and biomagnify could be attributed to their higher molecular weight; the bulkiness of the molecule may prevent them from being taken up by the living organism.[24]
>
> It is known, however, that the addition of chlorinated paraffins to the diet or in the water of various fish species will produce significant mortality and numerous sub-lethal effects.[25]

In short, the 1975 report strongly suggests that when EPA compiled the initial TSCA Inventory a few years later, it regarded chlorinated paraffins as appropriate for treatment as a category.

EPA now has information that, in its view, allows it to distinguish the health and environmental effects of some kinds of chlorinated paraffins from those of other kinds. This information was not available at the time that EPA added the two chlorinated paraffins categories to the Inventory, however. EPA first appears to have indicated publicly that it believed that short-chain chlorinated paraffins (SCCPs), those with alkyl chain lengths of C_{10-13}, were of greater concern than longer-chain chlorinated paraffins. This occurred in a 1994 EPCRA rulemaking.[26] EPA did

---

[20] Id. at 75.
[21] Id. at 80.
[22] Id. at 81.
[23] Id. at 82.
[24] Id. at 84-85.
[25] Id. at 100.
[26] EPA proposed to add the "category" of chlorinated paraffins to the Toxics Release Inventory regulations, where alkyl chain lengths of 10-30 would be included. 59 Fed. Reg. 1788 (Jan. 12, 1994). In the final rule, EPA indicated that it was "renaming this category polychlorinated alkanes" and limiting it to SCCPs "[s]ince EPA has determined that only the short-chain species meet the listing requirements of EPCRA section 313." 59 Fed. Reg. 61432. 61461,

not distinguish between SCCPs, MCCPs, and LCCPs in a TSCA context until it issued a Chemical Action Plan for SCCPs in 2009.[27] Thus, at the time EPA added the two chlorinated paraffin categories to the Inventory and for two decades thereafter, EPA had no basis for differentiating between the effects of different sub-categories of chlorinated paraffins in a way which might have made adoption of the two chlorinated paraffins categories inappropriate under the legislative history of section 8(b)(2).

5. EPA Regulated Chlorinated Paraffins Under TSCA as a Category From 1977 to 2011

Beginning with the first year of TSCA implementation, and continuing for more than 30 years, EPA regulated or proposed to regulate chlorinated paraffins as a category by citing the categorical entries on the TSCA Inventory, Alkanes, chloro, CAS No. 61788-76-9, and/or Paraffin waxes and Hydrocarbon waxes, chloro, CAS No. 63449-39-8. See the following chronology:

- 1977: The Interagency Testing Committee's Initial Report to EPA recommended testing of "chlorinated paraffins," 42 Fed. Reg. 55026 (Oct. 12, 1977). The description stated, "This category is comprised of mixtures of chlorination products of materials known commercially as paraffin oils or paraffin waxes; those having a chlorine content of 35% through 64% by weight are included."
- 1978: EPA included "chlorinated paraffins" in a proposed section 8(d) rule, 43 Fed. Reg. 4073 (Jan. 31, 1978), and a final section 8(d) rule, 43 Fed. Reg. 30984 (July 18, 1978). The preamble to the proposed rule recognized that the ITC had recommended the "category" of chlorinated paraffins.
- 1979: EPA included "chlorinated paraffins" in a proposed section 8(d) rule, 44 Fed. Reg. 77470 (Dec. 31, 1979).
- 1982: EPA included both CAS numbers in a final section 8(d) rule, 47 Fed. Reg. 38780 (Sept. 2, 1982).
- 1985: EPA included both CAS numbers in a proposed section 8(d) rule, 50 Fed. Reg. 39715 (Sept. 30, 1985). The listing was in the "category" section of the rule, rather than in the "substance" section of the rule.
- 1986: EPA included both CAS numbers in a final section 8(d) rule, 51 Fed. Reg. 32720 (Sept. 15, 1986). The listing was in the "category" section of the rule, rather than in the "substance" section of the rule.
- 2005: The Interagency Testing Committee's 55th Report recommended testing of CAS No. 61788-76-9 under section 4, 70 Fed. Reg. 7364 (Feb. 11, 2005). The action reflected classification of Alkanes, chloro as an orphan HPV chemical.

61463 (Nov. 30, 1994). EPA based this change largely on a 1989 report by NTP and a 1990 monograph by IARC that chlorinated paraffins with an average chain length of 12 may be carcinogenic.

[27] EPA, Short-Chain Chlorinated Paraffins (SCCPs) and Other Chlorinated Paraffins Action Plan (Dec. 2009), http://www.epa.gov/sites/production/files/2015-09/documents/sccps_ap_2009_1230_final.pdf. There EPA defined MCCPs as having alkyl chain lengths C_{14-17} and LCCPs as having alkyl chain lengths generally C_{18-28}. Later EPA defined LCCPs as having alkyl chain lengths C_{18-20}. 79 Fed. Reg. 7621, 7623 (Feb. 10, 2014) (proposed SNUR for very long-chain chlorinated paraffins (vLCCPs), undefined but presumably with alkyl chain lengths $> C_{20}$).

- 2006: EPA added CAS No. 61788-76-9 to the section 8(a) PAIR rule, 71 Fed. Reg. 47122 (Aug. 16, 2006). The action reflected classification of Alkanes, chloro as an orphan HPV chemical.
- 2006: EPA added CAS No. 61788-76-9 to the section 8(d) rule, 71 Fed. Reg. 47130 (Aug. 16, 2006). The action reflected classification of Alkanes, chloro as an orphan HPV chemical.
- 2010: EPA proposed to require testing of CAS No. 61788-76-9 under section 4, 75 Fed. Reg. 857502 (Feb. 25, 2010). The action reflected classification of Alkanes, chloro as an orphan HPV chemical.
- 2011: The Interagency Testing Committee removed CAS No. 61788-76-9 from the high priority testing list, 76 Fed. Reg. 46174 (Aug. 1, 2011). The action was based on EPA's 2010 proposed test rule.
- 2011: EPA deferred final action on CAS No. 61788-76-9 in a final test rule in light of the Inventory issue, 76 Fed. Reg. 65385 (Oct. 21, 2011). The preamble explained, "There is currently an unresolved issue regarding whether all the production previously reported to the Agency under CASRN 61788-76-9 should in fact be covered by that listing. Pending resolution of this issue, EPA will defer making a final decision regarding test rule requirements for CASRN 61788–76–9, and will reevaluate the testing needs for CASRN 61788–76–9 based on future CDR reports."

Thus, from 1977 until 2011, EPA regulated or proposed to regulate chlorinated paraffins on the basis of the categories on the Inventory. This 34-year period reflects a very well-established EPA understanding that chlorinated paraffins are a category for TSCA Inventory purposes.

CONCLUSION

OPPT has stated that it considers it appropriate to continue its evaluation of the MCCP and LCCP risk assessments under TSCA section 5 because the two manufacturers agreed to sign consent decrees in 2012 requiring them to submit PMNs and proceed under TSCA section 5. EPA's position arguably might have some merit if the only parties to be impacted by EPA's potential actions were the two manufacturers. However, because EPA also agreed that the manufacturers could continue manufacturing and distributing MCCPs and LCCPs in commerce while EPA reviewed the PMNs, EPA's threatened action to ban MCCPs and LCCPs will adversely impact hundreds or thousands of downstream users. Downstream users of MCCPs and LCCPs were not parties to or aware of the consent order negotiations occurring between 2009 and 2012, but they will be manifestly prejudiced if EPA insists on proceeding under section 5. EPA has an ample basis for considering regulation of MCCPs and LCCPs under section 6 of TSCA as existing chemical substances rather than under section 5 of TSCA as new chemical substances.

Attachment 8

Medium-Chain and Long-Chain Chlorinated Paraffins

TSCA Analysis

Of Counsel:
Mark N. Duvall
Beveridge & Diamond, P.C.
1350 I Street, N.W.
Washington, DC 20005
(202) 789-6090
mduvall@bdlaw.com

Christina Franz
Senior Director, Regulatory & Technical Affairs
American Chemistry Council
700 Second Street, N.E.
Washington, DC 20002
(202) 249-6406
christina_franz@americanchemistry.com

October 30, 2015

EPA Should Not Use TSCA Section 5 to Restrict Chlorinated Paraffins

EPA is attempting to force a nation-wide ban on the use of medium-chain chlorinated paraffins (MCCPs) and long-chain chlorinated paraffins (LCCPs) using its authority applicable to new chemical substances under section 5 of the Toxic Substances Control Act (TSCA). A ban would create very substantial impacts on jobs, trade, national defense, and the economy. This is because MCCPs and LCCPs and their uses are not "new" in any real sense, but only in a technical one under TSCA. In reality, MCCPs and LCCPs have been used at high volumes in this country for decades. EPA should not use section 5 to ban or restrict these chemical substances. Instead, it should use its ongoing TSCA Work Plan. After doing so, if unreasonable risks are found, it must use section 6 of TSCA, which Congress intended be used for existing chemical substances with ongoing uses, such as MCCPs and LCCPs.

1. MCCPs and LCCPs Have Been Used for Decades at High Volumes

MCCPs (C_{14-17} chloroalkanes) and LCCPs (C_{18-20} chloroalkanes) have been in commerce in the U.S. for decades. Production and imports have declined over time, but still totaled about 48 million pounds in 2011. EPA has reported that as many as 176,314 workers work with CAS No. 61788-76-9 nationally.[1] For practical purposes, these cannot be characterized as new chemicals.

Since TSCA was enacted, both EPA and industry have used the following CAS numbers, among others, to refer to chlorinated paraffins, including MCCPs and LCCPs:

- Alkanes, chloro, CAS No. 61788-76-9
- Paraffin waxes and hydrocarbon waxes, chloro, CAS No. 63449-39-8

The Chemical Data Reporting rule (CDR) and Inventory Update Rule (IUR) data for those CAS numbers are as follows:

Year of Domestic Production or Importation	**Alkanes, chloro, CAS No. 61788-76-9**	**Paraffin waxes and Hydrocarbon waxes, chloro, CAS No. 63449-39-8**	**Total**
2011	19,876,707 lbs.	28,561,575 lbs.	48,438,282 lbs.
2010	25,918,167 lbs.	26,762,309 lbs.	52,680,476 lbs.
2005	>10,000,000 – 50, 000,000 lbs.	>10,000,000 – 50, 000,000 lbs.	20,000,000 – 100,000,000 lbs.
2001	>10,000,000 – 50, 000,000 lbs.	50,000,000 – 100,000,000 lbs.	60,000,000 – 150,000,000 lbs.
1997	>10,000,000 –	>10,000,000 –	20,000,000 –

---

[1] "Testing of Certain High Production Volume Chemicals; Third Group of Chemicals," 75 Fed. Reg. 8575, 8580 (Feb. 25, 2010).

	50, 000,000 lbs.	50, 000,000 lbs.	100,000,000 lbs.
1993	>50,000,000 – 100,000,000 lbs.	>10,000,000 – 50, 000,000 lbs.	60,000,000 – 150,000,000 lbs.
1989	>10,000,000 – 50, 000,000 lbs.	>10,000,000 – 50, 000,000 lbs.	20,000,000 – 100,000,000 lbs.
1985	>1,000,000 – 5,000,000 lbs.	100,000,000 – 500,000,000 lbs.	101,000,000 – 505,000,000 lbs.

This data shows that chlorinated paraffins, including MCCPs and LCCPs, have been High Production Volume chemicals since EPA first adopted the IUR.

2. EPA Is Incorrectly Trying to Use Section 5 to Ban MCCPs and LCCPs

This issue concerns the existing CAS numbers included on the TSCA Inventory for these chemicals. CAS No. 61788-76-9 and CAS No. 63449-39-8 are not specific to particular MCCPs and LCCPs. For example, they do not indicate a specific carbon number range. Thus, they represent broad categories of MCCPs, LCCPs, as well as all other forms of chlorinated paraffins, including short-chain chlorinated paraffins (SCCPs). EPA's position is that MCCPs and LCCPs are not on the Inventory because they are not listed according to specific carbon number ranges.[2]

Such specific listings are not required under TSCA. Section 8(b)(2) of TSCA authorizes EPA to list categories of chemicals on the Inventory rather than list individual members of the category:

> To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

That is arguably what EPA did with CAS No. 61788-76-9 and CAS No 63449-39-8. These broad Inventory entries represent families of related chemical substances. For example, alkanes, chloro may be regarded as encompassing chlorinated alkanes (paraffins) of any carbon number or carbon number range. EPA encouraged companies to report those two CAS numbers for the TSCA Inventory. It listed CAS No. 61788-76-9 on the 1977 Candidate List of Chemical Substances, and it listed the predecessor CAS number for CAS No. 63449-39-8 on the Candidate List as well.[3] EPA explained that:

---

[2] In 1995, EPA issued guidance encouraging the use of specific carbon number ranges. EPA, "Toxic Substances Control Act Inventory Representation for Certain Chemical Substances Containing Varying Carbon Chain Lengths (Alkyl Ranges Using the Cx-y Notation)" (1995), http://www2.epa.gov/sites/production/files/2015-05/documents/alkyl-rg.pdf.

[3] See EPA, Toxic Substances Control Act (TSCA) PL 94-469 Candidate List of Chemical Substances (Apr. 1977), Vol. 3, p. 439 (listing CAS No. 61788-76-9, "Alkanes, chlorinated," and p. 332, listing CAS No. 8029-39-8, "Cereclor"), (Volume II, p. 968, listing CAS No. 8029-39-8, "Paraffin chlorinated"). Subsequently, CAS No. 8029-39-8 was replaced by CAS No. 63449-39-8. See EPA's Substance Registry Services entry for CAS No. 63449-39-8, http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=331603 (identifying CAS No. 8029-39-8 as a former CAS number for CAS No. 63449-39-8).

> The purpose of the Candidate List is to assist manufacturers and processors to identify chemicals they must report…. Manufacturers and processors are therefore encouraged to consult carefully the Candidate List to simplify compliance with the EPA inventory reporting requirements.[4]

When issuing the Candidate List, EPA recognized that it was suggesting some chemical names that were quite broad and might, in the future, need to be made more specific:

> EPA recognizes that some of the chemical substances listed in the Candidate List could be more precisely described …. EPA intends to revise any category on the inventory as appropriate based on information obtained through Section 8 of TSCA or other sources.[5]

EPA has never done so, however, as both CAS numbers remain on the Inventory, unrevised over 38 years after EPA included them in the Candidate List (other than the replacement of CAS No. 8029-39-8 by CAS No. 63449-39-8).

Nevertheless, in 2009 EPA filed complaints against the principal manufacturer and importer of MCCPs and LCCPs on the basis that the chlorinated paraffins they manufactured or imported were not specifically listed on the Inventory (i.e., that CAS No. 61788-76-9 and CAS No. 63449-39-8 did not cover specific MCCPs and LCCPs). In 2012 settlements, the two companies agreed to file PMNs for specific MCCPs and LCCPs within 30 days, which they did. The settlement allowed them to continue to manufacture, import, and sell the very same MCCPs and LCCPs for which they filed PMNs during the PMN review period.

More than three years have passed since then, and EPA has still not ended the statutory 90-day review period for those PMNs. Instead, EPA has repeatedly extended the review period. In January 2015, EPA informed those companies that they had an option: cease manufacture or import immediately or cease further manufacture or import of those PMN substances after a phase-out period ending in May 2016.

3. <u>Section 5 Is the Wrong Provision for Addressing MCCPs and LCCPs</u>

MCCPs and LCCPs have been in active U.S. commerce since before TSCA was enacted. Given that situation, section 5 is the wrong TSCA provision for EPA to use to address concerns about those chemical substances.

a. <u>MCCPs and LCCPs Are Already in Commerce</u>

The TSCA legislative history explained that Congress gave EPA strong regulatory powers under section 5 without many of the procedural protections of section 6 precisely because chemicals subject to section 5 (or their uses) were <u>not yet</u> in commerce:

---

[4] EPA, Toxic Substances Control Act (TSCA) PL 94-469 Candidate List of Chemical Substances (Apr. 1977), Vol. I, p. i.

[5] Id. at ii.

> The provisions of this section reflect the conferees' recognition that the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs **before commercial production begins.** Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized. For these reasons the conferees have given the Administrator broad authority to act during the notification period.[6]

Those considerations simply do not apply to MCCPs and LCCPs, since commercial production and/or import began some 70 years ago. A ban now would have an enormous cost in terms of loss of jobs and capital investment, as well as serious impacts on national security and public safety. Some of the potential impacts that we have been able to identify are described separately (See ACC Economic End-Use Market Footprint). All of these considerations make section 5 the wrong TSCA provision to use in this context.

b. EPA Cannot Adopt a SNUR for MCCPs or LCCPs Because Current Uses Are Ongoing

In the usual circumstance where EPA has concerns about PMN chemicals, it promulgates significant new use rules (SNURs) for those chemicals. However, EPA cannot adopt SNURs for the MCCP and LCCP PMN chemicals. SNURs are only available for "new" uses; all relevant uses of MCCPs and LCCPs are ongoing and thus are not "new."

This situation differs substantially from that of SCCPs. EPA determined that no uses of a particular SCCP was currently ongoing:

> No production volumes for alkanes, $C_{12–13}$ chloro (CAS No. 71011–12–6) were reported to the IUR during the 2006, 2002, 1998, and 1994 reporting cycles, and EPA found no additional evidence of any importation or manufacturing of the chemical.[7]

EPA was careful to limit the SNUR to a particular SCCP, because it had information that any particular SCCP was not in commerce:

> There are many different chemical substances that are members of the SCCP category …. Of the different SCCPs that are listed on the TSCA Inventory, EPA believes the SCCP named "Alkanes, C_{12-13}, chloro (CAS No. 71011–12–6)" is not in use in the United States and EPA has found no information that indicates it has ever been used.[8]

Accordingly, EPA was able to adopt a final SNUR for that particular SCCP in December 2014.[9] In contrast, EPA would be unable to adopt a SNUR for MCCPs and LCCPs, because their uses are ongoing. This situation further exemplifies why section 5 is the wrong provision for regulating MCCPs and LCCPs.

---

[6] H.R. Rep. 94-1679 (1976) at 65, Legislative History of the Toxic Substances Act (1976) at 678 (emphasis added).

[7] Proposed SNUR, 77 Fed. Reg. 1875218757-58 (Mar. 28, 2012).

[8] Id. at 18758.

[9] 40 C.F.R. § 721.10227, Alkanes, C_{12-13}, chloro (CAS No. 71011-12-6), 79 Fed. Reg. 77891 (Dec. 29, 2014).

c. Due Process Considerations

EPA's effort to ban MCCPs and LCCPs through section 5 denies processors and end users of those products the opportunity to be heard.

Section 5 negotiations are strictly between a PMN submitter and EPA. That is appropriate where they are the only affected parties. With MCCPs and LCCPs, however, they are not the only affected parties. EPA's negotiations with the three PMN submitters have been kept confidential, and no opportunity for comment has been afforded to other stakeholders. Yet hundreds or thousands of processors and end users of MCCPs and LCCPs, some of them small businesses, are also stakeholders. The PMN process being followed by EPA does not provide them with any mechanism to express their views on EPA's proposed actions.

4. EPA Has Regulated MCCPs and LCCPs Under the Categorical Inventory Entries

EPA's position since 2009 that CAS No. 61788-76-9 and CAS No. 63449-39-8 do not refer to any particular chlorinated paraffins, and that individual Inventory entries are needed for particular chlorinated paraffins, is inconsistent with how EPA has treated those Inventory entries during the history of TSCA. For example, it has issued rules under section 8(a) and section 8(d) for both CAS numbers and has proposed, and deferred, a test rule for CAS No. 61788-76-9 under section 4. Additional details appear in Attachment 1.

In short, EPA has repeatedly treated CAS No. 61788-76-9 and CAS No. 63449-39-8 as existing chemicals that encompass MCCPs and LCCPs. It cannot now assert that those CAS numbers are meaningless under TSCA.

5. EPA Should Continue With Its Announced Plan to Evaluate MCCPs and LCCPs Under the TSCA Work Plan

In 2012, EPA selected MCCPs and LCCPs for evaluation under the TSCA Work Plan as two of the original seven chemicals or chemical categories to be evaluated.[10] EPA published peer review plans for those assessments.[11] The risk assessments for MCCPs and LCCPs are currently listed as ongoing.[12] However, without any public notice, EPA has indicated that it no longer plans to evaluate those chemical substances under the TSCA Work Plan because it is proceeding under section 5 instead. EPA should revert to its publicly announced plan of addressing MCCPs and LCCPs under the TSCA Work Plan because of the transparency that process brings,

---

[10] EPA, TSCA Work Plan for Chemical Assessments (2014 update) (noting that MCCPs and LCCPs were among the original 2012 Work Plan chemicals and that they remain listed), http://www2.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

[11] OPPT workplan assessments for medium and long chain chlorinated paraffins, http://cfpub.epa.gov/si/si_public_pra_view.cfm?dirEntryID=245552.

[12] EPA, Assessments for TSCA Work Plan Chemicals,http://www2.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals

.

including the opportunity for public comment, and because it is the appropriate context in which to assess chemicals in commerce with ongoing uses.

The TSCA Work Plan calls for EPA to conduct a risk assessment of a priority chemical or chemical category and then to have the draft risk assessment report made available for public comment and peer review. Only after receipt of comments by the public and peer reviewers would EPA make the risk assessment final. Following issuance of the final risk assessment report, EPA may then initiate risk management action, as appropriate.[13]

EPA has shared the draft risk assessments for MCCPs and LCCPs with the PMN submitters, but it has not publicly released them so that other stakeholders have had an opportunity to see them. Other stakeholders certainly have had no opportunity to comment on them. EPA has also informed the PMN submitters that it no longer intends to seek peer review of the risk assessments, because doing so would be inconsistent with its practice under section 5.

These draft risk assessments should be made available for public comment and should be submitted for peer review, as would occur under the TSCA Work Plan. Apparently the draft risk assessments find that MCCPs and LCCPs pose an unreasonable risk. Authorities in both Canada and the EU have also studied MCCPs and LCCPs, but they have not proposed or adopted risk management actions for either MCCPs or LCCPs. This suggests that, unlike EPA, its peer agencies do not believe MCCPs and LCCPs should be banned. Public comment and peer review may help reconcile EPA's approach with the other conflicting regulatory authorities.

6. EPA Must Consider Regulating MCCPs and LCCPs Under Section 6 if Unreasonable Risks are Identified

EPA should only consider regulating MCCPs and LCCPs under section 6 if the final, peer-reviewed, risk assessments support such regulation. EPA has already indicated that it plans to propose regulation under section 6 of certain uses of three other TSCA Work Plan Chemicals that are currently ongoing.[14] Section 6 provides opportunity for stakeholder involvement, which can materially improve EPA's risk management decision-making. Consequently, it appears that EPA is proceeding under section 5 rather than section 6 with MCCPs and LCCPs largely to avoid the procedural and substantive requirements of section 6.

Congress imposed procedural and substantive requirements that EPA must meet before regulating under section 6. Those requirements reflect Congressional understanding that banning or restricting chemicals that are already in commerce can have significant economic and other impacts that should be evaluated before proceeding. MCCPs and LCCPs have been in commerce for decades and are still used today in substantial quantities. EPA must follow section

---

[13] EPA, TSCA Work Plan Chemicals: Methods Document (2012), http://www2.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.

[14] The three chemicals are TCE, NMP, and methylene chloride. EPA Regulatory Agenda Spring 2015 (May 21, 2015), http://resources.regulations.gov/public/ContentViewer?objectId=0900006481b05fff&disposition=attachment&contentType=pdf. EPA has also proposed a SNUR for use of TCE that are not ongoing, 80 Fed. Reg. 47,441 (Aug. 27, 2015), and encouraged a voluntary action on TCE, http://yosemite.epa.gov/opa/admpress.nsf/0/A4964AD93874985C85257E92005EE07F.

6 requirements (including as they may be revised under TSCA legislation) for these high-volume chemicals if its public and peer-reviewed risk assessments support such action from a scientific perspective.

A section 6 proceeding may well identify cost-effective alternatives to a ban of MCCPs and LCCPs. For example, EPA's primary concern apparently is with unrestricted disposal of MCCPs and LCCPs, neither of which are considered hazardous waste under RCRA. Appropriate disposal restrictions, while allowing continued use of MCCPs and LCCPs, may be a better regulatory choice than the ban that EPA is currently pursuing.

Attachment 1

Examples of How EPA Has Relied on CAS No. 61788-76-9 and CAS No. 63449-39-8 to Address MCCPs and LCCPs

- 1977: EPA included CAS No. 61788-76-9 in the April 1977 Candidate List. EPA included CAS No. 8029-39-8, Paraffin, chlorinated, in the Candidate List. (CAS No. 8029-39-8 was later replaced by CAS No. 63449-39-8.)
- 1977: The Interagency Testing Committee's Initial Report to EPA recommended testing of "chlorinated paraffins," 42 Fed. Reg. 55026 (Oct. 12, 1977).
- 1978: EPA included "chlorinated paraffins" in a proposed section 8(d) rule, 43 Fed. Reg. 4073 (Jan. 31, 1978), and a final section 8(d) rule, 43 Fed. Reg. 30984 (July 18, 1978).
- 1979: EPA included "chlorinated paraffins" in a proposed section 8(d) rule, 44 Fed. Reg. 77470 (Dec. 31, 1979).
- 1982: EPA included both CAS numbers in a final section 8(d) rule, 47 Fed. Reg. 38780 (Sept. 2, 1982).
- 1985: EPA included both CAS numbers in a proposed section 8(d) rule, 50 Fed. Reg. 39715 (Sept. 30, 1985).
- 1986: EPA included both CAS numbers in a final section 8(d) rule, 51 Fed. Reg. 32720 (Sept. 15, 1986).
- 2005: The Interagency Testing Committee's 55th Report recommended testing of CAS No. 61788-76-9 under section 4, 70 Fed. Reg. 7364 (Feb. 11, 2005).
- 2006: EPA added CAS No. 61788-76-9 to the section 8(a) PAIR rule, 71 Fed. Reg. 47122 (Aug. 16, 2006).
- 2006: EPA added CAS No. 61788-76-9 to the section 8(d) rule, 71 Fed. Reg. 47130 (Aug. 16, 2006).
- 2010: EPA proposed to require testing of CAS No. 61788-76-9 under section 4, 75 Fed. Reg. 857502 (Feb. 25, 2010).
- 2011: The Interagency Testing Committee removed CAS No. 61788-76-9 from the high priority testing list, 76 Fed. Reg. 46174 (Aug. 1, 2011).
- 2011: EPA deferred final action on CAS No. 61788-76-9 in a final test rule in light of the Inventory issue, 76 Fed. Reg. 65385 (Oct. 21, 2011).

Attachment 9

CHLORINATED PARAFFINS INDUSTRY ASSOCIATION

1250 Connecticut Avenue, NW • Suite 700 • Washington, DC 20036 • Phone: 202-419-1500

April 11, 2014

Document Controls Office 7407 M
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

ATTN: Docket ID Number EPA-HQ-OPPT-2013-0399

Re: Comments on the Proposed Significant New Use Rule for CAS 1417900-96-9 (P-12-539), 1401947-24-0 (P-13-107), and 1402738-52-6 (P-13-109)

To Whom It May Concern:

The Chlorinated Paraffins Industry Association (CPIA) is submitting these comments in response to the February 10, 2014 (79 FR 7621) proposed Significant New Use Rule (SNUR) on CAS Number 1417900-96-9 (P-12-539), CAS number 1401947-24-0 (P-13-107), and CAS Number 1402738-52-6 (P-13-109). CPIA has represented the chlorinated paraffin (CP) industry for over 30 years and has considerable experience with the existing and on-going assessments of CPs, including toxicology and ecotoxicology testing, chemical analysis, environmental fate, exposure and risk assessments. Most relevant to this particular proposed SNUR, CPIA was the lead organization in the development of both the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) dossier and the European Union REACH registration dossiers for long chain chlorinated paraffin (LCCP). CPIA also has extensive experience with the previous and ongoing assessments of short chain chlorinated paraffin (SCCP) and medium chain chlorinated paraffin (MCCP).

LCCP is a very well tested class of chemical products, including a 2-year chronic/cancer bioassay, genetic toxicity testing, numerous acute, repeat dose and developmental toxicity studies, and many aquatic toxicity and fate studies. These toxicity data indicate that LCCP products have a low order of mammalian toxicity and do not produce effects in aquatic organism at or below their water solubility limit. LCCP products are essentially insoluble in water and have a very low vapor pressure. LCCP products are generally used in controlled industrial operations, with minimal release to air or water. As such, exposure to LCCP is expected to be very low. Based on this extensive database and several recent reviews, CPIA believes LCCP production and use in the U.S. present an extremely low risk to human health and the environment. Given this, CPIA questions the need for EPA to take specific action under TSCA Section 5(a)(2) for any substances that could be considered LCCP.

It should be noted that CPIA questions the appropriateness of treating several of the substances in the proposed SNUR as chemical analogs to LCCP/vLCCP. Two of the three substances covered by this SNUR are described as being “branched and linear” chloroalkanes. Only linear chloroalkanes are desired in commercial CP products and any branched chloroalkane (i.e. chlorinated isoparaffin) content is considered an impurity and should be kept to a minimum. Existing LCCP/vLCCP test substances, including those used in all of the existing toxicology testing, were exclusively linear chloroalkanes with less than a few percent branched or isoparaffin content. Notwithstanding this concern, CPIA has reviewed the proposed testing approach in the SNUR as if it would be applied to LCCP products.

CPIA also notes that EPA has designated these substances as very long chain chlorinated paraffin (vLCCP), with a nominal carbon chain length of C21-30. EPA has designated LCCP to mean C18-20 chloroalkanes, although in all other venues, including EPA‟s previous CP testing program, the OECD SIDS assessment, the EU REACH dossier, and other recent assessments, LCCP has always been considered as C18-30. Most of the recent LCCP assessments have evaluated LCCP as a category comprised of three main subcategories:

C18-20 Liquid LCCP
C20-30 Liquid LCCP
C20-30 Solid LCCP

In the United States (U.S.), commercial LCCP products have generally always been in either the C20-30 liquid or C20-30 solid subcategories, with C18-20 liquid LCCP products found mostly in the European market. Given the lack of C18-20 liquid LCCP product in the U.S. market, CPIA does not necessarily object to EPA‟s division of the existing category into LCCP and vLCCP although it appears to be unnecessary based on recent reviews that CPIA and others have conducted on the overall LCCP category. This new vLCCP designation does, however, draw a very bright line at C20 which is questionable based on the toxicology and environmental fate data. A summary of the recent reviews on LCCP is discussed below, including the C18-20 subcategory.

Finally, CPIA has identified significant concerns regarding the appropriateness and the scientific feasibility of the environmental fate and toxicity testing program that EPA has developed for the further evaluation of LCCP/vLCCP under this SNUR (detailed in Attachment A). EPA‟s proposed testing approach appears both excessive, given the significant amount of existing aquatic data, and analytically impossible given the enormous number of possible isomers in the various proposed test substances.

I. Chlorinated Paraffins are Linear, Not Branch Chloroalkanes

CPIA believes that the substance names for two of the substances subject to this proposed SNUR call into question whether these substances should be considered LCCP/vLCCP. These chemical substances are:

Alkanes, C21–34-branched and linear, chloro; CAS no. 1417900-96-9 (P-12-539)
Alkanes, C22–30-branched and linear, chloro, CAS no. 1401947-24-0 (P-13-107)

CPIA could not find detailed compositional information about these substances in the rulemaking docket, regardless it is unexpected that anyone intending to make chlorinated paraffins would intentionally seek to make branched chloroalkanes. CP manufacturers have always used either n-paraffin or alpha-olefin feedstocks, both are which should be almost exclusively linear if they are to be used in CP manufacturing operations. To the extent that either of these hydrocarbon feedstocks contain branched or isoparaffin content it is considered an impurity and something to be minimized and closely controlled. The OECD SIDS dossier and SIAR[1] for LCCP discusses LCCP isoparaffin content in its section on impurities – excerpt provided below – and states that the amount should not be more than 1-2%. This is consistent with CPIA‟s understanding of the feedstocks used in LCCP manufacture.

Excerpt from the OECD SIDS SIAR for LCCP (Reviewed at SIAM-29[2] – October 2009)

> 1.2 Purity/Impurities/Additives
>
> The purity of the chlorinated paraffin is related to the purity of the n-paraffin used as feedstock. In North America and Western Europe, chlorinated paraffins are made from purified n-paraffin feedstocks containing no more than 1-2% isoparaffins and <100 ppm (<0.01%) aromatics (which are specifically removed from the paraffins feedstock by hydrodesulfurization). The n-alkane feedstocks may contain n-alkanes beyond the nominal or predominant carbon number range reported for the feedstock, as such chlorinated paraffin commercial products may contain some constituents outside this range. The carbon number range (C18-C30) of the LCCP category is generally fully encompassing of the main commercial products, though some C18-20 products may contain a significant (10-20%) amount of C17 chlorinated alkane.
>
> Stabilisers such as long-chain epoxidised soya oil are added to some LCCPs to inhibit the release of hydrogen chloride at elevated temperatures. These are used at concentrations <0.05% by weight.

If the branched or isoparaffin content of an LCCP feedstock goes above a few percent the resulting chlorinated product does not meet LCCP product specifications and cannot be sold.

CPIA believes that is inappropriate to include "branched" in the substance name if the intended product is to be considered an LCCP/vLCCP substance. The applicability of existing LCCP data and assessments should be re-evaluated by EPA for these two substances in light of this information. While the proposed SNUR specifically addresses carbon-chain length as a parameter to be controlled and evaluated, there is no discussion at all about the branched or isoparaffin content. CPIA believes that considerable branched content in a chlorinated substance is likely to have as much, if not more, impact on that substance‟s toxicity and environmental fate than small differences in carbon chain length.

It is possible that the manufacture is intending to make substances that are different than existing LCCP products, though given the available information presented in the rulemaking docket there

---

[1] SIDS Initial Assessment Report (SIAR) – the main assessment document for all OECD SIDS chemical assessments.

[2] SIAM – SIDS Initial Assessment Meeting; it should be noted that U.S. EPA attend SIAM-29 and was one of the reviewers of the LCCP dossier and SIAR.

is no indication of this. Without more information, CPIA cannot understand whether these substances should be considered LCCP/vLCCP.

II. Limited Information on EPA"s Assessment of vLCCP is Provided; Recent LCCP/CP Assessments Contain Information that Could Greatly Improve EPA"s Review of vLCCP

Notwithstanding CPIA"s concerns regarding the relevance of several of the SNUR substances to LCCP/vLCCP, CPIA has closely reviewed EPA"s assessment of LCCP/vLCCP as presented in the proposed SNUR and consent order[3]. The limited information in these documents (and the overall proposed rule docket) presents a significant challenge for the public to understand the data used in EPA"s assessment of LCCP/vLCCP and thus the basis for its conclusions. Perhaps this limited information is due to the nature of this proposed SNUR and the PMN review process. Regardless, CPIA believes that as this is EPA"s first review and discussion of LCCP/vLCCP in recent years, it is important that this assessment reflect the best available information on LCCP/vLCCP. To this end, CPIA has considered the key points from EPA"s summary of vLCCP and provided additional information and comments that EPA should consider for each.

EPA assessment of vLCCP states:

> *Due to the absence of data on chronic toxicity to aquatic organisms, sediment-dwelling organisms, and terrestrial plants these endpoints were assessed using experimental data from MCCPs (Cl4-17, 52 wt% Cl).*
>
> *By analogy to medium chain chlorinated paraffins (MCCPs—alkyl chain length of 14 to 17), EPA expects very long chain chlorinated paraffins (vLCCPs) and possible degradation products to be potentially highly persistent, potentially bioaccumulative, and potentially toxic.*
>
> *Within the vLCCPs category, EPA expects the shorter carbon chain range of these substances (C21-C24) and lower chlorinated substances (degree chlorinated less than 50%) to present the greatest potential for risk, as they may be the most bioaccumulative, mobile in the environment, and toxic.*
>
> *Transport and magnification across trophic levels may also result in toxicity to higher organisms, including fish, higher predators, and potentially humans.*
>
> *EPA has concerns about the potential for the vLCCPs to degrade to shorter chain chlorinated compounds,*
>
> *EPA also has concerns about potential impurities or small fractions of MCCPs and/or long-chain chlorinated paraffins ("LCCPs" - alkyl chain lengths of 18 to 20) that may be present as impurities.).*

---

[3] Consent Order between U.S. EPA and Trinity Manufacturing Inc. signed March 18, 2013 regarding P-12-0539, P-13-0107, and P-13-0109.

A. Chronic Aquatic Toxicity Data Available for LCCP/vLCCP

EPA‟s statements indicate that it was unable to locate any chronic aquatic toxicity data on LCCP and as a consequence has relied solely on MCCP data. Further, that based on these MCCP data there may be concerns regarding vLCCP‟s aquatic toxicity. EPA should be aware that there are both chronic fish and invertebrate toxicity data on various carbon chain length and chlorination level LCCP test materials. These were included in all of the recent reviews of LCCP, including the OECD SIDS assessment, the REACH registration dossier, and the U.K. LCCP Environmental Risk Assessment report (EA 2009).

The LCCP REACH Consortium, a sister group to CPIA that manages the REACH activities for LCCP, recently conducted an updated assessment of the LCCP aquatic toxicity database (see Attachment B). These data in this review are also in the OECD SIDS dossier and can be accessed via the ECHA website at: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fddfa25-f9d7-15bc-e044-00144f67d031/DISS-9fddfa25-f9d7-15bc-e044-00144f67d031_DISS-9fddfa25-f9d7-15bc-e044-00144f67d031.html . While this review was directed primarily at the classification of LCCP in the EU, it provides a concise review of the available acute and chronic aquatic toxicity data on LCCP. The review also discusses the critical role that water solubility plays in the interpretation of LCCP/vLCCP aquatic toxicity data. Also included in that review is a statistical re-evaluation by Dr. Roy Thompson of an LCCP study, C18-20, 52% Cl (wt.) (Hooftman et al. 1993) that originally reported possible toxicity (see Attachment B – Appendix 1). This re-evaluation clearly demonstrates that there were no significant effects shown in that study up to the solubility limit of the test material, which for that LCCP test material and conditions was 2 µg/L. It is worth noting that this aquatic toxicity assessment included both C18-20 and C20-30 LCCP substances and it concluded in both cases that there were no significant aquatic toxicity effects at or below the water solubility of the test substances.

CPIA believes that there are adequate chronic aquatic toxicity data for LCCP and, as such, there is no need to consider MCCP data for this endpoint. Moreover, that these chronic aquatic data indicate that both LCCP and vLCCP test substances are not toxic to aquatic organisms.

B. Addressing Data Gaps for vLCCP

CPIA readily acknowledges that, as EPA notes, toxicity to aquatic plant life and toxicity to sediment organisms are data gaps for LCCP. There have been several different approaches used to fill these data gaps.

In the case of aquatic plant life, some testing has been done on LCCP toxicity to aquatic plant life though the reliability of these data has been called into question by reviewers and the data were not deemed sufficiently valid to address the endpoint. Most assessments of LCCP have thus considered read-across data from MCCP as being adequate to fill this data gap. The data from MCCP indicate that neither MCCP, nor LCCP by analogy, are toxic to aquatic plant life. Given this, CPIA supports the use of MCCP data in the assessment of LCCP/vLCCP.

For LCCP sediment toxicity and risk, previous assessments by the U.K. Environment Agency (EA 2009) and the REACH registration dossier have extrapolated from LCCP aquatic toxicity data to sediment toxicity using the equilibrium partitioning method. This approach is detailed in Attachment C, which is a direct excerpt from the U.K. Environment Agency‟s (EA) LCCP assessment (EA 2009). Given the very low water solubility of LCCP and the very high predicted Kow, this method estimates rather high predicted no effect concentrations (PNECs) for LCCP. A PNEC is functionally similar to EPA‟s concentration of concern (CoC) in that both are points of departure for environmental risk assessment. The comparison between the sediment PNECs derived by the EA using the equilibrium partitioning method and the sediment CoC derived by EPA using an MCCP sediment toxicity study are orders of magnitude apart. Given this large difference and the fact that both methods have limitations, CPIA thinks that this may be a data gap to consider for additional testing of vLCCP assuming chemical analysis concerns can be addressed and only is exposure/release information actually dictate a need for this testing. The next section of these comments addresses EPA‟s proposed testing strategy for vLCCP.

C. Recent Testing and Evaluations of MCCP Environmental Fate

EPA states that vLCCP by analogy to MCCP may be "potentially highly persistent, potentially bioaccumulative and potentially toxic." EPA further indicates that, "[t]ransport and magnification across trophic levels may also result in toxicity to higher organisms, including fish, higher predators, and potentially humans," though it is not clear whether this statement is directed at vLCCP or MCCP as an analog. Regardless, EPA should be aware there has been considerable research done in recent years on the environmental fate of MCCP, including new research on biodegradation and the potential for bioaccumulation, including trophic magnification potential.

1. Recent MCCP Biodegradation Testing

Three different types of studies were carried out with a series of chlorinated tetradecanes (C_{14} linear alkanes). These were used as model compounds for obtaining a better understanding of the biodegradation behavior of the commercial MCCP products. The tetradecane was chlorinated at 5 different levels, - 40, 45, 50, 55, and 60 wt% of chlorine. These substances were used in the following studies:

- All 5 substance-mixtures were tested in closed bottle tests (CBT) with a methodology adapted to accommodate the hydrophobic nature of MCCPs, according to OECD Guidelines.
- Sequencing Batch Reactor studies (SCAS tests) were done both with infinite sludge retention times (no sludge removal) and also with fixed sludge retention times (20 days) resembling „real life‟ conditions. The SBR studies aimed to establish a mass balance to quantify the extent of overall biodegradation. This was achieved using Cl^- (chloride) analysis applying a totally chloride-free test medium.
- Detailed analytical evaluation of the original substances and the remaining fractions (effluent and sludge) from the SBRs after degradation.

The results from these experiments, both individually and in combination, can be summarized as follows:

Closed bottle tests, adapted for hydrophobic substances, demonstrated that:

- Chlorinated alkanes are far better degradable than previously thought; polychlorinated C_{14} alkanes with up to 50% chlorination even satisfied the criteria for classification as „readily biodegradable" (>60% biodegraded after 28 days).
- Higher chlorinated components that did not reach the 60% biodegradation level still showed some significant oxygen consumption, which indicates that partial biodegradation of components occurred, although full mineralization of all components was clearly not achieved.
- Biodegradability decreases with increasing chlorination level, which means that less densely chlorinated alkanes, or parts of alkane molecules, are biodegraded more easily than higher (more densely) chlorinated (parts of) alkanes. Therefore if an overall "readily biodegradable" result is reached, this indicates that the densely chlorinated recalcitrant fraction is very minor or negligible.

Sequencing batch reactor studies using Cl^- as a tracer confirmed the hypothesis of mineralization. The 40% chlorinated C_{14} alkane was almost completely mineralized, the 50% chlorinated C_{14} alkane reached 60% mineralization and the 60% chlorinated C_{14} alkanes reached about 10% mineralization (measured by the amount of recovered Cl^-). This confirms that higher chlorinated alkanes have larger fractions of the more recalcitrant parts of the component molecules.

Analytical studies were carried out to understand the composition of chemicals in relation to the biodegradation results. The most advanced technique available (GCxGC-ECD) is able to identify in a mixture, specific Cl_x components for individual alkane chains qualitatively, while their quantification has considerable uncertainties. The quantification is dependant on the number and molecular location of chlorine atoms for which no accurate correction is possible yet. More detailed analytical identifications also confirm that more densely chlorinated areas of the molecule are more recalcitrant to biodegradation. This results in an apparent increase in the relative fraction of higher Cl_x components in the samples after biodegradation.

2. Recent Assessment of MCCP Bioaccumulation

A weight of evidence assessment of the available bioaccumulation data, including laboratory and field data was recently done for both the MCCP REACH registration and also presented in a new publication by Dr. Roy Thompson et al. (Thompson 2014). This assessment indicates that, although some MCCP constituents show calculated growth-corrected BCFs that exceed regulatory criteria, MCCP is not likely to biomagnify in fish and aquatic food webs. The summary below highlights the key information for MCCP from this assessment.

Bioconcentration Factors (BCF):

The most reliable BCF value for an MCCP component is approximately 1,000 for a C_{15} 51% Cl substance. This falls below the regulatory criterion for bioaccumulation defined in Annex XIII of REACH which has threshold values of 2,000 and 5,000 L/kg for PBT and vB substances, respectively. Although in one case a BCF of over 5000 has been found for one MCCP component, a C_{14} 45% Cl substance, this component has also been shown to be readily biodegradable so it is not a PBT.

The primary biotransformation rate constant (k_M) has been identified as a key determinant for the bioaccumulation assessment of MCCP (Arnot 2013). There is no notable trend in differences in k_M for the range of carbon length and chlorine substitution included in available test data on MCCP and medium chain length polychlorinated alkanes (MC-PCA) which suggests that additional testing on individual components of MCCP may not provide any "new" information based on the BCF assessment metric.

Biomagnification Factors (BMF) and Trophic Magnification Factors (TMF):

Measured laboratory and field BMF values for MCCP range from 0.1-0.96 and all available TMF values for MCCP are also <1 (a value of >1 is indicative of bioaccumulation). Based on the tiered framework for bioaccumulation assessment put forward by Gobas et al. (2009), field measurements such as TMFs and BMFs are considered more convincing evidence for bioaccumulation behavior than laboratory-based BCFs. The current weight of evidence indicates that expected MCCP constituents are not likely to biomagnify in fish or in aquatic food webs based on laboratory and field biomagnification factors (BMFs) and field trophic magnification factors (TMFs), respectively.

Given these data, CPIA believes that any analogy to MCCP for vLCCP must consider that while lower chlorinated CP substances may have somewhat greater capacity to bioaccumulate – though bioaccumulation will also decrease significantly with increasing carbon chain length – these same lower chlorinated CPs show a greater potential to biodegrade. In fact, MCCP constituents up to 50% chlorination have been found to be readily biodegradable and therefore are not PBTs[4]. Higher chlorinated MCCP constituents also showed significant potential to biodegraded though the results did not reach the "ready" criteria. Perhaps even more telling is the fact that field studies have not shown MCCP to biomagnify across trophic levels (Thompson 2014). CPIA believes that vLCCP, which is less soluble in water and less bioavailable than MCCP, with have even less potential to move up through the troposphere and biomagnify. This conclusion was similarly reached by the OECD (OECD 2009), the U.K. Environment Agency (EA 2009), and the European Chemical Bureau (ECB) PBT Working Group (ECB 2007).

III. Concerns with Proposed vLCCP Sediment/Fate Testing Approach

CPIA is concerned that EPA‟s proposed testing approach for vLCCP in the proposed SNUR (Attachment A) fails to consider the highly complex nature of these LCCP/vLCCP (UVCB[5]) substances and the analytical limitations inherent to this complex composition. For example,

---

[4] Substances that meet ALL of the criteria for being **P**ersistent, **B**ioaccumulative, and **T**oxic.

[5] UVCB substances are chemical substances of **U**nknown or **V**ariable composition, **C**omplex reaction products and **B**iological materials.

even a single carbon-chain length straight-chain[6] chloroalkane, will have tens of thousands or more possible isomers. Tomy (1997) calculated that for a C_{13} chloroalkane at 60% chlorination by weight, the total number of possible isomers is 3549, even assuming no more than one chlorine atom bound to an individual carbon atom. This number of theoretical isomers more than doubles with each added carbon number, suggesting that by C_{21}, the lowest carbon chain-length that EPA has proposed testing, this test material could have hundreds of thousands of possible isomers.

This isomeric complexity is inherent to the manufacturing process of CPs. Chlorination of an n-alkane to produce a CP involves the substitution of hydrogen atoms along the carbon chain with chlorine atoms. This chlorine substitution process occurs with low selectivity with alkanes such that controlling the exact location of the chlorine atom substitution is impossible. Chemical dynamics do suggest a somewhat lower likelihood of adjacent carbon atoms being chlorinated or terminal CH_3 groups being chlorinated; however, given the much lower ratio of chlorine atoms to carbon atoms in CPs this still leaves many thousands of possible isomers. While the overall level of chlorination can be controlled (on average mass basis), it is impossible to control the exact location of the chlorine substitution along the carbon chain.

Given the complexities of the proposed test substances, there simply is no analytical means of identifying "individual congeners and degradation products" of these test substance or any vLCCP length chloroalkane test material. This means that there are not appropriate and reliable analytical methods with "sufficient accuracy and sensitivity" to conduct several of the test methods that EPA has proposed. For example, the OECD 307 test methods states that there needs to be available "analytical methods (including extraction and clean-up methods) for quantification and identification of the test substance and its transformation products." These analytical methods do not exist for vLCCP.

In addition to analytical chemical limitations, there are physical limitations that prevent vLCCP components from being able to be tested reliably using the OECD 302A or OECD 302B test guidelines. Both these tests measure the removal of the substance from the water phase. Assessing biodegradability is therefore only possible when the test substance is water soluble and does not adsorb significantly. Both of these guidelines require test substances (see below) which are soluble in water (at least 20 mg dissolved organic carbon/l) (OECD 302A) or in the case of OECD 302B at least 50 mg DOC/l. The water solubility of vLCCP is ≤ 5 µg/L or four orders of magnitude below the requirements for these tests.

SCAS - OECD 302A Guideline

The method is applicable only to those organic test substances which, at the concentration used in the test are soluble in water (at least 20 mg dissolved organic carbon/liter).

---

[6] CPIA notes that given the "branched and linear" nature of several of the SNUR materials, it is unclear whether the test materials designated are exclusively linear or a combination of branched and linear chloroalkanes. It should be noted that Tomy (1997) specifically mentions that any branched material would "add to the complexity" in regards the number of isomers present in the substance.

Zahn Wellens - OECD 302B Guideline
Applicability of the method. Chemicals which are nonvolatile and are soluble in water to at least 50 mg DOC/L may be assessed by this method, provided also that they do not significantly adsorb, are not lost by foaming and do not inhibit bacteria at the concentration tested.

This limited solubility and highly sorption to the organic material in the test systemwas identified as large confounder in previous biodegradation tests of LCCP. If the test substance remains isolated from the inoculum due to limit solubility little can be learned from the test.

IV. Conclusion

CPIA believes that existing information on LCCP/vLCCP is adequate for assessment the environmental risk of vLCCP. Existing aquatic toxicity data indicate that these substances do not adversely affect aquatic organisms even when tested at concentrations an order of magnitude or higher above the water solubility limit. This conclusion was stated in the OECD SIDS Initial Assessment Profile (SIAP) of LCCP:

> $C_{20\text{-}30}$ *liquid and solid LCCPs are of low concern for the environment based on their low hazard profiles… Adequate screening-level data are available to characterize the environmental hazard for the purposes of the OECD HPV Chemicals Programme.*

In addition, current guidance from manufacturers indicates that vLCCP substances should not be released to surface water and/or poured down the drain. When this guidance is applied to exposure models, the predicted releases levels to surface water and corresponding concentrations in sediment are below the levels concern.

Before EPA considers any new testing on vLCCP or any CP product, CPIA suggest that EPA work with CPIA and the CP manufactures to establish the best methods for CP chemical analysis and the limitations of those methods as they apply to environmental tests. There this nothing to be gained by doing studies whose results are either not valid or impossible to interpret. As such, CPIA does not feel EPA should move forward with these testing efforts until this issue is resolved.

Please do not hesitate to contact me with any questions or need access to any of the referenced materials. I can be reached by email at ajaques@regnet.com or by phone at 202-419-1504.

Best Regards,

Andrew M Jaques

Andrew Jaques

References

Arnot, Jon. 2013. Comments on Preliminary Bioaccumulation Assessment of Medium Chain Chlorinated Paraffins (MCCPs): Prepared for the MCCP REACH Consortium. April 30, 2013.

Environment Agency (EA). 2009. Environmental Risk Evaluation Report: Long-Chain Chlorinated Paraffins. January 2009.

European Chemicals Bureau (ECB) PBT Working Group. 2007. Results of the Evaluation of the PBT/vPvB Properties of Paraffin waxes and Hydrocarbon waxes, chlor; EC number 264-150-0; CAS number 63449-39-8. PBT List No. 110. September 11, 2007.

Organization for Economic Cooperation and Develop (OECD). 2009. SIDS Initial Assessment Report (SIAR) and SIDS Initial Assessment Profile (SIAP) for Long Chain Chlorinated Paraffins (LCCPs). Reviewed and approved at SIAM-29, October 20-23, 2009.

Thompson, Roy and Martin Vaugh. 2014. Medium-chain chlorinated paraffins (MCCPs): A review of bioaccumulation potential in the aquatic environment. Integrated Environmental Assessment and Management. Volume 10, Issue 1, pages 78–86, January 2014.

Tomy, Gregg T.; Gary A. Stern, Derek C. G. Muir, Aaron T. Fisk, Chris D. Cymbalisty, and John B. Westmore. 1997. Quantifying C10-C13 Polychloroalkanes in Environmental Samples by High-Resolution Gas Chromatography/Electron Capture Negative Ion High-Resolution Mass Spectrometry. Analytical Chemistry 69: 2762-2771.

Attachment A

EPA vLCCP Testing Program as Specified in the Proposed SNUR

Phase	**Test**	**Substances**
1 (due 1.2 million kg or 9 months)	Analysis for chain length and weight % Cl; GLP report; *additionally, report "all ,raw data"for congener analysis"*	All commercial vLCCP products
2a (due before 14.1 million kg of 4 yrs, 4 mos)	Inherent biodegradation study – highly modified SCAS (OPPTS 835.3210/835.5045 or OECD 302a) or Zahn Wellens (OPPTS 835.3200 or OECD 302B) – *with analytical procedures capable of measuring individual congeners and degradation products over time.*	9 test substances: - C_{21} (40, 55,>70% Cl) - C_{26} (40, 55, >70% Cl) - $C_{\text{product average}}$ (40, 55, >70% Cl)
2b (due before 59.1 million kg or 12 yrs, 8 mos)	Bioaccumulation in Sediment-dwelling Benthic Oligochaetes (OECD 315)	9 test substances: - C_{21} (40, 55,>70% Cl) - C_{26} (40, 55, >70% Cl) - $C_{\text{product average}}$ (40, 55, >70% Cl)
2b (due before 59.1 million kg or 12 yrs, 8 mos)	Aerobic and anaerobic soil metabolism studies (OECD 307) – *with analytical procedures capable of measuring individual congeners and degradation products over time.*	9 test substances: - C_{21} (40, 55,>70% Cl) - C_{26} (40, 55, >70% Cl) - $C_{\text{product average}}$ (40, 55, >70% Cl)
3 (due before 78.4 million kg or 15 yrs, 5 mos)	Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233) OR Sediment-Water *Lumbriculus* Toxicity Test Using Spiked Sediment (OECD 225)	TBD – For any of the parent substances in Phase 2b testing that are absorbed by the Benethic Oligochaetes
3 (due before 78.4 million kg or 15 yrs, 5 mos)	Bioaccumulation in Sediment-dwelling Benthic Oligochaetes (OECD 315)	TBD – For any of the degradation products in Phase 2a or 2b that are identified to potentially present an unreasonable risk or to further degrade to generate a substance of potential concern
4 (due before 86.1 million kg or 16 yrs, 5 mos)	Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233) OR Sediment-Water *Lumbriculus* Toxicity Test Using Spiked Sediment (OECD 225)	TBD – For any of the degradation substances in Phase 3 testing that are absorbed by the Benethic Oligochaetes

ATTACHMENT B

LCCP REACH Consortium

Review of Long Chain Chlorinated Paraffin (LCCP) Aquatic Toxicity Data in the REACH Dossier (EC 264-150-0) and the Classification of LCCP under the CLP Regulation:

Response to ECHA Decision number CCH-D-0000003881-71-03/F (13 December 2013)

Background

On 13 December 2013, ECHA issued a final decision (CCH-D-0000003881-71-03/F) to the lead registrant (ICC Industries, B.V.) of Long Chain Chlorinated Paraffin (LCCP) regarding the aquatic classification of LCCP under the CLP regulation. This paper was developed in response to this decision letter and provides a concise, yet comprehensive, summary of the LCCP aquatic data in the REACH dossier and a detailed rationale for the lack of aquatic hazard classification for LCCP.

In its decision letter, ECHA asked that the LCCP registration dossier be updated to include the classification of Aquatic Chronic Hazard Category 1. The basis for this classification is given solely in the following sentence from the decision letter:

> *"The technical dossier includes aquatic chronic toxicity studies indicating a NOEC or equivalent value equal to or lower that 0.01 mg/l which is consider reliable by the Registrant (Klimisch score 1 or 2)."*

The decision letter also states:

> *"In the alternative, the Registrant is required to provide reasons why no such classification is given."*

The Consortium and LCCP registrants believe that dossier did already clearly state why no aquatic classification was given to LCCP. In Section 6, Ecotoxicological Information, Conclusion on classification, Environmental classification justification, the dossier states:

> *"Based on the lack of effects in environmental organisms at or below the water solubility limit, LCCPs are not classified as dangerous to the environment."*

The current LCCP dossier did not expand on this justification, although the data are provide in the dossier (see Table 1 below). To alleviate any confusion on this point, the Consortium has provided an enhanced justification below.

LCCP Substance

LCCP is a highly complex UVCB substance and includes several sub-classes/grades within the REACH dossier. Because of this, LCCP test materials are often described with both their carbon number range (e.g. C_{20}-C_{30}) and their chlorination level by weight (e.g. 50% Cl wt.) since these are the two main chemical descriptors of every LCCP.

ATTACHMENT B

LCCP Water Solubility

LCCP products have incredibly low water solubility. As detailed in the registration dossier, water solubility estimates range from 5 x10^{-3} µg/L to 6 µg/L and some estimates are even lower. There is no single right answer for the water solubility of LCCP as it varies from study to study based on the test conditions of the study, the specific LCCP product being tested, and the analytical measurement techniques being employed. This is a critical point to understand since some LCCP aquatic study results are reported as the nominal or loading rate and others are based on an analytical measurement of the test material in solution.

In general, all of the LCCP aquatic toxicity studies are run at the absolute maximum water solubility limit due to the extremely low water solubility limit of LCCP. Studies are generally conducted by developing a water accommodated fraction (WAF) using a slow stirring method over an extended period. Free LCCP, test material not in the solution, should be avoided in the test system.

In order to fully evaluate the LCCP aquatic data one must look at the results for each study based on how the data were reported and what (if any) solubility limit was determined for that study.

Role of Water Solubility in Aquatic Classification

The CLP regulation clearly mentions the importance of evaluating water solubility in conjunction with the aquatic data. For example in Note 4 to Table 4.1.0 (EU no 286/2011), the regulation states:

> *"No acute toxicity" is taken to mean that the L(E)C50(s) is/are above the water solubility. Also for poorly soluble substances, (water solubility < 1 mg/l), where there is evidence that the acute test does not provide a true measure of the intrinsic toxicity.*

Further, Table 4.1.0 also notes that the basis for NOT classifying a substance for chronic aquatic toxicity can be evidence that "includes chronic toxicity NOECs > water solubility."

These statements are further supported and clarified in the various CLP guidance that ECHA has produced including the most recent November 2013, *Guidance on the Application of the CLP Criteria* (version 4.0). This document specifically states:

> *Although not used directly in the criteria, the water solubility and stability data are important since they are a valuable help in the data interpretation of the other properties.*

Review of LCCP Aquatic Data for CLP Classification

Table 1 shows a wide range of reported levels for LCCP aquatic toxicity studies. However, there is one commonality between all of these studies – no aquatic effects were observed at or below the water solubility of LCCP (as determined in that study). While some of these values are quite low, that is the value reported as the water solubility level determined for that study. For example, the Hooftman (1993) chronic daphnia study reported no statistically significant effects on daphnia reproduction over the 21-day test period at the limit of water solubility.

The value reported for this study - 2 µg/L - is simply the estimated water solubility limited determined for that study. It worth noting that the Hooftman results provided in the report were difficult to interpret, so a detailed statistical analysis of the actual study results was developed by Dr. Roy Thompson (see Appendix 1).

Based on these available studies, and including their water solubility level determinations, one can only reasonably conclude that LCCP is NOT classifiable as hazardous to the aquatic environment.

Table 1: Summary of LCCP Aquatic Toxicity Results in REACH Dossier
February 2014

IUCLID Section	Endpoint	Reference	Key Study	Test Material	Result	Reliability
Acute Fish Studies						
6.1.1	Fish: Acute	Howard 1975		C18-20, 39% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Johnson and Finley 1980		C18-20, 39% Cl	>300 mg/L	3
6.1.1	Fish: Acute	Hoechst 1976		C18-20, 35% Cl	400 mg/L	2
6.1.1	Fish: Acute	Hoechst 1976		C18-20, 35% Cl	400 mg/L	3
6.1.1	Fish: Acute	Hoechst 1976		C18-20, 44% Cl	500 mg/L	3
6.1.1	Fish: Acute	HRC/ICI 1982		C18-20, 44% Cl	500 mg/L	3
6.1.1	Fish: Acute	Hoechst 1976		C18-20, 49% Cl	>500 mg/L	2
6.1.1	Fish: Acute	Hoechst 1976		C18-20, 49% Cl	>500 mg/L	3
6.1.1	Fish: Acute	Hoechst 1977		C18-20, 52% Cl	>500 mg/L	2
6.1.1	Fish: Acute	Mayer 1986		C>20, 38-47% Cl	>300 mg/L	4
6.1.1	Fish: Acute	Mayer 1986		C>20, 38-47% Cl	>300 mg/L	4
6.1.1	Fish: Acute	Howard 1975		C20-30, 40% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Howard 1975		C20-30, 40% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Madeley 1980		C20-30, 42% Cl	>770 mg/L	2
6.1.1	Fish: Acute	Linden 1979		C22-26, 42% Cl	>5000 mg/L	2
6.1.1	Fish: Acute	Howard 1975		C22-26, 48-50% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Howard 1975		C22-26, 48-50% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Johnson and Finley 1980		C22-26, 70% Cl	>300 mg/L	2
6.1.1	Fish: Acute	Howard 1975		C22-26, 70% Cl	>300 mg/L	2
Chronic Fish Studies						
6.1.2	Fish: Chronic	Bentsson 1979	Key Study	C18-26, 49% Cl	>0.125 mg/L	2
6.1.2	Fish: Chronic	Zitko 1974		C20-30, 42% Cl	N/A	3
6.1.2	Fish: Chronic	Madeley 1983	Key Study	C22-26, 43% Cl	>=4 mg/L	2
6.1.2	Fish: Chronic	Madeley 1983	Key Study	C20-30, 70% Cl	>=3.8 mg/L	2
Acute Aquatic Invertebrate Studies						
6.1.3	Invert: Acute	Frank 1993	Key Study	C18-20, 52% Cl	EC0 = 0.36 mg/L	2
6.1.3	Invert: Acute	Frank 1994		C18-20, 52% Cl	EC0 >0.026-0.877 mg/L	2
6.1.3	Invert: Acute	Thompson 2005	Key Study	C20-30, 43% Cl	EC0 = 5.1 mg/L	2
6.1.3	Invert: Acute	Hoechst 1984		C18-27, 60% Cl	NOEC=23 mg/L	3
6.1.3	Invert: Acute	Hoechst 1984		C18-27, 60% Cl	NOEC=45 mg/L	3

6.1.3	Invert: Acute	Hoechst 1984		C18-27, 60% Cl	NOEC=100 mg/L	3
6.1.3	Invert: Acute	Hoechst 1984		C18-27, 60% Cl	NOEC=100 mg/L	3
Chronic Aquatic Invertebrate Studies						
6.1.4	Invert:Chronic	Frank 1993-1994		C18-20, 52% Cl	NOEC = 29-33 µg/L	2
6.1.4	Invert:Chronic	Hooftman 1993		C18-20, 52-56% Cl	NOEC = 2 µg/L	2
6.1.4	Invert:Chronic	Hoechst 1984		C18-27, 60% Cl	NOEC = 4.2 mg/L	4
6.1.4	Invert:Chronic	Sharpe 2007	Key Study	C>20, 43% Cl	55 µg/L	1
6.1.4	Invert:Chronic	Madeley 1983	Key Study	C22-26, 43% Cl	NOEC= 2.18 mg/L	2
6.1.4	Invert:Chronic	Madeley 1983	Key Study	C20-30, 70% Cl	NOEC=1.33 mg/L	2
Aquatic Algae Studies						
6.1.5	Algae	Craigie 1975		C20-30, 50% Cl		3
6.1.5	Algae	Thompson 1997	Key Study	MCCP; 52% Cl	NOEC - 0.1 mg/L; LOEC = 0.18 mg/L	1

Statistical review of:

TNO REPORT: IMW-R 93-018
"Semi-static reproduction test with chlorinated paraffins and *Daphnia magna*
(OECD Guideline no. 202)". Hooftman R N & Henzen L (1993)

The above TNO report describes concurrent testing of 3 chlorinated paraffins, including Hordaflex LC50 which is a long-chain chlorinated paraffin (C_{18-20}, approx 52% chlorinated). The work was sponsored by Hoechst AG, Germany who also provided the test substance samples. It is understood that the sample of Hordaflex LC50 was from the same batch as that used for the *Daphnia* work by Frank (1993) and Frank & Steinhauser (1994), although documentation of this has not been located.

In summary, the TNO study, which was GLP compliant and performed to the (then) current OECD Guideline, determined the survival and reproduction of *Daphnia* exposed for 21 days to saturated solutions of the CPs produced using saturation columns, with two controls consisting of dilution water alone ("DSWL") and dilution water passed through an untreated saturation column ("DSWL Column control", hereafter termed "Column control").

For Hordaflex LC50, there was no significant effect (P = 0.05) on survival (93% compared with 98% in both controls). However, the report contains contradictory statements regarding the statistical analysis of the reproduction data:

On Page 7 (Summary), it states "*The reproduction of the surviving animals in Chlorparaffin [„Hoechst 52 flüssig'] and Hordaflex LC50 was significantly less than in the control at ... p = 0.05* ". For Hordaflex LC50 this is also shown as a footnote to the summary table (Page 8) which indicates that it was the Column control that was used for the statistical comparison, (although the same table does not indicate a significant difference for „Hoechst 52 flüssig‟ despite the fact that this treatment gave lower reproduction than Hordaflex LC50).

However, in the main report text (Page 16) the report states "*The reproduction rate of the surviving animals in the saturated solutions of Chlorparaffin Hoechst 52 flüssig and Hordaflex LC50 was less than in the control but not significantly different from the control reproduction*".

To clarify this contradiction, the report data have been analysed by Brixham Environmental Laboratory, AstraZeneca. The TNO report provides the following raw data for reproduction, based on 4 replicates per treatment, each containing 10 (parent) *Daphnia*:

Replicate	Number of young born per living female (Ny/Nf)			
	DSWL control	Column control	**Hordaflex LC50 (C18-20)**	Hoechst 52 flüssig
A	130.9	134.6	90.5	127.0
B	106.4	140.6	93.5	101.5
C	111.3	126.1	103.6	97.7
D	105.9	107.7	115.7	72.9
Mean	113.63	127.25	100.83	99.78
% DSWL control	(100)	112.0	88.7	87.8
% Column control	89.3	(100)	79.2	78.4

(„Hoechst 56 flüssig‟, a short-chain CP, was also tested but reproduction in this treatment was zero and so this was not included in the statistical analysis).

The above data were analysed using MINITAB® for Windows® (Release 14.1). The data was found to be normally distributed and the variances were homogeneous, satisfying the requirements for the use of ANOVA (with Dunnett‟s procedure to maintain a family error rate of 0.05) to determine significant differences from the Column control (Appendix 1).

This showed that there were no significant differences from the Column control in any of the treatments, including the DSWL control, at the 5% significance level.

Because the differences from the Column control were greater than those from the DSWL control, this analysis also shows that there was no significant difference in reproduction between the Hordaflex LC50 treatment (or the „Hoechst 52 flüssig‟) and either of the controls.

The TNO report states that, as here, Dunnett‟s procedure was used to analyse the data (but with no details given) and therefore the same conclusion would have been obtained (and was probably that which was intended).

Normally, when 2 different controls are tested, the most extreme from the treatments is first used for the comparison and, if no significant differences are obtained, this also demonstrates no differences against the other control (as above). However, if differences are found against the first control, then the second control would normally be used for comparison. If this gave different conclusions, then a comparison against the "pooled" controls might be made*. This comparison against pooled controls has now been performed (Appendix 2) and showed no significant difference (p = 0.05) between Hordaflex LC50 (or „Hoechst 52 flüssig‟) and the pooled control data.

* Whilst the Column control could be considered the most appropriate, there is no *a priori* expectation or explanation of better reproduction than the DSWL control. Unlike for example a solvent control, which might theoretically either reduce or enhance reproduction, the Column control might only be expected to inhibit reproduction, for example from contaminants introduced (or essential elements removed) by the Chromosorb or stainless steel in the columns. Hence there would be a strong case for using pooled controls IF the different controls had given different conclusions.

Conclusions:

- Analyses to examine the contradictory statistical statements in the TNO report showed that a saturated solution of Hordaflex LC50 caused no significant (P = 0.05) inhibition of reproduction compared with either of the controls or with the pooled control data
- This suggests that the intended (correct) conclusion of the TNO report regarding Hordaflex LC50 was that given in the second sentence of Section 3.6
- This is supported by Table 1 of Section 3.6 which indicates that the reproduction value for „Hoechst 52 flüssig‟ (CP 52), which was lower than that for Hordaflex LC50, was "not significantly less than control reproduction"
- Hordaflex LC50 showed no effect on survival or reproduction of *Daphnia* at the limit of water solubility which was measured as 2 to 3 µg/l (1.0 to 1.5 µg EOX/litre)

Roy S Thompson

Attachment B – Appendix 1

Note: Hordaflex LC50 is abbreviated to 'HLC' in the following report

Minitab Project Report

```
Welcome to Minitab, press F1 for help.
Executing from file: \\ukbxapp01\Minitab14\MACROS\STARTUP.MAC
Minitab Release 14.1
```

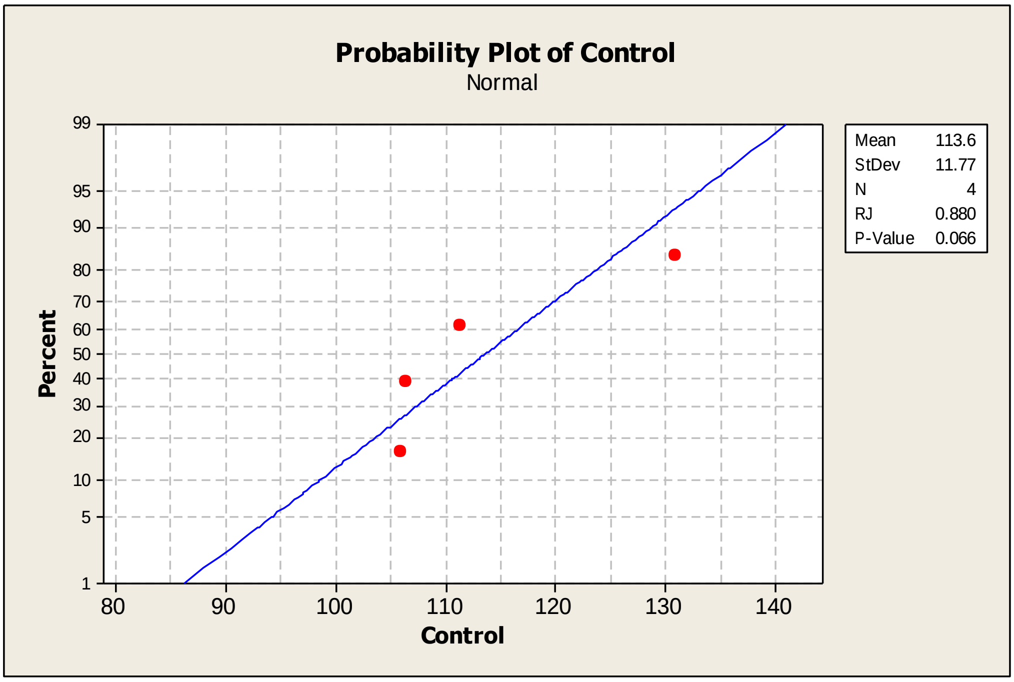
Data

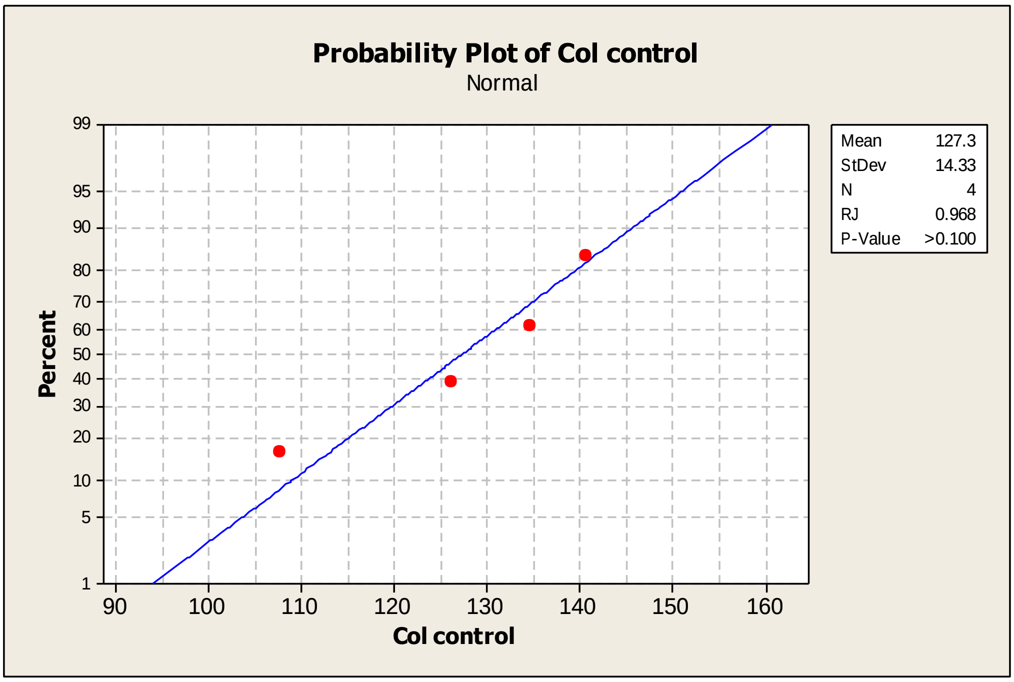
```
Control       Col control   HLC           H52 flussig
130.9         134.6         90.5          127.0
106.4         140.6         93.5          101.5
111.3         126.1         103.6         97.7
105.9         107.7         115.7         72.9
```

Descriptive Statistics: Control, Col control, HLC, H52 flussig

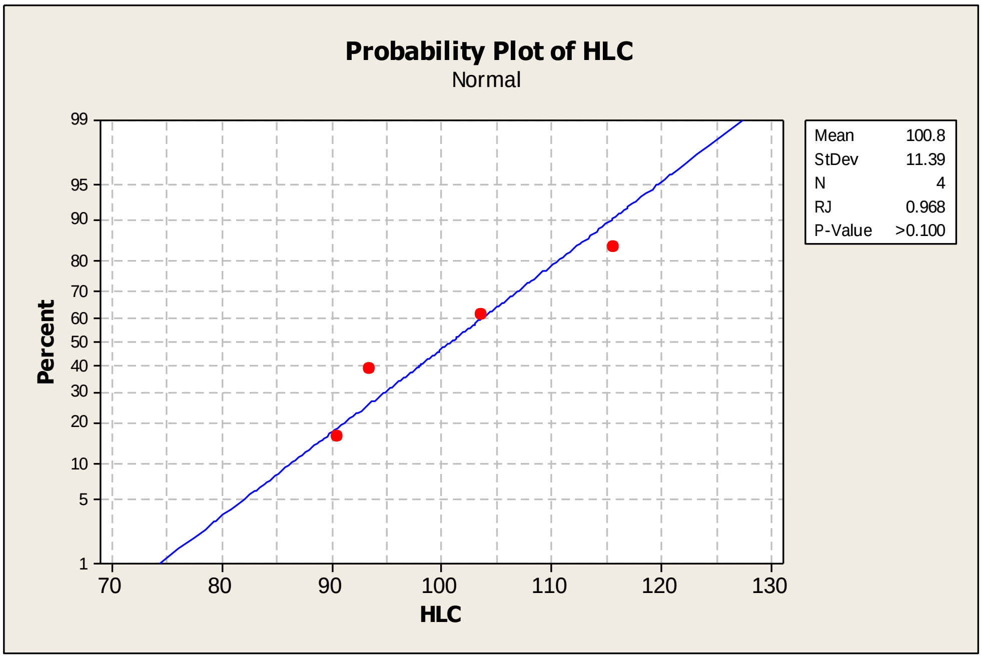
```
Variable     N  N*    Mean  SE Mean  StDev  CoefVar  Minimum  Maximum
Control      4   0  113.63     5.89  11.77    10.36   105.90   130.90
Col control  4   0  127.25     7.16  14.33    11.26   107.70   140.60
HLC          4   0  100.83     5.70  11.39    11.30    90.50   115.70
H52 flussig  4   0    99.8     11.1   22.1    22.19     72.9    127.0
```

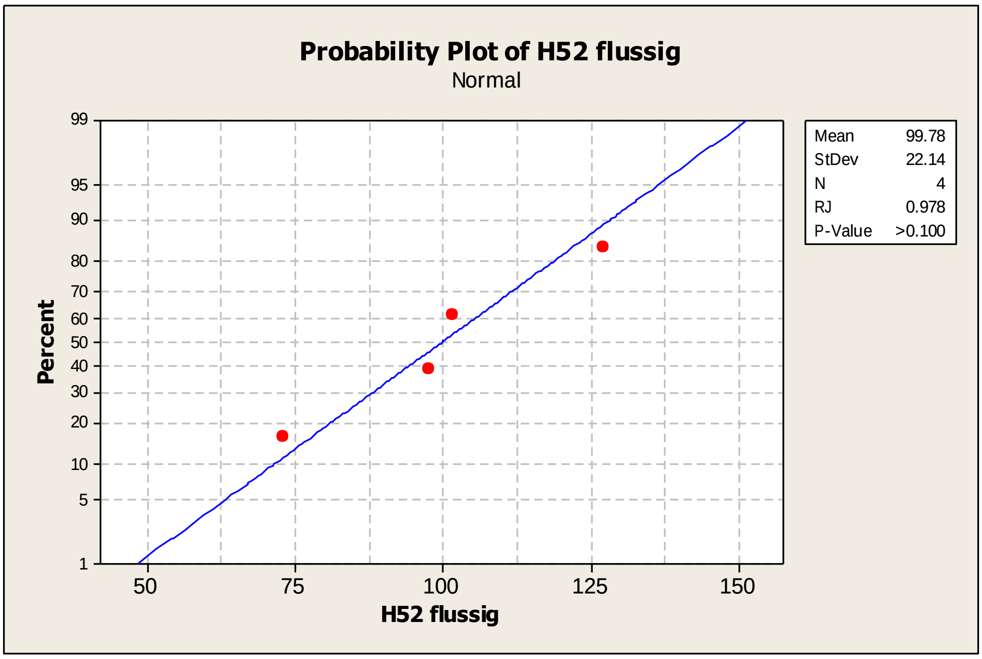
TESTING FOR NORMALITY





Attachment B – Appendix 1





Conclusion: p-value is greater than 0.05 for all data columns, therefore data are normally distributed

TESTING FOR HOMOGENEITY OF VARIANCE

Results for: Stacked data

Test for Equal Variances: C2 versus Subscripts

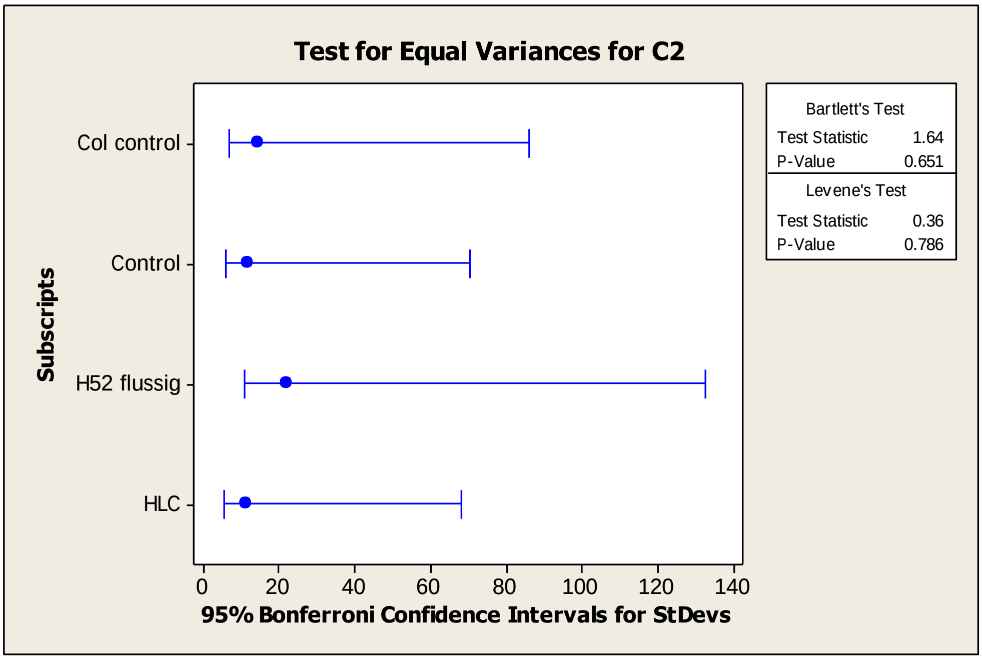
```
95% Bonferroni confidence intervals for standard deviations

 Subscripts  N    Lower    StDev    Upper
Col control  4   7.0587  14.3268   85.916
    Control  4   5.7997  11.7715   70.593
H52 flussig  4  10.9089  22.1416  132.781
        HLC  4   5.6120  11.3905   68.307


Bartlett's Test (normal distribution)
Test statistic = 1.64, p-value = 0.651


Levene's Test (any continuous distribution)
Test statistic = 0.36, p-value = 0.786
```

Test for Equal Variances: C2 versus Subscripts



Conclusion: by both tests, p-value is greater than 0.05, therefore data are homogeneous

Having satisfied criteria for normality and homogeneity of variance, ANOVA is suitable for analysis

TESTING FOR DIFFERENCES FROM COLUMN CONTROL (ANOVA with DUNNETT'S) Results for: Worksheet 1

One-way ANOVA: Control, Col control, HLC, H52 flussig

```
Source  DF    SS   MS     F      P
Factor   3  1996  665  2.76  0.088
Error   12  2891  241
Total   15  4887

S = 15.52   R-Sq = 40.83%   R-Sq(adj) = 26.04%


                               Individual 95% CIs For Mean Based on
                               Pooled StDev
Level        N    Mean  StDev  --------+---------+---------+---------+-
Control      4  113.63  11.77          (----------*----------)
Col control  4  127.25  14.33                   (----------*---------)
HLC          4  100.83  11.39  (----------*----------)
H52 flussig  4   99.78  22.14  (---------*----------)
                               --------+---------+---------+---------+-
                                      96       112       128       144

Pooled StDev = 15.52


Dunnett's comparisons with a control

Family error rate = 0.05
Individual error rate = 0.0199

Critical value = 2.68

Control = Col control

Intervals for treatment mean minus control mean

Level         Lower  Center  Upper  --------+---------+---------+---------+-
Control      -43.07  -13.62  15.82        (--------------*--------------)
HLC          -55.87  -26.43   3.02  (--------------*--------------)
H52 flussig  -56.92  -27.47   1.97  (-------------*--------------)
                                    --------+---------+---------+---------+-
                                          -40       -20         0        20
```

Conclusion: Intervals for treatment mean minus control mean include zero, therefore no significant differences from the Column Control

Attachment B – Appendix 1

POOLED CONTROLS

```
Welcome to Minitab, press F1 for help.
Retrieving project from file:
'\\ukbxfp01\usermd$\kqgb035\Chlorparaffins\Daphnia screens 04\TNO Daphnia
Stats.MPJ'
```

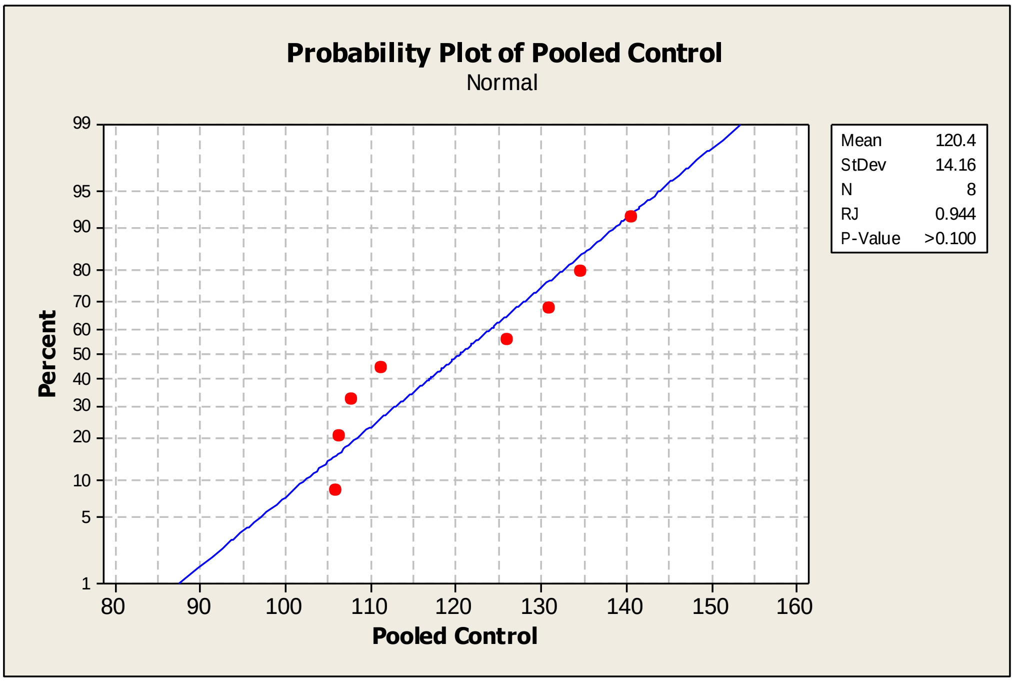
Data Display

```
                 H52   Pooled
Row    HLC   flussig  Control
  1    90.5    127.0    130.9
  2    93.5    101.5    106.4
  3   103.6     97.7    111.3
  4   115.7     72.9    105.9
  5                     134.6
  6                     140.6
  7                     126.1
  8                     107.7
```

Descriptive Statistics: Pooled Control, H52 flussig, HLC

```
Variable         N  N*    Mean  SE Mean  StDev  CoefVar  Minimum  Maximum
Pooled Control   8   0  120.44     5.00  14.16    11.75   105.90   140.60
H52 flussig      4   0    99.8     11.1   22.1    22.19     72.9    127.0
HLC              4   0  100.83     5.70  11.39    11.30    90.50   115.70
```

TESTING FOR NORMALITY



Conclusion: p-value is greater than 0.05, therefore data are normally distributed

Attachment B – Appendix 1

TESTING FOR HOMOGENEITY OF VARIANCE
Results for: Stacked data (pooled)

Test for Equal Variances: C2 versus Subscripts

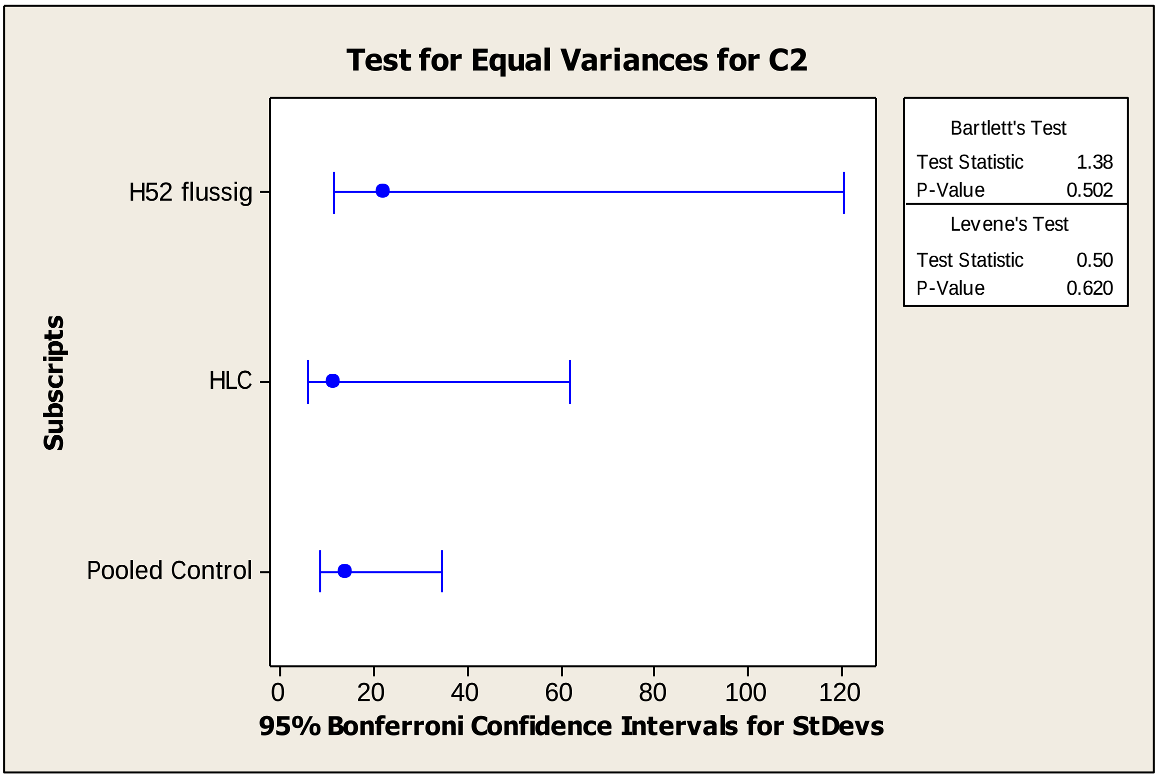
```
95% Bonferroni confidence intervals for standard deviations

    Subscripts  N    Lower    StDev    Upper
   H52 flussig  4  11.1932  22.1416  120.423
           HLC  4   5.7582  11.3905   61.950
Pooled Control  8   8.6029  14.1561   34.670


Bartlett's Test (normal distribution)
Test statistic = 1.38, p-value = 0.502


Levene's Test (any continuous distribution)
Test statistic = 0.50, p-value = 0.620
```

Test for Equal Variances: C2 versus Subscripts



Conclusion: by both tests, p-value is greater than 0.05, therefore data are homogeneous

Having satisfied criteria for normality and homogeneity of variance, ANOVA is suitable for analysis

TESTING FOR DIFFERENCES FROM POOLED CONTROL (ANOVA with DUNNETT'S)
Results for: Worksheet 1

One-way ANOVA: HLC, H52 flussig, Pooled Control

```
Source  DF    SS   MS     F      P
Factor   2  1624  812  3.24  0.072
Error   13  3263  251
Total   15  4887

S = 15.84   R-Sq = 33.24%   R-Sq(adj) = 22.97%


                                  Individual 95% CIs For Mean Based on
                                  Pooled StDev
Level           N    Mean  StDev  -----+---------+---------+---------+----
HLC             4  100.83  11.39   (----------*-----------)
H52 flussig     4   99.78  22.14  (-----------*----------)
Pooled Control  8  120.44  14.16                   (-------*-------)
                                  -----+---------+---------+---------+----
                                      90       105       120       135

Pooled StDev = 15.84


Dunnett's comparisons with a control

Family error rate = 0.05
Individual error rate = 0.0266

Critical value = 2.50

Control = Pooled Control

Intervals for treatment mean minus control mean

Level         Lower  Center  Upper    +---------+---------+---------+---------
HLC          -43.86  -19.61   4.63     (---------------*---------------)
H52 flussig  -44.91  -20.66   3.58    (---------------*---------------)
                                      +---------+---------+---------+---------
                                    -45       -30       -15         0
```

Conclusion: Intervals for treatment mean minus control mean include zero, therefore no significant differences from the Pooled Control

Sediment PNC Derivation from UK Environment Agency January 2009 LCCP Assessment

4.1.9.2 PNEC *for sediment*

There are no toxicity data available for LCCPs on sediment-dwelling organisms. In the absence of any ecotoxicological data, the PNEC can provisionally be calculated using the equilibrium partitioning method as follows.

$$PNEC_{sed} = \frac{K_{susp\text{-}water} \times PNEC_{water} \times 1000}{RHO_{susp}}$$

where $K_{susp\text{-}water}$ = suspended matter-water partition coefficient
= 2.27×10^6 m^3/m^3 for $C_{18–20}$ liquid chlorinated paraffin
= 6.93×10^6 m^3/m^3 for $C_{>20}$ liquid chlorinated paraffin
= $>2.5 \times 10^8$ m^3/m^3 for $C_{>20}$ solid chlorinated paraffin
RHO_{susp} = bulk density of suspended matter = 1,150 kg/m^3

Using this equation, the following $PNEC_{sed}$ can be derived:
$C_{18–20}$ liquid chlorinated paraffin $PNEC_{sed}$ = 5,710 mg/kg wet wt.
$C_{>20}$ liquid chlorinated paraffin $PNEC_{sed(screening)}$ = 33,100 mg/kg wet wt.
$C_{>20}$ solid chlorinated paraffin $PNEC_{sed(screening)}$ = >1,200,000 mg/kg wet wt.

These PNECs assume that the exposure, and hence effects of the substance, occurs mainly via sediment pore water. The ingestion of sediment-bound substance by the exposed organisms may not be sufficiently explained by this relationship for substances with a log Kow >5. The TGD suggests that in such cases, the PEC/PNEC ratio should be increased by a factor of 10.

Toxicity tests using medium-chain chlorinated paraffins with sediment organisms (*Chironomus riparius, Hyalella azteca* and *Lumbriculus variegatus*) have been carried out (Thompson *et al.*, 2001a, 2001b and 2002). The lowest NOEC for these species was 50 mg/kg wet wt. obtained for both *Lumbriculus variegatus* and *Hyalella azteca* in a sediment with a 4.9–5 per cent organic carbon content. A $PNEC_{sed}$ of 5 mg/kg wet wt. was derived from these data using an assessment factor of 5 (ECB, 2005a). This was very similar to the $PNEC_{sed}$ of 12.6 mg/kg derived for medium-chain chlorinated paraffins using the equilibrium partitioning method (the value is different by a factor of 2.6). At least some of the difference between the two values could be explained by the fact that the NOECs underlying both PNEC determinations depend to some extent on the actual concentrations and concentration intervals used in the various tests. Similar agreement is also evident in a comparative study of the toxicity of different medium-chain chlorinated paraffins to soil organisms (see Section 4.2). Taking these results into account, the equilibrium partitioning method appears to be appropriate for medium-chain chlorinated paraffins and direct ingestion of sediment-bound substance is only a minor contributor to the toxicity seen for this class of substance.

However, LCCPs are predicted to adsorb onto sediment to a greater extent than medium-chain chlorinated paraffins and so it is possible that direct ingestion of sediment-bound substance could become a more important route of exposure for these substances than was seen in the experiments with medium-chain chlorinated paraffins.

Therefore, the PEC/PNEC ratios based on the equilibrium partitioning method will be increased by a factor of 10 to take this possibility into account in this assessment.