



Independent Lubricant Manufacturers Association

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March 21, 2016

Via Regulations.Gov

Dr. Maria Doa
Director, Chemical Control Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Chlorinated Paraffins: Request for Available Information on PMN Risk Assessments, Docket Identification Number: EPA-HQ-OPPT-2015-0789

Dear Dr. Doa:

The Independent Lubricant Manufacturers Association¹ (“ILMA” or “Association”) submits these comments regarding the Environmental Protection Agency’s (“EPA” or “Agency”) pending review of the Pre-Manufacture Notices (“PMNs”) for medium-chain chlorinated paraffins (“MCCPs”) and long-chain chlorinated paraffins (“LCCPs”) submitted by Dover Chemical Corporation, INEOS Chlor Americas (now INOVYN Americas, Inc.), and Qualice, LLC.

While ILMA appreciates the opportunity to comment² on the risk assessments for MCCPs and LCCPs, EPA must review these chemicals as existing substances under Section 6 of the “Toxic Substances Control Act” (“TSCA”). ILMA consistently has raised its concerns with EPA’s treatment of MCCPs and LCCPs as new chemical substances given the historic and on-going use of the chemicals for decades and the Agency’s efforts to regulate these materials over the same time. Indeed, EPA previously announced in 2012 its intention to review MCCPs and LCCPs under its TSCA Work Plan that would include an appropriate comment period and independent scientific peer review

¹ ILMA is national trade association with 338 member companies. As a group, ILMA members blend, compound, and sell over 25 percent of the United States’ lubricant needs (e.g. passenger car motor oils) and nearly 80 percent of the metalworking fluids utilized in the country. Independent lubricant manufacturers by definition are neither owned nor controlled by companies that explore for or refine crude oil to produce lubricant base stocks or that produce chemical additives. Base oils are purchased from refiners, who also are competitors in the sale of finished products. Additives are purchased from suppliers, who also may be competitors in the sale of finished products. ILMA members succeed by processing, producing, and distributing high-quality, often specialized, lubricants.

² In addition to these comments, ILMA also is a party to the comments submitted by the coalition of affected industries.

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of the Agency's conclusions.³ The importance of this cannot be understated because of the immense cost associated with a regulatory ban,⁴ the difficulties of reformulation,⁵ and the "critical uses" for which no replacement exists.⁶ In a prior submission to EPA, ILMA estimated the cost of replacement to metalworking fluid ("MWF") formulators and their customers to be in excess of \$69 billion dollars.⁷ This cumulative cost alone is significantly above the \$500 million "highly influential scientific assessment" threshold that requires independent peer review according to Office of Management and Budget ("OMB")⁸ policy. Further, the Agency's own Peer Review Handbook acknowledges the necessity of independent peer review in this situation.⁹ Therefore, EPA should complete its review of MCCPs and LCCPs under its 2012 TSCA Work Plan.

The Risk Assessments

The *Federal Register* Notice (80 Fed. Reg. 79886 (December 23, 2015)) ("FR Notice") states "EPA is requesting new available data on chlorinated paraffins. . . in different industries and for different uses, to inform the risk assessments for chlorinated paraffins submitted as Toxic Substances Control Act (TSCA) Pre-Manufacture Notices (PMNs)." The risk assessments address the following PMNs:

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)

Given the similarities in the PMN submissions from Dover, INOVYN, and Qualice, and the Agency's Standard Review Risk Assessments ("Risk Assessments") for those submissions, these comments refer collectively to the Risk Assessments. In the Risk Assessments, the Agency stated numerous times that "due to the uncertainty at multiple downstream use sites, the most conservative data were chosen." ILMA understood that

³ See EPA 2012 Work Plan for MCCPs and LCCPs.

⁴ See ILMA Letter to Greg Schweer (July 24, 2015).

⁵ See ILMA Letter to Greg Schweer (June 10, 2015).

⁶ See ILMA Letter to Greg Schweer (September 10, 2015).

⁷ EPA's regulatory action will have a significant economic impact on an array of other U.S. industries as well.

⁸ See OMB's "Final Information Quality Bulletin for Peer Review."

⁹ See EPA Peer Review Handbook Section 1.3.3 "What is the Office of Management and Budget's Peer Review Bulletin, and How Does It Relate to Peer Review at EPA?"

initially the Agency opted to rely upon conservative data sets for its inputs as a result of those “uncertainties.”

In order to better inform EPA’s Risk Assessments, ILMA provided data on use of MCCPs and LCCPs in MWFs on several occasions in 2015. This information is highly relevant and specific to EPA’s Risk Assessments and includes data on use and disposal practices¹⁰ of 30 ILMA member companies that utilized over eight million of pounds of MCCPs and LCCPs in their MWF formulations in 2014.¹¹ In the FR Notice, EPA acknowledges receipt of “information from the Independent Lubricant Manufacturers Association.” However, despite acknowledged receipt of these data from ILMA, EPA has done nothing to augment its conservative assumptions. Further, and as a result, the Agency has created Risk Assessments that do not accurately portray the environmental risks of these substances. More troubling still, the Agency has yet to signal that it will consider the data that ILMA provided in 2015 in order to develop more accurate and real-world risk scenarios for MCCPs and LCCPs.

EPA must reevaluate its Risk Assessments, and, at a minimum, change the assumptions in its models where ILMA has provided data that reflect actual conditions. The survey results from the Association’s members should supersede the inputs EPA elected to use in its Risk Assessments regarding MWF formulators. ILMA provided data for EPA’s use, and the Agency has an obligation to use the best available information and data in its Risk Assessments.

EPA’s Risk Assessments are Fundamentally Flawed

ILMA’s survey indicated that members purchased 7,943,773 pounds of MCCPs and 1,664,500 pounds of LCCPs in 2014¹². Of the total pounds purchased in 2014, ILMA members utilized those MCCPs and LCCPs as extreme pressure additives in the following fluid formulations:

Fluid Type	Pounds of MCCP or LCCP Used
Straight Oil	2,847,420 lbs. of MCCPs
Straight Oil	1,098,347 lbs. of LCCPs
Water Soluble	2,908,500 lbs. of MCCPs
Water Soluble	203,172 lbs. of LCCPs
Semi-Synthetic	1,324,143 lbs. of MCCPs
Semi-Synthetic	3,000 lbs. of LCCPs
Synthetic	10,924 lbs. of MCCPs

¹⁰ For a more detailed “process” description that describes how the substances are handled, used, and disposed of see Appendix G and H.

¹¹ These are the most current data that were available to submit to EPA in advance of the deadline.

¹² These numbers are inclusive of the pounds purchased by the ILMA members that participated in the survey.

Synthetic	0 lbs. of LCCPs
Other	196,868 lbs. of MCCPs
Other	323,072 lbs. of LCCPs

While the survey did not capture the totality of MCCPs and/or LCCPs use in MWF formulations, it is representative of approximately 50 percent of the MCCPs and LCCPs used in MWFs and is statistically significant.

Of significant concern to ILMA is the Agency's election to use 776 total downstream use sites¹³ for many of its models. The survey reveals that ILMA members sold straight oil MWFs that contained MCCPs and/or LCCPs in the formulation to 2,652 facilities. Further, water-dilutable MWFs that contained MCCPs and/or LCCPs were sold to 3,748 end-users, and ILMA members sold both fluids to 2,383 customers in 2014. While ILMA believes that MWFs that contain MCCPs and/or LCCPs were sold to an even greater number of downstream sites than the survey revealed, the data set clearly represents a more realistic assessment of the total number of end-users of MWFs that contain MCCPs and/or LCCPs in the United States. As EPA undoubtedly understands, even increasing the number of sites from 776 to the several thousand from the survey significantly changes the fluid use concentration and distributes it more evenly to all end-users as opposed to dividing it among the unrealistically-low and artificial number of 776 sites EPA used in its Risk Assessments. Further, ILMA understands that the Organization for Economic Cooperation and Development's ("OECD") Emission Scenario Document ("ESD") assumed that "approximately 89,000 MP&M (metal products and machinery industry) sites operate in the United States." ILMA, therefore, requests that EPA revise its risk assessment number of 776 end-user sites to a more appropriate number of *at least* 8,783.

EPA's Assumed Release Pathways for MWF Formulators Are Problematic

The section in EPA's Risk Assessments that pertain to the formulation of MWFs that contain MCCPs and/or LCCPs make a number of assumptions regarding disposal practices via incineration, wastewater, and landfill that are overly conservative. While ILMA's survey did not ask members to detail the disposal practices as it related to specific sources, it asked for the overall poundage of MCCPs and LCCPs that were purchased and subsequently discharged. The survey details the overall volume of MCCPs and LCCPs that were discharged from formulation sites and is representative of current industry practices. Therefore, the survey data should be used to override every input EPA elected to use for the MWF formulation sections in its Risk Assessments.

ILMA contends this method is consistent with the Agency's own desired approach as EPA stated "[d]ue to the large number of customers and potential sites where the notification substances could be used, specific use information for each site could not be

¹³ EPA-HQ-OPPT-2015-0789-0016-2.pdf "Standard Review Risk Assessment on Medium-Chain Chlorinated Paraffins and Long-Chain Chlorinated Paraffins" for Dover Chemical Corporation.

obtained.” ILMA appreciates that the Agency, out of necessity, opted to use conservative assumptions in its Risk Assessments initially due to that lack of data. The Association further appreciates that EPA declared its desire in the FR Notice to use specific and reliable data from industry to better inform the inputs. The Association has now filled that specific data gap, and EPA should use the specific, reliable survey results instead of the Agency’s conservative inputs.

For example, it is instructive that despite the over nine million pounds of MCCPs and LCCPs purchased by ILMA members in 2014, only 750 pounds total of MCCPs and LCCPs were discharged in 2014 to a POTW, a *de minimis* amount. Also in 2014, only 7,740 pounds were disposed of via landfill and 34,318 pounds were disposed of via incineration. In contrast, the Agency used the following release parameters in its Risk Assessments, assuming that “at least 2 to 3% 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.” The Agency further presumed that “[t]hese water discharges do not assume any on site treatment.”

Table 1: EPA Model Inputs

Source	Apparent U.S. EPA Emission Factor Used in E-FAST	Frequency	U.S. EPA Basis
Equipment cleaning losses of liquids from a mixing tank	2% (Water)	38 days/year	EPA/OPPT Multiple Process Vessel Residual Model
Cleaning liquid residuals from drums used to transport raw material	~0.7% (Water)	35 days/year	EPA/OPPT Drum Residual Model
Cleaning liquid residuals from totes, tank trucks and rail cars	0% Note: Release of 0.5% estimated, but not included in modeled water concentration.	12 days/year	EPA/OPPT Bulk Transport Model

The Agency noted that the “results of these emissions factors that can be seen below in Table 2 were the estimated concentrations in the water. EPA’s target safe concentration is 1 µg/L – which is exceeded at all estimated concentrations.”

Table 2: EPA Environmental Modeling Results

Source	Scenario 1: 35 days/year	Scenario 2: 38 days/year
Emission Factor to Water Used in E-FAST		
Equipment cleaning losses of liquids from a mixing tank	2%	2%
Cleaning liquid residuals from drums used to transport raw material	~0.7%	--
Cleaning liquid residuals from totes, tank trucks and rail cars	--	--
<i>Total</i>	<i>2.7%</i>	<i>2%</i>
Predicted Surface Water Concentration (µg/L)		

7Q10 – 10 th Percentile	299	219
Harmonic Mean – 10 th Percentile	59	43
Harmonic Mean – 50 th Percentile	8.1	5.9
PDM Days Exceeded	35	38

ILMA fails to understand why the Agency continues to utilize flawed assumptions in its modeling when actual data provided by ILMA as described above shows that that little, if any, MCCP or LCCP makes its way to water via direct or indirect discharge.

The Agency’s End-User Discharge Assumptions are Problematic

ILMA also challenges the assumptions that the Agency elected to use in its Risk Assessments regarding discharges to water from users of MWFs. Aside from the significant undercounting of facilities actually using MWFs that contain MCCPs and/or LCCPs (Agency estimate of 776 compared to ILMA estimate of *at least* 8,783), ILMA contends that current Clean Water Act (“CWA”) regulations prohibit both direct and indirect dischargers from discharging more than *de minimis* amounts of oil into water.

In the Agency’s analysis of Environmental Exposure Monitoring, the following are the release factors that EPA assumed. In total, these emission factors assume that approximately “90 to 95% of the total MCCP or LCCP is discharged to water, including mass contained on filter media and cleaning losses.” Incredibly, despite the Agency’s own rules under the CWA which prohibit users from doing so, the Agency assumes that “[t]hese water discharges do not assume any on-site treatment.”

Table 1: 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	~3.4% (water)	218 days/year	EPA/OPPT Drum Residual Model
Filter media and other recycling waste	~35% (water)	247 days/year	Emission scenario document for MWF (2011)
Spent metal working fluid	~46% (water)	247 days/year	Emission scenario document for MWF (2011)

Using these flawed assumptions, the Agency concluded that the emission factors (shown in Table 2 below) would result in EPA’s target safe concentration of 1 µg/L being exceeded at all estimated concentrations.

Table 2: EPA Environmental Modeling Results

Source	Scenario 1: 218 days/year	Scenario 2: 247 days/year
Emission Factor to Water Used in E-FAST		
Dragout Losses	11%	11%

Cleaning liquid residuals from drums used to transport raw material	3.4%	--
Filter media and other recycling waste	35%	35%
Spent metal working fluid	45%	46%
<i>Total</i>	<i>94%</i>	<i>90%</i>
Predicted Surface Water Concentration (µg/L)		
7Q10 – 10 th Percentile	652	629
Harmonic Mean – 10 th Percentile	80	70
Harmonic Mean – 50 th Percentile	5.7	5.5
PDM Days Exceeded	218	247

On April 27, 2015, the Chlorinated Paraffins Industry Association (“CPIA”) submitted comments to the Agency, which included a summary of applicable CWA regulations. ILMA abstracts the following comments from that letter to illustrate its point:

The Clean Water Act (CWA) includes specific regulations for direct dischargers from metalworking fluid formulators and metal parts and machining operations, including 40 CFR Part 403 and local POTW regulations for then-current (in 2003) direct and indirect dischargers¹⁴, Part 438¹⁵ regulations for new direct dischargers of oily waste under the Metal Parts and Machinery Point Source Category and Part 433¹⁶ regulations for Metal Finishing Point Source Category. Other MCCP-containing MWF users are governed by 40 CFR Part 471, Non Ferrous Metals Forming.¹⁷ All of these regulations strictly limit oil and grease (O&G) discharges from these facilities, which include any MCCP and LCCP residuals that might be present in the oils and greases. For example, under Part 438.12, total O&G discharges from metalworking facilities are limited to 46 mg/L, maximum daily. Similarly, Part 433.13, O&G discharges are limited to 26 mg/L on average and 52 mg/L maximum. Discharge permits also often include mass limits, such as that of one discharger under Part 471 whose permit allows only 6.672 pounds per day in the wastewater discharged. And, while that facility’s permit allows discharge of up to 100 ppm of O&G, their normal discharge contains non-detectable amounts of total oil and grease as analyzed by EPA Method 1664A.

The CPIA letter further included these comments:

There are also discharge limits under the CWA regulations for publicly owned treatment works (POTWs) that receive wastewater from facilities. These limits include O&G of 38 mg/L on average and 127 mg/L maximum, under Part 437.21.

¹⁴ 68 Federal Register 25735 May 13, 2003

¹⁵ 40 CFR 438: SUBCHAPTER N—EFFLUENT GUIDELINES AND STANDARDS; PART 438—METAL PRODUCTS AND MACHINERY POINT SOURCE CATEGORY.

¹⁶ 40 CFR 433: SUBCHAPTER N—EFFLUENT GUIDELINES AND STANDARDS; PART 433 - METAL FINISHING POINT SOURCE CATEGORY.

¹⁷ 40 CFR 471: SUBCHAPTER N – EFFLUENT GUIDELINES AND STANDARDS; PART 471 – NON-FERROUS METAL FORMING CATEGORY

POTWs will apply their own local limits to facilities that discharge to the POTWs. And, while a daily maximum is the maximum daily effluent concentration without incurring a violation, exceedance of the monthly average may also be cause for violation, as many POTW's will site sources for exceedance of the monthly average if there are more than one analysis in a month. Often, a self-monitoring analysis report and the POTW's quarterly inspection analysis in the same month provides the data to generate a violation for the exceedance of the monthly average.

It is worth noting that MCCP and LCCP are readily soluble in n-hexane so Method 1664¹⁸, which is used to determine O&G discharges, will capture all MCCP and LCCP constituents. This method does not speciate chlorinated paraffins from the other O&G components; however, any MCCP or LCCP constituents in the total O&G discharge are expected to be relatively minor since they are small components even in most water-dilutable MWFs.

On-site wastewater treatment usually consists of either oil/water separation or ultrafiltration, typically followed by chemical precipitation and sedimentation. Ultrafiltration is more effective at removing oils (including emulsions) and organic constituents that are present in metalworking fluids.

For a variety of reasons (*e.g.*, non-disclosure agreements) quantitative information has been hard to obtain; however, ILMA believes that all end-users of MWFs that contain MCCPs and/or LCCPs adhere to the CWA regulations that apply to their facilities or to the appropriate local POTW regulations that limit oil discharges. As such, and in view of the fact that a MWF that contains MCCPs and/or LCCPs is only small portion of the oily waste processed and treated by any MWF user, ILMA sees virtually no possibility that any MWF end-user would discharge MCCP and/or LCCP-containing oil waste directly to water as the Agency assumes. Therefore, the Agency's environmental exposure modeling scenarios for both MWF formulators and for MWF users are fundamentally and fatally flawed and must be revised.

New U.S. Environmental Monitoring Data for MCCPs and LCCPs is Needed

EPA's position is that data gaps exist in the environmental monitoring section of its Risk Assessments. The Agency notes, "[t]he majority of the monitoring data were collected in Europe, and some more recent monitoring data were collected in China. Over time and across countries, industrial practices and effluent pre-treatment standards have varied." ILMA agrees with EPA's conclusion that effluent pre-treatment standards and industrial practices vary depending upon the jurisdiction. Nonetheless, it is significant that nearly

¹⁸EPA Method 1664, Revision A: N-Hexane Extractable Material (HEM; Oil and Grease) and Silica Gel Treated N-Hexane Extractable Material (SGT-HEM; Non-polar Material) by Extraction and Gravimetry.

all monitoring data that EPA included in the Risk Assessments are below the Agency's concentrations of concern ("CoC") for water and sediment.¹⁹

EPA further acknowledges the current limitations and shortcomings of the data set utilized for the environmental monitoring portion of its Risk Assessments:

The industrial sectors studied by other countries also are present in the US, suggesting that conditions may be similar. Even though the existing monitoring data were limited in quality and quantity, and it remains unclear how well the measured data describe the potential range of US MCCP and LCCP use scenarios . . . These data provide some evidence that MCCPs and LCCPs are released in to the environment; however, *these data reflect discrete locations and times, and the extent to which they are representative of the overall distribution of MCCPs and LCCPs is unknown.* [Emphasis added.]

Given that ILMA does not believe EPA's current conclusions are appropriately based upon correct monitoring information, the Association recommends that U.S. water and sediment monitoring be done. This project would be beneficial for EPA to understand current levels of these substances in the environment. Further, assuming current levels in the environment are below EPA's CoCs, it would demonstrate that current handling practices are appropriate and that these substances are not persistent in the environment. Additionally this would ensure that the Agency's conclusions are rooted in current U.S.-based monitoring data.²⁰

ILMA believes that water monitoring would clearly show that MCCP and LCCP emissions are extremely low, if not undetectable. Moreover, while there is a potential for analyses of sediments to show other chlorinated organic materials, with proper precautions taken in the methodology used, it should be possible to differentiate between MCCP and LCCP residues, if any indeed are found, from other chlorinated organic materials.

Industry Needs a Timeline

Because EPA elected to review MCCPs and LCCPs as "new chemicals" under the PMN process, this has created significant confusion within the marketplace. All throughout the supply chain there is uncertainty as to the prospective availability of these substances. Industry does not operate on a month-to-month basis. In order to remain competitive, MWF formulators undertake long-term strategic planning that accounts for a multitude of variables (including government regulation) to ensure their business model remains viable for the next five or ten years. Because EPA's PMN review exclusively involves an interaction between the PMN submitters and the Agency, there is no ability for

¹⁹ See CPIA May 2015 review of monitoring data.

²⁰ MCCP and LCCP have been used in the U.S. for over 70 years and, as such, monitoring data will both capture current releases and any material that has persisted in the environment.

downstream users of those products to gather concrete information regarding the current and prospective regulatory status of the chemicals. This creates significant issues for all segments of the supply chain. As a result, ILMA requests that EPA provide an outline of next steps once the March 23, 2016 comment deadline passes. This will equip MCCP and LCCP users with the requisite understanding of EPA's process so that they may interact with suppliers and customers on an informed basis.

Conclusion

ILMA shares EPA's commitment to sound process and the accurate utilization of appropriate data to inform the scientifically-grounded assessment for potential hazards to human health and the environment that a chemical substance may or may not present. Therefore, EPA should utilize the data already provided to the Agency in the Association's June 10, 2015 letter and subsequently redo the models that pertain to the MWF formulation sections of the Risk Assessments. This re-analysis, combined with the additional data that will be provided from other user groups, should provide for a more robust, scientifically sound data set for use in EPA's Risk Assessments for MCCPs and LCCPs.

EPA must then commence an independent scientific peer review and provide for public comment on these substances as outlined in the Agency's 2012 TSCA Work Plan for MCCPs and LCCPs. This will hopefully ensure appropriate, scientifically-based conclusions are drawn from accurate data and information.

Sincerely,



Holly Alfano
Chief Executive Officer

cc: Ken Moss, Team Leader, Notice and Regulations Management Team
ILMA Board of Directors
ILMA SHERA Committee
ILMA Metalworking Fluid Committee
Andrew Jaques, Executive Director, Chlorinated Paraffins Industry Association
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