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October 31, 2024

VIA EMAIL (Soliman.Sarah@epa.gov) and ONLINE (<https://www.regulations.gov>)

Ms. Sarah K. Soliman  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

**RE: Request for Comment Regarding Pre-Prioritization and Consideration of Existing Chemical Substances for Future Prioritization Under the Toxic Substances Control Act (TSCA) [Docket No. EPA-HQ-OPPT-2023-0606]**

Dear Ms. Soliman:

The Independent Lubricant Manufacturers Association (ILMA or Association) submits these comments on the Environmental Protection Agency's (EPA) pre-prioritization and prioritization process for certain chemical substances under the Toxic Substances Control Act (TSCA). Based on the discussion below, ILMA recommends that medium-chain and long-chain chlorinated paraffins (MCCPs and LCCPs) be given a Low-Priority Substance designation.

ILMA represents over 300 lubricant manufacturers, suppliers, and distributors. The Association's members produce more than three-quarters of the metalworking fluids (MWFs) sold in North America. Many of these MWFs contain MCCPs and LCCPs as extreme pressure additives to cut, draw, and shape metals. ILMA members have extensive experience with these substances and their use in formulating MWFs. The Association has worked with EPA and international agencies to demonstrate how its members and their customers responsibly use MCCPs and LCCPs.

For purposes of TSCA Section 6, chemicals that "may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use"<sup>1</sup> are prioritized for risk evaluations. Conversely, substances that do not meet the standard for high-priority are designated as low-priority substances, for which risk evaluations are not warranted at the time.

Based on the factors that guide prioritization screening decisions, EPA should designate MCCPs and LCCPs as low-priority substances. After all, EPA already has determined in its

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<sup>1</sup> 15 U.S.C. § 2605(b)(1)(B).

President: **Richard Camper**, Pacific Precision Formulators  
Immediate Past President: **Catharine Golden**, Etna Products, Inc.  
Treasurer: **David Richards**, RichardsApex, Inc.  
General Counsel: **Jeffrey L. Leiter**

Vice President: **James Carroll**, Schaeffer Manufacturing Co.  
Secretary: **Tom Schroeder**, Axel Americas, LLC  
Chief Executive Officer: **Holly Alfano**

significant new use rule (SNUR) issued pursuant to TSCA Section 5 that MCCPs and LCCPs, under their conditions of use in MWFs and other applications, do not pose an unreasonable risk to health and the environment. Since EPA is already managing risks under this SNUR for MCCPs and LCCPs, such that other or new circumstances will not occur absent notification to the Agency, there is no need for EPA to prioritize these chemical substances as high priority for evaluation under TSCA Section 6. ILMA comments further:

**I. The Risk-Based Preferential Criteria for Prioritization Indicate that MCCPs and LCCPs Should be Designated as Low-Priority Substances.**

MCCPs and LCCPs do not meet the conjunctive, preferential standard for prioritization. Pursuant to TSCA Section 6(b)(2)(D), when designating high-priority substances, EPA shall give preference to chemicals listed in the 2014 TSCA Work Plan for Chemical Assessments that:<sup>2</sup>

- (i) have a Persistence and Bioaccumulation Score of 3; *and*
- (ii) are known human carcinogens and have high acute and chronic toxicity

While MCCPs and LCCPs may have a Persistence and Bioaccumulation Score of 3 for their persistent and bioaccumulative properties, these chemical substances are not “known” carcinogens with “high” acute or chronic toxicity. Simply, EPA should not apply the joint preferential test to these chemical substances because they fail to meet the second prong of the Agency’s two-prong test.

*a. EPA Found the Health Risks Associated with MCCPs and LCCPs to be Low.*

ILMA urges EPA to guide its prioritization screening decision with its own finding that MCCPs and LCCPs are not associated with high carcinogenic, acute, or chronic risks. In other words, because these CPs do not meet risk-based preferential criteria, EPA should designate them as low-priority substances under TSCA Section 6.

EPA already found that these chemical substances present low health risks. In the 2015 risk assessment of MCCPs and LCCPs conducted pursuant to TSCA Section 5, EPA concluded that “there were low risks found to humans from environmental releases via exposure to drinking water or fish ingestion.”<sup>3</sup> Additionally, the Agency concluded that “there were low risks found for workers from either dermal or inhalation exposures” and consumers from dermal exposure.<sup>4</sup> These

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<sup>2</sup> 15 U.S.C. § 2605(b)(2)(D) (emphasis added).

<sup>3</sup> U.S. Environmental Protection Agency, *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)* (Dec. 22, 2015).

<sup>4</sup> *Id.*

conclusions support a low-priority designation, since the chemical substances do not pose a high risk to the general population or susceptible subpopulations.

*b. The Persistent and Bioaccumulative Characteristics of MCCPs and LCCPs Do Not Warrant Preferential Treatment.*

While MCCPs and LCCPs are considered by EPA to be persistent and bioaccumulative (PB) in the environment, the preferential standard requires prioritization for chemical substances that are also “known human carcinogens and have high acute and chronic toxicity.”<sup>5</sup> The legislative history of the statute confirms the textual emphasis on meeting both the PB and toxicity criteria of the standard for purposes of prioritization. After all, Congress was particularly concerned with PB substances “with recognized” toxicity concerns.<sup>6</sup> As mentioned in Section I, MCCPs and LCCPs are not carcinogenic, nor are they associated with high acute or chronic health risks.

Further, EPA already concluded that these chemical substances are adequately regulated under TSCA Section 5, for which they do not present an unreasonable risk to health or the environment. The Agency has been scrutinizing MCCPs and LCCPs through the New Chemicals Review program for many years. The Agency has claimed the authority to control the use, manufacture, and import of these chemical substances as “new” under TSCA Section 5. The regulatory toolbox at the Agency’s disposal to address any environmental risk is robust, including premanufacture notice requirements, significant new use rules, risk management actions, and enforcement. EPA has leveraged its tools under TSCA Section 5 for over a decade. In 2019, EPA explained that the Agency has determined that the “manufacture, processing, distribution in commerce, use and disposal of the [MCCPs and LCCPs] in accordance with the provisions of the TSCA section 5(e) order do not create an unreasonable risk of injury to health or the environment.”<sup>7</sup>

ILMA finds it unnecessary for the Agency to prioritize these chemicals that do not meet the conjunctive preferential standard, and for which risk management actions already exist. Given the chemical substances’ low risk based on carcinogenic, chronic, and acute toxicity associations and with EPA addressing MCCPs and LCCPs under TSCA Section 5, the Agency should designate these chemical substances as low priority for evaluation under TSCA Section 6.

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<sup>5</sup> 15 U.S.C. § 2605(b)(2)(D)(ii).

<sup>6</sup> S. Rep. No. 114-67, at 12 (June 18, 2015).

<sup>7</sup> Significant New Use Rules on Certain Chemical Substances, Fed. Reg. 49040, 49044 (Sept. 18, 2019).

## **II. Environmental Justice and Carbon Reduction Considerations Weigh in Favor of a Low-Priority Designation.**

To determine whether a chemical substance is high or low priority for purposes of TSCA Section 6, EPA also considers other risk-based criteria relevant to the priority screening decision. ILMA encourages the Agency to take into an account that MCCPs and LCCPs do not present environmental justice concerns while contributing to greenhouse gas emissions (GHG) reductions.

EPA's new framework for risk evaluations under TSCA Section 6 imposes a requirement to consider any unreasonable health risk that is disproportionately borne by communities with environmental justice concerns.<sup>8</sup> In its priority determination, the Agency should consider that MCCPs and LCCPs do not have known environmental justice concerns.

Further, another important risk-based environmental factor worthy of consideration is the carbon reduction attributes of MCCPs and LCCPs. An overlooked aspect of the environmental benefits of these CPs is its carbon reduction value downstream. Primarily used in the formulation of MWFs as a cost-effective "extreme pressure" (EP) additive, these chemicals enhance the efficiency of metalworking processes, leading to lower GHG emissions in a wide range of applications.

ILMA members' customers rely on MWFs to prevent excessive wear, friction, and damage to equipment in metalworking operations like cutting, drilling, and grinding. As EP additives, CPs form a protective layer between metal surfaces, improving lubrication under high pressure conditions. By reducing friction and wear between metal surfaces, CPs contribute to energy savings, extend the lifespan of machinery and tools, and, thus, indirectly provide carbon reduction benefits in the manufacturing and metalworking sectors.

## **III. EPA Should Prioritize its Limited Time and Resources in Evaluating Chemicals of High Concern.**

ILMA shares EPA's commitment to the accurate utilization of data to inform risk determinations for potential hazards to human health and the environment under TSCA. In this case, the factors guiding the prioritization determination show that MCCPs and LCCPs should be designated as low-priority substances. These chemical substances do not pose a high health risk, and the environmental risks have been addressed by the Agency for almost a decade under TSCA Section 5. EPA should prioritize its limited time and resources in evaluating chemicals of high concern.

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<sup>8</sup> Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA); 89 Fed. Reg. 37,028 (May 3, 2024).

Ms. Sarah Soliman  
October 31, 2024  
Page 5 of 5

Thank you for your consideration of ILMA's comments.

Sincerely,

A handwritten signature in black ink that reads "Holly Alfano". The signature is written in a cursive, flowing style.

Holly Alfano  
CEO

cc: Robin Dilts, Metalworking Fluids Committee Chair  
Jeffrey Leiter, Esq., General Counsel  
Jorge Roman, Esq., Regulatory Counsel