August 4, 2022

Ms. Ingrid Feustel
Office of Pollution Prevention and Toxics (7404M)
U.S. Environmental Protection Agency (EPA)
1200 Pennsylvania Avenue, NW
Washington, DC 20460–0001
Docket No. EPA-HQ-OPPT-2016-0742

Submitted via Regulations.gov

RE: EPA's Draft Revision to the TSCA Risk Determination for Methylene Chloride

Dear Ms. Feustel:

The Society of Chemical Manufacturers & Affiliates (SOCMA) appreciates the opportunity to submit comments regarding EPA's draft revision of the risk determination for methylene chloride (MCL) under the Toxic Substances Control Act (TSCA).[1]

SOCMA is the national trade association dedicated to the specialty and fine chemical industry. Founded in 1921, SOCMA represents a diverse membership of chemical companies who batch manufacture new and innovative chemistries used in a wide range of commercial, industrial, and consumer products. SOCMA maintains a strong record of member service through programs that maximize commercial opportunities, enhance regulatory and legal compliance, and promote industry stewardship. SOCMA's members also implement ChemStewards®, an EHS&S performance improvement program that is a mandatory component of membership.

SOCMA has a vital interest in ensuring that the risk management rulemaking being undertaken for MCL by EPA minimizes the potential significant economic impacts that the rule could have on its members who use MCL in their chemical manufacturing operations. More broadly, SOCMA has an interest in ensuring that TSCA risk management properly integrates with existing OSHA regulations and industry practices that mitigate risks.

[1] 87 Fed. Reg. 39824 (July 5, 2022).

In these comments, we:

1. Briefly summarize the submissions previously filed in this docket by SOCMA and two of our member companies;
2. Express our continued concern that EPA incorporate monitoring data submitted regarding those two companies into its risk evaluation; and
3. Reiterate our recommendation that EPA's forthcoming risk management rule for MCL
    a. Contain an exclusion for closed systems; and
    b. Rely to the maximum possible extent on the OSHA methylene chloride standard, other applicable OSHA rules, and industry workplace safety and health practices.

I. SOCMA Member Data Regarding Workplace Conditions of Use and Exposures

SOCMA filed comments on November 18, 2020 in connection with the Small Business Advocacy Review (SBAR) conducted for MCL. Two SOCMA member companies participated as Small Entity Representatives (SERs) in the SBAR process. Both companies use methylene chloride as a processing aid. Each company provided responses to EPA's questionnaire, relevant exposure data, and diagrams of their specific manufacturing processes. For EPA's convenience, we attach all those submissions again, and summarize each companies' circumstances briefly:

VanDeMark Chemical is a facility that falls under OSHA's Process Safety Management and the EPS's Risk Management Plan standards. It uses MCL as a reaction medium in a closed system for the production of polycarbonates. The substance is not consumed or incorporated into any chemical formulation; it is captive in a reaction trains that has other hazardous materials/gases, including phosgene. The process is strictly monitored for emissions as a result. The MeCl is recycled and re-used in the system each time the company runs a batch. Therefore, the only points of exposure are when MCL is introduced into the system, or during intervals of maintenance necessitating a line break. Both these activities are covered under well documented standard operating procedures where atmospheric monitoring occurs to ensure engineering controls and/or PPE are matching the potential level of risk to the workforce. Introduction of MCL is conducted mechanically through connections that are pressure tested before the transfer into pressure-rated tank and captive emission control system. Line breaks occur after the system has been purged with nitrogen to remove MeCl residuals, however, PPE can only be downgraded once measurements demonstrate a no-exposure environment has been achieved. It should be noted engineering controls are the primary mechanism that controls exposure and that employees also utilize PPE as a secondary safety measure as part of creating two layers of protection from the chemical hazard(s). Monitoring data demonstrates that ambient air exposures are far below the OSHA Permissible Exposure Limit (PEL) and action level. MCL is an ideal solvent for the company's manufacturing process due to its high vapor pressure and low boiling point, while other alternative solvents have much higher risk profiles, making substitution an unlikely prospect for VanDeMark's specific chemical manufacturing process.

Halocarbon Products Corporation uses MCL as a heat transfer fluid in a closed system for the production of pharmaceuticals, intermediates, and other industrial chemicals. The chemical performs as a heat transfer fluid and is not reacted during manufacturing. As with VanDeMark, the only points of exposure to the substance are from introduction into the system and from line breaks during routine maintenance. For line breaks, the substance is mechanically cleared from the system beforehand using

pressurized nitrogen, with employees utilizing appropriate PPE. Monitoring data shows exposure points are well below the OSHA PEL and action level. The company's manufacturing process was uniquely engineered around the use of MCL as a heat transfer fluid, and would require a full plant redesign with attendant shutdown time if MCL can no longer be used. Alternative substances are also unavailable, as other refrigerants lack the necessary physical properties for the prescribed process conditions and have other problematic environmental risk attributes.

II. As EPA Develops the Risk Management Proposed Rule, It Must Use Monitoring Data Submitted to It in Comments by SOCMA and Its Member Companies

SOCMA and its member SERs provided EPA with relevant exposure data for the draft risk evaluation in their comments on the draft risk evaluation. SOCMA supplied EPA with recent workplace air monitoring data on use of MCL as a reaction medium from two companies, VanDeMark and a manufacturer of active pharmaceutical ingredients (APIs). Halocarbon supplied exposure data via the Halogenated Solvents Industry Association (HSIA). Those submissions are also attached again for EPA's convenience. The data collectively was representative of current uses of MCL as a solvent or heat transfer fluid in a closed-loop manufacturing process, whether it be for pharmaceuticals, intermediates, or other specialty chemicals. However, the final risk evaluation did not incorporate this information when finalizing the risk evaluation. The Response-to-Comments (RTC) document stated that EPA did not consider the data because EPA had removed pharmaceutical production from the risk evaluation under the applicable TSCA exclusion.[2] But VanDeMark does not manufacture pharmaceutical ingredients in its process that uses MCL, and Halocarbon does not exclusively manufacture pharmaceutical ingredients in its process. Thus, EPA should not have excluded the data. Regardless of the exclusion, moreover, the data is still highly relevant for understanding air exposures from facilities in the "processing aid" category.

The RTC document also points back to a section of the final risk evaluation that says that EPA based all of its air monitoring analysis on data from governmental monitoring or published literature. It says nothing about data supplied in comments.[3] The document does, however, state that EPA (i) evaluated MCL workplace air monitoring data collected before and after OSHA issued its MCL standard, and (ii) decided that, since concentrations only dropped by 31-35% when the PEL dropped 90%, EPA might as well lump the data together to get "a more robust data set" – in effect creating a data set with higher values.[4] Problematically, this portion of the risk evaluation concludes by saying:

> EPA has sought additional data regarding exposures, particularly during the public comment phases on the documents preceding the draft version of this risk evaluation (e.g., the methylene chloride Section 6 rule and the problem formulation). With the exception of paint and coating removers, *EPA has not received information to date to indicate that workplace changes have occurred broadly in particular sectors over the past 40 years.*[5]

[2] RTC at 73-74.
[3] *Id.* at 78-79.
[4] See Final Risk Evaluation at 123.
[5] *Id.* at 125.

In its SBAR panel comments, SOCMA expressed its disappointment with the Agency's disregard of exposure data provided by these companies, which represented a transparent and earnest effort to accurately characterize their COU and improve the risk evaluation. TSCA requires EPA, in conducting risk evaluations, to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information *are reasonable for* and consistent with the intended use of the information; [and] (2) the extent to which the information *is relevant for* the Administrator's use in making a decision about a chemical substance or mixture. . . ."[6] The monitoring data supplied by SOCMA and its member companies is the best and most currently available technical information for the purposes of evaluating risk from use of MCL as a processing aid, and is the most reasonable and relevant data for estimating workplace exposures at that category of facilities.

The data submitted by SOCMA and its members is vastly more reasonable, relevant, and newer, than the information which EPA used when it found unreasonable risk for the entire category of processing aid use. The MCL risk evaluation used exposures from the production of cellulose triacetate film as the sole proxy for all of the exposures falling into this broad processing aid category. EPA lists four studies to estimate exposure from this process, one study from 1983 and three from 1999. All of these studies thus predated the compliance date of the 1997 OSHA MCL Standard (2000), and two of them involve non-U.S. workplaces. Collectively, these studies contained over 166 samples, with a central tendency 8-hr TWA of 1,000 mg/m3 – almost 12 times the PEL – and a high-end 8-hr TWA of 1,400 mg/3. EPA obliquely acknowledges the limitations of this data in the risk evaluation, noting that "uncertainties in the analysis include the representativeness of the monitoring data toward the true distribution of inhalation concentrations for the industries and sites using methylene chloride as processing aid."[7] As can be seen, however, EPA was in knowing possession of far more representative data than it used.

In the draft revised risk determination, EPA implies that it would use information of the sort submitted by SOCMA and its members:

> In addition, EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA's evaluation of risk under scenarios that, for example, incorporate use of engineering or administrative controls, or personal protective equipment, serves to inform its risk management efforts. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used to tailor risk mitigation appropriately to address worker exposures where the Agency has found unreasonable risk. In particular, EPA can use the information developed during its risk evaluation to determine whether alignment of EPA's risk management

[6] 15 U.S.C. § 2625(h) (emphasis added).
[7] Risk Evaluation at 492.

> requirements with existing OSHA requirements or industry best practices will adequately address unreasonable risk as required by TSCA.[8]

The scenarios in which SOCMA's members utilize MCL have been "clearly articulated" to EPA, and EPA should "characteriz[e] risks using [those] scenarios . . . to inform [EPA's] risk management efforts." The draft revised risk determination indicates that EPA may "formally supplement[] or revise[]" the final risk evaluation. EPA should also supplement or revise the final risk evaluation to reflect new risk characterizations based on the data submitted by SOCMA and its members. It can do so in parallel with its development of the risk management rule. While it is not legally required to do so, EPA could seek comment on its proposed revisions to the risk evaluation before, or at the same time as, it seeks comments on the proposed risk management rule. It could then finalize both of them together.

SOCMA reminds EPA that it would be arbitrary and capricious for EPA to impose risk management requirements on these companies based on a risk evaluation that fails to reflect the data submitted by SOCMA and its member companies.

III. Regulatory Options for the Use of MCL as a Processing Aid

EPA has at least two ways to substantially ameliorate the burden of any risk management requirements that it imposes on SOCMA's members.

A. EPA Should Provide for a Regulatory Exclusion for Closed Systems

In our comments to the SBAR Panel, SOCMA recommended that the risk management rule contain an exclusion for the use of MCL as a processing aid in a closed system. Both VanDeMark and Halocarbon utilize MCL in closed systems with very minimal exposures, as demonstrated by their documented sampling data. EPA anticipated just such an exclusion when it promulgated the risk evaluation framework rule. The preamble to that rule states:

> EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. For example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only 'de minimis' exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate.[9]

SOCMA reiterates that recommendation now.

B. The Risk Management Rulemaking Can and Should Account for Applicable OSHA Requirements

As noted earlier, EPA states in the draft revised risk determination that

---

[8] Draft Revised Risk Determination at 9.
[9] 82 FR 33726, 33729 (July 20, 2017).

> EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions), [and] EPA can use the information developed during its risk evaluation to determine whether alignment of EPA's risk management requirements with existing OSHA requirements.[10]

SOCMA welcomes this statement, and urges EPA to take this approach in the proposed risk management rule. Obviously, since EPA did not characterize those risks in the final risk evaluation, it will need to supplement or revise the document to reflect this further evaluation.

Based on that evaluation, SOCMA urges EPA, in its risk management rules, either to adopt relevant OSHA requirements or to confirm that compliance with such requirements would satisfy a comparable risk management requirement, whenever possible. This approach has precedent in EPA's Risk Management Plan (RMP) rule, which aligns its process hazard analysis (PHA) requirements with the OSHA Process Safety Management (PSM) standard, its safety information requirements with the OSHA Hazard Communication standard, and its fire prevention and protection requirements with the OSHA Welding, Cutting & Brazing standards.[11]

EPA should also consider letting entities comply with either an Existing Chemical Exposure Limit (ECEL) or exposure control work practices to satisfy the requirements of a risk management regulation. If EPA concludes that an ECEL must be instituted in a manner lower than the OSHA PEL, it should align its requirements with the MCL standard, but with the lower threshold replacing the OSHA 25ppm limit. It should also provide optional engineering and work practice control methods in lieu of the ECEL, which entities could choose to implement to adequately mitigate exposure. This two-pronged approach has strong precedent under OSHA's Respiratory Crystalline Silica (RCS) Standard, which provides that construction employers can either use a control method laid out in Table 1 of the standard, or they can measure workers' exposure to silica and independently decide which controls work best to limit exposures in their workplaces to the PEL.[12]

As discussed in SOCMA's comments to the SBAR panel, both VanDeMark and Halocarbon both use engineering controls, administrative controls, and PPE to reduce MCL exposures to levels well below the OSHA PEL (and the action level). EPA should adopt a risk management rule that recognizes when regulated entities use these advanced workplace safety practices. SOCMA prefers that, if necessary, EPA specify a performance standard that is both flexible and straightforward to implement, rather than imposing prescriptive requirements for particular types of control technology.

Conclusion

SOCMA appreciates the opportunity to comment on EPA's draft revised risk determination for methylene chloride. We look forward to continued involvement and collaboration with EPA on this and other TSCA regulatory efforts. If you have any questions about these comments, please feel free to contact me at rhelminiak@socma.org or 571-348-5107.

---

[10] Draft Revised Risk Determination at 9.
[11] See 40 C.F.R. § 68.67 (a), (f), § 68.48(a)(1), § 68.65, § 68.85(b).
[12] 29 C.F.R. § 1926.1153(c), (d).

Respectfully submitted,

Robert F. Helminiak
Vice President, Legal and Government Relations
Society of Chemical Manufacturers & Affiliates (SOCMA)
1400 Crystal Drive, Suite 630
Arlington, VA 22202