June 29, 2023

The Honorable Dr. Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
United States Environmental Protection Agency
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Comments submitted to www.regulations.gov, Docket EPA–HQ–OPPT–2020–0465; CBI attachments submitted via CDX

Re: Comments of Covestro LLC on *Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA)* (Proposed Rule), 88 Fed. Reg. 28284 (May 3, 2023)

Covestro LLC (Covestro) appreciates the opportunity to provide comments on the proposed methylene chloride risk management rule. Covestro is among the world's leading manufacturers of high-quality polymer materials and their components. These products support a significant amount of downstream manufacturing, which in turn, supports domestic American manufacturers and their highly skilled workforces.

Covestro's products rely on methylene chloride to deliver chemistry solutions for critical applications in high-growth industries such as automotive and transportation, building and living, as well as the electrical and electronics sector. Our polymers are also used in sectors such as life-saving medical devices, sports and leisure, appliances, and health, and in the chemical industry itself. As detailed in these comments, the proposed rule's prohibition on two Conditions of Use (COU) – Industrial and Commercial Use for Plastic and Rubber Products Manufacturing and Industrial and Commercial Use as a Processing Aid – would have an extremely adverse impact on the supply chain and the availability of key materials needed for these important products. Covestro respectfully requests EPA to evaluate the information being provided by Covestro and others and change the regulatory determinations for subsets of these two uses from prohibited to using the Workplace Chemical Protection Program (WCPP).

Covestro's first concern is the proposed prohibition on methylene chloride in polycarbonate manufacturing, a subset of the broader Industrial and Commercial Use for Plastic and Rubber Products Manufacturing. Covestro's second concern is the proposed ban on methylene chloride's use as a closed loop heat exchanger fluid, a subset of the Industrial and Commercial Use as a Processing Aid. As discussed in more detail below, Covestro uses methylene chloride as a heat transfer fluid in a fully enclosed system and has successfully employed stringent procedures to limit exposure to the chemical. Importantly, methylene chloride is used to chill a highly reactive underlying raw material crucial for polycarbonate production. Methylene chloride does not react with this raw material which helps to ensure safe operations, maintains the raw material at the correct temperature, and minimizes the risk of contamination.

The American Chemistry Council (ACC) is also submitting comments on behalf of the U.S. polycarbonate manufacturing industry. Covestro, along with the only other domestic manufacturer of polycarbonate, SABIC Innovative Plastics US LLC, has provided key information and data in support of the ACC's comments. The information contained herein is specific to Covestro's polycarbonate production and is provided in support of the ACC's submission.

In the proposed rule, EPA asked for monitoring data and detailed descriptions of activities involving methylene chloride for COU that could reasonably and safely comply with the WCPP. Covestro's comments, along with the ACC's submission on polycarbonate production, respond to EPA's request. To support our request to change the determination for two uses, we explain the effective design of our processes, protective procedures, and rigorous training programs. We also include industrial hygiene monitoring results that demonstrate our long-standing compliance with the current OSHA methylene chloride limits.

In addition to our safe handling of methylene chloride, these comments address key concerns with the proposed rule's ban on the use of methylene chloride in polycarbonate production and as a heat exchanger fluid. Covestro explains that there are no realistic alternatives for either use and that, unless EPA allows these uses to follow the WCPP requirements, the proposed rule would disrupt an extensive list of critical market applications. The affected industries include medical devices, automotive, electronics, and a range of military, aircraft, and police applications.

I. Covestro's Use of Methylene Chloride in the Interfacial Polycarbonate Production Process is Highly Controlled

One of the Covestro uses of methylene chloride is as a solvent in a continuous outdoor production process of polycarbonate manufacturing. The process is called interfacial polymerization. The process itself is controlled by a distributed control system that opens and closes valves automatically and does not require human intervention to charge materials, such as methylene chloride, into the reaction system. Any potential for exposure is highly controlled.

Interfacial polymerization relies on the reaction mixture forming two distinct phases, and the immiscibility of methylene chloride in water is a key attribute that makes its substitution extremely difficult. The polymerization reaction occurs at the interface between the organic phase and the aqueous phase with the polycarbonate dissolving in the organic phase. After the polymerization is complete, the organic phase is isolated from the reaction mixture. Next, the organic phase is thoroughly washed using dilute acid and several washes with demineralized water, which is a critical step to produce polycarbonate with high purity. The organic solvent, which includes methylene chloride, is removed from the polycarbonate using concentration/devolatilizing techniques at elevated temperature. This evaporated solvent mix is condensed, recycled, and fed back into the methylene chloride mixed solvent feed tank, from which it is fed back into the manufacturing process. The final product is pelletized.

The outdoor methylene chloride storage tank is maintained under a nitrogen blanket to minimize the methylene chloride in the head space. It is equipped with a relief valve, which exhausts any vapor emissions to onsite treatment. All process vessels in polycarbonate manufacturing vent to the same onsite treatment. See Attachment 1 for a copy of the process flow diagram. The only manual operations in the production process with possible exposure to methylene chloride are the following: (1) during the unloading of fresh methylene chloride into the storage tank; (2) sampling of the mixed solvent tank, and; (3) sampling at various sampling points during polycarbonate manufacture. A Job Hazard Analysis (JHA) for the unloading of the fresh methylene chloride (Attachment 2) and sampling (Attachment 3) provides an overview of the steps and the required personal protective equipment (PPE) where chemical exposure is possible. PPE includes a full chemical resistant suit, breathing air, rubber boots, and chemical gloves.

When preparing the process for maintenance, the state air permit (Attachment 4) has concentration limits for volatiles on the emptying and clearing of equipment and lines containing methylene chloride for maintenance activities. Attachment 5 demonstrates how the air permit requirements are implemented and then the line clearing procedure is followed. To protect workers during maintenance activities, employees must wear appropriate PPE (*i.e*., full chemical resistant suit, breathing air, rubber boots, and chemical gloves) for each step in the procedure where chemical exposure is possible (Attachments 6 and 7).

II. Covestro's Use of Methylene Chloride as a Heat Exchanger is in Closed Loop Refrigeration Unit

Another vital use of methylene chloride by Covestro is as a closed loop heat exchanger fluid. In interfacial polymerization, methylene chloride is a key component as it is used to chill one of the raw materials. Since 1975, Covestro has safely used it in a closed loop refrigeration unit. Additional chilling capacity in the system is used for other cooling applications. This is an entirely closed system, is controlled by a distributed control system, and runs continuously. See the process flow diagram at Attachment 8.

The removal of methylene chloride only occurs when the system is brought down for maintenance. During maintenance activities the system is emptied of methylene chloride. See JHA document at Attachment 9. This document lists the appropriate PPE, including a chemical protective suit, breathing air, rubber boots and chemical gloves. Following the removal of the liquid methylene chloride, the lines are cleared under the state operating permit (Attachment 4) and clearing procedure (Attachment 10). The material is not reintroduced back into the system once the maintenance activity is completed; rather, it is transferred to the site recovery system as part of the recycling process. When necessary, fresh methylene chloride is added into the surge tank under a defined and detailed unloading procedure (Attachment 2).

There is no sampling of the methylene chloride in the refrigeration unit. Just as important, no human interaction is required during operation except for adding methylene chloride to the system as needed (Attachment 2).

III. Covestro’s Facility Using Methylene Chloride has Comprehensive Processes to Control Exposure to Methylene Chloride

Both of Covestro’s uses of methylene chloride occur at the same facility and have been safely in use since its startup in 1975. The safe use is attributed to the design of the facility and significant employee protection measures and controls. The facility has a comprehensive written Methylene Chloride Safety Compliance Plan that ensures conformance with the OSHA Methylene Chloride Standard (Attachment 11). This plan includes initial and periodic industrial hygiene monitoring; communication of industrial hygiene results; identification of regulated areas; personal protective equipment (including respirators and dermal protection); and medical surveillance program requirements. In addition to the plan, the site has a web-based training program, which is assigned to workers whose job tasks include the potential for methylene chloride exposure. These workers are required to have both initial training and annual refresher training (Attachment 12). The program and the training are based upon the current OSHA Standard but, if EPA allows, would be revised for the requirements under the WCPP.

Covestro’s procedures to manage the exposure risk to methylene chloride are robust. To underscore the breadth of the efforts, several protective measures and controls are described in more detail below.

1. Engineering Controls to Minimize Exposure

The polycarbonate manufacturing process itself is controlled by a distributed control system, which opens and closes valves automatically and does not require human intervention to charge materials into the reaction system. The closed loop chiller is designed to run continuously without the need for human interaction. Any action that requires the addition or removal of methylene chloride from equipment is covered under a procedure or JHA which identifies the actions required to minimize exposure and the PPE required for the task.

2. PPE Program

As mentioned, Covestro maintains a robust PPE program. When engineering controls alone are not sufficient, appropriate PPE is provided to employees. In support of the company’s Methylene Chloride Compliance Plan, the site provides new employee training on PPE (Attachment 13). This augments OSHA’s PPE standard as well as Covestro’s PPE procedure S-035, "Minimum PPE Requirements” (Attachment 6), which includes specific requirements for specific chemicals (See Attachment 7 for an excerpt related to methylene chloride). Moreover, the “Hazard Recognition for PPE/Chemical Exposure” procedure (Attachment 14) provides additional guidance on chemical awareness and PPE, including information on warning properties, the NIOSH hierarchy of controls, and selection of appropriate PPE including skin, eye, and respiratory protection. In addition, and as discussed above, all JHAs identify the required PPE for each task.

3. Exposure Assessment Program

Covestro has a corporate exposure assessment guideline (Attachment 15) used to determine the need and frequency for exposure monitoring. This guideline defines how to identify similar exposure groups, establish priority ratings for both short-term exposure limits (STEL) and time-weighted average (TWA) monitoring, and determine monitoring frequency. The guidance plan is based on the OSHA Standard requirements and the specific site plan would be revised for the requirements under the WCPP.

4. Industrial Hygiene Monitoring

The initial determination and regular monitoring of airborne methylene chloride levels is necessary to assess employee exposure (Attachment 16). We also monitor to identify areas to improve our exposure control measures. Measured against OSHA's methylene chloride permissible exposure limit (PEL) and STEL, Covestro's industrial hygiene monitoring data demonstrates the effectiveness of our control measures. Since 2015, all the results show compliance with the OSHA's exposure limits. This includes 85 time-weighted averages and 81 STELs (Attachment 17). Given the long compliance track record with the OSHA requirements, Covestro is very well-positioned to satisfy the new ECEL and STEL standards under the WCPP.

Covestro also recognizes that with a lower exposure threshold, the limit of quantitation, which is the lowest number the lab can confidently report, would need to be lower. Covestro is conducting additional monitoring appropriate to evaluate compliance with the proposed rule's STEL and will provide this information when available.

IV. There is No Alternative to Polycarbonate Production Without Methylene Chloride for Covestro in the United States

Due to its ability to dissolve polycarbonate and immiscibility with water, methylene chloride is globally recognized as the optimal solvent for the manufacture of polycarbonate via the interfacial process. In the United States, Covestro manufactures polycarbonate in a blend of methylene chloride and another solvent. While it is theoretically possible to manufacture polycarbonate using this other solvent, the decrease in solubility would require a prohibitive increase in temperature and decline in yield and quality. Any alternative to methylene chloride must be substantially denser than water to serve as an effective solvent for polycarbonate. Covestro has performed abundant research on alternate solvents including aromatic sulfur compounds and has not identified a feasible alternative[1].

V. The Time and Cost to Replace an Interfacial Polycarbonate Manufacturing Facility is not Viable

There are no known alternatives to methylene chloride as a solvent for interfacial polymerization of polycarbonate. If an alternative system is identified – and this is

[1] This information is internal research and Covestro can provide it if necessary.

only hypothetical, as no alternative currently exists – retrofitting the existing production process to accommodate another approach would take at least 6-8 years of research and development to determine the correct operating conditions, and another 5-7 years to rebuild the existing facility. This outcome is both highly speculative and cost prohibitive. We estimate that this type of new facility would cost over $1 billion to build.

VI. Melt Polycarbonate is Not a Substitute for Covestro's Interfacial Polycarbonate

A different version of polycarbonate, melt polycarbonate, is manufactured overseas without methylene chloride. Importantly, this polycarbonate has different physical attributes and cannot be used interchangeably with interfacial polycarbonate. Interfacial polycarbonate is used in applications that require better optical qualities, have fewer impurities, and require specific mechanical performance qualities. The typical market for polycarbonate made by interfacial process includes finished products ranging from LED automotive headlamps, medical devices, ophthalmic lenses, LED lighting, films for security identification, components for electronic devices and ballistic-resistant windows such as fighter jet canopies. Melt polycarbonate cannot provide the high-quality polycarbonate required by these applications. Put simply, these applications must be manufactured with polycarbonate produced by the interfacial process.

VII. A Prohibition on Covestro's Use of Methylene Chloride in Interfacial Polycarbonate Production Would Significantly Affect Downstream Customers

If Covestro is unable to use methylene chloride in interfacial polycarbonate production, here are a few examples of critical supply chain and downstream applications that will be impacted:

1. Medical Devices

Interfacial polycarbonate has played a key role in the medical field since the 1960s. It is used to manufacture many medical devices, such as hemodialyzers, anesthesia containers, blood oxygenators, arterial filters, intravenous connectors, and endoscopic surgical appliances. It is one of the most used and most widely tested thermoplastics in use in the medical device industry today. This is based upon its strength, optical clarity, high heat distortion temperature and dimensional stability. Interfacial polycarbonate can be manufactured to withstand radiation, high temperature liquid resistance, or can be blended with other materials. Interfacial polycarbonate films are often used for sterile medical packaging. Any change to the manufacturing process or source of polycarbonate would impact the availability of these products.

Many Covestro polycarbonate grades have FDA Master Files, which include the manufacturing process and manufacturing location. These Master Files are referenced by Covestro customers in their medical device submissions to FDA. Any change to the manufacturing process or location requires updates to all affected Covestro Master Files and could affect FDA clearance of a customer's medical device. Thus, changes to the production process that affect the Master Files can disrupt the supply of medical devices to the US market.

Similarly, all Covestro polycarbonate marketed for food contact is manufactured under defined FDA regulations. Any changes to the production process that vary from the relevant FDA regulation would render the polycarbonate unusable for food contact applications.

2. Military, Aircraft and Police Applications

Interfacial polycarbonate made in the United States is used to manufacture certain devices utilized by the military, such as bulletproof glass for vehicle windows and portable shields, helmets, visors, riot gear, and even fighter jet canopies. Interruption to the domestic polycarbonate supply will require military and police related applications to be manufactured from foreign sourced materials.

3. Automotive Original Equipment Manufacturers (OEMs)

All forward lighting of all domestic produced motor vehicles is manufactured from interfacial polycarbonate. Polycarbonate is used to replace steel in certain parts of the car to minimize the weight of the automobiles. It is part of the housing for the battery packs for electric vehicles.

Many automotive producers have rigorous approval processes for materials used in cars and requirements related to the origin of materials. A change in the manufacturing process to make polycarbonate, or changing from domestic to nondomestic manufactured polycarbonate may necessitate that the material be reapproved by the OEM customers. This would have a significant impact on the supply chain for automotive OEM. Further, automotive manufacturers, as well as part manufacturers, must meet Rule of Origin (ROO) and the Regional Content Value (RCV) guidelines. This impacts the amount of duty applied to light vehicles and pickup trucks. Should polycarbonate not be available domestically and require importation, automotive manufacturers will not meet their minimum concentration of ROO and RCV on finished vehicles and resulting duties will increase vehicle prices.

4. Electronics

Polycarbonate blends, including interfacial polycarbonate, are used in the following electronic applications: housings for cell phones tablets; computers; chargers; base stations; servers; et al. Changes to these will require substantial redesign of electronic devices and resubmission of UL certifications (which take 2-4 years) and can have massive cost increases. In addition, changes to cell phones could disrupt the national 5G rollout.

5. Other Applications

Interfacial polycarbonate film is used in security films in applications such as passports and driver's licenses.

VIII. There is No Economically Realistic Alternative to Covestro's Use of Methylene Chloride as a Heat Transfer Fluid

As discussed, methylene chloride plays an irreplaceable role in the interfacial polycarbonate production because it chills one of the primary raw materials. Methylene chloride does not react with this raw material which helps to ensure safe operations, maintains the raw material at the correct temperature, and minimizes the risk of contamination.

For Covestro's use of methylene chloride as a closed loop heat exchanger fluid, the refrigeration unit at the facility was designed for the use of methylene chloride as the refrigeration fluid. The chemical was selected because of its lack of a flash point, its heat transfer properties at temperatures less than -10° C, and its lack of reactivity to phosgene. No other heat transfer fluid has been identified as a replacement.

If a heat transfer fluid with the above-listed characteristics could be identified, it would require the redesign and reconstruction of a new refrigeration system. Once designed, the estimated costs to construct this system are over $10 million with a demolition/construction window of at least 5-10 weeks. This would require a complete shutdown of manufacturing in the unit at an estimated cost of $35-70 million. In addition, there would be an impact on our employees and business operations that include disruptions to supply for downstream customers.

IX. The Residual Methylene Chloride in Polycarbonate is *De Minimis*

Using a publicly available study and supplemented with our own experiments, we determined that the airborne concentration of methylene chloride is two orders of magnitude below the EPA proposed ECEL during polycarbonate processing. This demonstrates that the methylene chloride exposure to workers during polycarbonate extrusion is *de minimis.* Our evaluation examined existing studies supplemented by experiments conducted by Covestro.

First, we considered the Rhodes, *et al*.[2] publication on methylene chloride emission factors for eight commercial grades of polycarbonate during extrusion. Using a steady state box model represented by the equation below, we estimated the concentration of methylene chloride in the air based on the emissions factors derived in the Rhodes study.

$$C = \frac{E \times F}{ACH \times V}$$

Where:
C = steady state concentration of methylene chloride
E = emissions factor
F = polycarbonate pellet feed rate
ACH= air change rate
V = room volume

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2 Rhodes, *et al*. 2002. *Development of Emission Factors in Polycarbonate Processing*. Air and Waste Management Association., 52: 781-788.

The highest emission factor reported in Rhodes, *et al*. was 0.35 ug/g methylene chloride. Using this emissions factor and extremely conservative values of ACH = 2, V = 32.6 $m^{3,}$ and F = 19,320 g/h, the steady state concentration of methylene chloride is 0.03 ppm. This value is approximately three orders of magnitude below the OSHA PEL and two orders of magnitude below the EPA proposed ECEL.

Covestro conducted additional experiments described in Attachment 18 to verify the results of the Rhodes paper. A secondary goal of the Covestro experiments was to evaluate methylene chloride airborne concentrations based on Covestro's publicly disclosed methylene chloride residual of <3ppm in polycarbonate. Results confirmed the values in the Rhodes paper. From this data, we conclude that Covestro and customer employees are extremely unlikely to be exposed to methylene chloride above the EPA proposed ECEL-Action level during various polycarbonate processes.

X. Conclusion

Thank you for your consideration of these comments. In summary, Covestro respectfully asks EPA to evaluate and consider the detailed and effective procedures and processes already in place that safeguard employees from the risks of methylene chloride for two subsets of uses discussed in the proposed rule: (1) Industrial and Commercial Use for Plastic and Rubber Products Manufacturing; and (2) Industrial and Commercial Use as a Processing Aid. Covestro is hopeful EPA will appreciate the robust programs and protective measures that are in place today and change the regulatory determinations for these two uses from "prohibited" to using the WCPP. In addition, the proposed rule, as written, presents potential significant and negative unintended consequences and could create significant disruption and unreliability of the chemical production capacity of the United States.

If you have any questions or would like to discuss further, please contact Dr. Robert Skoglund at robert.skoglund@covestro.com or 412-413-6347.

Sincerely,

Haakan Jonsson
Chairman and President

List of Attachments:

Attachment #	**Attachment Name**
1	PFD Polycarbonate manufacturing
2	JHA MeCl2 Unloading
3	JHA Sampling
4	NSR (State) Permit – 160 203A AMR RA00893 05242022
5	Example MSS Compliance form for Process Equipment containing MeCl2
6	S-035 Minimum PPE Requirements
7	S-035 8.1 PPE Table
8	Process Flow Diagram refrigeration unit
9	JHA recyclable solvents to drums/tote
10	S-042 Opening Process or Utility Lines or Equipment
11	Methylene Chloride Compliance Plan
12	Methylene Chloride Plan Training
13	PPE-C HSQ PPE General
14	Hazard recognition PPE/Chemical Exposure
15	Corporate Workplace Exposure Guidance
16	IHIP 004 Industrial Hygiene Sample Collection
17	IH Monitoring data
18	Methylene Chloride Emissions from Polycarbonate