March 15, 2017

U.S. Environmental Protection Agency
Docket Center
WJC West Building, Room 3334
1301 Constitution Avenue, NW
Washington, DC 20004

Re: Docket No. EPA-HQ-OPPT-2016-0742

Dear Sirs:

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers, distributors and users of methylene chloride. We offer these comments in response to EPA’s Risk Evaluation Scoping Efforts under TSCA and specifically as they relate to the circumstances in which methylene chloride is intended to be used, known to be used, or foreseen to be manufactured, distributed or disposed of in commerce.

HSIA notes at the outset that an important use of methylene chloride, paint stripping, is the subject of a proposed rule that would largely ban use in this application. 82 Fed. Reg. 7464 (Jan. 19, 2017). The deficiencies of the risk assessment on which this rule is based have been the subject of a Small Business Advisory Review on June 15, 2016 and an EO 12866 meeting at the Office of Management & Budget on October 31, 2016, and will be the subject of voluminous comment. We urge EPA to take steps now to include a review of this use as part of the current scoping exercise, so that any future regulation of methylene chloride in paint stripping will be in compliance with TSCA §§ 6 and 26.

Overview

Aerosol grade methylene chloride is used for applications in aerosol packages and adhesive and paint formulations. Methylene chloride is used in aerosols as a strong solvent, a flammability suppressant, vapor pressure depressant, and viscosity thinner. Decaffeination grade methylene is used as an extractant in the recovery and purification of a wide variety of materials including the extraction of naturally occurring heat-sensitive substances such as fats, butter, caffeine, cocoa, hops and extraction of pharmaceutically active natural products. It has also been used as a carrier for pharmaceutical tablet coating for which the FDA has established residue tolerances. Due to its relatively low boiling point, methylene chloride is utilized in the degreasing of temperature sensitive parts or where immediate handling is required. The electronics industry uses methylene chloride in the production of printed circuit boards.
The Occupational Safety and Health Administration (OSHA) Permissible Exposure Level (PEL) for methylene chloride is an 8-hour time-weighted average of 25 ppm. In addition, OSHA’s methylene chloride standard (29 C.F.R. Parts 1910.1052; 1915.1052) covers occupational exposures to methylene chloride. The standard requires employers to notify workers that are working with methylene chloride and to make them aware of the hazards associated with exposure, and mandates worker exposure monitoring.

Uses of Methylene Chloride

Coatings and Adhesives – Methylene chloride is used in the coatings and adhesives businesses. In aerosols it is used as a strong solvent, a flammability suppressant, vapor pressure depressant, and viscosity thinner. In adhesives, its strong dissolving power, low flammability and rapid drying time are essential. Methylene chloride is used in rubber cements, epoxies, and caulks and adhesive and sealant removers.

Degreasing – Methylene chloride is effective in degreasing operations due to its relatively low boiling point and is good for temperature sensitive parts or where immediate handling is required. It is used in critical cleaning operations such as for surgical instruments, automotive components, aircraft and spacecraft parts and electronics.

Automotive Industry Use – Methylene chloride is used by the automotive industry in paint stripping, brake cleaning, dissolving oils, removing contaminants and cleaning clutch components.

Chemical Processing – Methylene chloride is used in chemical processing due to its stability, ease of separation and high evaporation rate. It is used in a chemical reaction manufacturing process in the production of a fungicide product. Methylene chloride in this application will be present at a concentration of less than one percent in the intermediate material and will not be present in the final fungicide product.

Methylene chloride is also used as a processing aid that is not intended to become part of the final product to chemically weld plastic components together to form a joint. The solvent welding process is a controlled release process with local ventilation and carbon absorption filters for workplace control. The methylene chloride in this process does not remain in the product after the process is complete.

Feedstock Use – Methylene chloride is essential to the manufacture of certain fluorocarbons, including hydrofluoroolefins (HFOs). Fluorocarbons are used in refrigeration, automotive air conditioning, and household and industrial air conditioning.

Pharmaceuticals Use – Methylene chloride is used as an effective extraction and recrystallization coolant in the extraction of several pharmaceutical compounds and in the production of many antibiotics and vitamins.

Feedstock Use of Methylene Chloride
Methylen chloride is essential to the manufacture of certain fluorocarbons, including hydrofluoroolefins (HFOs). Fluorocarbons are used in refrigeration, automotive air conditioning, and household and industrial air conditioning.

When used in these feedstock applications, methylene chloride is only loaded in bulk and shipped directly to feedstock customers, all of whom operate large integrated chemical manufacturing operations.

HSIA strongly suggests that EPA build on the concepts from two regulatory frameworks, REACH and the Montreal Protocol on Substances That Deplete the Ozone Layer, which both provide exemptions for reporting on feedstock and intermediate uses, and use their flexibility in the scoping process to provide definitions for feedstock and intermediate uses and exclude them from risk evaluation.

Under the EU’s REACH law, exemptions are made for feedstock and intermediate uses in two ways. Hazard data requirements are reduced and there is no requirement to document the safety assessment as there is for regular substances. In order to qualify, the manufacturer needs to have written confirmation from its customer that the substances is used as an intermediate or feedstock under strictly controlled conditions as defined in the regulation. The rationale behind these exemptions is that the strict control of exposure and release and the oversight of the process by trained professionals allows a focus on areas where is a potential for exposure.

In addition, under the Montreal Protocol substances produced and converted into another substance are not considered in the inventory for produced volume. This is reflected in EPA’s summary of its regulations implementing the Montreal Protocol: “Feedstock EPA regulations exempt controlled substances used for feedstock purposes from the requirements. No allowances are needed when producing or importing these substances for feedstock use.”

Product Stewardship and Methylene Chloride

Manufacturers and users are in compliance with the OSHA methylene chloride standard and use engineering controls and adequate ventilation to ensure that airborne levels are maintained well below the guidelines and requirements.

Industrial Hygiene

As mentioned above, OSHA has a methylene chloride standard in place with employee monitoring required. Monitoring also allows employers to determine what other requirements of the standard need to be met. Please see Exhibit 1 for one company’s historical air sampling results for methylene chloride exposure by job category from 2012 to 2016 and its fugitive emissions for the last three years.

Other Resources
HSIA suggests that EPA consult a very valuable resource with information on the supply, demand, markets, and trade of the chlorinated solvents. We learned that EPA does have a subscription to this service—IHS Markit. You may want to contact the IHS Markit Director of Specialty Chemical Consulting Ray Will, at ray.will@ihsmarkit.com, for assistance in using these data.

We appreciate the opportunity to submit these comments and look forward to working with EPA on the path forward in implementing the Lautenberg Act.

Respectfully submitted,

Faye Graur
Executive Director

Attachment