

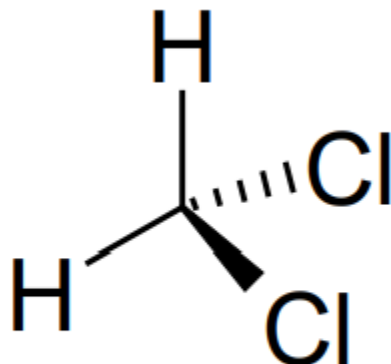


United States
Environmental Protection Agency

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Office of Chemical Safety and
Pollution Prevention

Non-Technical Summary of the Risk Evaluation for Methylene Chloride October 2022

CASRN: 75-09-2



October 2022

BACKGROUND

- The TSCA risk evaluation for methylene chloride was issued in June 2020.
- Uses for methylene chloride include use as a solvent in a variety of industries and applications, such as adhesives, paint and coating products, metal cleaning, chemical processing, and aerosols. In addition, it is used as a propellant, processing aid, or functional fluid in the manufacturing of other chemicals. A variety of consumer and commercial products use methylene chloride as a solvent including sealants, automotive products, and paint and coating removers.
- The total aggregate production volume of methylene chloride ranged from 100 to 500 million pounds between 2016 and 2019, as reported under the Chemical Data Reporting (CDR) rule in 2020.

ACTION

- EPA is releasing a final revision to the risk determination on methylene chloride with an order withdrawing the TSCA section 6(i)(1) order previously included in the June 2020 risk evaluation. This action follows issuance of a draft revised risk determination that EPA issued for comment in July 2022 (87 FR 39824). EPA has determined that methylene chloride presents an unreasonable risk of injury to health under its conditions of use.
- This final risk evaluation, which includes the 2020 risk evaluation and a 2022 final revised unreasonable risk determination, is conducted pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to prioritize and evaluate the risk of existing chemicals to determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. Under TSCA, if a chemical is determined to present an unreasonable risk, then EPA will propose risk management regulatory action to the extent necessary so that methylene chloride no longer presents an unreasonable risk.
- The 2020 risk evaluation, supplemental materials, 2022 revised unreasonable risk determination and corresponding response to public comments can be found in dockets EPA-HQ-OPPT-2019-0437 and EPA-HQ-OPPT-2016-0742 on www.regulations.gov.
- Methylene chloride was selected in 2016 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA.

KEY POINTS

- EPA has identified non-cancer adverse effects from acute and chronic inhalation and dermal exposures to methylene chloride, and cancer from chronic inhalation and dermal exposures to methylene chloride. In the methylene chloride risk characterization, neurotoxicity effects (central nervous system (CNS) depression) were identified as the most sensitive endpoint for non-cancer adverse effect from acute inhalation, and dermal exposures, and liver effects were identified as the most sensitive endpoint for non-cancer adverse effects from chronic inhalation and dermal exposures for all conditions of use.
- Additional risks associated with other adverse effects (e.g., other nervous system effects, immune system effects; reproductive and developmental effects; and irritation/burns) were identified for acute and chronic exposures.
- Public comments and external scientific peer review informed the development of the methylene chloride final risk evaluation. EPA published the methylene chloride final revised unreasonable risk determination in October 2022, the methylene chloride draft revised

unreasonable risk determination in July 2022, the methylene chloride risk evaluation in June 2020, the methylene chloride draft risk evaluation in October 2019 (for a 60-day public comment period), the methylene chloride problem formulation document in June 2018, and the scope document in June 2017.

- Additionally, EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of methylene chloride on December 3-4, 2019.
- In the revised unreasonable risk determination for methylene chloride, EPA is making an unreasonable risk determination for methylene chloride as a whole chemical substance, rather than a condition of use-specific approach. The whole chemical approach is appropriate for methylene chloride because there are benchmark exceedances for a substantial number of conditions of use (spanning across most aspects of the chemical lifecycle—from manufacturing (including import), processing, commercial and consumer use, and disposal) for human health and there are irreversible health effects (specifically cancer, coma, hypoxia, and death) associated with methylene chloride exposures.
- After evaluating 53 conditions of use, EPA determined that methylene chloride presents an unreasonable risk to human health under its conditions of use based on risk of injury to health of workers, occupational non-users (ONUs), consumers, and bystanders.
- In addition, EPA is revising the assumption that workers always and properly use personal protective equipment (PPE), although EPA does not question public comments received regarding the occupational safety practices often followed by industry. Information on the use of PPE as a means of mitigating risk will be considered during the risk management phase. Removing the assumption that workers wear PPE adds five additional conditions of use to the original 47 conditions of use that drive EPA's unreasonable risk determination for methylene chloride as a whole chemical: manufacturing (domestic manufacture); processing as a reactant; processing: recycling; industrial and commercial use as laboratory chemical; and disposal. Additionally, removing this assumption adds inhalation risks to workers - in addition to the previously identified inhalation risk to occupational non-users - as driving the unreasonable risk in three conditions of use, and adds risks to workers for acute and chronic non-cancer dermal exposures and for cancer from inhalation exposures as driving the unreasonable risk in many conditions of use.
- Overall, 52 of the 53 conditions of use evaluated drive the methylene chloride whole chemical unreasonable risk determination due to risks identified for human health. These conditions of use include but are not limited to: processing into a formulation, industrial and commercial uses such as degreasing and cleaning and adhesives, and consumer uses such as automotive care products.
- The condition of use that does not drive EPA's unreasonable risk determination for methylene chloride is distribution in commerce.
- For methylene chloride, the exposure pathways that were or could be regulated under another EPA-administered statute were excluded from the June 2020 methylene chloride risk evaluation. This resulted in the surface water, drinking water, and ambient air pathways for methylene chloride not being assessed for human health exposures or the general population. EPA is conducting a screening approach to assess potential risks from the air and water pathways for several of the first 10 chemicals, including methylene chloride. The goal of the recently-developed screening approach is to remedy this exclusion and to identify if there are risks that were unaccounted for in the methylene chloride risk evaluation. While this analysis is underway, EPA is not incorporating the screening-level approach into this revised

unreasonable risk determination. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed rule under TSCA section 6(a) for methylene chloride. EPA did not identify risks of injury to the environment that drive the unreasonable risk determination for methylene chloride.

- As noted above, EPA is releasing a final revision to the unreasonable risk determination with an order withdrawing the TSCA section 6(i)(1) order previously included in the June 2020 risk evaluation. EPA is also releasing a document with response to public comments received on the draft revised risk determination for methylene chloride published in July 2022.

NEXT STEPS

- EPA has issued the final risk evaluation (2020 risk evaluation and 2022 revised risk determination) for methylene chloride, meeting the requirements set forth in TSCA section 6(b) for chemical risk evaluations. EPA is now initiating the process to address the unreasonable risk identified. Following the issuance of the final risk evaluation, EPA will address, by rule, the unreasonable risk identified.

SUMMARY OF UNREASONABLE RISK DETERMINATION

EPA has determined that methylene chloride presents an unreasonable risk of injury to human health under the conditions of use.

EPA's unreasonable risk determination for methylene chloride is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacturing – Domestic manufacture;
- Manufacturing – Import;
- Processing into a formulation, mixture, or reaction product;
- Processing as a reactant;
- Processing: recycling;
- Repackaging;
- Industrial and commercial use as solvent for batch vapor degreasing;
- Industrial and commercial use as solvent for in-line vapor degreasing;
- Industrial and commercial use as solvent for cold cleaning; and commercial use as a solvent for aerosol spray degreasers/cleaners;
- Industrial and commercial use in adhesives, sealants, and caulks;
- Industrial and commercial use in paints and coatings;
- Industrial and commercial use in paint and coating removers;
- Industrial and commercial use in adhesive and caulk removers;
- Industrial and commercial use as metal aerosol degreasers;
- Industrial and commercial use in metal non-aerosol degreasers;
- Industrial and commercial use in finishing products for fabric, textiles, and leather;
- Industrial and commercial use in automotive care products (functional fluids for air conditioners);
- Industrial and commercial use in automotive care products (interior car care);
- Industrial and commercial use in automotive care products (degreasers);
- Industrial and commercial use in apparel and footwear care products;
- Industrial and commercial use in spot removers for apparel and textiles;

- Industrial and commercial use in liquid lubricants and greases;
- Industrial and commercial use in spray lubricants and greases;
- Industrial and commercial use in aerosol degreasers and cleaners;
- Industrial and commercial use in non-aerosol degreasers and cleaners;
- Industrial and commercial use in cold pipe insulations;
- Industrial and commercial use as solvent that becomes part of a formulation or mixture;
- Industrial and commercial use as a processing aid;
- Industrial and commercial use as propellant and blowing agent;
- Industrial and commercial use for electrical equipment, appliance, and component manufacturing;
- Industrial and commercial use for plastic and rubber products manufacturing;
- Industrial and commercial use for cellulose triacetate film production;
- Industrial and commercial use as anti-spatter welding aerosol;
- Industrial and commercial use for oil and gas drilling, extraction, and support activities;
- Industrial and commercial uses for toys, playgrounds, and sporting equipments (including novelty articles);
- Industrial and commercial use for carbon removers, wood floor cleaners, and brush cleaners;
- Industrial and commercial use as a lithographic printing plate cleaner;
- Industrial and commercial use as a laboratory chemical;
- Consumer use as a solvent in an aerosol cleaner/degreaser;
- Consumer use in adhesives and sealants;
- Consumer use in paints and coatings (brush cleaners for paints and coatings);
- Consumer use in adhesives/caulk removers;
- Consumer use in aerosol and non- aerosol metal degreasers;
- Consumer use in automotive functional fluids (air conditioners refrigerant, treatment, leak sealer);
- Consumer use in automotive degreasers (gasket remover, transmission cleaners, carburetor);
- Consumer use in aerosol and non-aerosol lubricants and greases, consumer use in cold pipe insulation;
- Consumer use in aerosol and non-aerosol lubricants/greases and aerosol and non-aerosol degreaser/cleaners;
- Consumer use in cold pipe insulation;
- Consumer use in crafting glue and cement/concrete;
- Consumer use in anti-adhesive agent—anti-spatter welding aerosol;
- Consumer use in carbon remover and brush cleaner; and
- Disposal.

The following condition of use does not drive EPA’s unreasonable risk determination for methylene chloride:

- Distribution in commerce.

EPA is not making a condition of use-specific risk determination for this condition of use, is not issuing a final order under TSCA section 6(i)(1) for this condition of use, and does not consider the revised risk determination for methylene chloride to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that methylene chloride no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.