

Public Webinar

Regulation of Methylene Chloride under TSCA Section 6(a)

June 4, 2024

RIN 2070-AK70

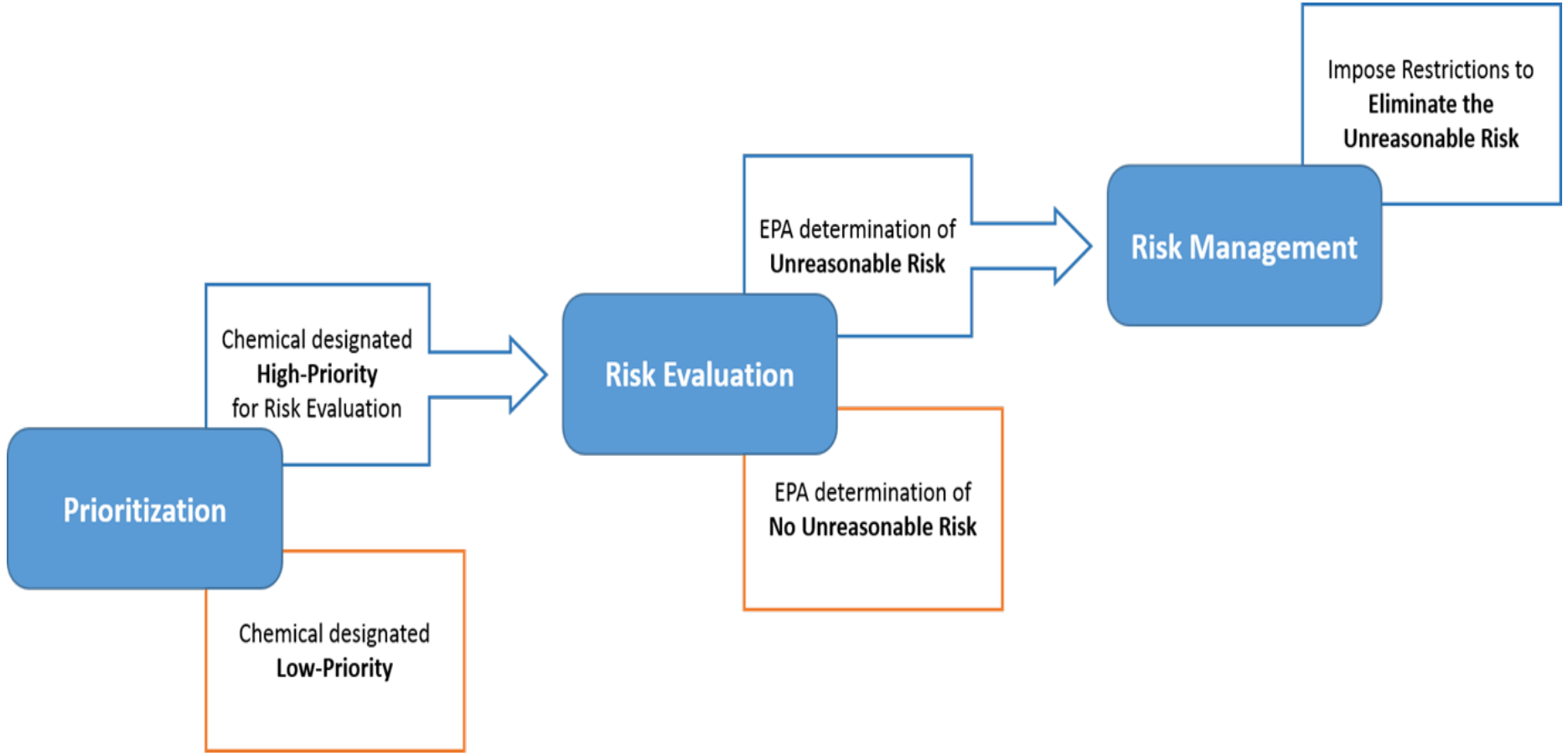
Agenda

- Overview of Toxic Substances Control Act (TSCA)
- Overview of Methylene Chloride Rulemaking
- Summary of Proposed Regulation
- Public Comment and Outreach
- Final Regulation
- Benefits
- Next Steps
- Opportunities for Engagement
- Additional Resources

Overview of the Toxics Substances Control Act (TSCA)

- In June 2016, Congress amended the Toxic Substances Control Act (TSCA)
 - Amended TSCA requires EPA to assess and address risks from chemicals currently in commerce
 - Amended TSCA imposes statutory timeframes for regulation
 - Provides protection for the public and predictable process for the regulated community
- Methylene Chloride was identified as one of the first chemicals for risk evaluation
- Per TSCA section 6(b)(4)(A) risk evaluation and determination of “unreasonable risk of injury to health or the environment under the conditions of use,” EPA must by rule apply requirements such that the “chemical substance or mixture no longer presents such risk.”

From Prioritization to Risk Management



TSCA Section 6 – Risk Management Consideration and Regulatory Scope

- Requires addressing unreasonable risk with consideration of alternatives, selecting among options, statement of effects, and economic analysis
- Input from stakeholders is essential to the process, and robust coordination with interagency partners is necessary
- TSCA provides authority to regulate entities including:
 - Manufacturers (including importers) and processors (e.g., formulators)
 - Distributors
 - Commercial users (workplaces and workers)
 - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
 - Under TSCA, EPA has authority to regulate at the manufacturing, processing and distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
 - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers

TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture (includes import), processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

The section 6(a) menu of regulatory options can be applied alone or in combination

Overview of Methylene Chloride under the Toxics Substances Control Act (TSCA)

- Methylene chloride is a volatile chemical used in a wide range of industrial, commercial, and consumer applications
- Methylene chloride is an acutely lethal neurotoxicant, and chronic exposure can affect liver function and cause cancer
 - Acute exposure resulted in at least 88 occupational deaths in the U.S. between 1985-2024
- EPA found that 52 of 53 conditions of use of methylene chloride contribute to the unreasonable risk of injury to health of workers, consumers, and bystanders

Previous TSCA Actions on Methylene Chloride

- 2014: Risk Assessment on use of Methylene Chloride in Paint and Coating Removal
- 2017: EPA proposed a regulation to prohibit consumer and commercial use of methylene chloride in paint and coating removal
- 2019: Consumer Paint and Coating Remover - Final Rule
 - Published in March 2019 and effective since November 2019
 - Prohibited the manufacture (including import), processing, and distribution of methylene chloride for consumer paint and coating removal
 - Requires Downstream notification and recordkeeping for all manufacturing, processing, and distribution of methylene chloride
- June 2020: Risk Evaluation released after peer review of draft risk evaluation
- November 2022: Final Revised Risk Determination

Summary of Proposed Rule for Methylene Chloride Under TSCA 6(a)

- On May 3, 2023, EPA proposed to:
 - Prohibit manufacture, processing, and distribution for all consumer uses
 - Prohibit most industrial and commercial uses
 - Allow 10 uses to continue under a Workplace Chemical Protection Program (WCPP)
 - Grant time-limited exemptions under TSCA section 6(g) for emergency use of methylene chloride in furtherance of the National Aeronautics and Space Administration mission
 - The alternative regulatory actions included several additional uses under WCPP and longer compliance timeframes
- The proposed rule was open for public comment from May 3 to July 3, 2023 (60 days)
 - Received and reviewed almost 40,000 public comments

Summary of Comments

- Received 39,529 total comments on various aspects of the proposed rule
- Vast majority of comments requested that EPA move expeditiously to protect workers and consumers and urged EPA to strengthen prohibitions
- Other commenters requested expansion of the WCPP to some or all industrial & commercial uses, additional time for compliance, additional section 6(g) exemptions, and a *de minimis* level
- Specific information was provided from several industry sectors, supporting changes from the proposed rule

Developing Effective Regulations

EPA's mandate is to address identified unreasonable risks

- TSCA additionally requires EPA to consider:
 - Effects and magnitude of exposure to human health and the environment
 - Benefits of a chemical substance
 - Economic consequences of the rule
 - Availability of alternatives
- EPA's proposed rule and final rule are based on best available science and reasonably available information
- EPA's final rule includes information received from commenters and targeted outreach
- EPA considered all information received on the proposed rule and modified elements of the proposed regulatory action
- EPA's goal is to promulgate regulations that are both practical and protective

The Final Regulation

EPA's final rule will:

- Prohibit manufacture, processing, and distribution of methylene chloride for all consumer uses
- Prohibit most industrial and commercial uses
- Require a Workplace Chemical Protection Program (WCPP) for 13 specified conditions of use (see slide 19)
- Include a critical use exemption under TSCA section 6(g)
- Establish recordkeeping and downstream notification requirements
- Provide *de minimis* threshold for regulation

Final Regulation: Applicability

- TSCA Chemical Substance: the provisions of this final rule only apply to chemical substances as defined under TSCA section 3, which excludes:
 - *“any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device” and “any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide.”*
- De Minimis Threshold for Compliance:
 - EPA’s final rule is adopting a de minimis threshold of 0.1% to account for impurities and the unintended presence of methylene chloride.
 - In other words, the provisions of this rulemaking only apply when methylene chloride is present in a formulation at 0.1% or greater.

Final Regulation: Prohibition of Consumer Use

- EPA determined methylene chloride could not be used safely in consumer products
 - As with the proposed rule, the final rule will prohibit manufacturing (including import), processing, and distribution for consumer use, and provides time for retailers to phase out their consumer product inventory
 - In almost all cases, alternatives are available
- EPA is prohibiting manufacture, processing, and distribution in commerce of methylene chloride for all consumer use, including:
 - Solvent in aerosol degreasers/cleaners
 - Adhesives and sealants
 - Brush cleaners for paints and coatings
 - Adhesive and caulk removers
 - Metal degreasers
 - Automotive care products (functional fluids for air conditioners)
 - Automotive care products (degreasers)
 - Lubricants and greases
 - Cold pipe insulation
 - Arts, crafts, and hobby materials glue
 - Anti-spatter welding aerosol
 - Carbon removers and other brush cleaners

Final Regulation: Prohibition of Industrial and Commercial Use

All industrial and commercial uses would be prohibited, except for uses covered by WCPP.

Prohibited industrial and commercial uses of methylene chloride include:

- Solvent for batch vapor degreasing
- Solvent for in-line vapor degreasing
- Solvent for cold cleaning
- Solvent for aerosol spray degreaser/cleaner
- Adhesives, sealants and caulks
- Paints and coatings
- Paint and coating removers
- Adhesive and caulk removers
- Metal degreasers
- Finishing products for fabric, textiles and leather
- Automotive care products
- Apparel and footwear care products
- Spot removers for apparel and textiles
- Lubricants and greases
- Aerosol degreasers and cleaners
- Non-aerosol degreasers and cleaners
- Cold pipe insulations
- Propellant and blowing agent
- Electrical equipment, appliance, and component manufacturing
- Cellulose triacetate film production
- Anti-spatter welding aerosol
- Toys, playground and sporting equipment
- Lithographic printing plate cleaner

Final Regulation: Delayed Compliance with Prohibitions under TSCA Section 6(d)

For two uses, EPA determined more time was needed to phase in alternatives:

- Furniture refinishing (pieces of historic, cultural, or artistic significance)
 - 5-year delayed prohibition on this use of methylene chloride (May 8, 2029)
 - Requires interim exposure controls to be in place by July 7, 2024, including:
 - Establishing a regulated area
 - Implementation of local exhaust ventilation
 - Use of minimum respiratory protection
 - Recordkeeping
- Adhesives and sealants for aircraft, space vehicles, or turbine applications
 - 5-year delayed prohibition on this use of methylene chloride (May 8, 2029)

Final Regulation: Exemption Under TSCA Section 6(g)

- Section 6(g)(1)(B) permits an exemption if EPA finds that compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt:
 - national economy
 - national security
 - critical infrastructure
- EPA is finalizing:
 - 10-year exemption for emergency uses of methylene chloride in furtherance of NASA's mission for 7 conditions of use, May 8, 2034
 - Must document efforts to comply with provisions of the WCPP, to the extent technically feasible in light of the emergency, until prohibition takes effect

Final Regulation: Timeframe of Prohibition of Industrial and Commercial Use

- Prohibited uses will have additional time for phase out

Lifecycle Designation	Final Prohibition Date	Working Timeframe from Publication of Final Rule
All persons – Distribution in commerce to retailers	February 3, 2025	9 months
All retailers – Distribution in commerce	May 5, 2025	12 months
Manufacturers	May 5, 2025	12 months
Processors	August 1, 2025	15 months
Distributors other than retailers	January 28, 2026	21 months
Most industrial and commercial use	April 28, 2026	24 months
M/P/D/Use of commercial paint and coating remover in furniture refinishing	May 8, 2029	5 years
M/P/D/Use of commercial adhesives/sealants in aircraft	May 8, 2029	5 years

Final Regulation: Workplace Chemical Protection Program

- A Workplace Chemical Protection Program (WCPP) protects people from unreasonable risk posed by occupational exposures from certain conditions of use
 - Workers are one of the potentially exposed or susceptible subpopulations (PESS) under TSCA
 - EPA’s WCPP applies to owners or operators and potentially exposed persons, which in some cases is broader definition than “employers” and “employees”
 - EPA consulted with OSHA and NIOSH and coordinated on WCPP development and finalization, and aligned requirements where possible
 - Includes exposure limits and ancillary requirements in support of those limits

Final Regulation: Workplace Chemical Protection Program

The following uses will continue with strict controls under the WCPP in the final rule:

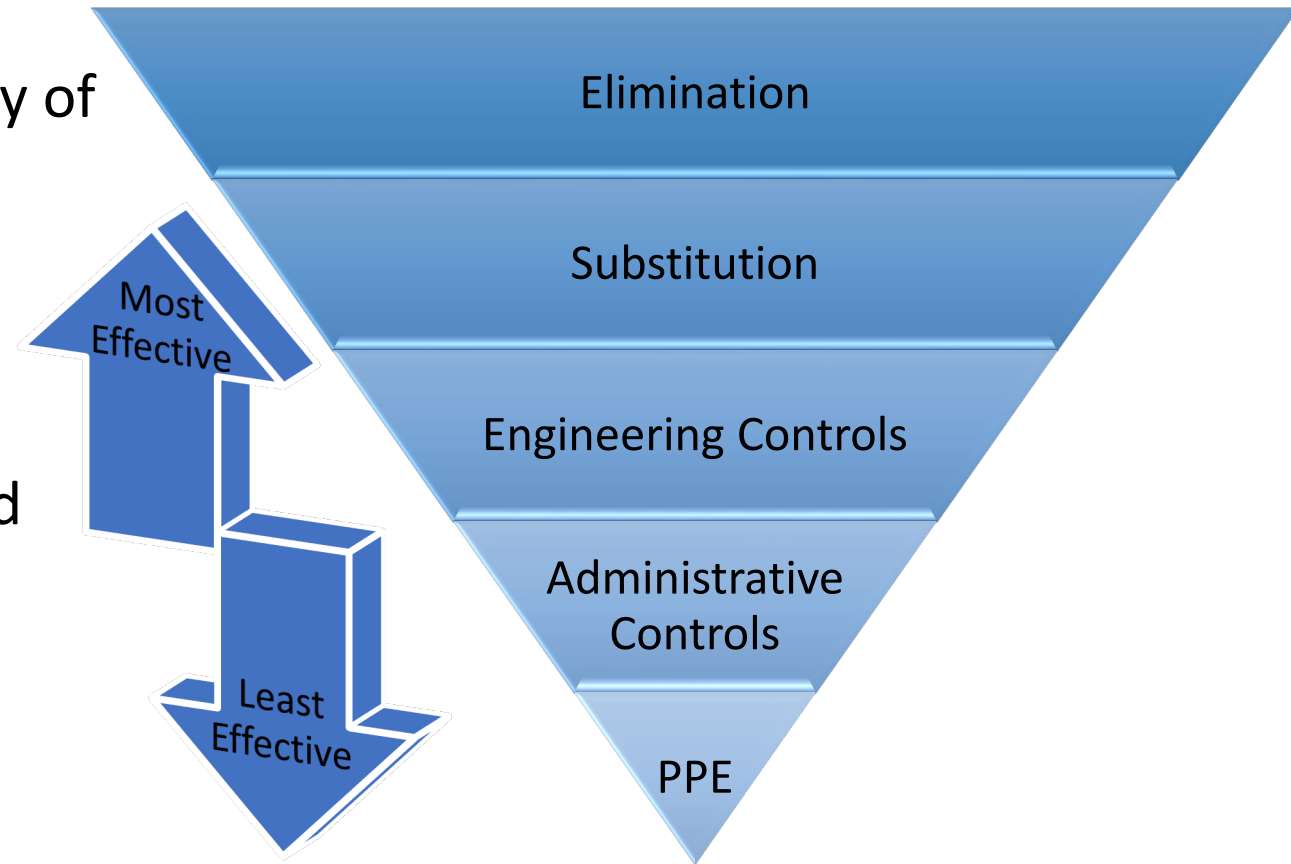
- Manufacturing (domestic manufacture)
- Manufacturing (import)
- Processing: processing as a reactant (AIM Act refrigerants)
- Processing: incorporation into a formulation, mixture, or reaction products
- Processing: recycling
- Processing: repackaging
- Industrial and commercial use as a laboratory chemical
- Industrial and commercial use as a paint and coating remover from safety critical, corrosion-sensitive components of aircraft and spacecraft
- Industrial or commercial use as a bonding agent for solvent welding
- Industrial and Commercial use as a processing aid
- Industrial and Commercial use for plastic and rubber products manufacturing
- Industrial and Commercial use as a solvent that becomes part of a formulation or mixture, where that formulation or mixture will be used inside a manufacturing process, and the solvent (methylene chloride) will be reclaimed
- Disposal

Final Regulation: Workplace Chemical Protection Program (Cont.)

- The WCPP finalizes inhalation exposure limits (Existing Chemical Exposure Limit, or ECEL):
 - 8-hour time-weighted average (TWA): 2 ppm (OSHA is 25 ppm)
 - 15-minute TWA: 16 ppm (OSHA is 125 ppm)
- Includes monitoring, recordkeeping requirements, dermal and respiratory protection requirements
- Provides flexibility for preventing exceedances of the identified EPA exposure limit

Final Regulation: Workplace Chemical Protection Program

- The WCPP reduces compliance burdens by following a familiar framework:
 - Initial monitoring to determine frequency of periodic monitoring
 - Periodic monitoring every 3 months, 6 months, or 5 years, based on ECEL, ECEL action level, and EPA STEL
 - Requirements to reduce exposures based on the NIOSH hierarchy of controls
 - Respirator selection criteria to protect workers from any remaining risks



Final Regulation: Timeframe for Workplace Chemical Protection Program (Cont.)

- WCPP uses will have additional time to achieve successful implementation

WCPP Compliance Phase	Final Compliance Dates & Working Timeframes from Publication of Final Rule	
	General Industry	Federal Agencies and Federal Contractors
Initial Monitoring	May 5, 2025 / 12 months	November 9, 2026 / 30 months
ECEL/EPA STEL	August 1, 2025 / 15 months	February 8, 2027 / 33 months
PPE/Respirators	August 1, 2025 / 15 months	February 8, 2027 / 33 months
Establish Regulated Area	August 1, 2025 / 15 months	February 8, 2027 / 33 months
Exposure Control Plan	October 30, 2025 / 18 months	May 10, 2027 / 36.5 months

Final Regulation: Recordkeeping and Downstream Notification

- SDS updates are required for downstream notification of the prohibitions
 - For conditions of use that would not be prohibited under the final regulation, the Safety Data Sheets (SDSs) must be updated by adding information on prohibitions and relevant dates
 - Downstream notification spreads awareness throughout the supply chain of the restrictions on methylene chloride under TSCA as well as provide information to commercial end users about allowable uses of methylene chloride
- Recordkeeping requirements include maintenance of normal business records and records related to WCPP monitoring and compliance

Benefits of Final Rule

- ✓ Addresses unreasonable risks for consumers and bystanders
- ✓ Addresses unreasonable risks for workers and occupational non-users
- ✓ Encompasses the majority of facilities, addressing the potential exposures to the neighboring communities
- ✓ Directly addresses conditions of use that have previously resulted in injuries, illnesses, and fatalities
- ✓ Provides regulated community with confidence in a protected and healthier workforce
- ✓ Ensures adequate time for successful phase out, WCPP implementation, and scaling safety industry to meet demand
- ✓ Ensures operational continuity of federal agencies towards critical infrastructure and national security needs
- ✓ Includes a *de minimis* threshold to aid with implementation
- ✓ Includes additional uses under the WCPP

Next Steps: Overview of Effective Dates

Prohibition		
Lifecycle Designation	Final Prohibition Date	
All persons - Distribution in commerce to retailers	February 3, 2025	
All retailers – Distribution in commerce	May 5, 2025	
Manufacturers	May 5, 2025	
Processers	August 1, 2025	
Distributers other than retailers	January 28, 2026	
Most industrial and commercial use	April 28, 2026	
M/P/D/Use of commercial paint and coating remover furniture refinishing	May 8, 2029	
M/P/D/Use of commercial adhesives/sealants in aircraft	May 8, 2029	
WCPP		
Compliance Phase	General Industry	Federal Agencies (and Federal contractors)
Initial Monitoring	May 5, 2025	November 9, 2026
ECEL/EPA STEL	August 1, 2025	February 8, 2027
PPE/Respirators	August 1, 2025	February 8, 2027
Establish Regulated Area	August 1, 2025	February 8, 2027
Exposure Control Plan	October 30, 2025	May 10, 2027

Additional Resources

- Risk management for methylene chloride: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride>
- Methylene Chloride risk evaluation, supplemental risk evaluation materials, and proposed rulemaking are in dockets [EPA-HQ-OPPT-2019-0437](#), [EPA-HQ-OPPT-2016-0742](#), and [EPA-HQ-OPPT-2020-0465](#) respectively, and may be accessed through www.regulations.gov
- General TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act> and TSCA 101 URL
- Chemicals Undergoing Risk Evaluation under TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca>
- Current Chemical Risk Management Activities: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>
- Methylene Chloride Fact Sheet: https://www.epa.gov/system/files/documents/2024-06/mecl-fact-sheet_final_6-03-24.pdf
- OSHA Methylene Chloride Standard 29 CFR 1910.1052: <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1052>
- TSCA hotline: 1-800-471-7127 and tsca-hotline@epa.gov

Contact Us

- For general questions, email EPA at MethyleneChlorideTSCA@epa.gov

Thank you!