Methylene Chloride: Small Entity Consultation on Proposed Rulemaking under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Small Entity Representative Pre-Panel Outreach Meeting
November 4, 2020

Overview

- SERs and the Regulatory Process
- Findings from the Risk Evaluation for Methylene Chloride
- Overview of conditions of use in the rulemaking
- Basis for unreasonable risk determination
- Risk Management Requirements under TSCA
- EPA's authority and "tools in the toolbox"
- Questions for SERs
- Groups for in-depth discussion of conditions of use

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Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)
- EPA will use this information to develop a regulatory flexibility analysis, which becomes part of the record for the potential regulation
- Key elements in this analysis:
  - Number of small entities to which the potential rule would apply
  - Projected compliance requirements of the potential rule
  - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the potential rule
  - Any significant alternatives to the potential rule which accomplish the stated objectives and which minimize significant economic impact of the potential rule on small entities

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SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
  - Provide specific examples of impacts
  - Provide cost data, if available
  - Please see detailed questions in a separate handout
- We are also seeking alternative methods of regulating these risks
  - Suggest other relevant options, including data costs and information on how to ensure compliance
  - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions
- We would like to minimize duplication
  - Provide information on any duplicative or contradictory Federal regulations you are aware of
  - For a list of existing regulations, please see the separate handout

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Overview of Risk Evaluation for Methylene Chloride

- Final risk evaluation published June 24, 2020
  - 53 conditions of use were evaluated
  - Methylene chloride (MC) draft risk evaluation: October 2019; MC problem formulation: June 2018; MC scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
  - 41 public comments received on the draft risk evaluation (comment period closed December 30, 2019)
  - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (December 2019)
- The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0437, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0742, on www.regulations.gov

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Unreasonable Risk Determinations

- EPA determined that 47 of the 53 conditions of use of MC present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
  - Workers and occupational non-users (ONUs) during occupational exposures
  - Consumers and bystanders during exposures to consumer use
- EPA's risk evaluation identified unreasonable risks for cancer and non-cancer adverse effects from acute (central nervous system) and chronic (liver) inhalation and dermal exposure to MC
- EPA used central nervous system effects to identify unreasonable risks because relatively small increases in exposure can range from central nervous system effects to more severe effects, including death

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Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk

- Import
- Processing: incorporation into formulation, mixture, or reaction products
- Processing: 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
- Industrial and commercial use as solvent for aerosol spray degreaser/cleaner
- 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 in 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 in spot removers for apparel and textiles

Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk cont.

- Industrial and commercial use in liquid lubricants and greases
- 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 in 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 use in toys, playground and sporting equipment
- Industrial and commercial use in lithographic printing plate cleaner
- Industrial and commercial use in carbon remover, wood floor cleaner, and brush cleaner

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Consumer Uses that Present an Unreasonable Risk

- Consumer use as solvent in aerosol degreasers/cleaners
- Consumer use in adhesives and sealants
- Consumer use in brush cleaners for paints and coatings
- Consumer use in adhesive and caulk removers
- Consumer use in metal degreasers
- Consumer use in automotive care products (functional fluids for air conditioners)
- Consumer use in automotive care products (degreasers)
- Consumer use in lubricants and greases
- Consumer use in cold pipe insulation
- Consumer use in arts, crafts, and hobby materials glue
- Consumer use in an anti-spatter welding aerosol
- Consumer use in carbon removers and other brush cleaners

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Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures of MC:
  - Central nervous system effects from acute inhalation
  - Liver effects from chronic inhalation
  - Cancer effects (liver and lung tumor) from chronic inhalation
- In some cases acute exposures to MC have led to fatalities
- Personal Protective Equipment (PPE):
  - The OSHA Methylene Chloride Standard sets a Permissible Exposure Limit (PEL) of 25 ppm and requires air supplied respirators for occupational use.
  - Many conditions of use presented an unreasonable risk to workers even with use of respirators assigned protection factor (APF) 25 or 50
  - No unreasonable risk to workers due to acute and chronic dermal exposures assuming use of gloves with protection factor (PF) of 5 or 10 in commercial settings and PF of 5 or 20 in industrial settings (exception: use of methylene chloride in spot removers for apparel and textiles)
  - EPA does not assume ONUs use PPE because they do not handle the chemical

Basis for Unreasonable Risk Determination: Consumers and Bystanders

- The unreasonable risk determinations for consumers and bystanders are based on the following health hazards during consumer exposures of MC:
  - Central nervous system effects from acute inhalation and dermal exposure
- EPA does not assume dermal exposure to MC for bystanders
- EPA does not assume consumers or bystanders use PPE
- The unreasonable risk determinations were based on the high-end risk estimates for consumers and bystanders. Unreasonable risk was also presented for central tendency risk estimates for many conditions of use (COUs)

Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- Following a determination of unreasonable risk, EPA must issue a section 6(a) rule so that the chemical no longer presents an unreasonable risk, within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements regarding consideration of alternatives depending on the options selected, and a statement of effects for each risk management rule
- Input from stakeholders is critical to the process

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TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce.
- Prohibit, limit or otherwise restrict manufacture, 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.

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TSCA Section 6(a)

- TSCA provides EPA with authority to address unreasonable risks in occupational settings, and to regulate entities including:
  - Manufacturers and processors (e.g., formulators)
  - Distributors
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes
- TSCA also requires EPA to address unreasonable risks to consumers
  - EPA has authority to regulate at the manufacturing, processing or distribution level in the supply chain to address unreasonable risks from consumer use
  - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers

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Potential Regulatory Options

Any regulatory option could be used alone or in combination so that methylene chloride no longer presents an unreasonable risk under any condition of use.

- Existing Chemical Exposure Limit (ECEL)
- Prescriptive PPE Controls
- Prescriptive Administrative Controls
- Prescriptive Engineering Controls
- Concentration Limit
- Regulate the Manufacturing, Processing, and/or Distribution
- Prohibition
- Combinations of regulatory options
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

See separate handout for more details

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Existing Chemical Exposure Limit (ECEL)	Unknown	Identifying specific requirements requires input from potentially regulated entities.
Engineering/Administrative Controls	Varies by control type and needs of user	
Reformulation of product to reduce or eliminate MC concentration	$13,000-$129,000 per product	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities.
Product Label or Warnings	$750 - $8,000 per product	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor.
Personal Protective Equipment (PPE) – Inhalation exposure (respirators)	APF 25: $1,200 APF 50: $500-$2,000 APF 1000: $600-$1,300 APF10000: $1,700-$2,000 See separate handout for detailed breakdown	Costs are per employee and include purchase of equipment (including filters), training, fit-testing, and medical clearance. Does not include existing PPE use nor PPE replacement due to employee turn-over.

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Substitute Products (average per ounce)	Varies with condition of use	Methylene chloride is expected to be less expensive per ounce than most substitutes, but the differences in efficacy of the substitute products is likely to be a more important factor for the costs of switching to using the substitute products.
Substitute Methods	Varies by job labor rate	This will primarily be labor cost and cost of alternative equipment (i.e. a heat gun).
Recordkeeping	$200-$325 per firm	Annual labor and material costs associated with documentation of ordinary business records
Downstream Notification	$112-$125 per product	Costs are per product and include labor and material costs to update the product's safety data sheet (SDS)

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Questions for SERs

- How do you use MC?
- What is your experience with exposure control and risk reduction?
- What are the workplace exposures to MC?
  - What routine worker activities result in worker exposure to MC?
  - What is the exposure? How many employees are exposed?
  - What exposure reduction is in place (e.g., engineering controls, administrative controls, PPE)?
- For product users:
  - What chemicals or processes have you considered as an alternative to those containing MC?
- For product formulators:
  - What alternatives could replace MC in your product?
  - How often do you reformulate or relabel your products and what is the typical cost?
- For distributors and retailers:
  - If you could no longer sell MC or certain products containing it, how would this impact your business?
  - Is it feasible to limit purchases only to certain customers?
- How can EPA reduce the impacts on small businesses of our upcoming regulation to address the unreasonable risks?

In-Depth Discussion Groups for Conditions of Use

- Group 1 – Industrial vapor degreasing and cold cleaning uses
- Group 2 – Commercial use of paints, coatings, and their removers
- Group 3 – Industrial and commercial uses of packaged or “off-the-shelf” formulated products
- Group 4 – Industrial and commercial uses of formulations made on-site or facility-specific formulations containing MC
- Group 5 – Other industrial and commercial uses
- Group 6 – Retailers and distributors, consumer users
- Group 7 – Formulators and processors

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Group 1

Industrial vapor degreasing and cold cleaning uses

Use and Application of Methylene Chloride (Group 1)

- Relevant conditions of use:
  - Industrial and commercial use as a solvent for batch vapor degreasing
  - Industrial and commercial use for in-line vapor degreasing
  - Industrial and commercial use as a solvent for cold cleaning
- What is MC used for? How is it applied?
  - MC is used as a degreasing solvent to remove drawing compounds, cutting fluids, coolants, and lubricants from metal parts. It can be used open top vapor degreasing, conveyorized vapor degreasing, or in cold cleaning
  - Cold cleaning operations include spraying, brushing, flushing, and immersion

Unreasonable Risk Determinations (Group 1)

- Who is at risk?
  - For workers, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures, even when assuming use of PPE
  - For ONUs, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures, and of cancer from chronic inhalation exposures
  - Some differences in unreasonable risk determinations for each type of degreasing operation
- Assumptions
  - EPA generally assumes compliance with OSHA requirements for protection of workers
  - For workers, EPA assumed use of respirators with APF 25 or 50
  - For ONUs, EPA did not assume use of PPE

Potential Regulatory Options (Group 1)

Any regulatory option could be used alone or in combination so that methylene chloride no longer presents an unreasonable risk under any condition of use.

- Existing Chemical Exposure Limit (ECEL)
- Prescriptive PPE controls
- Prescriptive engineering controls
- Prescriptive administrative controls
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion – Your Business and Methylene Chloride (Group 1)

- How does your organization use MC?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of MC use in your organization?
- How important to your business is the function that MC provides?

Discussion – Your Experience (Group 1)

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to MC, and for how long (days/years and hours/day)?
- What is the concentration of MC in the product you use?
- What routine worker activities result in worker exposure to MC and what type of exposure?
- What engineering controls are used to minimize exposure to MC? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to MC?
- What PPE is regularly worn by workers to minimize exposure to MC?

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Discussion – Implementation Considerations (Group 1)

- What chemicals or processes have you considered as an alternative to using MC or a product containing MC?
- Do you currently use any alternatives to MC or products containing MC?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?

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Discussion – Regulatory Options (Group 1)

- What regulatory approach should EPA take?
- What advice do you have for reducing impacts on small businesses?

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Group 2

Commercial use of paints, coatings, and their removers

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Use and Application of Methylene Chloride (Group 2)

- Relevant conditions of use
  - Industrial and commercial use in paints and coatings
  - Industrial and commercial use in paint and coating removers
- What is MC used for? How is it applied?
  - Typical industrial and commercial coating applications include manual application with roller or brush, air spray systems, airless and air-assisted airless spray systems, electrostatic spray systems, electrodeposition/electrocoating and auto deposition, dip coating, curtain coating systems, roll coating systems, and supercritical carbon dioxide systems. After application, solvent-based coatings typically undergo a drying stage in which the solvent evaporates from the coating
  - Paint strippers can be used by professional contractors to strip paint and varnish from walls, wood flooring, and kitchen and wood cabinets

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Unreasonable Risk Determinations (Group 2)

- Who is at risk?
  - For workers, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures, and of cancer from chronic inhalation, without assuming use of respirators
  - For ONUs, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures, and of cancer from chronic inhalation exposures
  - Some differences in unreasonable risk determinations for each condition of use. For example, for ONUs, the cancer risk estimates from use of MC in paints and coatings do not support an unreasonable risk determination
- Assumptions
  - EPA generally assumes compliance with OSHA requirements for protection of workers
  - For workers, for these conditions of use, EPA did not assume workers use respirators
  - For ONUs, EPA did not assume use of PPE

Potential Regulatory Options (Group 2)

Any regulatory option could be used alone or in combination so that methylene chloride no longer presents an unreasonable risk under any condition of use.

- Existing Chemical Exposure Limit (ECEL)
- Prescriptive PPE controls
- Prescriptive engineering controls
- Prescriptive administrative controls
- Concentration limit
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion – Your Business and Methylene Chloride (Group 2)

- How does your organization use MC?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of MC use in your organization?
- How important to your business is the function that MC provides?

Discussion – Your Experience (Group 2)

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to MC, and for how long (days/years and hours/day)?
- What is the concentration of MC in the product you use?
- What routine worker activities result in worker exposure to MC and what type of exposure?
- What engineering controls are used to minimize exposure to MC? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to MC?
- What PPE is regularly worn by workers to minimize exposure to MC?

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Discussion – Implementation Considerations (Group 2)

- What chemicals or processes have you considered as an alternative to using MC or a product containing MC?
- Do you currently use any alternatives to MC or products containing MC?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?

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Discussion – Regulatory Options (Group 2)

- What regulatory approach should EPA take?
- What advice do you have for reducing impacts on small businesses?

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Group 3

Industrial and commercial uses of packaged or “off-the-shelf” formulated products

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Use and Application of Methylene Chloride (Group 3)

- Relevant conditions of use:
  - Industrial and commercial use in solvent for aerosol spray degreaser/cleaner
  - Industrial and commercial use in metal aerosol degreasers
  - Industrial and commercial use in aerosol degreasers and cleaners
  - Industrial and commercial use in adhesives, sealants and caulks
  - Industrial and commercial use in cold pipe insulations
  - Industrial and commercial use in anti-spatter welding aerosol
  - Industrial and commercial use in spot removers for apparel and textiles
  - Industrial and commercial use for apparel and footwear care products
  - Industrial and commercial use for finishing products for fabric, textiles, and leather
  - Industrial and commercial use in liquid lubricants and greases
  - Industrial and commercial use in spray lubricants and greases
  - Industrial and commercial use in adhesive and caulk removers
  - Industrial and commercial use in carbon remover, wood flood cleaner, and brush cleaner
  - 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 non-aerosol degreasers and cleaners
  - Industrial and commercial use in metal non-aerosol degreasers

Use and Application of Methylene Chloride (Group 3)

- What is MC used for? How is it applied?
  - MC is found in many packaged or “off-the-shelf” formulated products for industrial and commercial use in automotive care, adhesives and sealants, lubricants and greases, and spot removers, among others
  - MC serves as a solvent and evaporates during adhesive and sealant drying and curing
  - MC is used in post-market wax and polish applied to footwear (e.g., shoe polish)
  - MC is applied to fabrics at industrial fabric mills in textile finishing and impregnating/surface treatment products (e.g., water repellant)
  - MC is used in spot remover for apparel and textiles in spot cleaning products either before or after a garment is dry cleaned
  - MC is used as a solvent in lithographic printing to clean the blankets and rollers. Press operators commonly apply the solvent to a wipe cloth and wipe the blanket to remove the ink, while companies have automated blanket wash systems where the solvent is applied to the blankets with a spray bar

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Unreasonable Risk Determinations (Group 3)

- Who is at risk?
  - For workers, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures. For spot removers for apparel and textiles, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) dermal exposure, without assuming use of gloves
  - For ONUs for many of these conditions of use, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures, and of cancer from chronic inhalation exposures
  - Some differences in unreasonable risk determinations for some of these conditions of use, especially regarding whether or not there is an unreasonable risk of injury to health of ONUs
- Assumptions
  - EPA generally assumes compliance with OSHA requirements for protection of workers
  - For workers, for some conditions of use, EPA assumed use of respirators with APF 25 or 50. Exceptions: EPA did not assume use of respirators for: solvent for aerosol spray degreaser/cleaner; paints and coatings; paint and coating removers; metal aerosol degreasing; spray lubricants and greases; aerosol degreasers and cleaners; finishing products for fabric, textiles and leather; anti-spatter welding aerosol; cold pipe insulation; spot removers for apparel and textiles; apparel and footwear care products; automotive care products (degreasers) (interior care); lithographic printing plate cleaner
  - For ONUs, EPA did not assume use of PPE

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Potential Regulatory Options (Group 3)

Any regulatory option could be used alone or in combination so that methylene chloride no longer presents an unreasonable risk under any condition of use.

- Existing Chemical Exposure Limit (ECEL)
- Prescriptive PPE controls
- Prescriptive engineering controls
- Prescriptive administrative controls
- Concentration limit
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion – Your Business and Methylene Chloride (Group 3)

- How does your organization use MC?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of MC use in your organization?
- How important to your business is the function that MC provides?

Discussion – Your Experience (Group 3)

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to MC, and for how long (days/years and hours/day)?
- What is the concentration of MC in the product you use?
- What routine worker activities result in worker exposure to MC and what type of exposure?
- What engineering controls are used to minimize exposure to MC? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to MC?
- What PPE is regularly worn by workers to minimize exposure to MC?

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Discussion – Implementation Considerations (Group 3)

- What chemicals or processes have you considered as an alternative to using MC or a product containing MC?
- Do you currently use any alternatives to MC or products containing MC?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?

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Discussion - Regulatory Options (Group 3)

- What regulatory approach should EPA take?
- What advice do you have for reducing impacts on small businesses?

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Group 4

Industrial uses of formulations made on-site or facility-specific formulations containing methylene chloride

Use and Application of Methylene Chloride (Group 4)

- Relevant conditions of use:
  - Industrial and commercial use in adhesives, sealants and caulks
  - Industrial and commercial use in paint and coating removers
  - Industrial and commercial use in adhesive and caulk removers
  - Industrial and commercial use in liquid lubricants and greases
  - Industrial and commercial use in spray lubricants and greases
  - Industrial and commercial use in lithographic printing plate cleaner
  - Industrial and commercial use in carbon remover, wood flood cleaner, and brush cleaner

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Use and Application of Methylene Chloride (Group 4)

- What is MC used for? How is it applied?
  - MC may be used in various formulations made on on-site and in facility-specific formulations, including in paints and coatings for industrial, commercial, and consumer applications; in lubricants and greases; and in adhesive and caulk removers
  - Paint and coating applications include manual application with roller or brush, air spray systems, airless and air-assisted airless spray systems, electrostatic spray systems, electrodeposition/electrocoating and auto deposition, dip coating, curtain coating systems, roll coating systems, and supercritical carbon dioxide systems. After application, solvent-based coatings typically undergo a drying stage in which the solvent evaporates from the coating
  - MC is used as a solvent in lithographic printing to clean the blankets and rollers. Press operators commonly apply the solvent to a wipe cloth and wipe the blanket to remove the ink, while companies have automated blanket wash systems where the solvent is applied to the blankets with a spray bar

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Unreasonable Risk Determinations (Group 4)

- Who is at risk?
  - For workers, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures, and of cancer from chronic inhalation exposures
  - For ONUs, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures
  - Some differences in unreasonable risk determinations for some of these conditions of use, especially regarding whether or not there is an unreasonable risk of injury to health of ONUs or an unreasonable risk to workers of cancer from chronic inhalation exposures
- Assumptions
  - EPA generally assumes compliance with OSHA requirements for protection of workers
  - For workers, for some conditions of use, EPA assumed use of respirators with APF 25 or 50. Exception: EPA did not assume use of respirators for: spray lubricants and greases; lithographic printing plate cleaner
  - For ONUs, EPA did not assume use of PPE

Potential Regulatory Options (Group 4)

Any regulatory option could be used alone or in combination so that methylene chloride no longer presents an unreasonable risk under any condition of use.

- Existing Chemical Exposure Limit (ECEL)
- Prescriptive PPE controls
- Prescriptive engineering controls
- Prescriptive administrative controls
- Concentration limit
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion – Your Business and Methylene Chloride (Group 4)

- How does your organization use MC?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of MC use in your organization?
- How important to your business is the function that MC provides?

Discussion – Your Experience (Group 4)

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to MC, and for how long (days/years and hours/day)?
- What is the concentration of MC in the product you use?
- What routine worker activities result in worker exposure to MC and what type of exposure?
- What engineering controls are used to minimize exposure to MC? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to MC?
- What PPE is regularly worn by workers to minimize exposure to MC?

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Discussion – Implementation Considerations (Group 4)

- What chemicals or processes have you considered as an alternative to using MC or a product containing MC?
- Do you currently use any alternatives to MC or products containing MC?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?

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Discussion – Regulatory Options (Group 4)

- What regulatory approach should EPA take?
- What advice do you have for reducing impacts on small businesses?

Group 5
Other industrial and commercial uses

Use and Application of Methylene Chloride (Group 5)

- Relevant conditions of use:
  - 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 in cellulose triacetate film production
  - Industrial and commercial use in toys, playground and sporting equipment
  - Industrial and commercial use as propellant and blowing agent
  - Industrial and commercial use as a processing aid
- What is MC used for? How is it applied?
  - A variety of uses for MC, including as a solvent or carrier in crafting glues and cements, novelty items, and miscellaneous cleaners and in interfacial polymerization for polycarbonate plastic manufacturing

Unreasonable Risk Determinations (Group 5)

- Who is at risk?
  - For workers, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures, even when assuming use of PPE
  - For ONUs, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures, and of cancer from chronic inhalation exposures
  - Some differences in unreasonable risk determinations for each condition of use. For example, plastic and rubber products manufacturing does not present an unreasonable risk of injury to health of workers
- Assumptions
  - EPA generally assumes compliance with OSHA requirements for protection of workers
  - For workers, EPA assumed use of respirators with APF 25 or 50
  - For ONUs, EPA did not assume use of PPE

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Potential Regulatory Options (Group 5)

Any regulatory option could be used alone or in combination so that methylene chloride no longer presents an unreasonable risk under any condition of use.

- Existing Chemical Exposure Limit (ECEL)
- Prescriptive PPE controls
- Prescriptive engineering controls
- Prescriptive administrative controls
- Concentration limit
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion – Your Business and Methylene Chloride (Group 5)

- How does your organization use MC?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of MC use in your organization?
- How important to your business is the function that MC provides?

Discussion – Your Experience (Group 5)

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to MC, and for how long (days/years and hours/day)?
- What is the concentration of MC in the product you use?
- What routine worker activities result in worker exposure to MC and what type of exposure?
- What engineering controls are used to minimize exposure to MC? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to MC?
- What PPE is regularly worn by workers to minimize exposure to MC?

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Discussion – Implementation Considerations (Group 5)

- What chemicals or processes have you considered as an alternative to using MC or a product containing MC?
- Do you currently use any alternatives to MC or products containing MC?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?

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Discussion – Regulatory Options (Group 5)

- What regulatory approach should EPA take?
- What advice do you have for reducing impacts on small businesses?

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Group 6

Distributors and retailers, consumer uses

Use and Application of Methylene Chloride (Group 6)

- Relevant conditions of use:
  - Consumer use as solvent in aerosol degreasers/cleaners
  - Consumer use in adhesives and sealants
  - Consumer use in brush cleaners for paints and coatings
  - Consumer use in adhesive and caulk removers
  - Consumer use in metal degreasers
  - Consumer use in automotive care products (functional fluids for air conditioners)
  - Consumer use in automotive care products (degreasers)
  - Consumer use in lubricants and greases
  - Consumer use in cold pipe insulation
  - Consumer use in arts, crafts, and hobby materials glue
  - Consumer use in an anti-spatter welding aerosol
  - Consumer use in carbon removers and other brush cleaners

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Unreasonable Risk Determinations (Group 6)

- Who is at risk?
  - For consumers, EPA found that there was an unreasonable risk of non-cancer effects (CNS) from acute inhalation and dermal exposures
  - For bystanders, EPA found that there was an unreasonable risk of non-cancer effects (CNS) from acute inhalation
  - Some differences in unreasonable risk determinations for each condition of use. For example, brush cleaners do not present an unreasonable risk to bystanders
- Assumptions
  - EPA did not assume dermal exposure to MC for bystanders
  - EPA did not assume consumers or bystanders use PPE

Potential Regulatory Options (Group 6)

Any regulatory option could be used alone or in combination so that methylene chloride no longer presents an unreasonable risk under any condition of use.

- Regulate manufacturing, processing, or distribution of products for consumer use
- Concentration limit
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion – Your Business and Methylene Chloride (Group 6)

- How does your organization use MC?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of MC use in your organization?
- How important to your business is the function that MC provides?
- For what industries or applications do you provide products and services for?

Discussion – Your Experience (Group 6)

- What is your experience with exposure control and risk reduction?
- If you could no longer sell products containing methylene chloride, how would this impact your business?
- Are there particular challenges to small business doing distribution of products containing methylene chloride that are different from large distributors?
- What is your preferred method of downstream notification?
- If you were required to limit sales of MC containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency?

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Discussion – Regulatory Options (Group 6)

- What regulatory approach should EPA take?
- What advice do you have for reducing impacts on small businesses?

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Group 7
Formulators and processors

Use and Application of Methylene Chloride (Group 7)

- Relevant conditions of use:
  - Processing – incorporation into a formulation, mixture, or reaction products
  - Industrial and commercial use as a solvent that becomes part of a formulation
- What is MC used for? How is it applied?
  - The uses of methylene chloride that may require incorporation into a formulation include paint removers; adhesives and sealants; paints and coatings; degreasers, cleaners, and spot removers; and lubricants
  - The formulation of paints and coatings typically involves dispersion, milling, finishing and filling into final packages
  - Adhesive/sealant formulation involves mixing volatile and non-volatile chemical components in sealed, unsealed or heated processes. Sealed processes are most common for adhesive/sealant formulation because many adhesives/sealants are designed to set or react when exposed to ambient conditions
  - Many of these formulated products may be packed in aerosol form. Methylene chloride cannot function alone as a propellant because of its low vapor pressure relative to other propellants. A solvent such as methylene chloride brings the active ingredient into solution with the propellants

Unreasonable Risk Determinations (Group 7)

- Who is at risk?
  - For workers, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures, even when assuming use of PPE
  - For ONUs, EPA found that there was unreasonable risk of non-cancer effects from acute (CNS) and chronic (liver) inhalation exposures
- Assumptions
  - EPA generally assumes compliance with OSHA requirements for protection of workers
  - For workers, EPA assumed use of respirators with APF 25 or 50
  - For ONUs, EPA did not assume use of PPE

Potential Regulatory Options (Group 7)

Any regulatory option could be used alone or in combination so that methylene chloride no longer presents an unreasonable risk under any condition of use.

- Existing Chemical Exposure Limit (ECEL)
- Prescriptive PPE controls
- Prescriptive engineering controls
- Prescriptive administrative controls
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion – Your Business and Methylene Chloride (Group 7)

- How does your organization use MC?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of MC use in your organization?
- How important to your business is the function that MC provides?
- For what industries or applications do you provide products or services for?

Discussion – Your Experience (Group 7)

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to MC, and for how long (days/years and hours/day)?
- What is the concentration of MC in the product you use?
- What routine worker activities result in worker exposure to MC and what type of exposure?
- What engineering controls are used to minimize exposure to MC? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to MC?
- What PPE is regularly worn by workers to minimize exposure to MC?

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Discussion – Implementation Considerations (Group 7)

- Product reformulation
  - How often do you reformulate your products?
  - What is the typical cost of reformulating your products?
  - What might reformulation costs be if you needed to reformulate your products without MC? (For example, costs might include R&D, testing, capital costs of production changes, packaging, labeling)
- Product relabeling
  - How often do you relabel your products?
  - What is the typical cost of relabeling?
- Alternatives
  - Do you sell another product that does not contain MC that is designed for the same use or application as the MC product?
    - If yes, what solvent replaces MC in the alternative product? How does the alternative product compare in terms of safety, efficacy, and cost?
    - If no, if you needed to reformulate this product with a lower concentration of MC, what would the implications be for the product in terms of cost and efficacy? What solvent would replace MC? How do you think the alternative would compare in terms of efficacy and cost?
  - Is there a subset of uses for your product where using a product formulated without MC would be problematic?

Discussion - Regulatory Options (Group 7)

- What regulatory approach should EPA take?
- What advice do you have for reducing impacts on small businesses?

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Closing Session

- Closing remarks from EPA, SBA, and OMB
- Next steps

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Additional Information

- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities
- Risk Management Activities for MC: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride
- Methylene chloride: Ingrid Feustel (Feustel.ingrid@epa.gov, 202-564-3199)
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)

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