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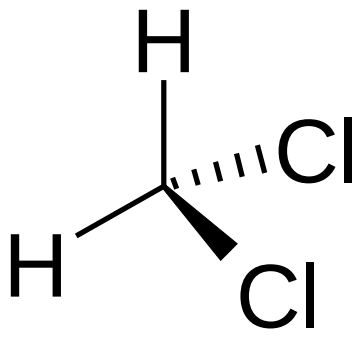
Scope of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)

CASRN: 75-09-2



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ABBREVIATIONS

°C	Degrees Celsius
ACGIH	American Conference of Government Industrial Hygienists
AEGL	Acute Exposure Guideline Level
atm	Atmosphere(s)
ATSDR	Agency for Toxic Substances and Disease Registry
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEPA	Canadian List of Toxic Substances
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CHIRP	Chemical Risk Information Platform
cm^3	Cubic Centimeter(s)
CNS	Central Nervous System
COC	Concentration of Concern
CoCAP	Cooperative Chemicals Assessment Program
COHb	Carboxyhemoglobin
CPSA	Consumer Product Safety Act
CPSC	Consumer Product Safety Commission
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DCM	Dichloromethane (Methylene Chloride)
DMR	Discharge Monitoring Report
DOT	Department of Transportation
ECHA	European Chemicals Agency
EG	Effluent Guidelines
EHC	Environmental Health Criteria
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ESD	Emission Scenario Document
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FSHA	Federal Hazardous Substance Act
g	Gram(s)
GACT	Generally Available Control Technology
HAP	Hazardous Air Pollutant
HFC	Hydrofluorocarbon
HHE	Health Hazard Evaluation
HMTA	Hazardous Materials Transportation Act
HPV	High Production Volume
IARC	International Agency for Research on Cancer

ICIS-NPDES	Integrated Compliance Information System for the National Pollutant Discharge Elimination System
IDLH	Immediately Dangerous to Life and Health
IMAP	Inventory Multi-Tiered Assessment and Prioritisation
IRIS	Integrated Risk Information System
ISHA	Industrial Safety and Health Act
L	Liter(s)
lb	Pound
Log K_{oc}	Logarithmic Organic Carbon:Water Partition Coefficient
Log K_{ow}	Logarithmic Octanol: Water Partition Coefficient
m^3	Cubic Meter(s)
MACT	Maximum Achievable Control Technology
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
mg	Milligram(s)
mmHg	Millimeter(s) of Mercury
MOA	Mode of Action
mPa·s	Millipascal(s)-Second
NAC	National Advisory Committee
NAICS	North American Industry Classification System
NAWQA	National Water Quality Assessment Program
NEI	National Emissions Inventory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NHANES	National Health and Nutrition Examination Survey
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIH	National Institutes of Health
NIOSH	National Institute of Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NOAA	National Oceanic and Atmospheric Administration
NPDWR	National Primary Drinking Water Regulation
NRC	National Research Council
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEHHA	Office of Environmental Health Hazard Assessment
OEL	Occupational Exposure Limits
OGC	Office of General Counsel
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
OSHA	Occupational Safety and Health Administration
OTVD	Open-Top Vapor Degreaser
OW	Office of Water
PEL	Permissible Exposure Limit
PHMSA	Pipeline and Hazardous Materials Safety Administration
POD	Point of Departure
POTW	Publicly Owned Treatment Works

ppb	Part(s) per Billion
ppm	Part(s) per Million
PWS	Public Water System
QC	Quality Control
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REL	Recommended Exposure Limit
RICE	Reciprocating Internal Combustion Engines
SDWA	Safe Drinking Water Act
SIAP	SIDS Initial Assessment Profile
SIDS	Screening Information Data Set
SMAC	Spacecraft Maximum Allowable Concentrations
SNAP	Significant New Alternatives Policy
STEL	Short-Term Exposure Limit
STORET	STOrage and RETrieval and Water Quality exchange
TCCR	Transparent, clear, consistent, and reasonable
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TTO	Total Toxic Organics
TWA	Time-Weighted Average
U.S.	United States
VOC	Volatile Organic Compound
WHO	World Health Organization

EXECUTIVE SUMMARY

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use." In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). Methylene chloride was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. This document fulfills the TSCA § 6(b)(4)(D) requirement for methylene chloride.

This document presents the scope of the risk evaluation to be conducted for methylene chloride. If a hazard, exposure, condition of use or potentially exposed or susceptible subpopulation has not been discussed, EPA, at this point in time, is not intending to include it in the scope of the risk evaluation. As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, with respect to conditions of use in conducting a risk evaluation under TSCA, EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for methylene chloride. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

Methylene chloride, also known as dichloromethane and DCM, is a volatile and high production volume (HPV) chemical that is used as a solvent in a wide range of industrial, commercial and consumer applications. Methylene chloride is subject to a number of federal and state regulations and reporting requirements. In 2014 EPA assessed the risk from methylene chloride in consumer and commercial paint removal, the Agency determined that those risks were unreasonable and, on January 19, 2017, proposed restrictions under TSCA section 6 to address the risks from methylene chloride in paint and coating removal by consumers and most commercial users (82 FR 7464, January 19, 2017). Methylene chloride is a reportable Toxics Release Inventory (TRI) chemical under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) since 1987. It is designated a

Hazardous Air Pollutant (HAP) under the Clean Air Act (CAA), a hazardous waste under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and a regulated drinking water contaminant under the Safe Drinking Water Act (SDWA), and products containing methylene chloride are required to be labeled under the Consumer Product Safety Act (CPSA).

Information on domestic manufacture, processing and use of methylene chloride is available to EPA through its Chemical Data Reporting (CDR) Rule, issued under TSCA. In 2015, more than 260 million lbs of methylene chloride was reported to be manufactured (including imported) in the U.S. According to the ICIS chemical profile in 2005, the primary uses for methylene chloride are paint stripping and removal (30%), adhesives (22%), pharmaceuticals (11%), metal cleaning (8%), aerosols (8%), chemical processing (8%), flexible polyurethane foam (5%) and miscellaneous (8%).

The initial conceptual models presented in Section 2 identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed populations, including potentially exposed or susceptible subpopulations; and hazards EPA expects to evaluate based on the inherent hazards of the chemical.

This document presents the occupational scenarios in which workers and occupational non-users may be exposed to methylene chloride during a variety of conditions of use, such as manufacturing, processing and uses in paint removal, adhesives and degreasing. EPA expects that the highest exposures to methylene chloride generally involve workers in industrial and commercial settings. Methylene chloride can be found in numerous products and can, therefore, result in exposures to commercial and consumer users. This document also presents the consumer conceptual model which indicates exposures occurring from methylene chloride containing products in either indoor or outdoor environments. For methylene chloride, EPA believes that workers, consumers, and bystanders as well as certain other groups of individuals may experience greater exposures than the general population. EPA will evaluate whether other groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) or have greater susceptibility than the general population, and should therefore be considered relevant potentially exposed or susceptible subpopulations for purposes of this risk evaluation.

Exposures to the general population may occur from industrial releases. The Toxics Release Inventory (TRI) identified releases of methylene chloride to air, water and land, with the majority being releases to air. The general population can be exposed to methylene chloride through inhalation, oral and dermal pathways due to its widespread presence in a variety of environmental media such as in air, drinking water, ground water and/or surface water. EPA considers workers, occupational non-users, consumers and bystanders and certain groups of individuals who may experience greater exposures due to proximity to conditions of use, as potentially exposed or susceptible subpopulations.

Methylene chloride has been the subject of numerous human health reviews including EPA's Integrated Risk Information System (IRIS) Toxicological Review and Agency for Toxic Substances and Disease Registry's (ATSDR's) Toxicological Profile and a 2014 assessment of risk in consumer and commercial paint removal. Along with other reasonably available information, EPA will use the existing TSCA risk assessments to inform its development of the methylene chloride risk evaluation. A number of targets of toxicity from exposures to methylene chloride have been identified in animal and human

studies for both oral and inhalation exposures. EPA expects to consider hazard endpoints for: acute toxicity (via central nervous system [CNS] depression which can result in death), irritation, liver toxicity and neurotoxicity. Methylene chloride is also likely carcinogenic in humans. If additional hazard concerns are identified during the systematic review of the literature, these will also be considered. These hazards will be evaluated based on the specific exposure scenarios identified.

The initial analysis plan describes EPA's plan for conducting systematic review of readily available information and identification of assessment approaches to be used in conducting the risk evaluation for methylene chloride. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the risk evaluation of methylene chloride.

1 INTRODUCTION

This document presents the scope of the risk evaluation to be conducted for methylene chloride. If a condition of use has not been discussed, U.S. Environmental Protection Agency (EPA), at this point in time, is not intending to include that condition of use in the scope of the risk evaluation. Moreover, during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation. Any condition of use that will not be evaluated will be clearly described in the problem formulation document.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), the nation's primary chemicals management law, was signed into law. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b)(4) requires the EPA to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use."

In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. On February 14, 2017, EPA convened a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of the risk evaluations under development for the ten chemical substances designated in December 2016 for risk evaluations pursuant to TSCA. EPA provided the public an opportunity to identify information, via oral comment or by submission to a public docket, specifically related to the conditions of use for the ten chemical substances. EPA used this information in developing this scope document, which fulfills the TSCA § 6(b)(4)(D) requirement for methylene chloride.

As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, in conducting a risk evaluation under TSCA EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. Based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities may not generally be considered to be conditions of use. In exercising its discretion, for example, EPA would not generally consider that a single unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a

chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. In addition, EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Furthermore, in exercising its discretion under section 6(b)(4)(D) to identify the conditions of use that EPA expects to consider in a risk evaluation, EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. Consequently, EPA may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern meriting an unreasonable risk consideration. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping, in order to determine which risk evaluation the potential risks from the chemical substance should be addressed in. As an additional example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.

The situations identified above are examples of the kinds of discretion that EPA will exercise in determining what activities constitute conditions of use, and what conditions of use are to be included in the scope of any given risk evaluation. See the preamble to *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)* for further discussion of these issues.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. The first 10 chemical substances were not subject to the prioritization process that will be used in the future in accordance with amendments to TSCA. EPA expects to collect and screen much of the relevant

information about chemical substances that will be subject to the risk evaluation process during and before prioritization. The volume of data and information about the first 10 chemicals that is available to EPA is extremely large and EPA is still in the process of reviewing it, since the Agency had limited ability to process the information gathered before issuing the scope documents for the first 10 chemicals. As a result of the statutory timeframes, EPA had limited time to process all of the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. For these reasons, EPA's initial screenings and designations with regard to applicability of data (e.g., on-topic vs. off-topic information and data) may change as EPA progresses through the risk evaluation process. Likewise, the Conceptual Models and Analysis Plans provided in the first 10 chemical scopes are designated as "Initial" to indicate that EPA expects to further refine them during problem formulation.

The aforementioned time constraints and uncertainty associated with developing the risk evaluation process rule has resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents. For these reasons, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to methylene chloride. EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. During risk evaluation, EPA will evaluate and consider the impact of these existing laws and regulations in the problem formulation step to determine what, if any further analysis might be necessary as part of the risk evaluation.

Federal Laws and Regulations

Methylene chloride is subject to federal statutes or regulations, other than TSCA, that are implemented by other offices within EPA and/or other federal agencies/departments. A summary of federal laws, regulations and implementing authorities is provided in Appendix A.1.

State Laws and Regulations

Methylene chloride is subject to state statutes or regulations implemented by state agencies or departments. A summary of state laws, regulations and implementing authorities is provided in Appendix A.2.

Laws and Regulations in Other Countries and International Treaties or Agreements

Methylene chloride is subject to statutes or regulations in countries other than the United States and/or international treaties and/or agreements. A summary of these laws, regulations, treaties and/or agreements is provided in Appendix A.3.

1.2 Assessment History

EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations—information useful to EPA in preparing this scope for risk evaluation. Table 1-1 shows the assessments that have been conducted. In addition to using this information, EPA intends to conduct a full review of the data collected (see *Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742) using the literature search strategy (see *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742) to ensure that EPA is considering information that has been made available since these assessments were conducted.

In the final 2014 risk assessment, U.S. EPA (2014a) identified risks from methylene chloride in consumer and commercial paint removal. The Agency determined those risks were unreasonable and, on January 19, 2017, proposed restrictions under TSCA section 6 to address the risks from methylene chloride in paint and coating removal by consumers and most commercial users (82 FR 7464, January 19, 2017). Along with other reasonably available information, EPA will use the existing TSCA risk assessments to inform its development of the methylene chloride risk evaluation.

Table 1-1. Assessment History of Methylene Chloride

Authoring Organization	Assessment
EPA Assessments	
U.S. EPA, Office of Pollution Prevention and Toxics (OPPT)	TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use CASRN: 75-09-2 U.S. EPA (2014a)
U.S. EPA, Integrated Risk Information System (IRIS)	Toxicological Review of Dichloromethane (Methylene Chloride) (CAS No. 75-09-2) U.S. EPA (2011)
U.S. EPA, Office of Water (OW)	Ambient Water Quality Criteria for the Protection of Human Health U.S. EPA (2015)
Other U.S.-Based Organizations	
Agency for Toxic Substances and Disease Registry (ATSDR)	Toxicological Profile for Methylene Chloride ATSDR (2000) and addendum ATSDR (2010)
National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee)	Interim Acute Exposure Guideline Levels (AEGL) for Methylene Chloride NAC/AEGL (2008)
U.S. National Academies, National Research Council (NRC)	Spacecraft Maximum Allowable Concentrations (SMAC) for Selected Airborne Contaminants: Methylene chloride (Volume 2) NRC (1996)
National Toxicology Program (NTP), National Institutes of Health (NIH)	Report on Carcinogens, Twelfth Edition, Dichloromethane NTP (2016)

Authoring Organization	Assessment
Occupational Safety and Health Administration (OSHA)	Occupational Exposure to Methylene Chloride OSHA (1997)
California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (OEHHA)	Acute Reference Exposure Level (REL) and Toxicity Summary for Methylene Chloride OEHHA (2008)
	Public Health Goal for Methylene Chloride in Drinking Water OEHHA (2000)
International	
Organisation for Economic Co-operation and Development (OECD), Cooperative Chemicals Assessment Program (CoCAP)	Dichloromethane: SIDS Initial Assessment Profile OECD (2011)
International Agency for Research on Cancer (IARC)	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 110 IARC (2016)
World Health Organization (WHO)	Air Quality Guidelines for Europe WHO (2000)
Government of Canada, Environment Canada, Health Canada	Dichloromethane. Priority substances list assessment report. Health Canada (1993)
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australian Government	Human Health Tier II Assessment for Methane, dichloro- CAS Number: 75-09-2 NICNAS (2016)

1.3 Data and Information Collection

EPA/OPPT generally applies a process and workflow that includes: (1) data collection; (2) data evaluation; and (3) data integration of the scientific data used in risk assessments developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects that multiple refinements regarding data collection will occur during the process of risk evaluation.

Data Collection: Data Search

EPA/OPPT conducted chemical-specific searches for data and information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations; ecological hazard, human health hazard, including potentially exposed or susceptible subpopulations.

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments and the

National Toxicology Program's (NTP) *Report on Carcinogens,* to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental File for the TSCA Scope Document* provides details about the data sources and search terms that were used in the initial search.

Data Collection: Data Screening

Following the data search, references were screened and categorized using selection criteria outlined in supplemental document: *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental File for the TSCA Scope Document.* Titles and abstracts were screened against the criteria as a first step with the goal of identifying a smaller subset of the relevant data to move into the subsequent data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the search and screening strategies, as informed by an evaluation of the performance of the initial title/abstract screening and categorization process.

The categorization scheme (or tagging structure) used for data screening varies by scientific discipline (i.e., physical and chemical properties; environmental fate and transport; chemical use/conditions of use information; human and environmental exposures, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard), but within each data set, there are two broad categories or data tags: (1) o*n-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. O*ff-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. The supplemental document: *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental File for the TSCA Scope Document* discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic*.

Additional data screening using sub-categories (or sub-tags) was also performed to facilitate further sorting of data/information - for example, identifying references by source type (e.g., published peer-reviewed journal article, government report); data type (e.g., primary data, review article); human health hazard (e.g., liver toxicity, cancer, reproductive toxicity); or chemical-specific and use-specific data or information. These sub-categories are described in supplemental document: *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental File for the TSCA Scope Document* and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review.

Results of the initial search and categorization results can be found in the *Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document.* This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and the initial categorization for *on-topic* and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *off-topic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for modeling); hence, additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

2 SCOPE OF THE EVALUATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA is including an initial life cycle diagram and initial conceptual models that describe the actual or potential relationships between methylene chloride and human and ecological receptors. An initial analysis plan is also included which identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards) and risks under the conditions of use for methylene chloride. As noted previously, EPA intends to refine this analysis plan during the problem formulation phase of risk evaluation.

2.1 Physical and Chemical Properties

Physical-chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways and routes and hazards that EPA intends to consider. For scope development, EPA considered the measured or estimated physical-chemical properties set forth in Table 2-1.

Table 2-1. Physical and Chemical Properties of Methylene Chloride

Property	Value [a]	References
Molecular formula	CH_2Cl_2	
Molecular weight	84.93 g/mol	
Physical form	Colorless liquid; sweet, pleasant odor resembling chloroform	U.S. Coast Guard (1984)
Melting point	-95°C	O'Neil (2013)
Boiling point	39.7°C	O'Neil (2013)
Density	1.33 g/cm^3 at 20°C	O'Neil (2013)
Vapor pressure	435 mmHg at 25°C	Boublík et al. (1984)
Vapor density	2.93 (relative to air)	Holbrook (2003)
Water solubility	13 g/L at 25°C	Horvath (1982)
Octanol/water partition coefficient (log K_{ow})	1.25	Hansch et al. (1995)
Henry's Law constant	0.00325 atm-m^3/mole	Leighton and Calo (1981)
Flash point	Not readily available	
Autoflammability	Not readily available	
Viscosity	0.437 mPa·s at 20°C	Rossberg et al. (2011)
Refractive index	1.4244 at 20°C	O'Neil (2013)

Property	Value [a]	References
Dielectric constant	9.02 at 20°C	Laurence et al. (1994)
[a] Measured unless otherwise noted.		

2.2 Conditions of Use

TSCA § 3(4) defines the conditions of use as ‘‘the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.’’

2.2.1 Data and Information Sources

As the first step in preparing these scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. As further described in this document, EPA searched a number of available data sources (e.g., *Use and Market Profile for Methylene Chloride*, EPA-HQ-OPPT-2016-0742). Based on this search, EPA published a preliminary list of information and sources related to chemical conditions of use (see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Methylene Chloride*, EPA-HQ-OPPT-2016-0742-0003) prior to a February 2017 public meeting on scoping efforts for risk evaluation convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public and stakeholder meetings has been incorporated into this scope document to the extent appropriate, as indicated in Table 2-3. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseen activities associated with the subject chemicals, based on reasonably available information. The documents do not, in most cases, specify whether activity under discussion is intended, known, or reasonably foreseen, in part due to the time constraints in preparing these documents.

2.2.2 Identification of Conditions of Use

As part of the scope, an initial life cycle diagram is provided (Figure 2-1) depicting the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer; when distinguishable), distribution and disposal. The information is grouped according to Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes for industrial uses and product categories for commercial and consumer uses), in combination with other data sources (e.g., published literature and consultation with stakeholders), to provide an overview of conditions of use. EPA notes that some subcategories may be grouped under multiple CDR categories.

For the purposes of this scope, CDR definitions were used. CDR use categories include the following: “industrial use” means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. “Commercial use” means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. “Consumer use” means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use (U.S. EPA, 2016c).

To understand conditions of use relative to one another and associated potential exposures under those conditions of use, the initial life cycle diagram includes the production volume associated with each stage of the life cycle, as reported in the 2016 CDR reporting (U.S. EPA, 2016c), when the volume was not claimed confidential business information (CBI). The 2016 CDR reporting data for methylene chloride are provided in Table 2-2 from EPA's CDR database.

Table 2-2. Production Volume of Methylene Chloride in CDR Reporting Period (2012 to 2015) [a]

Reporting Year	2012	2013	2014	2015
Total Aggregate Production Volume (lbs)	230,896,388	230,498,027	248,241,495	263,971,494

[a] The CDR data for the 2016 reporting period is available via ChemView (https://java.epa.gov/chemview) (U.S. EPA, 2016c). Because of an ongoing CBI substantiation process required by amended TSCA, the CDR data available in the scope document is more specific than currently in ChemView.

Figure 2-1 depicts the initial life cycle diagram of methylene chloride from manufacture to the point of disposal. EPA identified the use categories by reviewing the industrial processing use activities, and commercial and consumer use product categories reported in the 2016 CDR. Then, EPA identified the subcategories by supplementing CDR data with information from *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Methylene Chloride* and *Use and Market Profile for Methylene Chloride*, both available in the public docket (EPA-HQ-OPPT-2016-0742). For risk evaluations, EPA will assess each use subcategory by identifying all potential sources of release and human exposure associated with that subcategory.

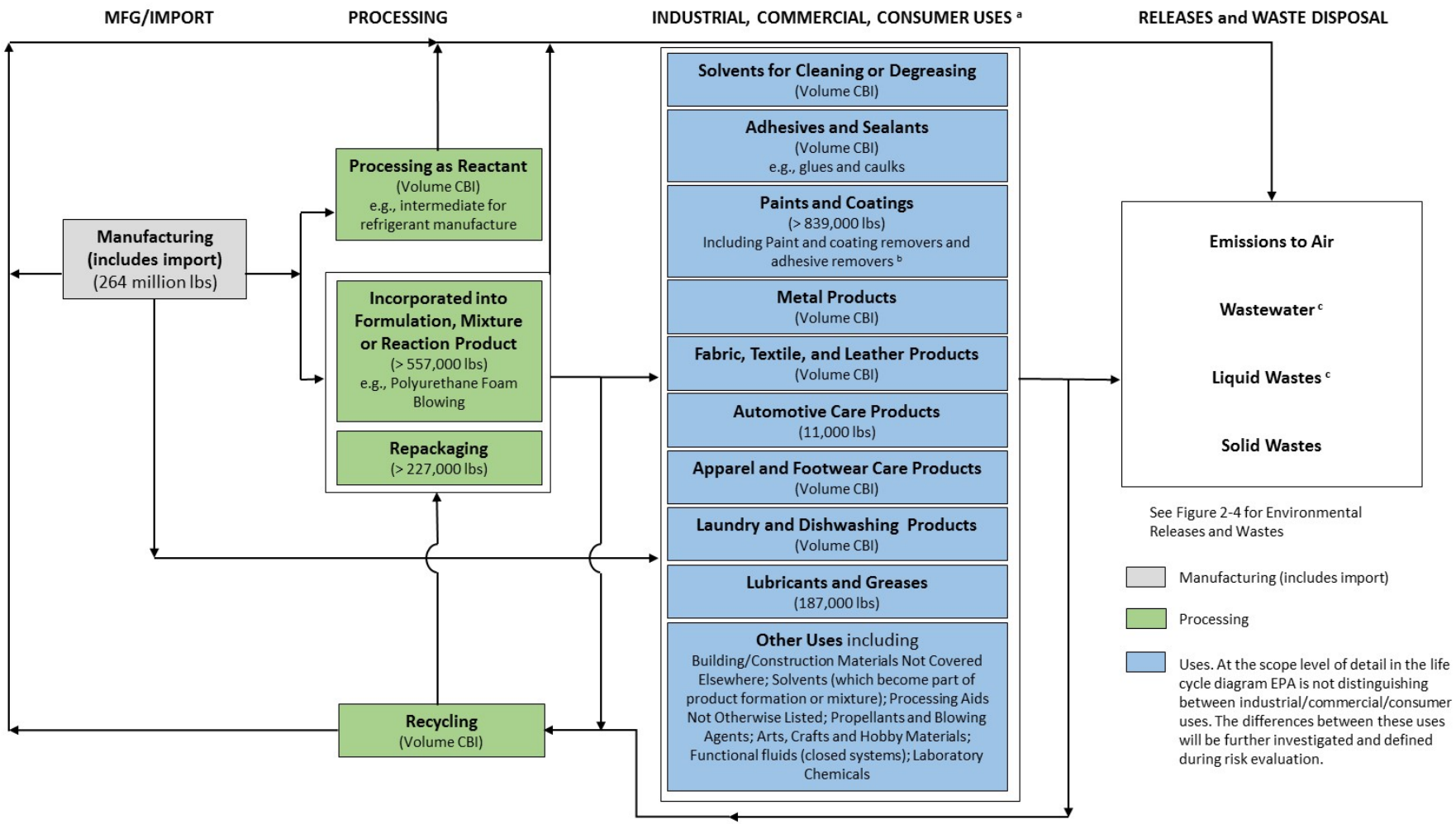

Figure 2-1. Initial Methylene Chloride Life Cycle Diagram

The initial life cycle diagram depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer), distribution and disposal. The production volumes shown are for reporting year 2015 from the 2016 CDR reporting period (U.S. EPA, 2016c). Activities related to distribution (e.g., loading and unloading) will be considered throughout the methylene chloride life cycle, rather than using a single distribution scenario.

[a] See Table 2-3 for additional uses not mentioned specifically in this diagram.

[b] This includes uses assessed in the U.S. EPA (2014a) risk assessment and therefore those uses are out of scope for the risk evaluation.

[c] Wastewater: combination of water and organic liquid, where the organic content is <50%. Liquid wastes: combination of water and organic liquid, where the organic content is >50%.

Descriptions of several of the industrial, commercial and consumer use categories identified from the 2016 CDR and included in the initial life cycle diagram are summarized below (U.S. EPA, 2016c). The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions and worker activities) for each manufacturing, processing, use and disposal category. The descriptions provided below are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions from the 2016 CDR and can be found in EPA's Instructions for Reporting 2016 TSCA Chemical Data Reporting (U.S. EPA, 2016a).

The **"Solvents for Cleaning and Degreasing"** category encompasses chemical substances used to dissolve oils, greases and similar materials from a variety of substrates including metal surfaces, glassware and textiles. This category includes the use of methylene chloride in vapor degreasers and cold cleaners and in industrial, commercial and consumer aerosol degreasing products. Methylene chloride degreasers are often designed to clean electronic parts, electric motors and other water-sensitive parts in industrial and commercial settings. Methylene chloride is also found in products available to consumers such as brush cleaners or products designed to remove oil and grease from electronic or mechanical parts.

The **"Adhesives and Sealants"** category encompasses chemical substances contained in adhesive and sealant products used to fasten other materials together. The adhesives and sealants are found in both liquid and aerosol forms. Examples include adhesives for bonding laminate to particle board or other surfaces, foam to textiles, fiberglass to metal ductwork, carpet installation and cement for bonding acrylic.

The **"Paints and Coatings"** category encompasses chemical substances used in a variety of paints, varnishes, lacquers or other types of coatings used on a variety of substrates including wood and metal. This category also covers paints and coatings removal uses, which include uses addressed in a previous risk evaluation. Both of these categories have industrial, commercial and consumer uses with products used in liquid, aerosol and paste forms.

The **"Metal Products Not Covered Elsewhere"** category encompasses chemical substances contained in metal products not covered elsewhere that are intended for consumer or commercial use. Examples of metal products not covered elsewhere include metal products produced by forging, stamping, plating, turning, and other processes; hand tools; metal tubing/pipes/duct work; wire fencing; tableware; and small appliances and cookware.

The **"Fabric, Textile, and Leather Products Not Covered Elsewhere"** category encompasses chemical substances used to clean and treat a variety of textiles including upholstery and leather. This category is primarily industrial and commercial users and the products are generally in liquid formulations.

The "**Automotive Care Products**" category encompasses chemical substances contained in products used to seal leaks in car air conditioners or used in auto air conditioner refrigerants. These products are generally used in aerosol form and used in both commercial and consumer settings.

The **"Apparel and Footwear Care Products"** category encompasses chemical substances contained in apparel and footwear care products that are applied post-market. Examples of apparel and footwear

care products include footwear polishes/waxes, garment waterproofing sprays, and stain repellents. These products are primarily consumer or commercial uses.

The **"Laundry and Dishwashing Products"** category encompasses chemical substances contained in laundry and dishwashing products and aids. Examples of laundry and dishwashing products include detergents, fabric softeners, pre-soaks and prewashes to remove soil and stains, dryer sheets, bleach, rinse aids, and film, lime and rust removers. These products are generally used as liquids, granular, powders, gels, cakes, and flakes and used in both consumer and commercial settings.

The **"Lubricants and Greases"** category encompasses chemical substances contained in products used in lubricants for cables, chains, metal parts, doors and dry film. These are primarily commercial or industrial uses with both liquid and aerosol formulations.

Other uses of methylene chloride include uses in building/construction materials not covered elsewhere; solvents (which become part of product formation or mixture); processing aids not otherwise listed; propellants and blowing agents; arts, crafts and hobby materials (e.g., crafting glue and cement), functional fluids (closed systems); laboratory chemicals; novelty items (e.g., Red Retro Happy Dippy Drinking Bird).

Table 2-3 summarizes each life cycle stage and the corresponding categories and subcategories of conditions of use for methylene chloride that EPA expects to consider in the risk evaluation. Using the 2016 CDR, EPA identified industrial processing or use activities, industrial function categories and commercial and consumer use product categories. EPA identified the subcategories by supplementing CDR data with other published literature and information obtained through stakeholder consultations. For risk evaluations, EPA intends to consider each life cycle stage (and corresponding use categories and subcategories) and assess relevant potential sources of release and human exposure associated with that life cycle stage.

Table 2-3. Categories and Subcategories of Conditions of Use for Methylene Chloride

Life Cycle Stage	Category [a]	Subcategory [b]	References
Manufacturing	Domestic manufacturing	Manufacturing	U.S. EPA (2016c)
	Import	Import	U.S. EPA (2016c)
Processing	Processing as a reactant	Intermediate in industrial gas manufacturing (e.g., manufacture of fluorinated gases used as refrigerants)	U.S. EPA (2016c); U.S. EPA (2014a) Market profile EPA-HQ-OPPT-2016-0742 Public Comments EPA-HQ-OPPT-2016-0742-0016, EPA-HQ-OPPT-2016-0742-0017, EPA-HQ-OPPT-2016-0742-0019
		Intermediate for pesticide, fertilizer, and other agricultural chemical manufacturing	U.S. EPA (2016c)

Life Cycle Stage	Category [a]	Subcategory [b]	References
Processing	Processing as a reactant	CBI function for petrochemical manufacturing	U.S. EPA (2016c)
		Intermediate for other chemicals	Public Comment EPA-HQ-OPPT-2016-0742-0008
	Incorporated into formulation, mixture, or reaction product	Solvents (for cleaning or degreasing), including manufacturing of: • All other basic organic chemical • Soap, cleaning compound and toilet preparation	U.S. EPA (2016c)
		Solvents (which become part of product formulation or mixture), including manufacturing of: • All other chemical product and preparation • Paints and coatings	U.S. EPA (2016c)
		Propellants and blowing agents for all other chemical product and preparation manufacturing	U.S. EPA (2016c)
		Propellants and blowing agents for plastics product manufacturing	Use document EPA-HQ-OPPT-2016-0742-0003, Market profile EPA-HQ-OPPT-2016-0742
		Paint additives and coating additives not described by other codes for CBI industrial sector	U.S. EPA (2016c)
		Laboratory chemicals for all other chemical product and preparation manufacturing	U.S. EPA (2016c), EPA-HQ-OPPT-2016-0742-0005, EPA-HQ-OPPT-2016-0742-0014
		Laboratory chemicals for CBI industrial sectors	U.S. EPA (2016c)
		Processing aid, not otherwise listed for petrochemical manufacturing	U.S. EPA (2016c)
		Adhesive and sealant chemicals in adhesive manufacturing	Use document EPA-HQ-OPPT-2016-0742-0003 U.S. EPA (2016c)

Life Cycle Stage	Category [a]	Subcategory [b]	References
Processing	Incorporated into formulation, mixture, or reaction product	Unknown function for oil and gas drilling, extraction, and support activities	Use document EPA-HQ-OPPT-2016-0742-0003 U.S. EPA (2016c)
	Repackaging	Solvents (which become part of product formulation or mixture) for all other chemical product and preparation manufacturing	Use document EPA-HQ-OPPT-2016-0742-0003 U.S. EPA (2016c)
		CBI functions for all other chemical product and preparation manufacturing	Use document EPA-HQ-OPPT-2016-0742-0003 U.S. EPA (2016c)
	Recycling	Recycling	U.S. EPA (2017)
Distribution in commerce	Distribution	Distribution	Use document EPA-HQ-OPPT-2016-0742-0003
Industrial, commercial and consumer uses	Solvents (for cleaning or degreasing) [c]	Batch vapor degreaser (e.g., open-top, closed-loop)	Use document EPA-HQ-OPPT-2016-0742-0003; U.S. EPA (2016c); Public comment EPA-HQ-OPPT-2016-0742-0017
		In-line vapor degreaser (e.g., conveyorized, web cleaner)	Use document EPA-HQ-OPPT-2016-0742-0003; U.S. EPA (2016c); Public comment EPA-HQ-OPPT-2016-0742-0017
		Cold cleaner	Use document EPA-HQ-OPPT-2016-0742-0003; U.S. EPA (2016c, 2014a)
		Aerosol spray degreaser/cleaner	U.S. EPA (2016c); Use document EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742; U.S. EPA (2014a)

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial, commercial and consumer uses	Adhesives and sealants	Single component glues and adhesives and sealants and caulks	Use document EPA-HQ-OPPT-2016-0742-0003; U.S. EPA (2016c); Public Comments EPA-HQ-OPPT-2016-0742-0005, EPA-HQ-OPPT-2016-0742-0013, EPA-HQ-OPPT-2016-0742-0014, EPA-HQ-OPPT-2016-0742-0017, EPA-HQ-OPPT-2016-0742-0021, EPA-HQ-OPPT-2016-0742-0033
	Paints and coatings including paint and coating removers [d]	Paints and coatings use and paints and coating removers, including furniture refinisher	U.S. EPA (2016c); U.S. EPA (2014a); Market profile EPA-HQ-OPPT-2016-0742 Public Comments EPA-HQ-OPPT-2016-0742-0005, EPA-HQ-OPPT-2016-0742-0009, EPA-HQ-OPPT-2016-0742-0014, EPA-HQ-OPPT-2016-0742-0017, EPA-HQ-OPPT-2016-0742-0021, EPA-HQ-OPPT-2016-0742-0025
		Adhesive/caulk removers	Use document EPA-HQ-OPPT-2016-0742-0003, Market profile EPA-HQ-OPPT-2016-0742
	Metal products not covered elsewhere	Degreasers – aerosol and non-aerosol degreasers and cleaners e.g., coil cleaners	Market profile EPA-HQ-OPPT-2016-0742 U.S. EPA (2016c)
	Fabric, textile and leather products not covered elsewhere	Textile finishing and impregnating/ surface treatment products e.g. water repellant	Market profile EPA-HQ-OPPT-2016-0742
	Automotive care products	Function fluids for air conditioners: refrigerant, treatment, leak sealer	Use document EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742 U.S. EPA (2016c)
		Interior car care – spot remover	Use document EPA-HQ-OPPT-2016-0742-0003

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial, commercial and consumer uses	Automotive care products	Degreasers: gasket remover, transmission cleaners, carburetor cleaner, brake quieter/cleaner	Use document EPA-HQ-OPPT-2016-0742-0003,Market profile EPA-HQ-OPPT-2016-0742 U.S. EPA (2016c)
	Apparel and footwear care products	Post-market waxes and polishes applied to footwear e.g. shoe polish	Market profile EPA-HQ-OPPT-2016-0742
	Laundry and dishwashing products	Spot remover for apparel and textiles	Use document EPA-HQ-OPPT-2016-0742-0003
	Lubricants and greases	Liquid and spray lubricants and greases	U.S. EPA (2016c); Use document EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742; Public Comment EPA-HQ-OPPT-2016-0742-0021
		Degreasers – aerosol and non-aerosol degreasers and cleaners	U.S. EPA (2016c); Use document EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742; Public Comments EPA-HQ-OPPT-2016-0742-0005, EPA-HQ-OPPT-2016-0742-0014
	Building/ construction materials not covered elsewhere	Cold pipe insulation	Use document EPA-HQ-OPPT-2016-0742-0003
	Solvents (which become part of product formulation or mixture)	All other chemical product and preparation manufacturing	U.S. EPA (2016c)
	Processing aid not otherwise listed	In multiple manufacturing sectors[e]	Use document EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742; U.S. EPA (2016c)

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial, commercial and consumer uses	Propellants and blowing agents	Flexible polyurethane foam manufacturing	Market profile EPA-HQ-OPPT-2016-0742
	Arts, crafts and hobby materials	Crafting glue and cement/concrete	Use document EPA-HQ-OPPT-2016-0742-0003
	Other Uses	Laboratory chemicals - all other chemical product and preparation manufacturing	Use document EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742; U.S. EPA (2016c)
		Electrical equipment, appliance, and component manufacturing	U.S. EPA (2016c), Public Comment EPA-HQ-OPPT-2016-0742-0017
		Plastic and rubber products	U.S. EPA (2016c)
		Other (CBI)	U.S. EPA (2016c)
		Anti-adhesive agent - anti-spatter welding aerosol	Use document EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742; Public Comment EPA-HQ-OPPT-2016-0742-0005
		Oil and gas drilling, extraction, and support activities	Use document EPA-HQ-OPPT-2016-0742-0003; U.S. EPA (2016c)
		Extraction solvent for oils, waxes, fats, spices and hops in agricultural chemical manufacturing and food processing	Market profile EPA-HQ-OPPT-2016-0742; U.S. EPA (2016c)
		Functional fluids (closed systems) in pharmaceutical and medicine manufacturing	U.S. EPA (2016c)
		Toys, playground, and sporting equipment - including novelty articles (toys, gifts, etc.)	Use document EPA-HQ-OPPT-2016-0742-0003; U.S. EPA (2016c)

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial, commercial and consumer uses	Other Uses	Carbon remover, lithographic printing cleaner, wood floor cleaner, brush cleaner	Use document EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742; U.S. EPA (2016c)
Disposal	Emissions to air	Emissions to air	U.S. EPA (2017)
	Wastewater or liquid wastes	Wastewater	
	Liquid wastes	Industrial pre-treatment	
		Industrial wastewater treatment	
		Publicly owned treatment works (POTW)	
		Underground injection	
	Waste (solid and/or liquid)	Municipal landfill	
		Hazardous landfill	
		Other land disposal	
		Municipal waste incinerator	
		Hazardous waste incinerator	
		Off-site waste transfer	

[a] These categories of conditions of use appear in the initial life cycle diagram, reflect CDR codes and broadly represent conditions of use for methylene chloride in industrial and/or commercial settings.
[b] These subcategories reflect more specific uses of methylene chloride.
[c] Reported for the following sectors in the 2016 CDR for manufacturing of: plastic materials and resins, plastics products, miscellaneous, all other chemical product and preparation (U.S. EPA, 2016c).
[d] This includes uses assessed in the U.S. EPA (2014a) risk assessment and therefore those uses are out of scope for the risk evaluation
[e] Reported for the following sectors in the 2016 CDR for manufacturing of: petrochemicals, plastic materials and resins, plastics products, miscellaneous, all other chemical product and CBI (U.S. EPA, 2016c) which may include chemical processor for polycarbonate resins and cellulose triacetate – photographic film, developer (Market profile EPA-HQ-OPPT-2016-0742).

Methylene chloride has known applications as a process solvent in paint removers and the manufacture of pharmaceuticals and film coatings. It is used as an agent in urethane foam blowing and in the manufacture of hydrofluorocarbon (HFC) refrigerants, such as HFC-32. It can also be found in aerosol propellants and in solvents for electronics manufacturing, metal cleaning and degreasing and furniture finishing. Additionally, it has been used for agricultural and food processing purposes such as an extraction solvent for spice oleoresins and hops and for the removal of caffeine from coffee (Processing Magazine, 2015; U.S. EPA, 2000a).

According to the ICIS (2005) chemical profile, the use percentages of methylene chloride by sector were as follows: paint stripping and removal (30%), adhesives (22%), pharmaceuticals (11%), metal

cleaning (8%), aerosols (8%), chemical processing (8%), flexible polyurethane foam (5%) and miscellaneous (8%).

In the final 2014 risk assessment, U.S. EPA (2014a) identified risks from methylene chloride in consumer and commercial paint removal. The Agency determined those risks were unreasonable and, on January 19, 2017, proposed restrictions under TSCA section 6 to address the risks from methylene chloride in paint and coating removal by consumers and most commercial users (82 FR 7464, January 19, 2017). While paint and coating removal falls under the conditions of use for methylene chloride, scenarios already assessed in the 2014 risk assessment will not be re-evaluated in the risk evaluation to which this scope applies. Therefore, this use is out of scope for the risk evaluation.

2.3 Exposures

For TSCA exposure assessments, EPA expects to evaluate exposures and releases to the environment resulting from the conditions of use applicable to methylene chloride. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use for methylene chloride and the exposure to human receptors, including potentially exposed or susceptible subpopulations and ecological receptors. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to methylene chloride.

2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and environmental receptors EPA expects to consider in the risk evaluation. Table 2-4 provides environmental fate data that EPA has identified and considered in developing the scope for methylene chloride.

Table 2-4. Environmental Fate Characteristics of Methylene Chloride

Property or Endpoint	Value [a]	References
Indirect photodegradation	107 days (estimated)	OECD (2011)
Hydrolysis half-life	18 months	OECD (2011)
Biodegradation	13% in 28 days (not readily biodegradable) (aerobic sludge)	NITE (2002)
Bioconcentration factor (BCF)	2.0 to 5.4 (carp) <6.4 to 40 (carp)	NITE (2002)
Bioaccumulation factor (BAF)	2.6 (estimated)	U.S. EPA (2012)
Organic carbon:water partition coefficient (log K_{oc})	1.4 (estimated)	U.S. EPA (2012)

[a] Measured unless otherwise noted. Data retrieved from the 2014 EPA risk assessment on methylene chloride (U.S. EPA, 2014a).

Releases of methylene chloride to the environment are likely to evaporate to the atmosphere, or if released to soil, migrate to ground water. Methylene chloride is expected to undergo photooxidation in the atmosphere but considering its photodegradation half-life (107 days) it is moderately persistent and methylene chloride is expected to be subject to atmospheric transport.

Methylene chloride is not readily biodegradable but has been shown to biodegrade over a range of rates under aerobic and anaerobic conditions. Measured BCFs for methylene chloride considered in the 2014 EPA risk assessment on methylene chloride (U.S. EPA, 2014a) are 40 (log BCF 1.60) or below. The estimated bioaccumulation factor for methylene chloride is 2.6 (log BAF 0.4). Therefore, methylene chloride is not considered to be bioaccumulative.

2.3.2 Releases to the Environment

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

A source of information that EPA expects to consider in evaluating exposure are data reported under the Toxics Release Inventory (TRI) program. Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 rule, methylene chloride is a TRI-reportable substance effective January 1, 1987.

Table 2-5 provides production-related waste managed data (also referred to as waste managed) for methylene chloride reported by industrial facilities to the TRI program for 2015. Table 2-6 provides more detailed information on the quantities released to air or water or disposed of on land.

Table 2-5. Summary of Methylene Chloride TRI Production-Related Waste Managed in 2015 (lbs)

Number of Facilities	Recycling	Energy Recovery	Treatment	Releases [a, b]	Total Production Related Waste
271	96,865,223	15,619,010	37,832,075	3,390,985	153,707,292

Data source: 2015 TRI Data (updated March 2017) (U.S. EPA, 2017).
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.

In 2015, 271 facilities reported a total of about 153.7 million pounds of methylene chloride waste managed. Of this total, about 96.9 million pounds were recycled, 15.6 million pounds were recovered for energy, 37.8 million pounds were treated, and 3.4 million pounds were released into the environment.

Of these releases, the majority, 75%, were released to air: 2.5 million pounds (stack and fugitive air emissions), 2,366 pounds were released to water (surface water discharges), 114 thousand pounds were released to land (of which Class I Underground Injection and Resource Conservation and Recovery Act (RCRA) Subtitle C landfills are the primary disposal methods) and 713 thousand pounds were released in other forms such as to waste brokers.

Table 2-6. Summary of Methylene Chloride TRI Releases to the Environment in 2015 (lbs)

	Number of Facilities	Air Releases		Water Releases	Land Releases			Other Releases [a]	Total Releases [b]
		Stack Air Releases	Fugitive Air Releases		Class I Under-ground Injection	RCRA Subtitle C Landfills	All other Land Disposal [a]		
Subtotal		1,279,661	1,262,485		59,711	36,091	18,199		
Totals	271	2,542,146		2,366	114,001			713,241	3,371,754

Data source: 2015 TRI Data (updated March 2017) (U.S. EPA, 2017).
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] These release quantities do include releases due to one-time events not associated with production such as remedial actions or earthquakes.

While production-related waste managed shown in Table 2-5 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), release quantities shown in Table 2-6 include both production-related and non-routine quantities (TRI section 5 and 6 data). As a result, release quantities may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2017).

Other sources of information provide evidence of releases of methylene chloride, including EPA effluent guidelines (EGs) promulgated under the Clean Water Act (CWA), National Emission Standards for Hazardous Air Pollutants (NESHAPs) promulgated under the Clean Air Act (CAA), or other EPA standards and regulations that set legal limits on the amount of methylene chloride that can be emitted to a particular media. EPA expects to consider these data in conducting the exposure assessment component of the risk evaluation for methylene chloride.

EPA is aware of additional agency resources for methylene chloride emissions data, including National Emissions Inventory (NEI) and the Discharge Monitoring Report (DMR) Pollutant Loading Tool, which provide additional release data specific to air and surface water, respectively. NEI provides comprehensive and detailed estimates of air emissions for criteria pollutants, criteria precursors and Hazardous Air Pollutants (HAPs) on a 3-year cycle. Recent methylene chloride air emissions data from NEI will be analyzed for point and non-point sources in the next phase of risk evaluation. The DMR loading tool calculates pollutant loadings from permit and DMR data from EPA's Integrated Compliance Information System for the National Pollutant Discharge Elimination System (ICIS-NPDES). DMR data are available for the years 2007 to present and will be analyzed in the problem formulation phase of risk evaluation.

2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure.

Monitoring and biomonitoring data were identified in EPA's data search for methylene chloride. Due to its variety of uses and subsequent release to the environment, methylene chloride is present and measurable through monitoring in a variety of environmental media including ambient and indoor air, surface water and ground water, including sources used for drinking water supplies, sediment, soil and food products.

Ambient air samples worldwide have shown measured levels of methylene chloride, with background levels usually around 50 parts per trillion (ATSDR, 2000). National Oceanic and Atmospheric Administration (NOAA) monitoring data between 1994 and 2016 show mid-latitude northern hemisphere atmospheric concentrations to decrease slightly from 1994 to the early 2000s, and then increase thereafter to present day, with monthly mean concentrations ranging from approximately 30-80 parts per trillion (Hossaini et al., 2015). Similarly, air concentrations in the continental U.S. between 2003 and 2014 showed either no trend or increasing levels of methylene chloride (U.S. EPA, 2016b). While available indoor air measurements for methylene chloride are less prevalent, it may be present in this environment due to its variety of uses including consumer uses.

Methylene chloride has been detected in ground water and surface water, including finished drinking water through varied national monitoring efforts and water quality databases such as U.S. EPA's STOrage and RETrieval and Water Quality exchange (STORET) and U.S. Geological Survey's National Water Quality Assessment Program (NAWQA) (U.S. EPA, 2009; ATSDR, 2000). As part of its 6-year review of drinking water regulations, U.S. EPA (U.S. EPA, 2009) compiled a nationwide dataset of over 372,000 samples of ground water and surface water used for drinking water. Methylene chloride was detected approximately 1% of the time, with median concentrations similar for ground water and surface water. Other monitoring efforts have shown that with volatilization being limited in a ground water environment and the ability of methylene chloride to readily transport to ground water, concentrations are often higher in ground water as compared to surface water. Data compiled between 1992 and 2001 from NAWQA showed methylene chloride to be found in 6% of all ground water and surface water samples, with occurrences more common in surface water (U.S. EPA, 2009). Methylene chloride was detected in 20% of sediment samples in the STORET database (ATSDR, 2000).

Methylene chloride and its metabolites have been measured in expired air, blood, urine and breast milk (ATSDR, 2000). Elimination of methylene chloride from the body is rapid and therefore, is only representative of recent exposures. Blood concentrations of methylene chloride were below the level of detection in 1,165 individuals who participated in the National Health and Nutrition Examination Survey (NHANES) 2003-2004 subsample of the U.S. population (CDC, 2009). The methylene chloride metabolite, carboxyhemoglobin (COHb), has also been measured in blood and used as a biomarker; however, COHb results from exposure to carbon monoxide (such as in tobacco smoke and automobile exhaust) and is not specific to methylene chloride (ATSDR, 2000).

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of methylene chloride can result in releases to the environment. EPA expects to consider exposures to the environment and ecological receptors that occur via the exposure pathways or media shown in Figure 2-4 in conducting the risk evaluation for methylene chloride.

2.3.5 Human Exposures

EPA expects to consider three broad categories of human exposures: occupational exposures, consumer exposures and general population exposures. Subpopulations within these exposure categories will also be considered as described herein.

2.3.5.1 Occupational Exposures

EPA expects to consider worker activities where there is a potential for exposure under the various conditions of use described in section 2.2. In addition, EPA expects to consider exposure to

occupational non-users, who do not directly handle the chemical but perform work in an area where the chemical is present. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment have on occupational exposure levels.

In the previous 2014 risk evaluation (U.S. EPA, 2014a), EPA assessed inhalation exposures to methylene chloride for occupational use in paint and coating removal, which will not be re-evaluated. During this scoping, additional uses were identified and described in section 2.2. The additional uses resulting in occupational exposures will be considered during the risk evaluation.

Workers and occupational non-users may be exposed to methylene chloride when performing activities associated with the conditions of use described in section 2.2, that may include:

- Unloading and transferring methylene chloride to and from storage containers to process vessels;
- Using methylene chloride in process equipment (e.g., vapor degreasing machine, process equipment used to manufacture refrigerants);
- Applying formulations and products containing methylene chloride onto substrates (e.g., applying paint removers containing methylene chloride onto painted substrates);
- Cleaning and maintaining equipment;
- Sampling chemical, formulations or products containing methylene chloride for quality control (QC);
- Repackaging chemical, formulations or products containing methylene chloride;
- Handling, transporting and disposing waste containing methylene chloride;
- Performing other work activities in or near areas where methylene chloride is used.

Based on these activities, EPA expects to consider inhalation exposure to vapor and mists and anticipates these are the most important methylene chloride exposure pathway for workers and occupational non-users based on the high volatility of methylene chloride and the potential for spray application of some products containing methylene chloride. Dermal exposure, including skin contact with liquids and vapors for workers and occupational non-users may also be significant when performing certain work activities. EPA also expects to consider potential worker exposure through mists that deposit in the upper respiratory tract and are swallowed.

The United States has several regulatory and non-regulatory exposure limits for methylene chloride: an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) of 25 ppm 8-hour time-weighted average (TWA) and Short-Term Exposure Limit (STEL) of 125 ppm 15-minute TWA (OSHA, 1997), and an American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of 50 ppm 8-hour TWA (ACGIH, 2001). Also, the National Institute for Occupational Safety and Health (NIOSH) indicates that methylene chloride has an immediately dangerous to life and health (IDLH) value of 2,300 ppm based on effects that might occur from a 30-minute exposure, and NIOSH provides a notation that methylene chloride is a potential occupational carcinogen (NIOSH, 2011).

Key data that inform occupational exposure assessment and which EPA expects to consider include: the OSHA Chemical Exposure Health Data (CEHD) and NIOSH Health Hazard Evaluation (HHE) program data. OSHA data are workplace monitoring data from OSHA inspections. The inspections can be

random or targeted, or can be the result of a worker complaint. OSHA data can be obtained through the OSHA Integrated Management Information System (IMIS) at https://www.osha.gov/oshstats/index.html. Table_Apx B-1 in Appendix B provides a summary of industry sectors with methylene chloride personal monitoring air samples obtained from OSHA inspections conducted between 2011 and 2016. NIOSH HHEs are conducted at the request of employees, union officials, or employers and help inform potential hazards at the workplace. HHEs can be downloaded at https://www.cdc.gov/niosh/hhe/. During the problem formulation, EPA will review these data and evaluate their utility in the risk evaluation.

2.3.5.2 Consumer Exposures

Methylene chloride can be found in consumer products and/or commercial products that are readily available for public purchase at common retailers (EPA-HQ-OPPT-2016-0742-0003, Sections 3 and 4 and Table 2-3) and can therefore result in exposures to consumers.

Exposure routes for consumers using methylene chloride-containing products may include inhalation of vapors, mists and aerosols (e.g., aerosols from spray applications), dermal exposure to products and oral exposure to mists that deposit in the upper respiratory tract and are swallowed. Although unlikely given the physical-chemical properties, EPA also expects to consider oral ingestion via oral route such as from incidental ingestion of methylene chloride residue on hands and body.

In EPA's 2014 risk evaluation for methylene chloride paint stripping use, consumer inhalation exposures in residential settings were assessed using a variety of indoor exposure scenarios (U.S. EPA, 2014a). Scenarios differed in their type of application (i.e., brush vs. spray), location of product application (workshop vs. bathroom), mass of methylene chloride emitted, user's location during the wait period and air exchange rate between the rest of the house with outdoor air. EPA will not reassess those uses, but expects to develop exposure scenarios using similar approaches.

EPA expects to consider inhalation, dermal and oral exposures to consumers and bystanders associated with the consumer use in the home.

2.3.5.3 General Population Exposures

Wastewater/liquid wastes, solid wastes or air emissions of methylene chloride could result in potential pathways for oral, dermal or inhalation exposure to the general population. EPA will consider each media, route and pathway to estimate general population exposures.

Inhalation

Inhalation serves as the expected primary route of exposure for the general population due to both its high volatility and propensity to be released to air from ongoing commercial and industrial activities (U.S. EPA, 2014a, 2009; ATSDR, 2000). Between 1998 and 2006, >90% of all reported TRI releases of methylene chloride were air releases (U.S. EPA, 2014a) and levels of methylene chloride in the ambient air are widespread and shown to be increasing (section 2.3.2).

Based on these potential sources and pathways of exposure, EPA expects to consider inhalation exposures of the general population to methylene chloride in air that may result from the conditions of use for methylene chloride.

Oral
The general population may ingest methylene chloride via contaminated drinking water, ground water, and/or surface water. Ingestion of drinking water is expected to be the primary route of oral exposure. Oral ingestion may include exposure to contaminated breast milk. EPA also expects to consider ingestion via the oral route such as from incidental ingestion of methylene chloride residue on the hand/body. Based on the presence of methylene chloride in water used for bathing or recreation, the oral ingestion of contaminated water could contribute, to a lesser degree, to oral exposures. Methylene chloride has been measured in oysters and clams (ATSDR, 2000), however EPA does not anticipate this to be a significant general population exposure pathway for methylene chloride based on the low bioaccumulation potential in aquatic organisms (BCF 2.0 – 40, see the fate and transport section 2.3.1).

Based on these potential sources and pathways of exposure, EPA expects to consider oral exposures to the general population that may result from the conditions of use for methylene chloride.

Dermal
General population exposures to methylene chloride through the dermal route may occur through contact with water such as while bathing in household water that has residual methylene chloride or public recreation in contaminated waterways. Methylene chloride can be absorbed through the skin; however, based on its physical and chemical properties once exposed to air most of the amount on skin would be expected to volatize before being absorbed. EPA's previous risk evaluation of methylene chloride used in paint removal focused on inhalation as the main exposure pathway. In that assessment, not including dermal exposures may have resulted in underestimating the total exposure to methylene chloride and this was described as an uncertainty of the assessment (U.S. EPA, 2014a).

Based on these potential sources and pathways of exposure, EPA expects to consider dermal exposures to the general population that may result from the conditions of use for methylene chloride.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."

In this section, EPA addresses the potentially exposed or susceptible subpopulations identified as relevant based on greater exposure. EPA will address the subpopulations identified as relevant based on greater susceptibility in the hazard section.

Of the human receptors identified in the previous sections, EPA identifies the following as potentially exposed or susceptible subpopulations due to their *greater exposure* that EPA expects to consider in the risk evaluation:

- Workers and occupational bystanders including women of childbearing age.
- Consumers and bystanders associated with consumer use. Methylene chloride has been identified as being used in products available to consumers; however, only some individuals

within the general population may use these products. Therefore, those who do use these products are a potentially exposed or susceptible subpopulation due to greater exposure.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, use or disposal sites).

In developing exposure scenarios, EPA will evaluate available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or lifestage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006a).

In summary, in the risk evaluation for methylene chloride, EPA expects to consider the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use. As described above, EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of methylene chloride, as described in *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental File for the TSCA Scope Document*. Based on initial screening, EPA expects to consider the hazards of methylene chloride identified in this scope document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every hazard identified in the scope will be considered for every exposure scenario.

2.4.1 Environmental Hazards

For scoping purposes, EPA consulted the following sources of environmental hazard data for methylene chloride: EPA's 2014 TSCA Work Plan Chemical Risk Assessment (U.S. EPA, 2014a), Canadian 1993 Priority Substance Risk Report (Health Canada, 1993), OECD 2011 SIDS Initial Assessment Profile (SIAP) (OECD, 2011) and World Health Organization (WHO)'s 1996 INCHEM Environmental Health Criteria (EHC) 164 (WHO, 1996). However, EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for methylene chloride (*Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document*).

For U.S. EPA (2014a) risk evaluation, EPA reviewed acute and chronic (mortality and growth) toxicity data for fish, aquatic invertebrates (immobilization), and aquatic plants. EPA did not assess the risks of environmental effects from methylene chloride in their 2014 risk evaluation based on the selected uses reviewed, expected concentrations of methylene chloride in the aquatic environment, methylene chloride's physical and chemical properties, environmental fate characteristics and low aquatic toxicity characterization.

The Health Canada (1993) Priority Substances List Assessment Report suggested hazard to the environment. In the Canadian report, there was acute and chronic (mortality, growth and teratogenicity) toxicity in fish and acute toxicity (immobilization and teratogenicity) reported in aquatic invertebrates. Mortality was observed in terrestrial invertebrates and amphibians, and effects (growth inhibition or enhancement) were reported on seed germination in terrestrial plants.

The WHO (1996) International Programme on Chemical Safety (INCHEM) EHC on methylene chloride indicated no significant impact to the environment. The EHC reported acute and chronic toxicity to fish, acute toxicity to aquatic invertebrates and toxicity (cell number, photosynthesis) to aquatic plants. Growth inhibition in terrestrial plants and mortality in soil invertebrates, birds, insects and amphibians were also observed.

The OECD (2011) Screening Information Data Set (SIDS) SIAP for methylene chloride suggests a hazard for the environment. The SIAP reported acute and chronic effects (mortality, growth and teratogenicity) in fish, acute toxicity (immobilization) in aquatic invertebrates and toxicity to aquatic plants that were briefly exposed to methylene chloride.

EPA expects to consider the hazards of methylene chloride to aquatic species including fish, aquatic invertebrates and aquatic plants exposed to relevant media under acute and chronic exposure conditions. EPA expects to consider the hazards of methylene chloride to terrestrial organisms including soil invertebrates, birds, insects and mammals and amphibians exposed to relevant media under acute and/or chronic exposure conditions.

2.4.2 Human Health Hazards

Methylene chloride has an existing EPA IRIS Assessment (U.S. EPA, 2011), an ATSDR Toxicological Profile (ATSDR, 2010, 2000), and assessments of the effects of acute exposures in the AEGL (NAC/AEGL, 2008), Spacecraft Maximum Allowable Concentrations (SMAC) for Methylene Chloride (NRC, 1996) and an acute Recommended Exposure Limit (REL) published by the Office of Environmental Health Hazard Assessment (OEHHA) (OEHHA, 2008); hence, many of the hazards of methylene chloride have been previously compiled and systematically reviewed. EPA has relied heavily on these comprehensive reviews in preparing this scope. EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for methylene chloride (*Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document*). EPA expects to consider all potential hazards associated with methylene chloride. Based on reasonably available information, the following are the hazards that have been identified in previous government documents and that EPA currently expects will likely be the focus of its analysis.

2.4.2.1 Non-Cancer Hazards

Acute Toxicity

Neurotoxicity indicative of CNS depression is a primary effect of methylene chloride in humans following acute oral and inhalation exposures (U.S. EPA, 2011). Identified CNS depressive symptoms include drowsiness, confusion, headache, dizziness and neurobehavioral deficits when performing various tasks. Acute and/or short-term inhalation and oral exposure by animals to methylene chloride has also resulted in CNS depressant effects; decreased motor activity; impaired learning and memory; and changes in responses to sensory stimuli. CNS depressant effects can result in loss of consciousness

and respiratory depression, resulting in irreversible coma, hypoxia and eventual death (NAC/AEGL, 2008).

Liver Toxicity

The liver is a sensitive target organ after inhalation and oral exposure (U.S. EPA, 2011). There is limited evidence of liver effects in workers. Following chronic repeated inhalation and oral exposures to methylene chloride, rats and mice exhibited hepatocyte vacuolation, necrosis and degeneration (U.S. EPA, 2011).

Neurotoxicity

The brain is often affected by exposures to methylene chloride (U.S. EPA, 2011). As noted above, acute non-lethal effects in humans include general CNS depressive symptoms. There is some limited evidence of increased prevalence of neurological symptoms among workers and possible detriments in attention and reaction time in complex tasks in retired workers after longer-term exposures (U.S. EPA, 2011).

Irritation

Following exposures to methylene chloride vapors, irritation has been observed in the respiratory tract and eyes (ATSDR, 2000). Direct contact with liquid methylene chloride on the skin has caused chemical burns in workers and gastrointestinal irritation in individuals who ingested methylene chloride (U.S. EPA, 2011; ATSDR, 2000).

2.4.2.2 Genotoxicity and Cancer Hazards

Methylene chloride and some of its key metabolites have been extensively evaluated in carcinogenicity, genotoxicity and other MOA studies. Most of these studies have been thoroughly reviewed in the EPA IRIS Assessment (U.S. EPA, 2011). Studies in humans provide evidence for an association between occupational exposure to methylene chloride and increased risk for some specific cancers, including brain cancer, liver cancer, non-Hodgkin's lymphoma and multiple myeloma (U.S. EPA, 2011). In addition, several cancer bioassays in animals have identified the liver and lung as the most sensitive target organs for methylene chloride-induced tumor development (U.S. EPA, 2011). EPA hypothesized that methylene chloride induced lung and liver tumors through a mutagenic mode of carcinogenic action. A weight-of-evidence analysis of *in vivo* and *in vitro* data provide support to the proposed mutagenicity of methylene chloride (U.S. EPA, 2011).

In the 2011 IRIS assessment, following U.S. EPA (2005) *Guidelines for Carcinogen Risk Assessment* U.S. EPA (2005) using a weight-of-evidence judgment of the likelihood that methylene chloride is a human carcinogen, EPA concluded that methylene chloride is "likely to be carcinogenic in humans by all routes of exposure" and calculated quantitative estimates of risk from oral and inhalation exposure (U.S. EPA, 2011).

2.4.2.3 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical

substance or mixture, such as infants, children, pregnant women, workers, or the elderly." In developing the hazard assessment, EPA will evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

The IRIS assessment for methylene chloride indicates that there is some evidence that certain populations may be more susceptible to exposure to methylene chloride and examined lifestage, gender-specific, genetic variation, preexisting health status, lifestyle factors and nutrition status factors (U.S. EPA, 2011). Genetic polymorphisms that impact the enzymes that metabolize methylene chloride may lead to differences in susceptibility of individuals to the effects of methylene chloride and this susceptibility was quantified by (U.S. EPA, 2011). There are inadequate chemical-specific data to quantify the degree of differential susceptibility due to other susceptibility factors.

2.5 Initial Conceptual Models

A conceptual model describes the actual or predicted relationships between the chemical substance and receptors, either human or environmental. These conceptual models are integrated depictions of the conditions of use, exposures (pathways and routes), hazards and receptors. As part of the scope for methylene chloride, EPA developed three conceptual models, presented here.

2.5.1 Initial Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

Figure 2-2 presents the initial conceptual model for human receptors from industrial and commercial activities and uses of methylene chloride. EPA expects that workers and occupational non-users may be exposed to methylene chloride via inhalation and dermal routes. In the U.S. EPA (2014a) risk assessment, inhalation exposures to vapor were assessed as the most likely exposure route; however, there are potential dermal exposures for some conditions of use, such as maintenance of industrial degreasing tanks. EPA also expects to consider potential worker exposure through mists that deposit in the upper respiratory tract and are swallowed. The pathways assessed in the U.S. EPA (2014a) risk assessment are shaded in green.

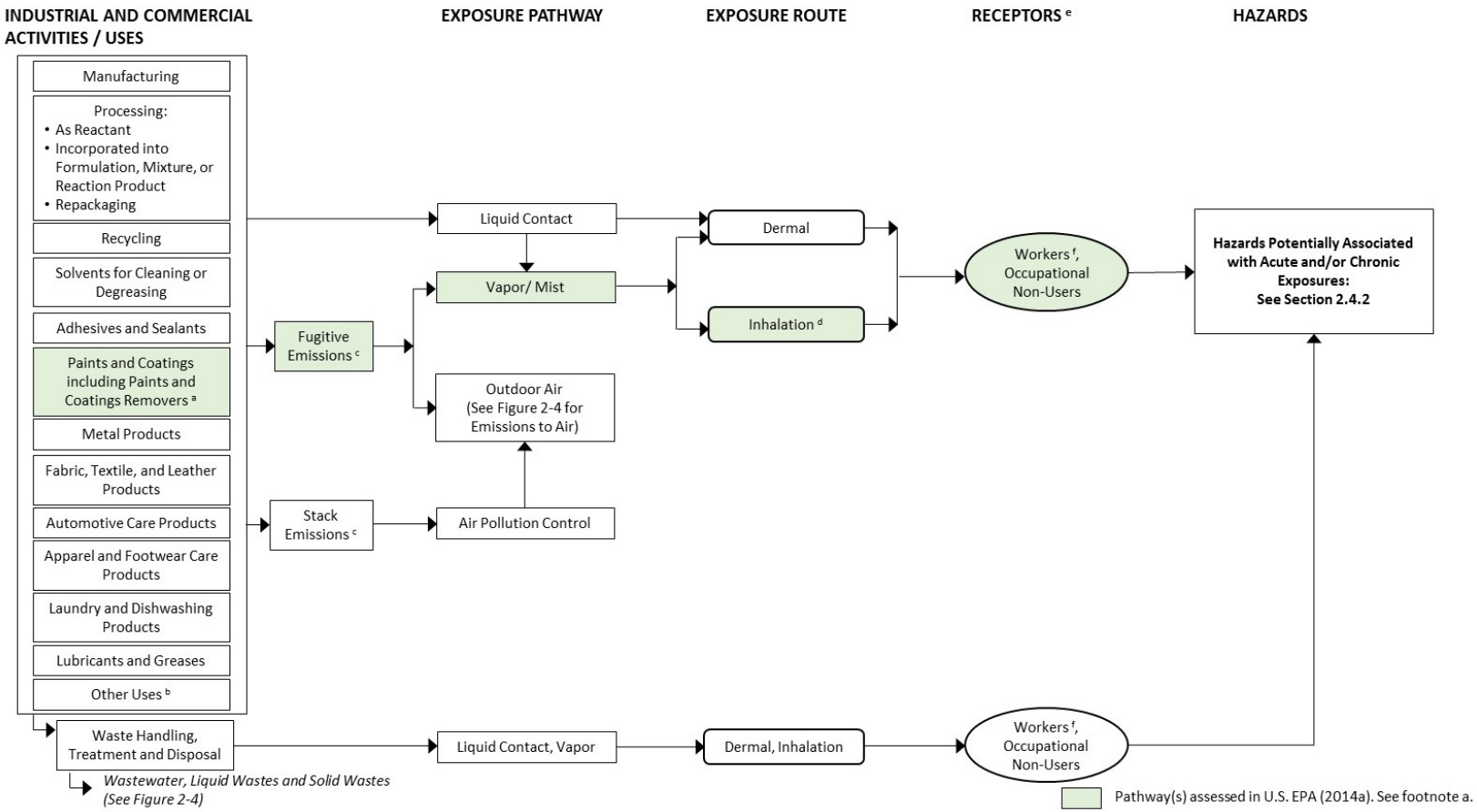

Figure 2-2. Initial Methylene Chloride Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of methylene chloride.

[a] U.S. EPA (2014a) assessed paint removal uses in industrial and commercial settings and therefore those uses are out of scope for the risk evaluation.

[b] Some products are used in both commercial and consumer applications such adhesives and sealants. Additional uses of methylene chloride are included in Table 2-3.

[c] Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

[d] Exposure may occur through mists that deposit in the upper respiratory tract and are swallowed.

[e] Receptors include potentially exposed or susceptible subpopulations.

[f] When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

2.5.2 Initial Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

Figure 2-3 presents the initial conceptual model for human receptors from consumer uses of methylene chloride. Similar to Figure 2-2, EPA expects that consumers and bystanders may be exposed via inhalation, dermal and oral routes. In the U.S. EPA (2014a) risk assessment, inhalation exposures to vapor and mist were assessed as the most likely exposure route; however, there are potential dermal and oral exposures for some conditions of use. It should be noted that some consumers may purchase and use products primarily intended for commercial use. It also shows emissions of methylene chloride to wastewater, liquid and solid wastes containing methylene chloride.

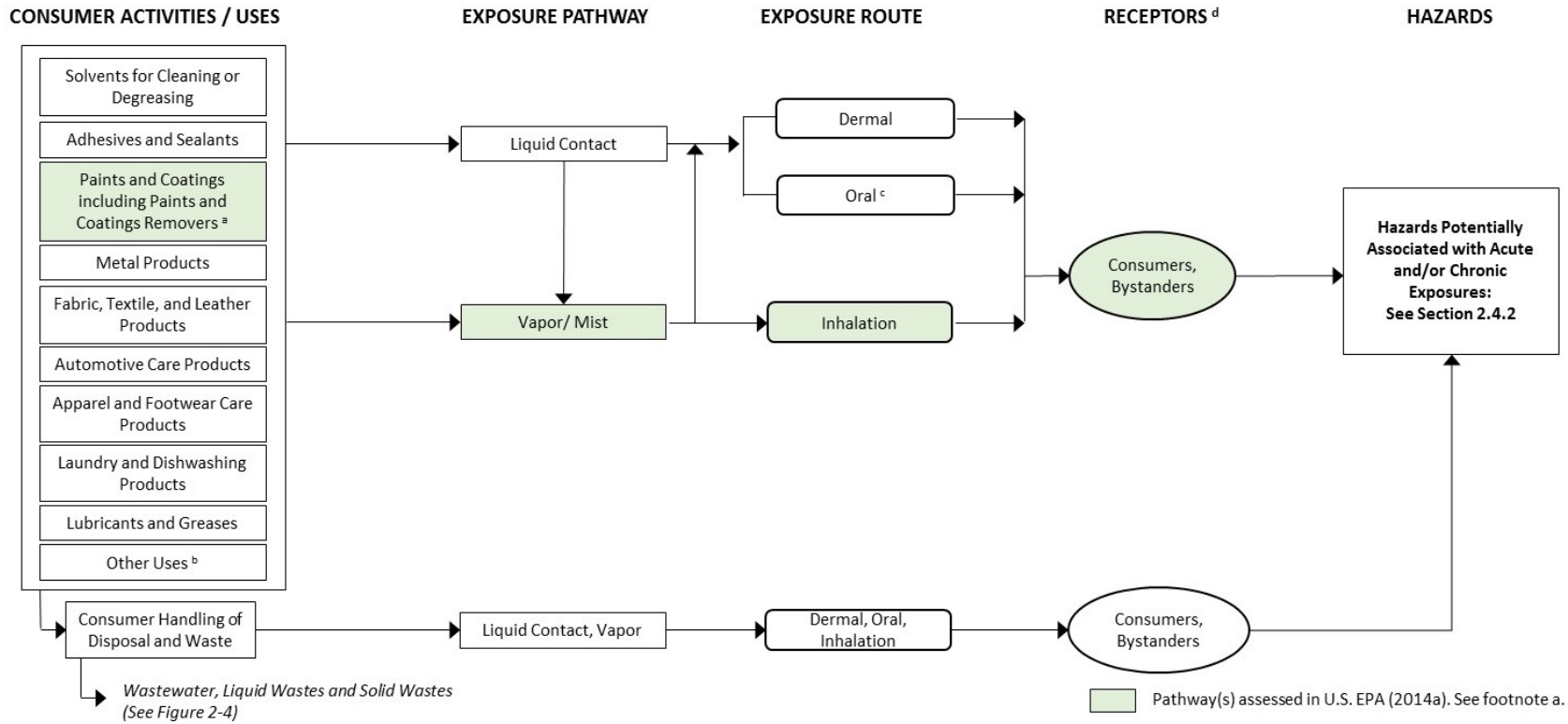

Figure 2-3. Initial Methylene Chloride Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of methylene chloride.

[a] U.S. EPA (2014a) assessed paint removal uses in consumer settings and therefore those uses are out of scope for the risk evaluation.

[b] Some products are used in both commercial and consumer applications. Additional uses of methylene chloride are included in Table 2-3.

[c] Exposure may occur through mists that deposit in the upper respiratory tract and are swallowed. Although unlikely given the physical-chemical properties, oral exposure may occur from incidental ingestion of methylene chloride on hands and body.

[d] Receptors include potentially exposed or susceptible subpopulations.

2.5.3 Initial Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

As shown in Figure 2-4, EPA anticipates that general populations living near industrial and commercial facilities using methylene chloride may be exposed via inhalation of outdoor air. General populations may also be exposed via the oral, dermal or inhalation routes to contaminated surface, ground and drinking water. In addition, aquatic and terrestrial life may be exposed to methylene chloride-contaminated water and soil. Exposures to ecological species from releases of methylene chloride to environmental media and disposal of wastes containing methylene chloride are depicted in Figure 2-4.

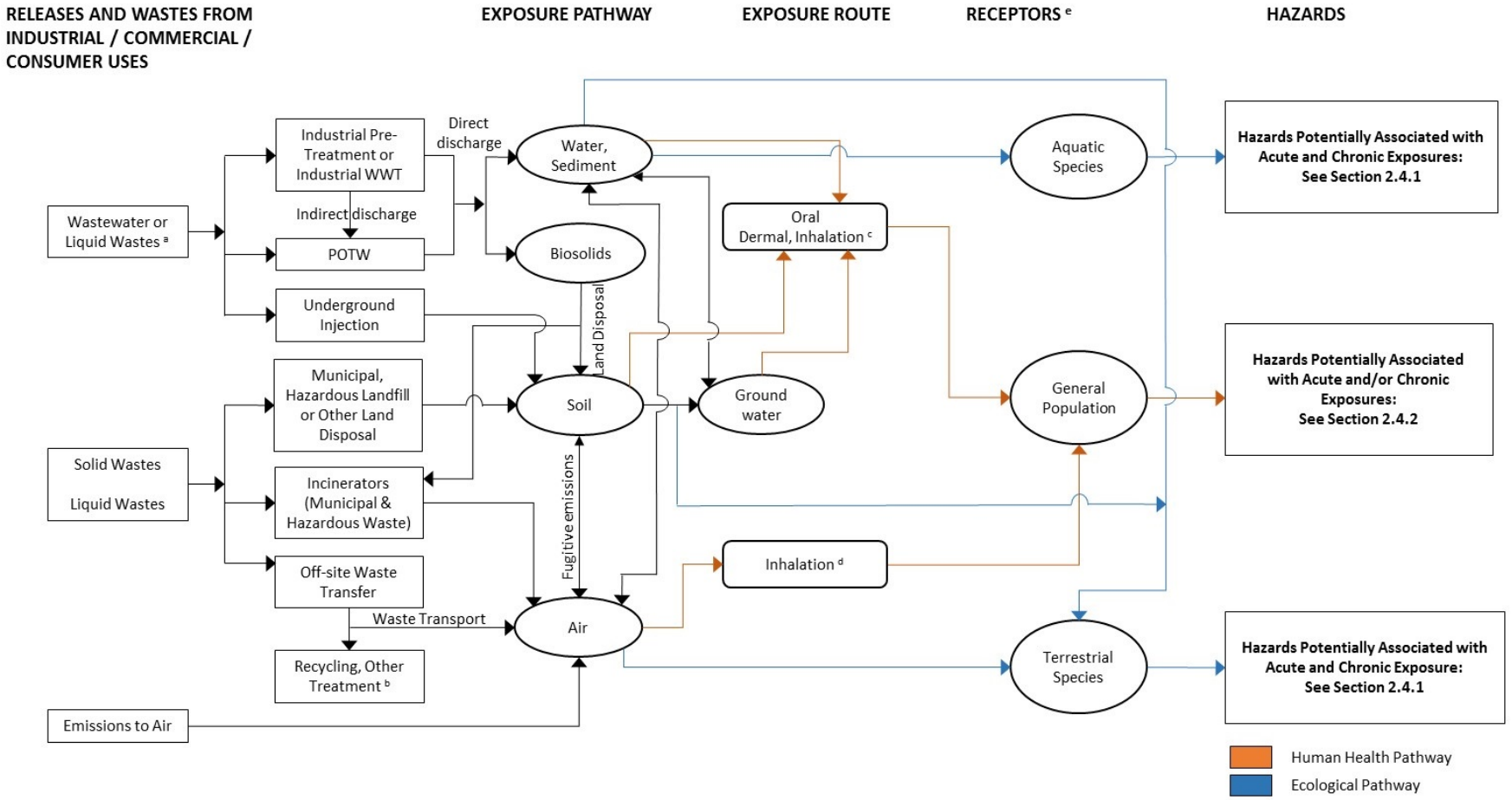

Figure 2-4. Initial Methylene Chloride Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of methylene chloride.

[a] Industrial wastewater may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, wastewater may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

[b] Additional releases may occur from recycling and other waste treatment.

[c] Volatilization from or liquid contact with tap water in the home during showering, bathing, washing, etc. represents another potential in-home exposure pathway.

[d] Presence of mist is not expected; dermal and oral exposures are negligible.

[e] Receptors include potentially exposed or susceptible subpopulations.

2.6 Initial Analysis Plan

The initial analysis plan will be used to develop the eventual problem formulation and final analysis plan for the risk evaluation. While EPA has conducted a search for readily available data and information from public sources (see *Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document*) as described in section 1.3, EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations.

The analysis plan outlined here is based on the conditions of use for methylene chloride, as described in section 2.2 of this scope. The analysis plan may be refined as EPA proceeds with the systematic review of the information in the *Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document*. EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent.

2.6.1 Exposure

2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to environmental media as follows:

1) Review reasonably available published literature or information on processes and activities associated with the conditions of use to evaluate the types of releases and wastes generated.
2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI and NEI programs).
3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses, volatility, chemical and physical properties.
4) Understand and consider regulatory limits that may inform estimation of environmental releases.
5) Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.
6) Evaluate the weight of the evidence of environmental release data.
7) Map or group each condition(s) of use to a release assessment scenario.

2.6.1.2 Environmental Fate

EPA expects to consider and analyze fate and transport in environmental media as follows:

1) Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.
2) Using measured data and/or modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.
3) Evaluate the weight of the evidence of environmental fate data.

2.6.1.3 Environmental Exposures

EPA expects to consider the following in developing its environmental exposure assessment of methylene chloride:

1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.
2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: release into the media of interest, fate and transport and characteristics of the environment.
3) Review reasonably available biomonitoring data. Consider whether these monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are available, and characterize exposed aquatic and terrestrial populations.
5) Evaluate the weight of evidence of environmental occurrence data and modeled estimates.
6) Map or group each condition(s) of use to environmental assessment scenario(s).

2.6.1.4 Occupational Exposures

EPA expects to consider and analyze both worker and occupational non-user exposures as follows:

1) Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as OSHA and NIOSH, and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements).
2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to methylene chloride.
3) For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.
5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.
6) Evaluate the weight of the evidence of occupational exposure data.
7) Map or group each condition of use to occupational exposure assessment scenario(s).

2.6.1.5 Consumer Exposures

EPA expects to consider and analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

1) Review reasonably available consumer product-specific exposure data related to consumer uses/exposures.
2) Evaluate the weight of the evidence of consumer exposure data.
3) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.

4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with those reported in monitoring data.
6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further refined.
7) Map or group each condition of use to consumer exposure assessment scenario(s).

2.6.1.6 General Population

EPA expects to consider and analyze general population exposures as follows:

1) Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
2) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
3) Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
5) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined.
7) Evaluate the weight of the evidence of general population exposure data.
8) Map or group each condition of use to general population exposure assessment scenario(s).

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

EPA will conduct an environmental hazard assessment of methylene chloride as follows:

1) Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies).
2) Conduct hazard identification (the qualitative process of identifying acute and chronic endpoints) and concentration-response assessment (the quantitative relationship between hazard and exposure) for all identified environmental hazard endpoints.
3) Derive concentrations of concern (COC) for all identified ecological endpoints.
4) Evaluate the weight of the evidence of environmental hazard data.
5) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

2.6.2.2 Human Health Hazards

EPA expects to consider and analyze human health hazards as follows:

1) Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).
2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for all identified human health hazard endpoints.
4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.
5) Evaluate the weight of the evidence of human health hazard data.
6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000b). As defined in EPA's *Risk Characterization Policy*, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (TCCR) (U.S. EPA, 2000b). EPA will also present information in this section consistent with approaches described in the Risk Evaluation Framework Rule.

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APPENDICES

Appendix A REGULATORY HISTORY

A.1 Federal Laws and Regulations

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
TSCA – Section 6(a)	Provides EPA with the authority to prohibit or limit the manufacture (including import), processing, distribution in commerce, use or disposal of a chemical if EPA evaluates the risk and concludes that the chemical presents an unreasonable risk to human health or the environment.	Proposed rule (82 FR 7464) regulating certain uses of methylene chloride and N-methylpyrrolidone in paint and coating removal.
TSCA – Section 6(b)	EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	Methylene chloride is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).
TSCA – Section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	Methylene chloride manufacturing (including importing), processing, and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).
TSCA – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed or imported in the United States.	Methylene chloride was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5 (60 FR 16309, March 29, 1995).
TSCA – Section 8(d)	Provides EPA with authority to issue rules requiring producers,	One submission received in 2001 (U.S. EPA, Chemical Data

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	importers, and (if specified) processors of a chemical substance or mixture to submit lists and/or copies of health and safety studies.	Access Tool. Accessed April 24, 2017).
TSCA – Section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Sixteen submissions received 1992-1994 (U.S. EPA, ChemView. Accessed April 24, 2017).
TSCA – Section 4	Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	Five chemical data from test rules (Section 4) from 1947 and (U.S. EPA, ChemView. Accessed April 24, 2017).
Emergency Planning and Community Right-to-Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels.	Methylene chloride is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 01, 1987.
Federal Food, Drug, and Cosmetic Act (FFDCA) – Section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to set tolerances (rules that establish maximum allowable residue limits), or exemptions from the requirement of a tolerance, for all residues of a pesticide (including both active and inert ingredients) that are in or on food. Prior to issuing a tolerance or exemption from tolerance, EPA must	Methylene chloride was registered as antimicrobial, conventional chemical in 1974, but this tolerance was revoked in 2002, and there are currently no registrations for use as a pesticide (67 FR 16027, April 4, 2002).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	determine that the tolerance or exemption is "safe." Sections 408(b) and (c) of the FFDCA define "safe" to mean the Agency has a reasonable certainty that no harm will result from aggregate exposures to the pesticide residue, including all dietary exposure and all other exposure (e.g., non-occupational exposures) for which there is reliable information. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation. In the absence of a tolerance or an exemption from tolerance, a food containing a pesticide residue is considered adulterated and may not be distributed in interstate commerce.	
Clean Air Act (CAA) – Section 112(b)	Defines the original list of 189 HAPs. Under 112(c) of the CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	Lists methylene chloride as a HAP (42 U.S. Code section 7412), and is considered an "urban air toxic" (CAA Section 112(k)).
CAA – Section 112(d)	Section 112(d) states that the EPA must establish NESHAPs for each category or subcategory of major sources and area sources of HAPs (listed pursuant to Section 112(c)).	There are a number of source-specific NESHAPs for methylene chloride, including: • Foam production and fabrication process (68 FR

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	The standards must require the maximum degree of emission reduction that the EPA determines to be achievable by each particular source category. Different criteria for maximum achievable control technology (MACT) apply for new and existing sources. Less stringent standards, known as generally available control technology (GACT) standards, are allowed at the Administrator's discretion for area sources.	18062, April 14, 2003; 72 FR 38864, July 16, 20027; 73 FR 15923, March 26, 2008; 79 FR 48073, August 15, 2014). • Aerospace (60 FR 45948, September 1, 1995). • Boat manufacturing (66FR 44218, August 22, 2001). • Chemical manufacturing industry (agricultural chemicals and pesticides, cyclic crude and intermediate production, industrial inorganic chemicals, industrial and miscellaneous organic chemicals, inorganic pigments, plastic materials and resins, pharmaceutical production, synthetic rubber) (74 FR 56008, October 29, 2009). • Fabric printing, coating and dyeing (68 FR 32172, May 29, 2003). • Halogenated Solvent Cleaning (72 FR 25138, May 3, 2007). • Miscellaneous organic chemical production and processes (MON) (68 FR 63852, November 10, 2003). • Paint and allied products manufacturing (area sources) (74 FR 63504, December 3, 2009). • Paint stripping and miscellaneous surface coating operations (area sources) (73 FR 1738, January 9, 2008).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		• Paper and other web surface coating (67 FR 72330, December 4, 2002). • Pesticide active ingredient production (67 Fr 38200, June 3, 2002). • Pharmaceutical production (63 FR 50280, September 21, 1998). • Publicly Owned Treatment Works (64 FR 57572, October 26, 1999). • Reciprocating Internal Combustion Engines (RICE) (75 FR 51570, August 20, 2010). • Reinforced plastic composites production (68 FR 19375, April 21, 2003). • Wood preserving (area sources) (72 FR 38864, July 16, 2007).)
CAA – Section 612	Under Section 612 of the CAA, EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ozone-depleting substances within a comparative risk framework. EPA publishes lists of acceptable and unacceptable alternatives. A determination that an alternative is unacceptable, or acceptable only with conditions, is made through rulemaking.	Under the SNAP program, EPA listed methylene chloride as an acceptable substitute in multiple industries, including in foam blowing agents for polyurethane, in cleaning solvents, in aerosol solvents and in adhesives and coatings (59 FR, March 18 1994). In 2016, methylene chloride was listed as an unacceptable substitute for use in flexible polyurethane (81 FR 86778 December 1, 2016).
Clean Water Act (CWA) – Section 301(b), 304(b), 306, and 307(b)	Requires establishment of Effluent Limitations Guidelines and Standards for conventional, toxic, and non-conventional pollutants. For toxic and non-conventional	Methylene chloride is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such is subject to effluent limitations. Also under

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	pollutants, EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	section 304, methylene chloride is included in the list of total toxic organics (TTO) (40 CFR413.02(i)).
CWA – Section 307(a)	Establishes a list of toxic pollutants or combination of pollutants under the CWA. The statue specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 401.15. The "priority pollutants" specified by those families are listed in 40 CFR Part 423 Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (Sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in NPDES permits (Section 402(a)(1)(B)).	
Safe Drinking Water Act (SDWA) – Section 1412	Requires EPA to publish a non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgement of the Administrator, regulation of the contaminant presents a	Methylene chloride is subject to NPDWR under the SDWA with a MCLG of zero and an enforceable MCL of 0.005 mg/L or 5 ppb (Section 1412).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	Methylene chloride is a hazardous substance under CERCLA. Releases of methylene chloride in excess of 1,000 pounds must be reported (40 CFR 302.4).
Resource Conservation and Recovery Act (RCRA) – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation	Methylene chloride is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: F001, F002; U080

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	In 2013, EPA modified its hazardous waste management regulations to conditionally exclude solvent-contaminated wipes that have been cleaned and reused from the definition of solid waste under RCRA (78 FR 46447 July 31, 2013, 40 CFR 261.4(a)(26)).
Other Federal Regulations		
Federal Hazardous Substance Act (FHSA)	Requires precautionary labeling on the immediate container of hazardous household products and allows the Consumer Product Safety Commission (CPSC) to ban certain products that are so dangerous or the nature of the hazard is such that required labeling is not adequate to protect consumers.	The CPSA, as implemented by the CPSC, requires products that contain methylene chloride to be labelled (52 FR 34698, September 14, 1987). In 2016, the Halogenated Solvents Industry Alliance petitioned to the CPSC to amend the labeling requirement (81 FR 60298, September 1, 2016).
Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to: • Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. • Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	Methylene chloride is listed as a hazardous material with regard to transportation and regulated by agencies including the Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT) and the U.S. Coast Guard (70 FR 34381 June 14 2005).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics.	Methylene chloride is banned by the FDA as an ingredient in all cosmetic products (54 FR 27328, June 29, 1989).
Occupational Safety and Health Act (OSH Act)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C section651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as PELs, exposure monitoring, engineering and administrative control measures, and respiratory protection.	In 1997, OSHA revised an existing occupational safety and health standards for methylene chloride, to include a PEL of 25 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1052 App. A).

A.2 State Laws and Regulations

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
State PELs	California (PEL of 25 ppm and a STEL of 100) (Cal Code Regs. title 8, section 5155)
State Right-to-Know Acts	Massachusetts (454 Code Mass. Regs. section 21.00), New Jersey (8:59 N.J. Admin. Code section 9.1) and Pennsylvania (34 Pa. Code section 323).
State Drinking Water Standards and Guidelines	Arizona (14 Ariz. Admin. Register 2978, August 1, 2008), California (Cal Code Regs. Title 26, section 22-64444), Delaware (Del. Admin. Code Title 16, section 4462), Connecticut (Conn. Agencies Regs. section 19-13-B102), Florida (Fla. Admin. Code R. Chap. 62-550), Maine (10 144 Me. Code R. Chap. 231), Massachusetts (310 Code Mass. Regs. section 22.00), Minnesota (Minn R. Chap. 4720), New Jersey (7:10 N.J Admin. Code section 5.2), Pennsylvania (25 Pa. Code section 109.202), Rhode Island (14 R.I. Code R. section 180-003), Texas (30 Tex. Admin. Code section 290.104).

State Actions	Description of Action
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products that include methylene chloride, including Maine (38 MRSA Chapter 16-D), Minnesota (Minnesota Statutes 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A section 1776) and Washington State (WAC 173-334-130).
Volatile Organic Compound (VOC) Regulations for Consumer Products	Many states regulate methylene chloride as a VOC. These regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. Regulated products vary from state to state, and could include contact and aerosol adhesives, aerosols, electronic cleaners, footwear or leather care products and general degreasers, among other products. California (Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Articles 1, 2, 3 and 4), Connecticut (R.C.S.A Sections 22a-174-40, 22a-174-41, and 22a-174-44), Delaware (Adm. Code Title 7, 1141), District of Columbia (Rules 20-720, 20-721, 20-735, 20-736, 20-737), Illinois (35 Adm Code 223), Indiana (326 IAC 8-15), Maine (Chapter 152 of the Maine Department of Environmental Protection Regulations), Maryland (COMAR 26.11.32.00 to 26.11.32.26), Michigan (R 336.1660 and R 336. 1661), New Hampshire (Env-A 4100) New Jersey (Title 7, Chapter 27, Subchapter 24), New York (6 CRR-NY III A 235), Rhode Island (Air Pollution Control Regulation No. 31) and Virginia (9VAC5 CHAPTER 45) all have VOC regulations or limits for consumer products. Some of these states also require emissions reporting.
Other	California listed methylene chloride on Proposition 65 (Cal Code Regs. title 27, section 27001) Massachusetts designated methylene chloride as a Higher Hazard Substance which will require reporting starting in 2014 (301 CMR 41.00).

A.3 International Laws and Regulations

Table_Apx A-3. Regulatory Actions by Other Governments and Tribes

Country/ Organization	Requirements and Restrictions
Canada	Methylene chloride is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). Canada required pollution prevention plan implementation for methylene chloride in 2003 for aircraft paint stripping; flexible polyurethane foam blowing; pharmaceuticals and chemical intermediates manufacturing and tablet coating; industrial cleaning; and adhesive formulations. The overall reduction objective of 85% was exceeded (*Canada Gazette*, Part I, Saturday, February 28, 2004; Vol. 138, No. 9, p. 409).

Country/ Organization	Requirements and Restrictions
European Union	In 2010, a restriction of sale and use of paint removers containing 0.1% or more methylene chloride was added to Annex XVII of regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). The restriction included provisions for individual member states to issue a derogation for professional uses if they have completed proper training and demonstrate they are capable of safely use the paint removers containing methylene chloride (European Chemicals Agency (ECHA) database. Accessed April 18, 2017).
Australia	Methylene chloride was assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). Uses reported include solvent in paint removers, adhesives, detergents, print developing, aerosol propellants (products not specified), cold tank degreasing and metal cleaning, as well as uses in waterproof membranes, in urethane foam and plastic manufacturing, and as an extraction solvent for spices, caffeine and hops (NICNAS, 2017, *Human Health Tier II assessment for Methane, dichloro-*. Accessed April, 18 2017*)*.
Japan	Methylene chloride is regulated in Japan under the following legislation: Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) • Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof • Industrial Safety and Health Act (ISHA) • Air Pollution Control Law • Water Pollution Control Law • Soil Contamination Countermeasures Act (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP]. Accessed April 17, 2017).
Basel Convention	Halogenated organic solvents (Y41) are listed as a category of waste under the Basel Convention. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters.
OECD Control of Transboundary Movements of Wastes Destined for Recovery Operations	Halogenated organic solvents (A3150) are listed as a category of waste subject to The Amber Control Procedure under Council Decision C (2001) 107/Final.

Country/ Organization	Requirements and Restrictions
Australia, Austria, Belgium, Canada, Denmark, European Union, Finland, France, Germany, Hungary, Ireland, Israel, Japan, Latvia New Zealand, People's Republic of China, Poland, Singapore, South Korea, Spain, Sweden, Switzerland, United Kingdom	Occupational exposure limits for methylene chloride (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2017).

Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for methylene chloride.

B.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities.

Note that the processing information below is representative of methylene chloride, but not inclusive of all uses. EPA will consider this information and data in combination with other data and methods for use in the risk evaluation.

B.1.1 Manufacturing (Includes Import)

According to 2016 public CDR data, methylene chloride is both manufactured in and imported into the United States (U.S. EPA, 2016c).

B.1.1.1 Domestic Manufacturing

Methylene chloride is primarily manufactured through the gas-phase reaction of hydrogen chloride with methanol to produce methyl chloride, which is then reacted with chlorine to produce methylene chloride, along with chloroform and carbon tetrachloride as coproducts. This reaction is typically driven by high temperature, but may also be driven through catalysis or photolysis. This reaction may alternatively be conducted in the liquid phase at low temperatures and high pressures, which can yield high selectivities of methylene chloride (Holbrook, 2003).

An antiquated production method of methylene chloride is the reaction of excess methane with chlorine at temperatures of approximately 400 to 500°C. Lower reaction temperatures are possible through the use of catalysis or photolysis. This reaction produces methylene chloride with methyl chloride, chloroform and carbon tetrachloride as coproducts and unreacted methane with hydrogen chloride as byproducts. The unreacted methane and hydrogen chloride are removed through a water wash, dried, and recycled. The liquid stream of chlorinated organic products is washed, alkali scrubbed, dried and fractionated (Holbrook, 2003).

Other minor production methods of methylene chloride exist, such as: the reduction of chloroform or carbon tetrachloride with hydrogen over a platinum catalyst; the molten salt oxychlorination of methane; the reaction of phosgene and formaldehyde over an activated carbon catalyst; and the reduction of carbon tetrachloride with ferrous hydroxide in the presence of alkaline hydroxides or carbonates (Holbrook, 2003).

B.1.1.2 Import

Based on EPA's knowledge of the chemical industry, typical import activities include storage in warehouses prior to distribution for further processing and use and QC sampling.
Methylene chloride may be transported in drums, trucks, railcars, barges and oceangoing ships. Storage contains should be constructed of galvanized or otherwise suitably lined mild or plain steel.

Bulk storage tanks should include a vent equipped with a desiccant-packed dryer, such as calcium chloride, or an inert gas pad with pressure/vacuum relief valve (Holbrook, 2003).

B.1.2 Processing and Distribution

B.1.2.1 Processing as Reactant

Processing as a reactant or intermediate is the use of methylene chloride as a feedstock in the production of another chemical product via a chemical reaction in which methylene chloride is consumed to form the product. Methylene chloride is used as an intermediate for the production of difluoromethane, also known as HFC-32, which is used in fluorocarbon blends for refrigerants (Marshall, 2016).

Methylene chloride is also a feedstock in the production of bromochloromethane. Bromochloro-methane is produced through a halogen exchange reaction with methylene chloride and either bromine or hydrogen bromide with an aluminum or aluminum trihalide catalyst. Alternative processes include the gas-phase bromination of methylene chloride with hydrogen bromide and the liquid-phase displacement reaction of methylene chloride with inorganic bromides (Ioffe, 2011).

B.1.2.2 Incorporated into Formulation, Mixture, or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. 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. Methylene chloride-specific formulation processes were not identified; however, several ESDs published by the OECD have been identified that provide general process descriptions for some of these types of products. The formulation of paints and coatings typically involves dispersion, milling, finishing and filling into final packages (OECD, 2009b). Adhesive formulation involves mixing together volatile and non-volatile chemical components in sealed, unsealed or heated processes (OECD, 2009a). Sealed processes are most common for adhesive formulation because many adhesives are designed to set or react when exposed to ambient conditions (OECD, 2009a). Lubricant formulation typically involves the blending of two or more components, including liquid and solid additives, together in a blending vessel (OECD, 2004).

B.1.2.3 Repackaging

Based on EPA's knowledge of the chemical industry, typical repackaging sites receive the chemical in bulk containers and transfer the chemical from the bulk container into another smaller container in preparation for distribution in commerce.

B.1.2.4 Recycling

TRI data from 2015 indicate that many sites ship methylene chloride for off-site recycling. A general description of waste solvent recovery processes was identified. Waste solvents are generated when it becomes contaminated with suspended and dissolved solids, organics, water, or other substance (U.S. EPA, 1980). Waste solvents can be restored to a condition that permits reuse via solvent reclamation/recycling (U.S. EPA, 1980). The recovery process involves an initial vapor recovery (e.g., condensation, adsorption, and absorption) or mechanical separation (e.g., decanting, filtering, draining, setline, and centrifuging) step followed by distillation, purification, and final packaging (U.S. EPA, 1980).

B.1.3 Uses

In this scope document, EPA has grouped uses based on CDR categories and identified examples within these categories as subcategories. Note that some subcategories may be grouped under multiple CDR categories. The differences between these uses will be further investigated and defined during risk evaluation.

B.1.3.1 Solvents for Cleaning or Degreasing

EPA has gathered information on different types of cleaning and degreasing systems from recent trichloroethylene risk evaluation (U.S. EPA, 2014b) and risk management (82 FR 7432, January 19, 2017; 81 FR 91592, December 16, 2016) activities and 1-Bromopropane Draft Risk Assessment (U.S. EPA, 2016d) activities. Provided below are descriptions of three cleaning and degreasing uses of methylene chloride.

Vapor Degreasers

Vapor degreasing is a process used to remove dirt, grease and surface contaminants in a variety of metal cleaning industries. Vapor degreasing may take place in batches or as part of an in-line (i.e., continuous) system. Vapor degreasing equipment can generally be categorized into one of three degreaser types described below:

1) Batch vapor degreasers – In batch machines, each load (parts or baskets of parts) is loaded into the machine after the previous load is completed. Individual organizations, regulations and academic studies have classified batch vapor degreasers differently. For the purposes of the scope document, EPA categories the batch vapor degreasers into five types: open-top vapor degreasers (OTVDs); OTVDs with enclosures; closed-loop degreasing systems (airtight); airless degreasing systems (vacuum drying); and airless vacuum-to-vacuum degreasing systems.
2) Conveyorized vapor degreasers – In conveyorized systems, an automated parts handling system, typically a conveyor, continuously loads parts into and through the vapor degreasing equipment and the subsequent drying steps. Conveyorized degreasing systems are usually fully enclosed except for the conveyor inlet and outlet portals. Conveyorized degreasers are likely used in shops where there are a large number of parts being cleaned. There are seven major types of conveyorized degreasers: monorail degreasers; cross-rod degreasers; vibra degreasers; ferris wheel degreasers; belt degreasers; strip degreasers; and circuit board degreasers (U.S. EPA, 1977).
3) Continuous web vapor degreasers – Continuous web cleaning machines are a subset of in-line degreasers but differ in that they are specifically designed for cleaning parts that are coiled or on spools such as films, wires and metal strips (Kanegsberg and Kanegsberg, 2011; U.S. EPA, 2006b). In continuous web degreasers, parts are uncoiled and loaded onto rollers that transport the parts through the cleaning and drying zones at speeds >11 feet/minute (U.S. EPA, 2006b). The parts are then recoiled or cut after exiting the cleaning machine (Kanegsberg and Kanegsberg, 2011; U.S. EPA, 2006b).

Cold Cleaners

Methylene chloride can also be used as a solvent in cold cleaners, which are non-boiling solvent degreasing units. Cold cleaning operations include spraying, brushing, flushing and immersion; the use process and worker activities associated with cold cleaning have been previously described in EPA's 1-Bromopropane Draft Risk Assessment (U.S. EPA, 2016d).

Aerosol Spray Degreasers and Cleaners

Aerosol degreasing is a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts. Products containing methylene chloride may be used in aerosol degreasing applications such as brake cleaning, engine degreasing and metal product cleaning (see the *Preliminary Information on Manufacturing, Processing, Distribution, Use and Disposal for Methylene Chloride* EPA-HQ-OPPT-2016-0742-0003). This use has been previously described in EPA's 1-Bromopropane Draft Risk Assessment (U.S. EPA, 2016d). Aerosol degreasing may occur at either industrial facilities or at commercial repair shops to remove contaminants on items being serviced. Aerosol degreasing products may also be purchased and used by consumers for various applications.

B.1.3.2 Adhesives and Sealants

Based on products identified in EPA's *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal for Methylene Chloride* (EPA-HQ-OPPT-2016-0742-0003) and 2016 CDR reporting (U.S. EPA, 2016c), methylene chloride may be used in adhesives and sealants for industrial, commercial and consumer applications. The *Preliminary Information on Manufacturing, Processing, Distribution, Use and Disposal for Methylene Chloride* (EPA-HQ-OPPT-2016-0742-0003) identifies aerosol and canister adhesive products that contain methylene chloride. In these applications, the methylene chloride likely serves as a propellant or solvent and evaporates during adhesive drying. These adhesive products are identified for use on substrates such as metal, foam, plastic, rubber, fabric, leather, wood and fiberglass. The types of adhesives identified in the *Preliminary Information on Manufacturing, Processing, Distribution, Use and Disposal for Methylene Chloride* (EPA-HQ-OPPT-2016-0742-0003) include contact adhesives, crosslinking adhesives, pressure sensitive adhesives, sealers and cements.

The OECD ESD for Use of Adhesives (OECD, 2013) provides general process descriptions and worker activities for industrial adhesive uses. Given the identified applications of methylene chloride in aerosol and canister adhesives, EPA anticipates workers spray apply the adhesive to substrates. The adhesives are likely sold and used in sealed containers such as spray cans or canister tanks.

B.1.3.3 Paints and Coatings

Based on the *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Methylene Chloride* and *Use and Market Profile for Methylene Chloride*, both available in the public docket (EPA-HQ-OPPT-2016-0742), methylene chloride may be used in various paints and coatings for industrial, commercial and consumer applications. Typical process descriptions and worker activities for industrial and commercial uses in 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 autodeposition, dip coating, curtain coating systems, roll coating systems and supercritical carbon dioxide systems (OECD, 2009b). After application, solvent-based coatings typically undergo a drying stage in which the solvent evaporates from the coating (OECD, 2009b).

Methylene chloride is used for paint removal in a variety of industries, such as the automotive, aircraft, construction and refinishing industries. Application methods include manual or automated application, with techniques such as spray application, pouring, wiping and rolling. Additional details on this use of methylene chloride can be found in the U.S. EPA (2014a) TSCA Work Plan Chemical Risk Assessment for the use of methylene chloride as a paint remover. While paint and coating removal falls under the

conditions of use for methylene chloride, scenarios already assessed in the 2014 risk assessment will not be re-evaluated in the risk evaluation to which this scope applies. Therefore, this use is out of scope for the risk evaluation.

B.1.3.4 Laundry and Dishwashing Products

Spot Cleaner

Methylene chloride is found in products used to spot clean garments (EPA-HQ-OPPT-2016-0742-0003). Spot cleaning products can be applied to the garment either before or after the garment is dry cleaned. The process and worker activities associated with commercial dry cleaning and spot cleaning have been previously described in EPA's 1-Bromopropane Draft Risk Assessment (U.S. EPA, 2016d).

B.1.3.5 Lubricants and Greases

EPA identified several commercial and consumer lubricant products that contain methylene chloride. These lubricants are used to reduce friction and wear and prevent seizing where metal-to-metal contact is possible and inhibit rusting and corrosion by displacing water in a wide variety of applications, including machinery, hardware, cables, and chains. The majority of these lubricant products are aerosol lubricants (available in aerosol cans), although one liquid-based lubricant product (available in pails and drums) was also identified. Aerosol lubricants are sprayed directly onto metal substrates, while liquid lubricants may be brushed or spray applied to metal substrates. The methylene chloride is anticipated to completely evaporate during the drying phase, leaving behind a lubricating film (*Use and Market Profile for Methylene Chloride* EPA-HQ-OPPT-2016-0742)

B.1.3.6 Other Uses

Based on products identified in EPA's *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Methylene Chloride*, EPA-HQ-OPPT-2016-0742-0003, a variety of other uses may exist for methylene chloride, including use in weld spatter protectants, shoe polish, crafting glues and cements, novelty items, and miscellaneous cleaners. It is unclear at this time the total volume of methylene chloride used in any of these applications.

B.1.4 Disposal

Methylene chloride is a U-listed hazardous waste under code U080 under RCRA; therefore, discarded, unused pure and commercial grades of methylene chloride are regulated as a hazardous waste under RCRA (40 CFR § 261.33(f)). Additionally, methylene chloride is included in multiple waste codes under the F-list of non-specific source wastes (40 CFR § 261.31(a)).

B.2 Occupational Exposure Data

EPA presents below an example of occupational exposure-related information from the preliminary data gathering. EPA will consider this information and data in combination with other data and methods for use in the risk evaluation.

Table_Apx B-1 summarizes the industry sectors with methylene chloride OSHA CEHD data (OSHA, 2017).

Table_Apx B-1. Summary of Industry Sectors with Methylene Chloride Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2011 and 2016

NAICS Code	NAICS Description
238320	Painting and wall covering contractors
238390	Other building finishing contractors
313312	Textile and fabric finishing (except broadwoven fabric) mills [a]
315240	Women's, girls', and infants' cut and sew apparel manufacturing
316998	All other leather good and allied product manufacturing
321211	Hardwood veneer and plywood manufacturing
321911	Wood window and door manufacturing
321999	All other miscellaneous wood product manufacturing
322121	Paper (except newsprint) mills
323113	Commercial screen printing
325199	All other basic organic chemical manufacturing
325211	Plastics material and resin manufacturing
325212	Synthetic rubber manufacturing
325412	Pharmaceutical preparation manufacturing
325991	Custom compounding of purchased resins
325998	All other miscellaneous chemical product and preparation manufacturing
326150	Urethane and other foam product (except polystyrene) manufacturing
326199	All other plastics product manufacturing
327390	Other concrete product manufacturing
327991	Cut stone and stone product manufacturing
331316	Aluminum extruded product manufacturing [b]
331513	Steel foundries (except investment)
332312	Fabricated structural metal manufacturing
332321	Metal window and door manufacturing
332710	Machine shops
332811	Metal heat treating
332999	All other miscellaneous fabricated metal product manufacturing
333132	Oil and gas field machinery and equipment manufacturing
333921	Elevator and moving stairway manufacturing
334416	Capacitor, resistor, coil, transformer, and other inductor manufacturing

NAICS Code	NAICS Description
335121	Residential electric lighting fixture manufacturing
336211	Motor vehicle body manufacturing
337110	Wood kitchen cabinet and countertop manufacturing
337212	Custom architectural woodwork and millwork manufacturing
339950	Sign manufacturing
339999	All other miscellaneous manufacturing
423810	Construction and mining (except oil well) machinery and equipment merchant wholesalers
423930	Recyclable material merchant wholesalers
424610	Plastics materials and basic forms and shapes merchant wholesalers
424990	Other miscellaneous non-durable goods merchant wholesalers
443112	Radio, television, and other electronics stores [c]
443141	Household appliance stores
448190	Other clothing stores
451110	Sporting goods stores
485410	School and employee bus transportation
532299	All other consumer goods rental
541380	Testing laboratories
621511	Medical laboratories
713110	Amusement and theme parks
811111	General automotive repair
811121	Automotive body, paint, and interior repair and maintenance
811310	Commercial and industrial machinery and equipment (except automotive and electronic) repair and maintenance
811420	Reupholstery and furniture repair
811490	Other personal and household goods repair and maintenance
926150	Regulation, licensing, and inspection of miscellaneous commercial sectors

[a] This is a 2007 NAICS code; the corresponding 2012 and 2017 NAICS code is 313310 for "Textile and Fabric Finishing Mills."
[b] This is a 2007 NAICS code; the corresponding 2012 and 2017 NAICS code is 331318 for “Other Aluminum Rolling, Drawing, and Extruding.”
[c] This is a 2007 NAICS code; the corresponding 2012 and 2017 NAICS code is 443142 for “Electronics Stores.”