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

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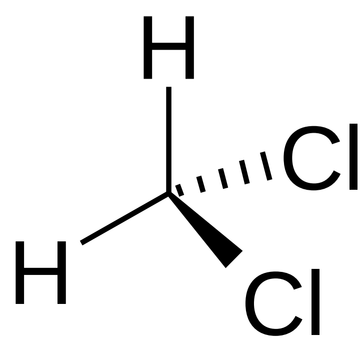

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ABBREVIATIONS

°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
CFR	Code of Federal Regulations
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
CSHO	Certified Safety and Health Official
CWA	Clean Water Act
DCM	Dichloromethane (Methylene Chloride)
DIY	Do it yourself
DMR	Discharge Monitoring Report
DOT	Department of Transportation
EC_{50}	Effect concentration at which 50% of test organisms exhibit an effect
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)
HAP	Hazardous Air Pollutant
HFC	Hydrofluorocarbon
HHE	Health Hazard Evaluation
HMTA	Hazardous Materials Transportation Act
HPV	High Production Volume
Hr	Hour

IARC	International Agency for Research on Cancer
ICIS	Integrated Compliance Information 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
K_{oc}	Soil Organic Carbon-Water Partitioning Coefficient
K_{ow}	Octanol/Water Partition Coefficient
kg	Kilogram(s)
L	Liter(s)
lb	Pound(s)
LC_{50}	Lethal Concentration at which 50% of test organisms die
LD_{50}	Lethal Dose at which 50% of test organisms die
LOD	Limit of detection
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
MSW	Municipal Solid Waste
NAC	National Advisory Committee
NAICS	North American Industry Classification System
NATA	National Scale Air-Toxics Assessment
NAWQA	National Water Quality Assessment Program
ND	Non-detect
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
NPDES	National Pollutant Discharge Elimination System
NPDWR	National Primary Drinking Water Regulation
NRC	National Research Council
NTP	National Toxicology Program
NWIS	National Water Information System
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
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics

OSHA	Occupational Safety and Health Administration
OTVD	Open-Top Vapor Degreaser
PBPK	Physiologically-Based Pharmacokinetic
PBZ	Personal Breathing Zone
PECO	Population, Exposure, Comparator, and Outcome
PEL	Permissible Exposure Limit
PESS	Potentially Exposed or Susceptible Subpopulations
POD	Point of Departure
POTW	Publicly Owned Treatment Works
ppb	Part(s) per Billion
PPE	Personal Protective Equipment
ppm	Part(s) per Million
PSD	Particle Size Distribution
PV	Production Volume
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
RTR	Risk and Technology Review
SDS	Safety Data Sheets
SDWA	Safe Drinking Water Act
SIDS	Screening Information Data Set
SMAC	Spacecraft Maximum Allowable Concentrations
SNAP	Significant New Alternatives Policy
SpERC	Specific Environmental Release Categories
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
USGS	United States Geological Survey
VOC	Volatile Organic Compound
VP	Vapor Pressure
WHO	World Health Organization
Yr	Year(s)

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. In June 2017, EPA published the Scope of the Risk Evaluation for methylene chloride. As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for methylene chloride. Comments received on this problem formulation document will inform development of the draft risk evaluation.

This problem formulation document refines the conditions of use, exposures and hazards presented in the scope of the risk evaluation for methylene chloride and presents refined conceptual models and analysis plans that describe how EPA expects to evaluate the risk for methylene chloride.

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. Methylene chloride has been 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), a drinking water contaminant subject to national primary drinking water regulations under the Safe Drinking Water Act (SDWA), and certain household products containing methylene chloride are hazardous substances required to be labeled under the Federal Hazardous Substances Act (FHSA) by the Consumer Product Safety Commission (CPSC) including a recent update to the labelling for paint removers (83 FR 12254, March 21, 2018 and 83 FR 18219, April 26, 2018).

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 (2007) 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%).

This document presents the potential exposures that may result from the conditions of use of methylene chloride. Exposures may occur to workers and occupational non-users (workers who do not directly handle the chemical but perform work in an area where the chemical is used), consumers and bystanders (non-product users that are incidentally exposed to the product) and the general population through inhalation, dermal and oral pathways. Workers and occupational non-users may be exposed to methylene chloride during a variety of conditions of use, such as manufacturing, processing and industrial and commercial uses, including 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 in indoor or outdoor environments. For methylene chloride, EPA considers workers, occupational non-users, consumers, bystanders, and certain other groups of individuals who may experience greater exposures than the general population due to proximity to conditions of use to be potentially exposed or susceptible subpopulations. Exposures to the general population may occur from industrial and/or commercial uses; industrial releases to air, water or land; and other conditions of use. EPA will evaluate whether 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) that increase exposure and whether groups of individuals have heightened susceptibility, and should therefore be considered potentially exposed or susceptible subpopulations for purposes of the risk evaluation. EPA plans to further analyze inhalation exposures to vapors and mists for workers and occupational non-users (workers who do not directly handle the chemical but perform work in an area where the chemical is present) and dermal exposures for skin contact with liquids in occluded situations for workers in the risk evaluation. EPA plans to further analyze inhalation exposures to vapors and mists for consumers and bystanders and dermal exposures for skin contact with liquids in the risk evaluation. For environmental release pathways, EPA plans to further analyze surface water exposure to aquatic invertebrates and aquatic plants in the risk evaluation.

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. 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 plans to evaluate all potential hazards for methylene chloride, using these previous analyses as a starting point for identifying key and supporting studies and including any found in recent literature. The relevant studies will be evaluated using the data quality criteria in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). Hazard endpoints identified in previous assessments include: 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 revised conceptual models presented in this problem formulation identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed or susceptible subpopulations; and hazards EPA expects to consider in the risk evaluation. The initial conceptual models provided in the scope document were revised during problem formulation based on evaluation of reasonably available information for physical and chemical properties, fate, exposures, hazards, and conditions of use and based upon consideration of other statutory and regulatory authorities. In each problem formulation document for the first 10 chemical substances, EPA also refined the activities, hazards and exposure pathways that will be included in and excluded from the risk evaluation.

EPA's overall objectives in the risk evaluation process are to conduct timely, relevant, high-quality, and scientifically credible risk evaluations within the statutory deadlines, and to evaluate the conditions of use that raise greatest potential for risk 82 FR 33726, 33728 (July 20, 2017).

1 INTRODUCTION

This document presents for comment the problem formulation of the risk evaluation to be conducted for methylene chloride under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA), the Nation's primary chemicals management law, on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

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, within 6 months after the initiation of a risk evaluation. The scope documents for all first 10 chemical substances were issued on June 22, 2017. The first 10 problem formulation documents are a refinement of what was presented in the first 10 scope documents. TSCA § 6(b)(4)(D) does not distinguish between scoping and problem formulation, and requires EPA to issue scope documents that include information about the chemical substance, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that the Administrator expects to consider in the risk evaluation. In the future, EPA expects scoping and problem formulation to be completed prior to the issuance of scope documents and intends to issue scope documents that include problem formulation.

As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for methylene chloride. Comments received on this problem formulation document will inform development of the draft risk evaluation.

The Agency defines problem formulation as the analytical phase of the risk assessment in which "the purpose for the assessment is articulated, the problem is defined and a plan for analyzing and characterizing risk is determined" (see Section 2.2 of the Framework for Human Health Risk Assessment to Inform Decision Making). The outcome of problem formulation is a conceptual model(s) and an analysis plan. The conceptual model describes the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed life stage(s) and population(s), and endpoint(s) that will be addressed in the risk evaluation (U.S. EPA, 2014a). The analysis plan follows the development of the conceptual model(s) and is intended to describe the approach for conducting the risk evaluation, including its design, methods and key inputs and intended outputs as described in the EPA Human Health Risk Assessment Framework (U.S. EPA, 2014a). The problem formulation documents refine the initial conceptual models and analysis plans that were provided in the scope documents.

First, EPA has removed from the risk evaluation any activities and exposure pathways that EPA has concluded do not warrant inclusion in the risk evaluation. For example, for some activities which were listed as "conditions of use" in the scope document, EPA has insufficient information following the further investigations during problem formulation to find they are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

Second, EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA) – and which EPA does not expect to include in the risk evaluation.

As a general matter, EPA believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes.[1] EPA does not expect to include any such excluded pathways as further explained below in the risk evaluation. The provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes.

Third, EPA identified any conditions of use, hazards, or exposure pathways which were included in the scope document and that EPA expects to include in the risk evaluation but which EPA does not expect to further analyze in the risk evaluation. EPA expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis and therefore expects to conduct no further analysis on those conditions of use, hazards or exposure pathways in order to focus the Agency's resources on more extensive or quantitative analyses. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations 82 FR 33726, 33734, 33739 (July 20, 2017).

EPA received comments on the published scope document for methylene chloride and has considered the comments specific to methylene chloride in this problem formulation document. EPA is soliciting public comment on this problem formulation document and when the draft risk evaluation is issued the Agency intends to respond to comments that are submitted. In its draft risk evaluation, EPA may revise the conclusions and approaches contained in this problem formulations, including the conditions of use and pathways covered and the conceptual models and analysis plans, based on comments received.

[1] As explained in the final rule for chemical risk evaluation procedures, "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, and consequently merit an unreasonable risk determination." [82 FR 33726, 33729 (July 20, 2017)]

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. EPA evaluated and considered the impact of existing laws and regulations (e.g., regulations on landfill disposal, design, and operations) in the problem formulation step to determine what, if any future analysis might be necessary as part of the risk evaluation. Consideration of the nexus between these existing regulations and TSCA conditions of use may additionally be made as detailed/specific conditions of use and exposure scenarios are developed in conducting the analysis phase 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. Table 1-1 shows the assessments that have been conducted. EPA found no additional assessments beyond those listed in the Scope document, but the WHO IPCS Environmental Health Criteria (EHC) document which was cited in the Scope document was added to the assessment history table.

In addition to using this information, EPA intends to conduct a full review of the relevant data and information collected in the initial comprehensive search [see *Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742-0059 (U.S. EPA, 2017a)] using the literature search and screening strategies documented in the *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742-0060 (U.S. EPA, 2017c). This will ensure that EPA considers data and information that has been made available since these assessments were conducted.

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 (2014b)

Authoring Organization	Assessment
U.S. EPA, Integrated Risk Information System (IRIS)	Toxicological Review of Dichloromethane (Methylene Chloride) (CAS No. 75-09-2) U.S. EPA (2011b)
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 ATSDR (2010)addendum
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 (1996a)
National Toxicology Program (NTP), National Institutes of Health (NIH)	Report on Carcinogens, Twelfth Edition, Dichloromethane NIH (2016)
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)
WHO International Programme on Chemical Safety (IPCS)	Environmental Health Criteria 164 Methylene Chloride WHO (1996)
Government of Canada, Environment Canada, Health Canada	Dichloromethane. Priority substances list assessment report. Health and Environment Canada (1993)

Authoring Organization	Assessment
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 systematic review process and workflow that includes: (1) data collection; (2) data evaluation; and (3) data integration of the scientific data used in risk evaluations 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. Additional information that may be considered and was not part of the initial comprehensive bibliographies will be documented in the Draft Risk Evaluation for methylene chloride.

Data Collection: Data Search

EPA/OPPT conducted chemical-specific searches for information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental and human exposures, including potentially exposed or susceptible subpopulations; ecological and 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 information potentially relevant to the risk evaluation. For most disciplines, 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). For human health hazard, EPA/OPPT relied on the search strategies from recent assessments, such as the 2011 EPA Integrated Risk Information System (IRIS) assessment to identify relevant information published after the end date of the previous search to capture more recent literature. The *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742-0060 (U.S. EPA, 2017c) provides details about the data and information sources and search terms that were used in the literature search.

Data Collection: Data Screening

Following the data search, references were screened and categorized using selection criteria outlined in the *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742-0060 (U.S. EPA, 2017c). 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). However, 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* EPA-HQ-OPPT-2016-0742-0060 (U.S. EPA, 2017c), 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 the supplemental document, *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742-0060 (U.S. EPA, 2017c), 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 can be found in the *Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742-0059 (U.S. EPA, 2017a). 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.

1.4 Data Screening During Problem Formulation

EPA/OPPT is in the process of completing the full text screening of the *on-topic* references identified in the *Methylene Chloride* (*CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742-0059 (U.S. EPA, 2017a). The screening process at the full-text level is described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Appendix F provides the inclusion and exclusion criteria applied at the full text screening. The eligibility criteria are guided by the analytical considerations in the revised conceptual models and analysis plan, as discussed in the problem formulation document. Thus, it is expected that the number of data/information sources entering evaluation is reduced to those that are relevant to address the technical approach and issues described in the analysis plan of this document.

Following the screening process, the quality of the included data/information sources will be assessed using the evaluation strategies that are described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2 PROBLEM FORMULATION

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 included in the scope document a life cycle diagram and conceptual models that describe the actual or potential relationships between methylene chloride and human and ecological receptors. During the problem formulation, EPA revised the conceptual models based on further data gathering and analysis, as presented in this problem formulation document. An updated 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.

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; EPA found no additional information during problem formulation that would change these values.

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)
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

In the scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. 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 was incorporated into this problem formulation document to the extent appropriate. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities constitute the intended, known, and reasonably foreseeable activities associated with the subject chemical, based on reasonably available information.

2.2.2 Identification of Conditions of Use

To determine the current conditions of use of methylene chloride and inversely, activities that do not qualify as conditions of use, EPA conducted extensive research and outreach. This included EPA’s review of published literature and online databases including the most recent data available from EPA’s Chemical Data Reporting program (CDR) and Safety Data Sheets (SDSs). EPA also conducted online research by reviewing company websites of potential manufacturers, importers, distributors, retailers, or other users of methylene chloride and queried government and commercial trade databases. EPA also received comments on the *Scope of the Risk Evaluation for Methylene Chloride* (EPA-HQ-OPPT-2016-0742) that were used to determine the conditions of use. In addition, EPA convened meetings with companies, industry groups, chemical users, states, environmental groups, and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. Those meetings included a February 14, 2017 public meeting with such entities (EPA-HQ-OPPT-2016-0742).

EPA has removed from the risk evaluation any activities that EPA concluded do not constitute conditions of use – for example because EPA has insufficient information to find certain activities are circumstances under which the chemical is actually “intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.” EPA has also identified any conditions of use that EPA does not expect to include in the risk evaluation. As explained in the final rule for Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, TSCA section 6(b)(4)(D) requires EPA to identify "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider” in a risk evaluation, suggesting that EPA may exclude certain activities that EPA has determined to be conditions of use on a case-by-case basis. (82 FR 33726, 33729; July 20, 2017). For example, EPA may exclude conditions of use that the Agency has sufficient basis to conclude would present only de minimis exposures or otherwise insignificant risks (such as use in a closed system that effectively precludes exposure or use as an intermediate).

The activities that EPA no longer believes are conditions of use or were otherwise excluded during problem formulation are described in Section 2.2.2.1. The conditions of use included in the scope of the risk evaluation are summarized in Section 2.2.2.2.

2.2.2.1 Categories and Subcategories Determined Not to be Conditions of Use or Otherwise Excluded During Problem Formulation

For methylene chloride, EPA has conducted public outreach and literature searches to collect information about methylene chloride's conditions of use and has reviewed reasonably available information obtained or possessed by EPA concerning activities associated with methylene chloride. Based on this research and outreach, other than the category and subcategory described in Section 2.2.2.1, EPA does not have reason to believe that any conditions of use identified in the methylene chloride scope should be excluded from risk evaluation. Therefore, all the conditions of use for methylene chloride will be included in the risk evaluation.

During problem formulation, EPA determined that methylene chloride-based extraction solvents for oils, waxes, fats, spices, and hops meet the definition of food additive in section 201 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321, and are therefore excluded from the definition of “chemical substance” in TSCA § 3(2)(B)(vi). Activities and releases associated with such extraction solvents are therefore not “conditions of use” (defined as circumstances associated with “a chemical substance,” TSCA § 3(4)) and will not be evaluated during risk evaluation. In particular, the use of methylene chloride-based extraction solvent for oils, waxes, fats, spices, and hops in agricultural chemical manufacturing and food processing was identified as a condition of use in the methylene chloride scope document but is no longer considered a condition of use and will not be evaluated in the risk evaluation.

In its 2014 risk evaluation, EPA assessed the risk from methylene chloride in consumer and commercial paint removal (U.S. EPA, 2014b). 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 except for commercial furniture stripping (82 FR 7464, January 19, 2017). While paint and coating removal falls under the conditions of use for methylene chloride, based on the intention to finalize the rulemaking the scenarios already assessed in the 2014 risk assessment these uses will not be re-evaluated and EPA will rely on the 2014 risk evaluation (https://www.epa.gov/newsreleases/epa-announces-action-methylene-chloride).

Table 2-2. Categories and Subcategories Determined Not to be Conditions of Use or Otherwise Excluded During Problem Formulation

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial, commercial and consumer uses	Other Uses	Extraction solvent for oils, waxes, fats, spices and hops in agricultural chemical manufacturing and food processing	U.S. EPA (2016b) Market profile EPA-HQ-OPPT-2016-0742
	Paints and coatings	Paints and coating removers except for commercial furniture stripping	proposed restrictions under TSCA section 6 (82 FR 7464, January 19, 2017).

2.2.2.2 Categories and Subcategories of Conditions of Use Included In the Scope of Risk Evaluation

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.

According to the ICIS (2007) 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%).

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 (U.S. EPA, 2016b), 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 certain relevant potential sources of release and human exposure associated with that life cycle stage.

Beyond the uses identified in the *Scope of the Risk Evaluation for Methylene Chloride*, EPA has received no additional information identifying additional current conditions of use for methylene chloride from public comment and stakeholder meetings.

Table 2-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category [a]	Subcategory [b]	References
Manufacturing	Domestic manufacturing	Manufacturing	U.S. EPA (2016b)
	Import	Import	U.S. EPA (2016b)
Processing	Processing as a reactant	Intermediate in industrial gas manufacturing (e.g., manufacture of fluorinated gases used as refrigerants)	U.S. EPA (2016b); U.S. EPA (2014b) 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 (2016b)
		CBI function for petrochemical manufacturing	U.S. EPA (2016b)

Life Cycle Stage	Category [a]	Subcategory [b]	References
Processing	Processing as a reactant	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 (2016b)
	Incorporated into formulation, mixture, or reaction product	Solvents (which become part of product formulation or mixture), including manufacturing of: • All other chemical product and preparation • Paints and coatings	U.S. EPA (2016b)
		Propellants and blowing agents for all other chemical product and preparation manufacturing;	U.S. EPA (2016b)
		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 (2016b)
		Laboratory chemicals for all other chemical product and preparation manufacturing	U.S. EPA (2016b), EPA-HQ-OPPT-2016-0742-0005, EPA-HQ-OPPT-2016-0742-0014
		Laboratory chemicals for CBI industrial sectors	U.S. EPA (2016b)
		Processing aid, not otherwise listed for petrochemical manufacturing	U.S. EPA (2016b)
		Adhesive and sealant chemicals in adhesive manufacturing	Use document EPA-HQ-OPPT-2016-0742-0003; U.S. EPA (2016b)
		Unknown function for oil and gas drilling, extraction, and support activities	Use document EPA-HQ-OPPT-2016-0742-0003; U.S. EPA (2016b)

Life Cycle Stage	Category [a]	Subcategory [b]	References
Processing	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 (2016b)
		CBI functions for all other chemical product and preparation manufacturing	Use document EPA-HQ-OPPT-2016-0742-0003; U.S. EPA (2016b)
	Recycling	Recycling	U.S. EPA (2017d)
Distribution in commerce	Distribution	Distribution	Use document EPA-HQ-OPPT-2016-0742-0003 U.S. EPA (2016b)
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 (2016b); 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 (2016b); Public comment EPA-HQ-OPPT-2016-0742-0017
		Cold cleaner	Use document EPA-HQ-OPPT-2016-0742-0003; U.S. EPA (2016b, 2014b)
		Aerosol spray degreaser/cleaner	U.S. EPA (2016b, 2014b) EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742

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 (2016b); 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 for commercial furniture stripping	Paints and coatings use and paints and coating removers for commercial furniture stripping	U.S. EPA (2016b, 2014b); 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 (2016b)
	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 (2016b)

Life Cycle Stage	**Category** [a]	**Subcategory** [b]	**References**
Industrial, commercial and consumer uses	Automotive care products	Interior car care – spot remover	Use document EPA-HQ-OPPT-2016-0742-0003
		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 (2016b)
	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 (2016b); 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 (2016b); 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 (2016b)

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial, commercial and consumer uses	Processing aid not otherwise listed	In multiple manufacturing sectors[d]	Use document EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742; U.S. EPA (2016b)
	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; Public Comment: EPA-HQ-OPPT-2016-0742-0066
		Electrical equipment, appliance, and component manufacturing	U.S. EPA (2016b), Public Comment EPA-HQ-OPPT-2016-0742-0017
		Plastic and rubber products	U.S. EPA (2016b)
		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 (2016b)
		Functional fluids (closed systems) in pharmaceutical and medicine manufacturing	U.S. EPA (2016b)
		Toys, playground, and sporting equipment - including novelty articles (toys, gifts, etc.)	Use document EPA-HQ-OPPT-2016-0742-0003; EPA-HQ-OPPT-2016-0742-0069;

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial, commercial and consumer uses	Other Uses	Carbon remover, lithographic printing cleaner, brush cleaner, use in taxidermy, and wood floor cleaner	Use document EPA-HQ-OPPT-2016-0742-0003; Market profile EPA-HQ-OPPT-2016-0742; U.S. EPA (2016b)
Disposal	Disposal	Industrial pre-treatment	U.S. EPA (2017d)
		Industrial wastewater treatment	
		Publicly owned treatment works (POTW)	
		Underground injection	
		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, 2016b).
[d] 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, 2016b) also including as a chemical processor for polycarbonate resins and cellulose triacetate (photographic film).

2.2.2.3 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-1 depicts the conditions of use that are considered within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, distribution, use (industrial, commercial, consumer; when distinguishable) and disposal. Additions or changes to conditions of use based on additional information gathered or analyzed during problem formulation were described in Section 2.2.2.1 and 2.2.2.2. The activities that EPA determined are out of scope during problem formulation are not included in the life cycle diagram. 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.

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, 2016b).

To understand conditions of use relative to one another and associated potential exposures under those conditions of use, the 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, 2016b), when the volume was not claimed confidential business information (CBI).

The 2016 CDR reporting data for methylene chloride are provided in Table 2-4 from EPA's CDR database. This information has not changed during problem formulation from that provided in the scope document.

Table 2-4. 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, 2016b). 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.

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR (U.S. EPA, 2016b) and included in the life cycle diagram (Figure 2-1) are summarized below. 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 assessment. 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).

Figure 2-1 depicts the life cycle diagram of methylene chloride from manufacture to the point of disposal. Activities related to the distribution (e.g., loading, unloading) will be considered throughout the methylene chloride life cycle rather, than using a single distribution scenario.

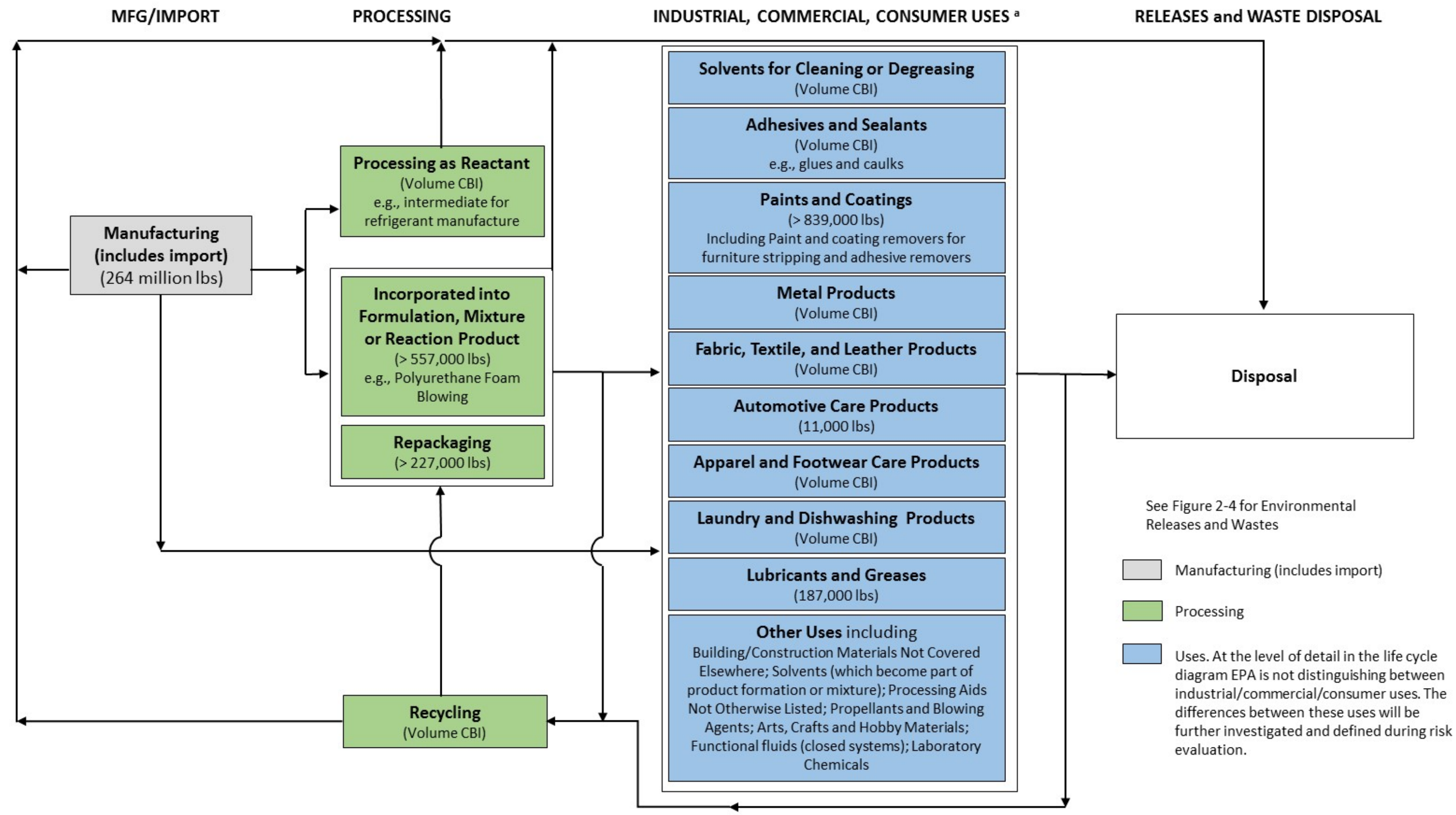

Figure 2-1. Methylene Chloride Life Cycle Diagram

The 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, 2016b). 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.

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 2-5 provides environmental fate data that EPA identified and considered in developing the scope for methylene chloride. This information has not changed from that provided in the scope document.

Fate data including volatilization during wastewater treatment, volatilization from lakes and rivers, biodegradation rates, and organic carbon:water partition coefficient (log K_{OC}) were used when considering changes to the conceptual models. Model results and basic principles were used to support the fate data used in problem formulation while the literature review is currently underway through the systematic review process.

EPI Suite™ (U.S. EPA, 2012b) modules were used to estimate volatilization of methylene chloride from wastewater treatment plants, lakes, and rivers and to confirm the data showing slow biodegradation. The EPI Suite™ module that estimates chemical removal in sewage treatment plants ("STP" module) was run using default settings to evaluate the potential for methylene chloride to volatilize to air or adsorb to sludge during wastewater treatment. The STP module estimates that 56% of methylene chloride in wastewater will be removed by volatilization while < 1% of methylene chloride will be removed by adsorption.

The EPI Suite™ module that estimates volatilization from lakes and rivers ("Volatilization" module) was run using default settings to evaluate the volatilization half-life of methylene chloride in surface water. The parameters required for volatilization (evaporation) rate of an organic chemical from the water body are water depth, wind and current velocity of the river or lake. The volatilization module estimates that the half-life of methylene chloride in a model river will be 1.1 hours and the half-life in a model lake will be 3.7 days.

The EPI Suite™ module that predicts biodegradation rates ("BIOWIN" module) was run using default settings to estimate biodegradation rates of methylene chloride in soil and sediment. The aerobic biodegradation models (BIOWIN 1-6) estimate that methylene chloride is not readily biodegradable in aerobic environments, which supports the biodegradation data presented in the methylene chloride scoping document demonstrating slow biodegradation under aerobic conditions. The anaerobic biodegradation model (BIOWIN 7) predicts that methylene chloride will rapidly biodegrade under anaerobic conditions. Previous assessments of methylene chloride reported moderate aerobic biodegradation, particularly following an acclimation period, and evidence of anaerobic biodegradation (OECD, 2011; U.S. EPA, 2011b; ATSDR, 2010, 2000; Health and Environment Canada, 1993).

The organic carbon:water partition coefficient (log K_{OC}) reported in the methylene chloride scoping document was predicted using EPI Suite™. That value (1.4) is supported by the basic principles of environmental chemistry which states that the K_{OC} is typically within one order of magnitude (one log unit) of the octanol:water partition coefficient (K_{OW}). Indeed, the log K_{OW} reported for methylene chloride in the scoping document was 1.25, which is within the expected range. The log K_{OC} reported in previous assessments of methylene chloride were in the range of 1.27 – 1.4 (ATSDR, 2000; Health and Environment Canada, 1993).

Table 2-5. 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 (2012b)
Organic carbon:water partition coefficient (log K_{oc})	1.4 (estimated)	U.S. EPA (2012b)

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

Releases of methylene chloride to the air and water 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 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, 2014b) 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 considered 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. During problem formulation EPA further analyzed the TRI data and examined the definitions of elements in the TRI data to determine the level of confidence that a release would result from certain types of disposal to land (e.g. RCRA Subtitle C hazardous landfill and Class I underground Injection wells) and incineration. EPA also examined how methylene chloride is treated at industrial facilities.

Table 2-6 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 2-7 provides more detailed information on the quantities released to air or water or disposed of on land.

Table 2-6. Summary of Methylene Chloride TRI Production-Related Waste Managed in 2015 (lbs)

Number of Facilities	Recycling	Energy Recovery	Treatment	Releases [a, b, c]	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, 2017d)
[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.
[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

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.

Table 2-7. Summary of Methylene Chloride TRI Releases to the Environment in 2015 (lbs)

		Air Releases			Land Disposal				
	Number of Facilities	Stack Air Releases	Fugitive Air Releases	Water Releases	Class I Under-ground Injection	RCRA Subtitle C Landfills	All other Land Disposal [a]	Other Releases [a]	Total On- and Off-site Disposal or Other Releases [b, c]
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, 2017d)
[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.
[c] Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

Of these releases, 75%, or 2.5 million pounds, were released to air (stack and fugitive air emissions), 2,366 pounds were released to water (surface water discharges), 114,000 pounds were released to land (of which Class I Underground Injection and Resource Conservation and Recovery Act (RCRA) Subtitle C landfills were the primary disposal methods) and 713,000 pounds were released in other forms such as to waste brokers. For stack releases, multiple types of facilities reported on incineration destruction, including hazardous waste facilities and facilities that perform other industrial activities and may be privately or publicly (i.e., federal, state or municipality) owned or operated. Off-site transfers for incineration (energy recovery, incineration/thermal treatment, incineration/insignificant fuel value)[2] of methylene chloride from TRI facilities nearly all go to RCRA Subtitle C facilities. Of the 14.9 million

[2] Quantities reported as managed on-site or off-site through incineration are within the energy recovery category and a portion of treatment category in Table 2-6.

lbs transferred for incineration, only 89,000 lbs were instead sent to facilities in Canada. The 713 thousand pounds released in other forms were transfers off-site for disposal. The majority were to waste brokers (662 thousand pounds), 39 thousand pounds were for disposal by other techniques, 8 thousand pounds were for off-site storage and 3 thousand pounds for unknown disposal.

Of the methylene chloride that went to on-site land disposal in 2015, most was disposed of in Class I underground injection wells (about 59,700 lbs) or RCRA Subtitle C Landfills (about 30,800 lbs). An additional 250 lbs were disposed of in landfills other than RCRA Subtitle C. No methylene chloride was reported to be disposed of in on-site Class II-V underground injection wells, on-site land treatment, or on-site surface impoundments. Of the off-site land disposal, about 5,300 lbs went to RCRA Subtitle C Landfills and about 8,200 lbs went to landfills other than RCRA Subtitle C. Almost negligible amounts were transferred off-site to land treatment, and Class I underground injection wells.

While production-related waste managed shown in Table 2-6 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), release quantities shown in Table 2-7 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, 2017d).

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 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. 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). EPA expects to consider these data in conducting the exposure assessment component of the risk evaluation for methylene chloride.

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).

The 2011 National Air Toxics Assessment (NATA) modeled concentrations for various air toxics nationwide at a census tract level. This screening level tool modeled a maximum total methylene chloride concentration of 5,000 parts per trillion (18 µg/m^3). Greater than 94% of all modeled tracts were less than 100 parts per trillion. 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 however methylene chloride measurements in human milk have not been quantified and there are no animal studies testing to what extent methylene chloride can pass into 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) 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. In this section, EPA presents exposures to aquatic and terrestrial organisms.

Aquatic Environmental Exposures

Based on national-scale monitoring data from EPA's STORET and U.S.G.S.'s NAWQA, methylene chloride is detected in surface and ground water. In an evaluation of the STORET database containing nearly 9,000 samples, methylene chloride was detected 30% of the time at a median concentration of 0.1 ppb (ATSDR, 2000; Staples et al., 1985). In an evaluation of USGS NAWQA data from 1992-2001, methylene chloride was found above the reporting limit in both groundwater and surface water at 2.9% and 14.6% of all samples respectively and 5.6% overall. When calculated as a percentage of sampled sites, 3.2% of all groundwater sites, 31.9% of all surface water sites and 4.4% of all sites overall recorded a detectable result (U.S. EPA, 2009). Methylene chloride was detected in groundwater with a median value of 0.05 µg/L and ranged from 0.008 to 25.8 µg/L (99^{th} percentile = 21.6 µg/L) and in surface water samples with a median of 0.035 µg/L and ranged from 0.0055 to 34 µg/L (99^{th} percentile = 1.55 µg/L).

A recent review of the multi-agency Water Quality Portal which includes data from the National Water Information System (NWIS), STORET, and USDA STEWARDS databases also shows hundreds of measures of methylene chloride in soil and sediment. In a literature review of various VOC concentrations found in landfill leachates, Klett et al. (2005) found methylene chloride ranged in concentration from 1.0 – 58,200 µg/L. Staples et al. (1985) reported that methylene chloride was found in 20% of sediment samples in the STORET database. Methylene chloride concentrations in soil and sediment pore water are expected to be similar to the concentrations in groundwater (in soil) or overlying water (in sediment) because methylene chloride does not partition to organic matter (estimated log K_{OC} = 1.4) and biodegrades slowly (13% biodegradation in 28 days; (NITE, 2002)). Thus, the methylene chloride detected in soil and sediments is likely from the pore water and not methylene chloride that was adsorbed to the soil or sediment solids.

Terrestrial Environmental Exposures

Terrestrial species populations living near industrial and commercial facilities using methylene chloride may be exposed via multiple routes such as ingestion of surface waters and inhalation of outdoor air. As described in Section 2.3.3 methylene chloride is present and measurable through monitoring in a variety of environmental media including ambient and indoor air, surface water and ground water.

2.3.5 Human Exposures

In this section, EPA presents occupational, consumer and general population exposures. Subpopulations, including potentially exposed and susceptible subpopulations, within these exposure categories are also presented.

2.3.5.1 Occupational Exposures

Exposure pathways and exposure routes are listed below for worker activities under the various conditions of use (industrial or commercial) described in Section 2.2. In addition, exposures to occupational non-users (ONU), who do not directly handle the chemical but perform work in an area where the chemical is present are listed. Engineering controls and/or personal protective equipment may impact the occupational exposure levels.

In the previous 2014 risk assessments (U.S. EPA, 2014b), EPA assessed inhalation exposures to methylene chloride for occupational use in paint and coating removal, which will be considered in the methylene chloride 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, including, but not limited to:

- 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 adhesive removers containing methylene chloride onto substrates requiring adhesive removal);
- 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.

Key Data

Key data that inform occupational exposure assessment 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. OSHA data can be obtained through CEHD https://www.osha.gov/opengov/healthsamples.html. Table_Apx B-1 and Table_Apx B-2 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/. EPA identified several HHEs during the problem formulation; these HHEs are listed in Table_Apx B-3 in Appendix B. EPA also identified additional sources of potentially relevant occupational exposure data. These sources are listed in Table_Apx B-4 through Table_Apx B-7 in Appendix B, and EPA will review these data and evaluate their utility in the risk evaluation.

Inhalation

Based on these occupational exposure scenarios, inhalation exposure to vapor is expected. EPA anticipates this is the most important methylene chloride exposure pathway for workers and occupational nonusers based on the high volatility of methylene chloride. Based on the potential for spray application of some products containing methylene chloride exposures to mists are also expected for workers and ONU and will be incorporated into the occupational inhalation exposure estimates.

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).

Dermal

Based on the conditions of use EPA expects workers to have potential for skin contact with liquids and vapors. Where workers may be exposed to methylene chloride, the OSHA standard requires that workers are protected from contact (e.g. gloves) (29 CFR 1910.1052). Occupational non-users are not directly handling methylene chloride; therefore, skin contact with liquid methylene chloride is not expected for occupational non-users but skin contact with vapors is expected for occupational nonusers.

Oral

Exposure may occur through mists that deposit in the upper respiratory tract however, based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate and will be considered as an inhalation exposure.

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 and bystanders (non-product users that are incidentally exposed to the product).

In EPA's 2014 risk assessment for methylene chloride paint stripping use, consumer inhalation exposures in residential settings were assessed using a variety of indoor exposure scenarios (U.S. EPA, 2014b). 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.

Inhalation

EPA expects that inhalation exposure to vapor will be the most significant route of exposure for consumer and bystander exposure scenarios, in line with EPA's 2014 risk assessment of methylene chloride paint stripping use, which assumed that inhalation is the main exposure pathway based on the physical-chemical properties of methylene chloride (e.g. high vapor pressure) (U.S. EPA, 2014b). Based on the potential for spray application of some products containing methylene chloride exposures to mists are also expected. These exposures to consumers and bystanders through mists may deposit in the upper respiratory tract; EPA assumes these are absorbed via inhalation

Dermal

There is a potential for dermal exposures to methylene chloride in consumer uses. Dermal exposure may occur via contact with vapor or mist deposition onto the skin or via direct liquid contact during use. Exposures to skin would be expected to evaporate fairly quickly based on physical chemical properties including vapor pressure, water solubility and log K_{OW} but some methylene chloride would also be dermally absorbed. When evaporation of methylene chloride is reduced such as in occluded scenarios (e.g. continued contact with a methylene chloride soaked rag) dermal absorption would be higher due to the longer duration of exposure. These dermal exposures would be concurrent with inhalation exposures and the overall contribution of dermal exposure to total exposure is expected to be smaller than via inhalation however there may be exceptions for the occluded scenarios. Overall, dermal exposures to consumers in occluded and non-occluded scenarios are expected. Bystanders will not have dermal contact with liquid methylene chloride but will have dermal exposures to methylene chloride vapor.

Oral

Consumers may be exposed to methylene chloride via transfer of methylene chloride from hand to mouth. This exposure pathway will be limited by a combination of dermal absorption and volatilization.

Exposures from Disposal

EPA does not expect exposure to consumers from disposal of consumer products. It is anticipated that most products will be disposed of in original containers, particularly those products that are purchased as aerosol cans. Liquid products may be recaptured in an alternate container following use (e.g. paint scrapings after paint removal as was done in EPA's 2014 risk assessment for methylene chloride paint stripping use).

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.

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, 2014b, 2009; ATSDR, 2000). Between 1998 and 2006, >90% of all reported TRI releases of methylene chloride were air releases (U.S. EPA, 2014b) and levels of methylene chloride in the ambient air are widespread and shown to be increasing (Section 2.3.2). The 2011 NATA modeled concentrations at a census tract level found a maximum total methylene chloride concentration of 5,000 parts per trillion (18 μg/m^3) and maximum human inhalation exposure concentrations of 3,900 parts per trillion (14 μg/m^3). Greater than 94% of all modeled tracts were less than 100 parts per trillion. 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.

Oral

The general population may ingest methylene chloride via contaminated drinking water, ground water, and/or surface water. Ingestion of contaminated drinking water is expected to be the primary route of oral exposure. Oral ingestion may include exposure to contaminated breast milk or 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.

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.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires the determination of whether a chemical substance presents an 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." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011c).

As part of the Problem Formulation, EPA identified potentially exposed and susceptible subpopulations for further analysis during the development and refinement of the life cycle, conceptual models, exposure scenarios, and analysis plan. 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.

EPA identifies the following as potentially exposed or susceptible subpopulations that EPA expects to consider in the risk evaluation due to their *greater exposure*:

- Workers and occupational non-users.
- Consumers and bystanders associated with consumer use. Methylene chloride has been identified 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 analyze 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 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 analyze the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use, and other groups of individuals within the general population who may experience greater exposure. 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* EPA-HQ-OPPT-2016-0742-0060 (U.S. EPA, 2017c). Based on initial screening, EPA expects to analyze the hazards of methylene chloride identified in this problem formulation 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 will be analyzed for every exposure scenario.

2.4.1 Environmental Hazards

EPA identified the following sources of environmental hazard data for methylene chloride: (U.S. EPA, 2014b; OECD, 2011; WHO, 1996; Health and Environment Canada, 1993). Only the *on-topic* references listed in the Ecological Hazard Literature Search Results were considered as potentially relevant data/information sources for the risk evaluation. Inclusion criteria were used to screen the results of the ECOTOX literature search (as explained in the *Strategy for Conducting Literature Searches for Methylene Chloride: Supplemental Document to the TSCA Scope Document, CASRN:79-09-2*). Data from the screened literature are summarized below (Table 2-8) as ranges (min-max). EPA expects to review these data/information sources during risk evaluation using the data quality review evaluation metrics and the rating criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

Toxicity to Aquatic Organisms

Fish exposed to methylene chloride between 24 hours and 9 days had LC_{50} concentrations ranging from 34 mg/L to 1,100 mg/L(U.S. EPA, 2014b; OECD, 2011; Health and Environment Canada, 1993). In a 24-hour cytotoxicity test in cultured fish cells, protein content decreased 50% at a calculated *in vitro* concentration of 49,000 mg/L ((Dierickx, 1993). Amphibians exposed to methylene chloride from 48 hours to 9.5 days had EC_{50} concentrations ranging from 16.92 mg/L to > 48 mg/L for mortality and teratogenicity and a no observed effect concentration range of 0.017 mg/L to 0.1 mg/L. Aquatic invertebrates exposed to methylene chloride between 4 hours to 12 days had EC_{50} concentrations ranging from 27 mg/L to 69,160 mg/L (as needed, units were converted to mg/L based on the methylene chloride MW of 84.93 g/mol and density of 1.33 g/cm^3) and there was a 96-hour LOEC for developmental and teratogenic effects between concentrations of 0.0008 and 0.0009 mg/L. Aquatic plants exposed between 3 to 96 hours to methylene chloride had various effects, including biomass and growth inhibition and population-level effects, at concentrations ranging from 0.98 to 2,292 mg/L. Mortality to freshwater fungi was observed when exposed to methylene chloride at concentrations of

2400 mg/L for 2 to 30 hours. There were no available acute sediment toxicity studies, however, toxicity is expected to be similar to that of aquatic invertebrates when exposed to methylene chloride in sediment pore water.

For chronic exposures to methylene chloride, there was one fish study with 23 to 27-day LC_{50} concentrations between 13.16 mg/L and 13.51 mg/L, respectively. Developmental and other effects in fish were observed at LOECs ranging from 5.5 mg/L to 209 mg/L. Aquatic plants had a 10-day LOEC of 0.002 mg/L for reduction in Chlorophyll A.

Toxicity to Soil and Terrestrial Organisms

Terrestrial mammals exposed to methylene chloride, by injection for 0.25 hours, had physiological effects with an EC_{50} of 326.3 mg/kg-body weight. Mammals exposed via oral administration for up to 30 days had LOAELs ranging from 115 to 1720 mg/kg-body weight per day. In two studies, bird eggs injected with methylene chloride for 14 days had LD_{50} concentration of > 8.5 and 14.1 mg/egg, respectively, but teratogenicity was not observed. Terrestrial invertebrates fumigated with methylene chloride for 24 hours had LD_{50}s ranging from 81.28 – 129.9 mg/L. Soil invertebrates had a 48-hr LC_{50} of 0.304 mg/cm^2 after topical exposures to methylene chloride. The 48-hr LC_{50} was >1.0 mg/cm^2 for invertebrates exposed to methylene chloride in soil. Fungi exposed in an assay to methylene chloride demonstrated cellular effects at LOECs ranging from 5.3 – 11.5 mg/L (converted from 62.4 to 135.7 mM).

Mammals with oral exposures to methylene chloride for 18-weeks to 31-weeks had a NOAEC of 225 mg/kg body weight per day with no mortality or reproductive effects at the highest concentrations tested. Mammals with inhalation exposures to methylene chloride over a two-year period had a NOAEC of 695 mg/m^3 and a LOAEC of 1737 mg/m^3. Terrestrial plants exposed to methylene chloride for 14-days had no growth effects.

Table 2-8. Summary of Ecological Hazard Information for Methylene Chloride

Duration	Test Organism	Endpoint	Hazard Values*	Units	Effect Endpoint	References
Aquatic Organisms and Amphibians						
Acute	Fish	LC_{50}	34 – 1,100	mg/L	Mortality/ Immobility	U.S. EPA (2014b); OECD (2011); Health and Environment Canada (1993); Tsuji et al. (1986)
		EC_{50} (assay)	49,000	mg/L	Biochemical/ Protein Content	Dierickx (1993)
	Amphibians	EC_{50}	16.93 – > 48	mg/L	Mortality/ Teratogenicity	Marquis et al. (2006); WHO (1996); Health and Environment Canada (1993)
		NOEC	0.017 – 0.1			
		LOEC	0.822 – 0.981			
	Aquatic invertebrates	EC_{50}	27 – 69,160	mg/L	Mortality/ Immobility	U.S. EPA (2014b); OECD (2011); Rayburn and Fisher

Duration	Test Organism	Endpoint	Hazard Values*	Units	Effect Endpoint	References
Acute	Aquatic invertebrates	NOEC	68 – 133,000	mg/L	Mortality/ Immobility/ Development	(1999); Wilson (1998); Sanchez-Fortun et al. (1997); WHO (1996); Health and Environment Canada (1993)
		LOEC	0.0008 – 0.0009	mg/L	Development/ Teratogenicity	
	Aquatic Plants	EC_{50}	0.98 – 2,292	mg/L	Growth Rate/ Biomass/ Cellular/ Biochemical	U.S. EPA (2014b); Wu et al. (2014); OECD (2011); Tsai and Chen (2007); Ando et al. (2003); WHO (1996); Brack and Rottler (1994)
		NOEC	0.98 - 221	mg/L	Population/ Cellular/ Biochemical	Wu et al. (2014); Tsai and Chen (2007); Ando et al. (2003); Brack and Rottler (1994)
		LOEC	0.98 –403			
	Fungi	LT_{50}	2400	mg/L	Mortality	Steiman et al. (1995)
Chronic	Fish	LC_{50}	13.16 – 13.51	mg/L	Mortality	WHO (1996); Health and Environment Canada (1993)
		LOEC	5.5 – 209	mg/L	Mortality/Development/Body Weight	U.S. EPA (2014b); OECD (2011); WHO (1996); Health and Environment Canada (1993)
		MATC	108	mg/L	Body Weight	U.S. EPA (2014b); WHO (1996)
	Aquatic Plants	NOEC	2	mg/L	Population/ Cellular	Wu et al. (2014); Tsai and Chen (2007); Ando et al. (2003); Brack and Rottler (1994)
		LOEC	0.002			
Terrestrial Organisms						
Acute	Mammals	EC_{50}	326.3	mg/kg bdwt/d	Mortality/Growth /Physiological	Sasaki et al. (1998); Herr and Boyes (1997)
		NOAEC	25 - 600			
		LOAEC	75 - 1720			
	Avian	LD_{50}	>8.5 – 14.1	mg/egg	Mortality	Health and Environment Canada (1993)
	Terrestrial Invertebrates	LD_{50}	81.28 – 129.9	mg/L	Mortality	Health and Environment Canada (1993)

Duration	Test Organism	Endpoint	Hazard Values*	Units	Effect Endpoint	References
Acute	Soil Invertebrates	LC_{50}	0.304 – >1.0	mg/cm^2	Mortality	OECD (2011); WHO (1996)
	Fungi	LOEC	5300 – 11,525	mg/L	Cellular/Genetic	Crebelli et al. (1995)
Chronic	Mammals	NOAEC	225 - 695	mg/m^3	Mortality/Liver/ CNS	OECD (2011); U.S. EPA (2011b); WHO (1996)

* Values in the tables are presented as reported by the study authors, unless units were converted for consistency.

Based on the information listed in Table 2-8, fish and aquatic invertebrates with acute exposures to methylene chloride resulted in mortality or immobilization. Mortality and other adverse effects were observed to amphibians with acute exposures. When algae were exposed to methylene chloride, adverse effects to biomass, growth rate, and cellular effects were observed. There was mortality and/or developmental effects in fish, aquatic invertebrates and amphibians with acute and chronic exposures. The most sensitive taxa in the dataset were:

- aquatic invertebrates, including insect larvae, had EC_{50}s as low as 27 mg/L and developmental effects with a 96-h LOEC of 0.0008 mg/L
- amphibians had EC_{50}s as low as 16.93 mg/L and LOECs from 0.822 mg/L to 0.981 mg/L
- aquatic plants had a LOEC of 0.002 mg/L for reduction in Chlorophyll A

Based on the studies listed in Table 2-8, acute toxicity to terrestrial species was observed, including cellular effects in mammals, mortality in soil and terrestrial invertebrates, growth and cellular effects in terrestrial plants and cellular effects in fungi. There was mortality in mammals and bird embryos with acute exposures to methylene chloride and effects chronic exposures had growth effects. The most sensitive taxa in the dataset were:

- soil invertebrates had a LC_{50} of 0.304 mg/cm^2 from topical application of methylene chloride
- terrestrial mammals with an oral LOAEC of 115 mg/kg bdwt/day and a NOAEC of 25 mg/kg bdwt/day and an inhalation LOAEC of 1737 mg/m^3 and NOAEC of 695 mg/m^3
- terrestrial invertebrates with a LD_{50} of 81.28 mg/L

Environmental hazard data will be further reviewed for overall data quality confidence and integrated during the risk evaluation phase. The lowest values were used for hazard levels of concern to estimate lower bound effect levels that would likely encompass more sensitive species not specifically represented by the available experimental data. It should be noted that these hazard levels of concern do not account for differences in inter- and intra-species variability, as well as laboratory-to-field variability and are dependent upon the availability of datasets that can be used to characterize relative sensitivities across multiple species within a given taxa or species group, since the data available for most industrial chemicals are limited.

2.4.2 Human Health Hazards

Methylene chloride has an existing EPA IRIS Assessment (U.S. EPA, 2011b), 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, 1996a) 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 reviewed. EPA expects to use these previous analyses as a starting point for identifying key and supporting studies to inform the human health hazard assessment, including dose-response analysis. The relevant studies will be evaluated using the data quality criteria in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). 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-HQ-OPPT-2016-0742-0059 (U.S. EPA, 2017a)]. Based on reasonably available information, the following sections describe the potential hazards associated with methylene chloride.

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, 2011b). CNS depressive effects may be a result of methylene chloride or its metabolite carbon monoxide and will be evaluated. 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 for inhalation and oral exposure (U.S. EPA, 2011b). Based on studies of workers there is limited evidence of liver effects. Following chronic repeated inhalation and oral exposures to methylene chloride, rats and mice exhibited hepatocyte vacuolation, necrosis and degeneration (U.S. EPA, 2011b).

Neurotoxicity

The brain is often affected by exposures to methylene chloride (U.S. EPA, 2011b). 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, 2011b).

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, 2011b; 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, 2011b). 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, 2011b). 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, 2011b). In the IRIS assessment, 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, 2011b).

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" (U.S. EPA, 2011b).

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).

2.5 Conceptual Models

EPA risk assessment guidance (U.S. EPA, 2014a, 1998), defines Problem Formulation as the part of the risk assessment framework that identifies the major factors to be considered in the assessment. It draws from the regulatory, decision-making and policy context of the assessment and informs the assessment's technical approach.

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. The initial conceptual models describing the scope of the assessment for methylene chloride, have been refined during problem formulation. The changes to the conceptual models in this problem formulation are described along with the rationales.

In this section, EPA outlines those pathways that will be included and further analyzed in the risk evaluation; will be included but will not be further analyzed in risk evaluation; and will not be included in the TSCA risk evaluation; and the underlying rationale for these decisions.

EPA determined as part of problem formulation that it is not necessary to conduct further analysis on certain exposure pathways that were identified in the methylene chloride scope document and that remain in the risk evaluation. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations 82 FR 33726, 33734, 33739 (July 20, 2017).

As part of this problem formulation, EPA also identified exposure pathways under regulatory programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist, i.e., the Clean

Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA). OPPT worked closely with the offices within EPA that administer and implement the regulatory programs under these statutes. In some cases, EPA has determined that chemicals present in various media pathways (i.e., air, water, land) fall under the jurisdiction of existing regulatory programs and associated analytical processes carried out under other EPA-administered statutes and have been assessed and effectively managed under those programs. EPA believes that the TSCA risk evaluation should generally focus on those exposure pathways associated with TSCA conditions of use that are not adequately assessed and effectively managed under the regulatory regimes discussed above because these pathways are likely to represent the greatest areas of risk concern. As a result, EPA does not expect to include in the risk evaluation certain exposure pathways identified in the methylene chloride scope document.

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

The revised conceptual model (Figure 2-2) describes the pathways of exposure from industrial and commercial activities and uses of methylene chloride that EPA expects to include in the risk evaluation. There are exposures to workers and/or occupational non-users via inhalation routes and/or exposures to workers via dermal routes for all conditions of use identified in this problem formulation. In the (U.S. EPA, 2014b) 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 and manual handling of metal parts removed from industrial degreasing tanks. In addition to the pathways illustrated in the figure, EPA will evaluate activities resulting in exposures associated with distribution in commerce (e.g. loading, unloading) throughout the various lifecycle stages and conditions of use (e.g. manufacturing, processing, industrial use, commercial use, disposal) rather than a single distribution scenario.

Inhalation

EPA/OPPT's 2014 risk assessment of methylene chloride paint stripping use assumed that inhalation is the main exposure pathway based on the physical-chemical properties of methylene chloride (e.g. high vapor pressure) (U.S. EPA, 2014b). Inhalation exposures for workers are regulated by OSHA's occupational safety and health standards for methylene chloride which include a PEL of 25 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1052 App. A). EPA expects that for workers and occupational non-users exposure via inhalation will be the most significant route of exposure for most exposure scenarios. EPA expects to further analyze inhalation exposures to vapors and mists for workers and occupational non-users in the risk evaluation.

Dermal

There is the potential for dermal exposures to methylene chloride in many worker scenarios. Where workers may be exposed to methylene chloride, the OSHA standard requires that workers are protected from contact (e.g. gloves) (29 CFR 1910.1052). EPA's 2014 risk assessment of methylene chloride paint stripping use included the potential dermal exposures to methylene chloride as an area of uncertainty that may underestimate the total exposures (U.S. EPA, 2014b). These dermal exposures would be concurrent with inhalation exposures and the overall contribution of dermal exposure to the total exposure is expected to be small however there may be exceptions for occluded scenarios. Occupational non-users are not directly handling methylene chloride; therefore, skin contact with liquid methylene chloride is not expected for occupational non-users and EPA does not expect to further analyze this pathway in the risk evaluation. EPA expects to further analyze dermal exposures for skin contact with liquids in occluded situations for workers.

Workers and occupational non-users can have skin contact with methylene chloride vapor concurrently with inhalation exposures. The parameters determining the absorption of methylene chloride vapor are based on the concentration of the vapor, the duration of exposure and absorption. The concentration of the vapor and the duration of exposure are the same for concurrent dermal and inhalation exposures. Therefore, the differences between dermal and inhalation exposures depend on the absorption. The dermal absorption can be estimated from the skin permeation coefficient (0.28 cm/hr for methylene chloride vapor (ATSDR, 2010, 2000)) and exposed skin surface area (on the order of 0.2 m^2 (U.S. EPA, 2011a)). The absorption of inhaled vapors can be estimated from the volumetric inhalation rate (approximately 1.25 m^3/hr for a person performing light activity (U.S. EPA, 2011a) adjusted by a retention factor such as 0.75. Based on these parameters the absorption of methylene chloride vapor via skin will be orders of magnitude lower than via inhalation and will not be further analyzed.

Waste Handling, Treatment and Disposal

Figure 2-2 shows that waste handling, treatment and disposal is expected to lead to the same pathways as other industrial and commercial activities and uses. The path leading from the “Waste Handling, Treatment and Disposal” box to the “Hazards Potentially Associated with Acute and/or Chronic Exposures See Section 2.4.2” box was re-routed to accurately reflect the expected exposure pathways, routes, and receptors associated with these conditions of use of methylene chloride.

For each condition of use identified in Table 2-3, a determination was made as to whether or not each unique combination of exposure pathway, route, and receptor will be further analyzed in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix C and Appendix E.

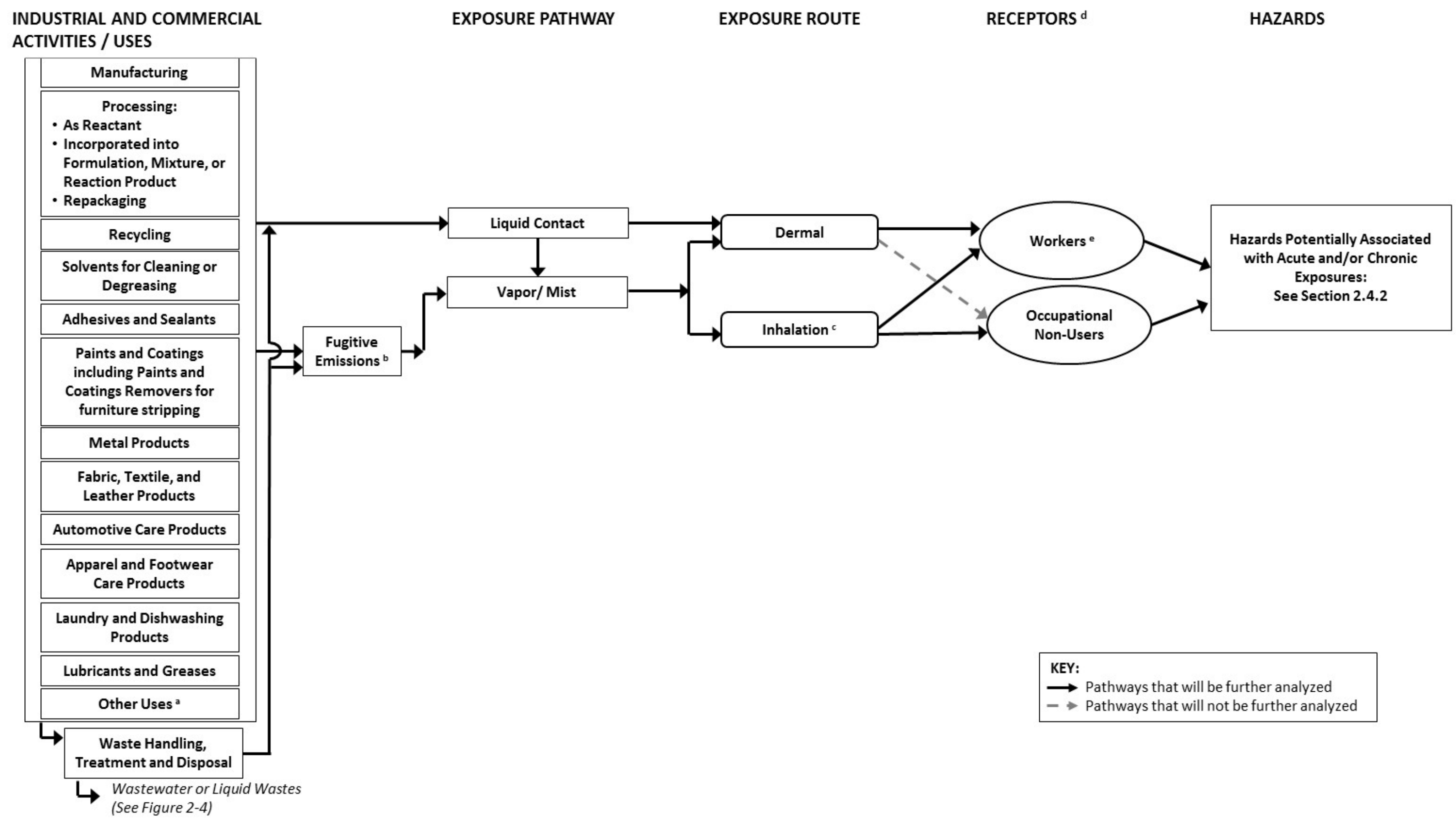

Figure 2-2. Methylene Chloride Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

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] 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.

[b] 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.

[c] Exposure may occur through mists that deposit in the upper respiratory tract however, based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate and will be considered as an inhalation exposure.

[d] Receptors include potentially exposed or susceptible subpopulations.

[e] 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 Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

The revised conceptual model (Figure 2-3) illustrates the pathways of exposure from consumer uses of methylene chloride that EPA expects to include in the risk evaluation. In the (U.S. EPA, 2014b) risk assessment, inhalation exposures to vapor and mist were assessed as the most likely exposure route; however, there are potential dermal exposures for some conditions of use. It should be noted that some consumers may purchase and use products primarily intended for commercial use.

Inhalation

As mentioned above, EPA/OPPT's 2014 risk assessment of methylene chloride paint stripping use assumed that inhalation of methylene chloride vapor is the main exposure pathway based on the physical-chemical properties of methylene chloride (e.g. high vapor pressure) (U.S. EPA, 2014b). EPA expects inhalation to be the primary route of exposure and expects to further analyze inhalation exposures to methylene chloride vapor and mist for consumers and bystanders.

Dermal

There is potential for dermal exposures to methylene chloride from consumer uses. Dermal exposure may occur via contact with vapor or mist deposition onto the skin or via direct liquid contact during use. Direct contact with liquid methylene chloride would be concurrent with inhalation exposures and dermal exposures to consumers in occluded and non-occluded scenarios are expected. Bystanders will not have direct dermal contact with liquid methylene chloride. EPA expects to further analyze direct dermal contact with liquid methylene chloride for consumers.

Consumers and bystanders can have skin contact with methylene chloride vapor concurrently with inhalation exposures. Similar to workers (see Section 2.5.1) the parameters determining the absorption of methylene chloride vapor are based on the concentration of the vapor, the duration of exposure and absorption. The concentration of the vapor and the duration of exposure are the same for concurrent dermal and inhalation exposures. Therefore, the differences between dermal and inhalation exposures depend on the absorption. The dermal absorption can be estimated from the skin permeation coefficient (0.28 cm/hr for methylene chloride vapor (ATSDR, 2010, 2000)) and exposed skin surface area (on the order of 0.2 m^2 (U.S. EPA, 2011a)). The absorption of inhaled vapors can be estimated from the volumetric inhalation rate (approximately 1.25 m^3/hr for a person performing light activity (U.S. EPA, 2011a) adjusted by a retention factor such as 0.75. Based on these parameters the absorption of methylene chloride vapor via skin will be orders of magnitude lower than via inhalation and will not be further analyzed.

Oral

Consumers may be exposed to methylene chloride via transfer of methylene chloride from hand to mouth. This exposure pathway will be limited by a combination of dermal absorption and volatilization; therefore, this pathway will not be further evaluated.

Furthermore, based on available toxicological data, EPA does not expect that considering separate oral routes of exposure for incidental ingestion would have significantly different toxicity, rather skin contact will be included as part of consumer dermal exposures. Bystanders are not directly handling methylene chloride; therefore, incidental ingestion via contact with methylene chloride is not expected for bystanders. Therefore, this pathway will not be further evaluated for consumers or bystanders.

Disposal

EPA does not expect to further analyze exposure to consumers from disposal of consumer products. It is anticipated that most products will be disposed of in original containers, particularly those products that are purchased as aerosol cans. Liquid products may be recaptured in an alternate container following use (e.g. paint scrapings after paint removal as was done in EPA's 2014 risk assessment for methylene chloride paint stripping use) (U.S. EPA, 2014b).

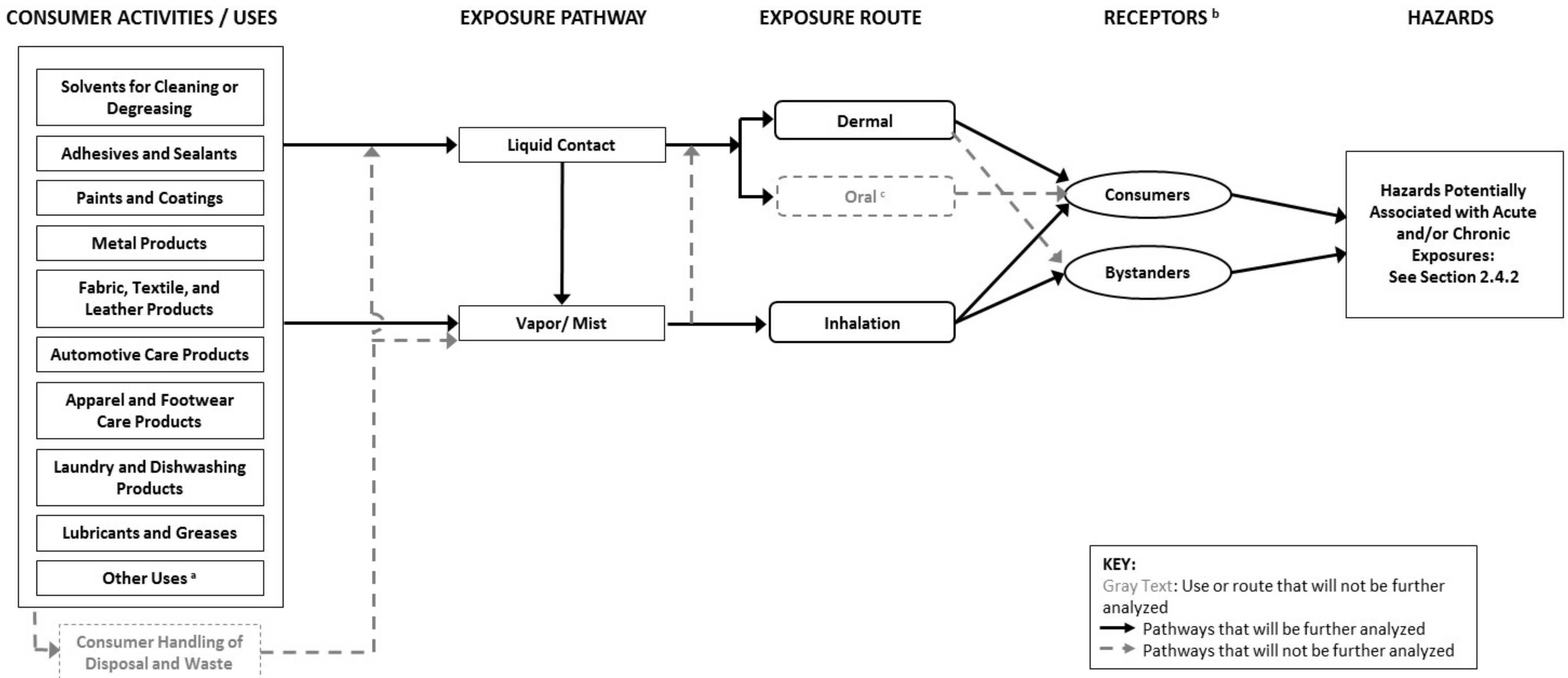

Figure 2-3. Methylene Chloride Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

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

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

[b] Receptors include potentially exposed or susceptible subpopulations.

[c] Exposure may occur via transfer of methylene chloride from hand to mouth however this exposure pathway will be limited by a combination of dermal absorption and volatilization; therefore, this pathway will not be further evaluated

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

The revised conceptual model (Figure 2-4) illustrates the expected exposure pathways to human and ecological receptors from environmental releases and waste streams associated with industrial and commercial activities for methylene chloride that EPA expects to include in the risk evaluation. The pathway that EPA expects to include and analyze further in the risk evaluation is described in Section 2.5.3.1 and shown in the conceptual model Figure 2-4. The pathways that EPA expects to include but not further analyze in risk evaluation are described in Section 2.5.3.2 and shown in the conceptual model Figure 2-4. The pathways that EPA does not expect to include in risk evaluation are described in Section 2.5.3.3.

2.5.3.1 Pathways That EPA Expects to Include and Further Analyze in Risk Evaluation

EPA expects to analyze aquatic invertebrates and aquatic plants exposed via contaminated surface water.

There are no national recommended water quality criteria for the protection of aquatic life for methylene chloride and as a result EPA does not believe that methylene chloride exposure to aquatic organisms in surface water has been adequately assessed or effectively managed under other EPA statutory authorities (see Section 2.5.3.3). Based on the national-scale environmental monitoring data for methylene chloride described in Section 2.3.4 methylene chloride was detected in 14.6% of all surface water samples with a median of 0.035 µg/L and ranged from 0.0055 to 34 µg/L (99^{th} percentile = 1.55 µg/L). As summarized in Section 2.4.1 methylene chloride demonstrated hazard at concentrations as low as 0.9 µg/L for aquatic invertebrate developmental delays/non-development and 2 µg/L for aquatic plant reduction in Chlorophyll A. These hazard levels are not sufficiently below the range of monitored concentrations to eliminate risk concerns. Therefore, EPA expects to evaluate risks to aquatic invertebrates and aquatic plants from exposures to methylene chloride in surface waters.

2.5.3.2 Pathways That EPA Expects to Include in Risk Evaluation But Not Further Analyze

Species in the environment including aquatic organisms, amphibians and terrestrial organisms may come into contact with methylene chloride-contaminated biosolids and soil pore water when the biosolids are land applied. Methylene chloride is not expected to adsorb to soil and sediment due to its low partitioning to organic matter (estimated log K_{OC} = 1.4), so methylene chloride detected in biosolids is in the aqueous phase associated with the biosolids, not adsorbed to the organic matter. Thus, methylene chloride concentrations in surface waters and soil pore water are representative of exposures to amphibians and terrestrial organisms since only limited amounts of methylene chloride will be adsorbed to the organic matter in associated sediments and soils. Based on methylene chloride concentrations in surface waters and soil pore water described in Section 2.3.4 and hazard information summarized in Section 2.4.1, the exposures are orders of magnitude below levels observed to cause effects in amphibians and terrestrial organisms, including mammals, soil invertebrates and birds.

If methylene chloride-contaminated biosolids are released to the environment, including when the biosolids are land applied, methylene chloride will be present mainly in aqueous compartments based on its physical-chemical properties (water solubility, organic carbon:water partition coefficient [log K_{OC}], Henry's Law constant, vapor pressure). Overall, methylene chloride in land-applied biosolids is expected to be mobile in soil, volatilizing to air or migrating into surface and groundwater in the aqueous phase. However, methylene chloride concentrations in biosolids-associated water are expected to be no greater than the concentrations in the WWTP effluent, which represents a much larger fraction of the water released from WWTP (the volume of water removed with biosolids represents < 2% of wastewater treatment plant influent volume (U.S. EPA, 1974), and is < 1% of influent volume when the sludge is dewatered and the excess water is returned to treatment, a process that is commonly used (NRC, 1996b)). Concentrations of methylene chloride in biosolids-associated water will further decrease through volatilization to air during transport, processing (including dewatering), handling, and application to soil (which may include spraying, which increases surface area and can enhance volatilization). Overall, the exposures to surface water from biosolids will be negligible compared to the direct release of WWTP effluent to surface water, and therefore exposures of aquatic organisms to methylene chloride from surface water due to land-applied biosolids will not be further analyzed.

2.5.3.3 Pathways That EPA Does Not Expect to Include in the Risk Evaluation

Exposures to receptors (i.e. general population, terrestrial species) may occur from industrial and/or commercial uses; industrial releases to air, water or land; and other conditions of use. As described in section 2.5, EPA does not expect to include in the risk evaluation pathways under programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist. These pathways are described below.

Ambient Air Pathway

The Clean Air Act (CAA) contains a list of hazardous air pollutants (HAP) and provides EPA with the authority to add to that list pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects. For stationary source categories emitting HAP, the CAA requires issuance of technology-based standards and, if necessary, additions or revisions to address developments in practices, processes, and control technologies, and to ensure the standards adequately protect public health and the environment. The CAA thereby provides EPA with comprehensive authority to regulate emissions to ambient air of any hazardous air pollutant.

Methylene chloride is a HAP. EPA has issued a number of technology-based standards for source categories that emit perchloroethylene to ambient air and, as appropriate, has reviewed, or is in the process of reviewing remaining risks. Because stationary source releases of methylene chloride to ambient air are adequately assessed and any risks effectively managed when under the jurisdiction of the CAA, EPA does not expect to evaluate emission pathways to ambient air from commercial and industrial stationary sources or associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation.

Drinking Water Pathway

EPA has regular analytical processes to identify and evaluate drinking water contaminants of potential regulatory concern for public water systems under the Safe Drinking Water Act (SDWA). Under SDWA, EPA must also review and revise "as appropriate" existing drinking water regulations every 6 years.

EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) for methylene chloride under the Safe Drinking Water Act. EPA has set an enforceable Maximum Contaminant Level (MCL) as close as feasible to a health based, non-enforceable Maximum Contaminant Level Goal (MCLG). Feasibility refers to both the ability to treat water to meet the MCL and the ability to monitor water quality at the MCL, SDWA Section 1412(b)(4)(D), and public water systems are required to monitor for the regulated chemical based on a standardized monitoring schedule to ensure compliance with the maximum contaminant level (MCL).

Hence, because the drinking water exposure pathway for methylene chloride is currently addressed in the SDWA regulatory analytical process for public water systems, EPA does not expect to include this pathway in the risk evaluation for methylene chloride under TSCA. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together providing understanding and analysis of the SDWA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

Ambient Water Pathways

EPA develops recommended water quality criteria under section 304(a) of the CWA for pollutants in surface water that are protective of aquatic life or human health designated uses. EPA develops and publishes water quality criteria based on priorities of states and others that reflect the latest scientific knowledge. A subset of these chemicals are identified as "priority pollutants" (103 human health and 27 aquatic life). The CWA requires states adopt numeric criteria for priority pollutants for which EPA has published recommended criteria under section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with designated uses adopted the state. When states adopt criteria that EPA approves as part of state's regulatory water quality standards, exposure is considered when state permit writers determine if permit limits are needed and at what level for a specific discharger of a pollutant to ensure protection of the designated uses of the receiving water. Once states adopt criteria as water quality standards, the CWA requires National Pollutant Discharge Elimination System (NPDES) discharge permits include effluent limits as stringent as necessary to meet standards. CWA section 301(b)(1)(C). This is the process used under the CWA to address risk to human health and aquatic life from exposure to a pollutant in ambient waters.

EPA has identified methylene chloride as a priority pollutant and EPA has developed recommended water quality criteria for protection of human health for methylene chloride which are available for adoption into state water quality standards for the protection of human health and are available for use by NPDES permitting authorities in deriving effluent limits to meet state narrative criteria. As such, EPA does not expect to include this pathway in the risk evaluation under TSCA. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together providing understanding and analysis of the CWA water quality criteria development process and to exchange information related to toxicity of chemicals undergoing risk evaluation under TSCA. EPA may update its CWA section 304(a) water quality criteria for methylene chloride in the future under the CWA.

EPA has not developed CWA section 304(a) recommended water quality criteria for the protection of aquatic life for methylene chloride, so there are no national recommended criteria for this use available for adoption into state water quality standards and available for use in NPDES permits. As a result, this pathway will undergo aquatic life risk evaluation under TSCA (see Section 2.5.3.1). EPA may publish CWA section 304(a) aquatic life criteria for methylene chloride in the future if it is identified as a priority under the CWA.

Disposal Pathways

Methylene chloride is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a listed waste on the F, K, and U lists. The general standard in section RCRA 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those "necessary to protect human health and the environment," RCRA 3004(a). The regulatory criteria for identifying "characteristic" hazardous wastes and for "listing" a waste as hazardous also relate solely to the potential risks to human health or the environment. 40 C.F.R. §§ 261.11, 261.21-261.24. RCRA statutory criteria for identifying hazardous wastes require EPA to "tak[e] into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics." Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion MACT) or injected into UIC Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

EPA does not expect to include emissions to ambient air from municipal and industrial waste incineration and energy recovery units in the risk evaluation, as they are regulated under section 129 of the Clean Air Act. CAA section 129 requires EPA to review and, if necessary, add provisions to ensure the standards adequately protect public health and the environment. Thus, combustion by-products from incineration treatment of methylene chloride wastes (the majority of the 37.8 million lbs identified as treated in Table 2-6) would be subject to these regulations, as would methylene chloride burned for energy recovery (15.6 million lbs).

EPA does not expect to include on-site releases to land that go to underground injection in its risk evaluation. TRI reporting in 2016 indicated 59,711 pounds released to underground injection to a Class I well and no releases to underground injection wells of Classes II-VI. Environmental disposal of methylene chloride injected into Class I well types are managed and prevented from further environmental release by RCRA and SDWA regulations. Therefore, disposal of methylene chloride via underground injection is not likely to result in environmental and general population exposures.

EPA does not expect to include on-site releases to land from RCRA Subtitle C hazardous waste landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. Based on 2015 reporting to TRI, the majority of the land disposals occur in Subtitle C landfills (30,757 lbs on-site and 5,334 lbs off site). Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general population exposure to methylene chloride in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

EPA does not expect to include on-site releases to land from RCRA Subtitle D municipal solid waste (MSW) landfills or exposures of the general population (including susceptible populations) or terrestrial species from such releases in the TSCA evaluation. While permitted and managed by the individual states, municipal solid waste landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements, and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lbs per month). Bulk liquids, such as free solvent, may not be disposed of at MSW landfills.

EPA does not expect to include on-site releases to land from industrial non-hazardous waste and construction/demolition waste landfills in the methylene chloride risk evaluation. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under state regulatory programs. States must also implement limited federal regulatory requirements for siting, groundwater monitoring and corrective action and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirements such as for liners, post-closure and financial assurance, but are not required to do so. Therefore, EPA does not expect to include this pathway in the risk evaluation.

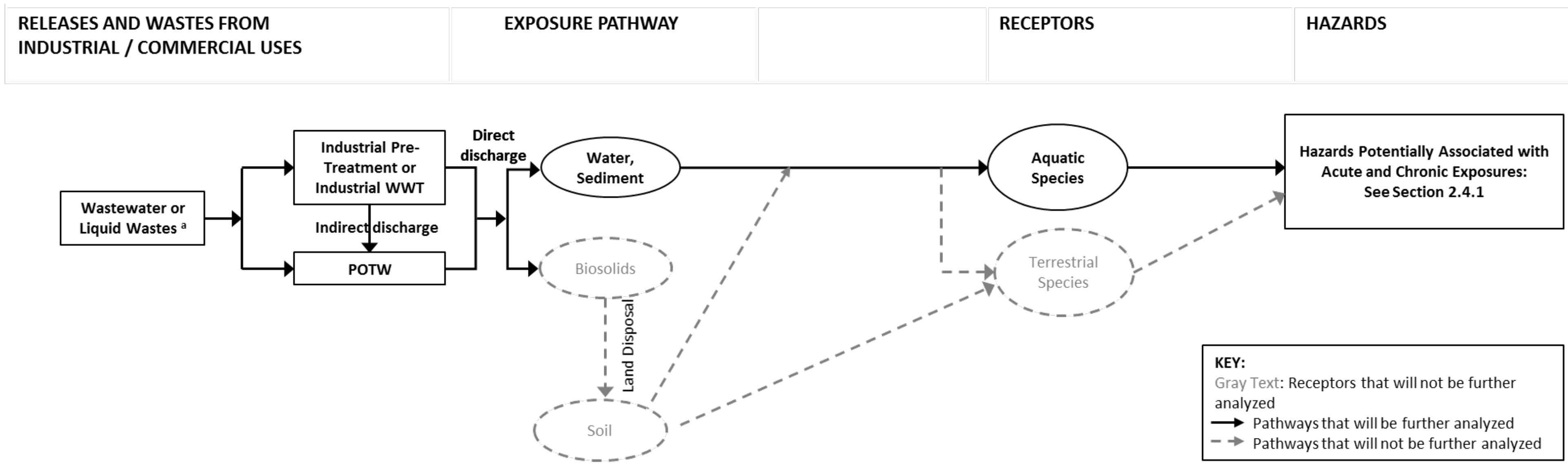

Figure 2-4. Methylene Chloride Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of methylene chloride.
[a] Industrial wastewater may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge).

2.6 Analysis Plan

The analysis plan presented in the problem formulation is a refinement of the initial analysis plan that was published in the *Scope of the Risk Evaluation for Methylene Chloride (Dichloromethane)*.

The analysis plan outlined here is based on the conditions of use for methylene chloride, as described in Section 2.2 of this problem formulation. EPA is implementing systematic review approaches to identify, select, assess, integrate and summarize the findings of studies supporting the TSCA risk evaluation. The analytical approaches and considerations in the analysis plan are used to frame the scope of the systematic review activities for this assessment. The supplemental document, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018), provides additional information about criteria and methods that have been and will be applied to the first 10 chemical risk evaluations.

While EPA has conducted a comprehensive search for reasonably available data as described in the Scope of the Risk Evaluation for Methylene Chloride, 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 during the risk evaluation. EPA will continue to consider new information submitted by the public.

During risk evaluation, EPA will rely on the comprehensive literature results [*Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742-0059 (U.S. EPA, 2017a)] or supplemental literature searches to address specific questions. Further, EPA may consider any relevant confidential business information (CBI) in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. The analysis plan is based on EPA's knowledge of methylene chloride to date, which includes partial, but not complete review of identified literature. If additional data or approaches become available, EPA may refine its analysis plan based on this information.

2.6.1 Exposure

Based on their physical-chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment chemical substances are more likely to be present in some media and less likely to be present in others. Media-specific levels will vary based on the chemical substance of interest. For most chemical substances level(s) can be characterized through a combination of available monitoring data and modeling approaches.

2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to relevant 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. EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is shown in Appendix B.1. EPA will continue to review potentially relevant data sources identified in Table_Apx B-4 in Appendix B during risk evaluation.

   EPA plans to review the following key data sources in Table 2-9 for additional information on activities resulting in environmental releases. The evaluation strategy for engineering and occupational data sources discussed in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018) describes how data, information, and studies will be reviewed.

Table 2-9. Potential Sources of Environmental Release Data

U.S. EPA TRI Data (Reporting Year 2016 only)
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
EU Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Specific Environmental Release Categories (SpERC) factsheets
Discharge Monitoring Report (DMR) surface water discharge data for methylene chloride from NPDES-permitted facilities

2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI program). EPA has reviewed key release data sources including the Toxics Release Inventory (TRI), and the data from this source is summarized in Section 2.3.2 above and also in Appendix B. EPA will continue to review relevant data sources as identified in Table_Apx B-5 in Appendix B during risk evaluation. EPA will match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA will attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.
3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and chemical and physical properties. Data for solvents that are used in the same types of applications may be considered as surrogate data for methylene chloride. As with methylene chloride, trichloroethylene is used in paints and coatings, in adhesives and sealants, and as solvents for cleaning and degreasing. EPA will evaluate the use of data for solvents such as trichloroethylene as surrogates to fill data gaps where uses of methylene chloride and other solvents align. If surrogate data are used, EPA normally converts air concentrations using the ratio of the vapor pressures of the two chemicals. EPA will review literature sources identified and if surrogate data are found, EPA will match these data to applicable conditions of use for potentially filling data gaps.
4) Understand and consider regulatory limits that may inform estimation of environmental releases. EPA has identified information from various EPA statutes (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to release estimation. Some of the information has informed revision of the conceptual models during problem formulation. EPA will further consider relevant regulatory requirements in estimating releases during risk evaluation.
5) Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases. Potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) have been identified that correspond to some conditions of use. For example, the ESD on Industrial Use of Adhesives for Substrate Bonding, the ESD on the Coating Industry (Paints, Lacquers and Varnishes), and the GS on the Use of Vapor Degreasers are some of the ESDs and GSs that EPA may use to assess potential releases. EPA will need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA was not able to identify ESDs or GSs corresponding to several conditions of use, including manufacture and import of methylene chloride, use of methylene chloride as an anti-spatter welding aerosol, and use of methylene chloride in pharmaceutical manufacturing. EPA will perform additional targeted research to understand those conditions of use which may inform identification of release scenarios. EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. If ESDs and GSs are not available, other methods may be considered. Additionally, for conditions of use where no measured data on releases are

available, EPA may use a variety of methods including the application of default assumptions such as standard loss fractions associated with drum cleaning (3%) or single process vessel cleanout (1%).

6) Map or group each condition(s) of use to a release assessment scenario. EPA has identified release scenarios and mapped them to some conditions of use. For example, some scenario groupings include Contractor Adhesive Removal and Industrial In-line Vapor Degreasing. EPA grouped similar conditions of use (based on factors including process equipment and handling, release sources and usage rates of methylene chloride and formulations containing methylene chloride, or professional judgment) into scenario groupings but may further refine these groupings as additional information becomes available during risk evaluation.
   EPA was not able to identify release scenarios corresponding to several conditions of use due to a lack of general knowledge of those conditions of use. EPA will perform additional targeted research to understand those uses which may inform identification of release scenarios.

7) Complete the weight of the evidence of environmental release data.
   EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental release data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

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.

   A general overview of persistence and bioaccumulation was presented in the TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use (U.S. EPA, 2014b). Key environmental fate characteristics were included in the TSCA Scope for Methylene Chloride (U.S. EPA, 2017b) and in previous assessments of methylene chloride, including those conducted by the EPA Integrated Risk Information System (U.S. EPA, 2011b), EPA Office of Water (OW, 2015), US Agency for Toxic Substances and Disease Registry (ATSDR, 2010, 2000), Environment Canada (Health and Environment Canada, 1993), and Organization for Economic Cooperation and Development Cooperative Chemicals Assessment Program (OECD, 2011). These information sources will be used as a starting point for the environmental fate assessment. Other sources that will be consulted include those that are identified through the systematic review process. Studies will be evaluated using the evaluation strategies laid out in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

   If measured values resulting from sufficiently high-quality studies are not available (to be determined through the systematic review process), chemical properties will be estimated using EPI Suite, SPARC, and other chemical parameter estimation models. Estimated fate properties will be reviewed for applicability and quality.

2) Using measured environmental fate data and/or environmental fate modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to environmental receptors.

Measured fate data including volatilization from water, sorption to organic matter in soil and sediments, aqueous and atmospheric photolysis rates, and aerobic and anaerobic biodegradation rates, along with physical-chemical properties and models such as the EPI Suite™ STP model (which estimates removal in wastewater treatment due to adsorption to sludge and volatilization to air) and volatility model (which estimates half-life from volatilization from a model river and model lake), will be used to characterize the movement of methylene chloride within and among environmental media and the persistence of methylene chloride in media.

3) Evaluate the weight of the evidence of environmental fate data.
EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental fate data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.3 Environmental Exposures

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

1) Refine and finalize exposure scenarios for environmental receptors by considering unique combinations of sources (use descriptors), exposure pathways, exposure settings, populations exposed, and exposure routes. For methylene chloride, exposure scenarios for environmental receptors include exposures from surface water.
2) Review reasonably available environmental and biological monitoring data for environmental exposure to surface water. EPA will rely on databases (see examples below) and literature obtained during systematic review to include ranges and trends of chemical in surface water, including any trends seen in concentrations and spatial trends.
    - STORET and NWIS (USGS/EPS): https://www.epa.gov/waterdata/storage-and-retrieval-and-water-quality-exchange#portal
    - OPPT monitoring database

3) 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 that estimate surface water (e.g. E-FAST) will be evaluated and considered alongside available surface water data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations generally consider the following inputs: direct release into surface water and transport (partitioning within media) and characteristics of the environment (river flow, volume of pond, meteorological data).
4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. For example, site/location, time period, and conditions under which monitored data were collected will be evaluated to determine relevance and applicability to wider scenario development. Any studies which relate levels of methylene chloride in the environment or biota with specific sources or groups of sources will be evaluated.
5) Evaluate the weight of evidence of environmental occurrence data and modeled estimates.
EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental exposure data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.4 Occupational Exposures

EPA expects to consider and analyze both worker and occupational nonuser 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)). Data, information, and studies will be evaluated using the evaluation strategies laid out in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). For some OSHA data, NAICS codes included with the data will be matched with potentially applicable conditions of use, and data gaps will be identified where no data are found for particular conditions of use. EPA will attempt to address data gaps identified as described in steps 2 and 3 below. Where possible, job descriptions may be useful in distinguishing exposures to different subpopulations within a particular condition of use. EPA has also identified additional data sources that may contain relevant monitoring data for the various conditions of use. EPA will review these sources, identified in Table 2-10 and in Table_Apx B-6 in Appendix B, and will extract relevant data for consideration and analysis during risk evaluation.

Table 2-10. Potential Sources of Occupational Exposure Data

2014 TSCA Work Plan Chemical Risk Assessment Report for Methylene Chloride (Paint Stripping use)
U.S. NIOSH Health Hazard Evaluation (HHE) Program reports
U.S. OSHA Chemical Exposure Health Data (CEHD) program data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
Sector-specific Worker Exposure Descriptions (SWEDs)
2000 ATSDR Tox Profile

2) Review reasonably available exposure data for surrogate chemicals that have uses and chemical and physical properties similar to methylene chloride. If surrogate data are identified, these data will be matched with applicable conditions of use for potentially filling data gaps. For several uses including use of adhesives, cleaners, and laundry and dishwashing products, EPA believes that trichloroethylene and other similar solvents may share the same or similar conditions of use and may be considered as surrogates for 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. Models may be generic, broadly applicable models or may be specific to conditions of use (e.g., some OECD Emission Scenario Documents and US EPA Generic Scenarios may be identified as potentially mapping to some conditions of use). EPA has identified potentially relevant OECD ESDs and EPA GSs corresponding to some conditions of use. For example, the ESD on Industrial Use of Adhesives for Substrate Bonding, the ESD on the Industrial Use of Industrial Cleaners, and the GS on Textile Finishing are some of the ESDs and GSs that EPA may use to estimate occupational exposures. Where mappings are identified, the scenario documents will be reviewed for whether they contain exposure models that may apply to the conditions of use. An example of a generic model that has been used in addressing data gaps in some conditions of use is the Near-Field/ Far-Field (NF/FF) model e.g. in the recent trichloroethylene risk evaluation (U.S. EPA, 2014c). This or other models, including the assumption of compliance with the OSHA PEL for methylene chloride, may be explored where models specific to conditions of use are not found. If any models are identified as applicable, EPA will search for appropriate model parameter data. If parameter data can be located or assumed,

exposure estimates generated from these models may be used for potentially filling data gaps. EPA was not able to identify ESDs or GSs corresponding to several conditions of use, including recycling of methylene chloride and solvent mixtures containing methylene chloride, and processing and formulation of methylene chloride into industrial, commercial and consumer products. EPA will perform additional targeted research to understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. This step will be performed after Steps #2 and #3 above. Based on information developed from Step #2 and Step #3, EPA will evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios).
5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios. EPA will review potentially relevant data sources on engineering controls and personal protective equipment as identified in Table 2-10 and in Table_Apx B-7 in Appendix B and determine their applicability for incorporation into exposure scenarios during risk evaluation.
6) Map or group each condition of use to occupational exposure assessment scenario(s). For scenarios and worker exposure estimates, some key information and data to consider for grouping include per-site throughput or use rates of methylene chloride and formulations containing methylene chloride, process equipment and handling, and worker exposure activities and factors impacting exposures/ doses (routes, exposure factors or modeling). These main drivers must be similar enough between uses to allow for uses to be grouped for worker exposure. EPA has identified occupational exposure scenarios and mapped them to conditions of use. For example, one scenario grouping is commercial aerosol degreasing, where cleaning products containing methylene chloride are applied to substrates via spraying methods in a commercial setting. EPA grouped similar conditions of use (based on factors including process equipment and handling, usage rates of methylene chloride and formulations containing methylene chloride, exposure/release sources, or professional judgment) into scenario groupings but may further refine these groupings as additional information is identified during risk evaluation.
7) EPA was not able to identify occupational exposure scenarios corresponding to several conditions of use due to a lack of understanding of those conditions of use. EPA will perform targeted research to understand those uses which may inform identification of occupational exposure scenarios. If no data are available EPA may use appropriate conservative default assumptions in assessing occupational exposure.
8) Evaluate the weight of the evidence of occupational exposure data. EPA will rely on the weight of the scientific evidence when evaluating and integrating occupational exposure data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

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) Refine and finalize exposure scenarios for consumers by mapping sources of exposure (i.e., consumer products), exposure pathways, exposure settings, exposure routes, and populations exposed. Considerations for constructing exposure scenarios for consumers:

- Reasonably available data on consumer products or products available for consumer use including the weight fraction of methylene chloride in products;
- Information characterizing the use patterns of consumer products containing methylene chloride including the following: intended or likely consumer activity, method of application (e.g., spray-applied, brush-applied, dip), formulation type, amount of product used, frequency and duration of individual use events, and room or setting of use;
- The associated route of exposure for consumers; and
- Populations who may be exposed to products as users or bystanders in the home, including potentially exposed and susceptible subpopulations such as children or women of child bearing age and subsets of consumers who may use commercially-available products or those who may use products more frequently than typical consumers.

During consumer exposure modeling, these factors determine the resulting exposure route and magnitude. For example, while the product with the highest weight fraction in a given consumer product scenario could be run early on to indicate preliminary levels of exposure, that product may not actually result in the highest potential exposure due to having a lower frequency of use.

2) Evaluate the relative potential and magnitude of exposure routes based on available data. For methylene chloride, inhalation of vapor is expected to result in higher exposure to consumers and bystanders as compared to other pathways due to fate and exposure properties. We expect to comprehensively evaluate the data sources to effectively evaluate these pathways moving forward, but quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet possible.
3) Review and use existing indoor exposure models that may be applicable in estimating indoor air (vapor). For example, U.S. EPA (2014b) used the Multi-Chamber Concentration and Exposure Model (MCCEM) to estimate and evaluate indoor exposures to methylene chloride-based paint strippers. EPA anticipates using similar models and approaches to evaluate indoor exposures moving forward.
9) Review reasonably available empirical 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. For methylene chloride, existing scenarios and data parameters associated with modeling exposure from the use of methylene chloride-based paint strippers have already been developed (U.S. EPA, 2014b). EPA anticipates using this and other developed models for evaluation moving forward.
10) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with each other and with indoor monitoring data reporting methylene chloride in dust or indoor air.
11) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further refined.
12) Evaluate the weight of the evidence of consumer exposure estimates based on different approaches. EPA will rely on the weight of the scientific evidence when evaluating and integrating consumer exposure data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.6 General Population

EPA does not expect to include general population exposures in the risk evaluation for methylene chloride. EPA has determined that the existing regulatory programs and associated analytical processes adequately assess and effectively manage the risks of methylene chloride that may be present in various media pathways (e.g., air, water, land) for the general population. For these cases, EPA believes that the TSCA risk evaluation should focus not on those exposure pathways, but rather on exposure pathways associated with TSCA conditions of use that are not subject to those regulatory processes, because the latter pathways are likely to represent the greatest areas of concern to EPA.

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).
   Environmental hazard data will be evaluated using the ecological toxicity data quality criteria outlined in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). The study evaluation results will be documented in the risk evaluation phase and data from suitable studies will be extracted and integrated in the risk evaluation process.

   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. Suitable environmental hazard data will be reviewed for acute and chronic endpoints for mortality and other effects (e.g. growth, immobility, reproduction, etc.). EPA will evaluate the character of the concentration-response relationship (*i.e.* positive, negative or no response) as part of the review.

   Sufficient environmental hazard studies are available to assess the hazards of environmental concentrations of methylene chloride to terrestrial and aquatic species. EPA did not find suitable sediment invertebrate hazard data, but will use hazard information from aquatic invertebrates to infer hazards to sediment invertebrates from exposures to methylene chloride in sediment pore water.

2) Derive aquatic and terrestrial concentrations of concern (COC) for acute and, where possible, chronic endpoints.
   The aquatic environmental hazard studies may be used to derive acute and chronic concentrations of concern (COC) for mortality, behavioral, developmental and reproductive or other endpoints determined to be detrimental to environmental populations. Depending on the robustness of the evaluated data for a particular organism (*e.g.* aquatic invertebrates), environmental hazard values (e.g. ECx/LCx/NOEC/LOEC, etc.) may be derived and used to further understand the hazard characteristics of methylene chloride to aquatic species.
3) Evaluate the weight of the evidence of environmental hazard data.

   EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental hazard data. The data integration strategy will be designed to be fit-for-purpose. EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

4) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

EPA believes there is sufficient information to evaluate the potential risks to aquatic invertebrates, aquatic plants and amphibians from exposures to methylene chloride in ground water and surface water.

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 as needed (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; in vitro studies; systems biology).

   For the methylene chloride risk evaluation, EPA will evaluate information in the IRIS assessment and human health studies using OPPT's structured process described in the document, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Human and animal data will be identified and included as described in the inclusion and exclusion criteria in Appendix F. EPA plans to prioritize the evaluation of mechanistic evidence. Specifically, EPA does not plan to evaluate mechanistic studies unless needed to clarify questions about associations between methylene chloride and health effects and its relevance to humans. The *Applications of Systematic Review* document (U.S. EPA, 2018) describes the process of how studies will be evaluated using specific data evaluation criteria and a predetermined approach. Study results will be extracted and presented in evidence tables by hazard endpoint. EPA plans to evaluate relevant studies identified in the Integrated Risk Information System (IRIS) *Toxicological Review of Dichloromethane (Methylene Chloride)* (U.S. EPA, 2011b) and the *TSCA Work Plan Chemical Risk Assessment - Methylene Chloride: Paint Striping Use* (U.S. EPA, 2014b). In addition for identifying human and animal data, EPA intends to review studies published after the most recent of the multiple acute reference values were published (e.g. AEGLs). These studies were published from January 1, 2008 to March 2, 2017 and are captured in the comprehensive literature search conducted by the Agency for methylene chloride (see *Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document*; EPA-HQ-OPPT-2016-0742-0059 (U.S. EPA, 2017a)) using the approaches described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). To more fully understand circumstances related to deaths by individuals using methylene chloride, EPA/OPPT will review case reports, case series and ecological studies related to deaths and effects that may imminently lead to death (respiratory distress). EPA/OPPT will not be evaluating case reports and series or ecological studies for endpoints that appear to be less severe endpoints (e.g., nausea).

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.

   Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to methylene chloride hazard(s).

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.

Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the data quality criteria described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Data quality evaluation will be performed on relevant studies identified in the IRIS assessment (U.S. EPA, 2011b), the TSCA work plan risk assessment (U.S. EPA, 2014b), and assessments of the effects of acute exposures in the (NAC/AEGL, 2008), SMAC for methylene chloride (NRC, 1996a) and an acute REL published by (OEHHA, 2008). Data quality evaluation will also be performed on studies published from January 1, 2008 to March 2, 2017 that were identified in the comprehensive literature search and that met the inclusion criteria for full-text screening (see *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (oral, inhalation) and by cancer and noncancer endpoints.

Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011a, 1994). Dose-response analyses performed to support the U.S. EPA (2011b) IRIS oral and inhalation reference dose determinations and for the cancer unit risk and slope factor may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints or additional hazard endpoints would not alter the analysis.

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.

   Hazard data will be evaluated to determine the type of dose-response modeling that is applicable, if the dose-response modeling requires updating. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with the EPA *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2012a). Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified.

   EPA will evaluate whether the available physiologically-based pharmacokinetic (PBPK) and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD, or for extrapolation of the POD to appropriate exposure durations for the risk evaluation.

5) 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.

   EPA believes there are sufficient data to conduct dose-response analysis with benchmark dose modeling or NOAELs or LOAELs for both inhalation and oral routes of exposure.

   A route-to-route extrapolation from the inhalation and oral toxicity studies is needed to assess systemic risks from dermal exposures. Without an adequate PBPK model, the approaches described in the EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* could be applied. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure.

6) Evaluate the weight of the evidence of human health hazard data.

EPA will rely on the weight of the scientific evidence when evaluating and integrating human health hazard data. The strategy will be designed to be fit-for-purpose. EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

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, 2000). 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, 2000). EPA will also present information in this section consistent with approaches described in the Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726). For instance, in the risk characterization summary, EPA will further carry out the obligations under TSCA section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. EPA will also be guided by EPA's Information Quality Guidelines (U.S. EPA, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA will also identify: (1) Each population addressed by an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; (3) each appropriate upper-bound or lower bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

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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, January 19, 2017) regulating certain uses of methylene chloride and N-methylpyrrolidone in paint and coating removal. EPA intends to finalize the methylene chloride rule (https://www.epa.gov/newsreleases/epa-announces-action-methylene-chloride)
TSCA – Section 6(b)	Directs EPA to promulgate regulations to establish processes for prioritizing chemicals and conducting risk evaluations on priority chemicals. In the meantime, EPA 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	Methylene chloride was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	substance manufactured, processed or imported in the United States.	process under TSCA section 5 (60 FR 16309, March 29, 1995).
TSCA – Section 8(d)	Provides EPA with authority to issue rules requiring producers, importers, and (if specified) processors of a chemical substance or mixture to submit lists and/or copies of ongoing and completed, unpublished health and safety studies.	One submission received in 2001 (U.S. EPA, Chemical Data 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 1974 and (U.S. EPA, ChemView. Accessed April 24, 2017).
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. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (e.g., quantities	Methylene chloride is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 01, 1987.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (i.e., air, land and water).	
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 pesticide residues (including inert ingredients) on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the pesticide residues permitted under the action are "safe." Section 408(b) of the FFDCA defines "safe" to mean a reasonable certainty that no harm will result from aggregate, nonoccupational exposures to the pesticide. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation under FFDCA section 408(d) or (e). 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.	Methylene chloride was registered as an antimicrobial, conventional chemical in 1974. In 1998, EPA removed methylene chloride from its list of pesticide product inert ingredients that are currently used in pesticide products (63 FR 34384). The tolerance exemptions for methylene chloride were revoked in 2002 (67 FR 16027, April 4, 2002).
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	Methylene chloride is listed as a HAP (42 U.S. Code section 7412), and is considered an "urban air toxic" (CAA Section 112(k)).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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.	
CAA – Section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). The standards must require the maximum degree of emission reduction that the EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT).	There are a number of source-specific NESHAPs for methylene chloride, including: • Foam production and fabrication process (68 FR 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 (66 FR 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).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		• Paint stripping and miscellaneous surface coating operations (area sources) (73 FR 1738, January 9, 2008). • Paper and other web surface coating (67 FR 72330, December 4, 2002). • Pesticide active ingredient production (64 FR 33550, June 23, 1999; 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 sections 112(d) and 112(f)	Risk and technology review (RTR) of section 112(d) MACT standards. Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to section 112(d) MACT standards, and to determine if additional standards are needed to reduce remaining risks. Section 112(d)(6) requires EPA to review and revise the MACT standards, as necessary, taking into account developments in practices, processes and control technologies.	EPA has promulgated a number of RTR NESHAP (e.g., the RTR NESHAP for Halogenated Solvent Cleaning (72 FR 25138; May 3, 2007) and will do so, as required, for the remaining source categories with NESHAP.
CAA – Section 612	Under Section 612 of the CAA, EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ozone-depleting substances within	Under the SNAP program, EPA listed methylene chloride as an acceptable substitute in multiple industrial end-uses, including as a blowing agent in polyurethane foam, in cleaning

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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.	solvents, in aerosol solvents and in adhesives and coatings (59 FR 13044, March 18, 1994). In 2016, methylene chloride was listed as an unacceptable substitute for use as a blowing agent in the production of flexible polyurethane foam (81 FR 86778, December 1, 2016).
CWA – Section 301(b), 304(b), 306, and 307(b)	Requires establishment of Effluent Limitations Guidelines and Standards for conventional, toxic, and nonconventional pollutants. For toxic and non-conventional 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.	Methylene chloride is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such is subject to effluent limitations. Under CWA section 304, methylene chloride is included in the list of total toxic organics (TTO) (40 CFR 413.02(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, see Section 402(a)(1)(B).	

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
SDWA – Section 1412	Requires EPA to publish 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 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.	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).
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	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).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	
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 in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Methylene chloride is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: F001, F002, U080; see 40 CFR 261.31, 261.32. 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 and to conditionally exclude solvent-contaminated wipes that are disposed from the definition of hazardous waste (78 FR 46448, 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 labeling is not adequate to protect consumers.	Certain household products that contain methylene chloride are hazardous substances required to be labelled under the FHSA (52 FR 34698, September 14, 1987). In 2016, the Halogenated Solvents Industry Alliance petitioned the CPSC to amend the CPSC's labeling interpretation and policy on those products (81 FR 60298, September 1, 2016). In 2018, CPSC updated the labelling policy for paint strippers containing methylene chloride (83 FR 12254, March 21, 2018 and 83 FR 18219, April 26, 2018)
Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to:	Methylene chloride is listed as a hazardous material with regard to transportation and is subject to

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	• 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.	regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials (70 FR 34381, June 14 2005).
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	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 section 651 et seq.).	In 1997, OSHA revised an existing occupational safety and health standards for methylene chloride, to include an 8-hour TWA 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 Actions	Description of Action
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).
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).
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

Country/ Organization	Requirements and Restrictions
	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.
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 (Including Import)

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

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

B.1.2.1 Reactant or Intermediate

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 and Pottenger, 2016).

Methylene chloride is also a feedstock in the production of bromochloromethane. Bromochloromethane 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 and Frim, 2011).

B.1.2.2 Incorporating 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, 2014c) 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, 2016c) 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 (U.S. EPA, 2016c) 1-Bromopropane Draft Risk Assessment.

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 (U.S. EPA, 2016c) 1-Bromopropane Draft Risk Assessment. 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, 2016b), 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 (2013) ESD for Use of Adhesives 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 EPA's 2014 TSCA Work Plan Chemical Risk Assessment for the use of methylene chloride as a paint remover (U.S. EPA, 2014b). The Agency proposed restrictions under TSCA section 6 to address the risks from methylene chloride in paint and coating removal by consumers and most commercial users except for commercial furniture stripping (82 FR 7464, January 19, 2017). While paint and coating removal falls under the conditions of use for methylene chloride, based on the intention to finalize the rulemaking the scenarios already assessed in the 2014 risk assessment these uses will not be re-evaluated and EPA will rely on the 2014 risk evaluation (https://www.epa.gov/newsreleases/epa-announces-action-methylene-chloride) see Section 2.2.2.1.

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 (U.S. EPA, 2016c) 1-Bromopropane Draft Risk Assessment.

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-2016-0742-0003)

B.1.3.6 Other Uses

Methylene chloride is a U-listed hazardous waste under RCRA code U080 (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.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 examples 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-1and Table_Apx B-2 show mappings of release and worker exposure scenarios to industry sectors with available OSHA data for methylene chloride, obtained from OSHA inspections between 2002 and 2016 for personal monitoring data and area monitoring data, respectively. EPA attempted to group industry sectors according to possible release/exposure scenarios, but there is a great degree of uncertainty where and how methylene chloride may be used in these industries. The industry sectors in Table_Apx B-1and Table_Apx B-2 were extracted from the OSHA CEHD (OSHA, 2017).

EPA also found some NIOSH HHE data since 2000 that are summarized and included in Table_Apx B-3.

Table_Apx B-1 Mapping of Scenarios to Industry Sectors with Methylene Chloride Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2002 and 2016

Possible Release / Exposure Scenarios	NAICS	NAICS Description (Job Titles from OSHA)
Manufacture of methylene chloride; Processing as a Reactant; Incorporated into Formulation, Mixture or Reaction Product	325199	All Other Basic Organic Chemical Manufacturing (Operator)
	325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing (Technician)

Table_Apx B-1 Mapping of Scenarios to Industry Sectors with Methylene Chloride Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2002 and 2016

Possible Release / Exposure Scenarios	NAICS	NAICS Description (Job Titles from OSHA)
Solvents (for cleaning and degreasing); Metal products not covered elsewhere	331316	Aluminum Extruded Product Manufacturing (2007 NAICS - 2012 is 331318 Other Aluminum Rolling, Drawing, and Extruding) (Poly-Pour Setup)
	331513	Steel Foundries (except Investment) (Machine Operator, Industrial Hygienist)
	332710	Machine Shops (Shipping and Receiving)
	332811	Metal Heat Treating (Controller)
	332999	All Other Miscellaneous Fabricated Metal Product Manufacturing (Welder)
	333132	Oil and Gas Field Machinery and Equipment Manufacturing (Laborer)
	336211	Motor Vehicle Body Manufacturing (Welder)
	334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing (Operator)
	327390	Other Concrete Product Manufacturing (Rspecta Machine Cleaner, Rspecta Machine Operator)
Application of Adhesives; Solvents (for cleaning and degreasing); Metal products not covered elsewhere	332321	Metal Window and Door Manufacturing (Adhesive Sprayer)
	335121	Residential Electric Lighting Fixture Manufacturing (Glue Application)
	333921	Elevator and Moving Stairway Manufacturing (Carpenter, Adhesive Sprayer)
Paint and Coating Application; Solvents (for cleaning and degreasing); Metal products not covered elsewhere	332312	Fabricated Structural Metal Manufacturing (Painter)
Paint and Coating Application	238320	Painting and Wall Covering Contractors (apprentice painter employee)
	238390	Other Building Finishing Contractors (laborer)
	713110	Amusement and Theme Parks (Painter)
	811420	Reupholstery and Furniture Repair (Owner, Refinisher, Laborer, Stripper)
	448190	Other Clothing Stores (Screen Printer)
	451110	Sporting Goods Stores (Screen Printing)
	323113	Commercial Screen Printing (Quality Control, Production/Sprayer, Screen Print Lead)
Fabric Finishing	313312	Textile and Fabric Finishing (except Broadwoven Fabric) Mills (2007 NAICS - 2012 is 313310 Textile and Fabric Finishing Mills) (Production specialist)
	315240	Women's, Girls', and Infants' Cut and Sew Apparel Manufacturing (Presser, Supervisor – Finishing Dept)
	316998	All Other Leather Good and Allied Product Manufacturing (Spray Finishing, Sprayer of Methylene Chloride, Press Operator, Miscellaneous)
Plastic product manufacturing (converting)	325211	Plastics Material and Resin Manufacturing (Plastic Fabricator, CSHO, Assistant Supervisor, Extruder Operator)
	326199	All Other Plastics Product Manufacturing (ADA Area, Hop Area Operator, Injection Molding Operator, Assembler)
	325991	Custom Compounding of Purchased Resins (Fabricator)
Rubber product manufacturing (converting); Solvents (for cleaning and degreasing)	325212	Synthetic Rubber Manufacturing (Insert Prep / Degreaser Operator, Compliance Officer)

Table_Apx B-1 Mapping of Scenarios to Industry Sectors with Methylene Chloride Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2002 and 2016

Possible Release / Exposure Scenarios	NAICS	NAICS Description (Job Titles from OSHA)
Pharmaceutical product manufacturing; Processing aid, not otherwise listed; Laboratory use	325412	Pharmaceutical Preparation Manufacturing (Laboratory Technician)
Polyurethane foam blowing; Application of Adhesives	326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing (Molder/Painter, Mold Machine Operator, Blue Zone, Adhesive Application)
Paint and Coating Application; Automotive care products (Functional fluids for air conditioners: refrigerant, treatment, leak sealer, Interior car care – spot remover, degreasers)	811111	General Automotive Repair (Paint, Production)
Automotive care products (Functional fluids for air conditioners: refrigerant, treatment, leak sealer, Interior car care – spot remover, degreasers); Aerosol degreasing/ cleaning by contractors	811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance (Mechanic)
	811121	Automotive Body, Paint, and Interior Repair and Maintenance (Manager)
Laboratory use	541380	Testing Laboratories (Analyst, Lab Tech)
	621511	Medical Laboratories (Lab Tech)
Paint and Coating Application; Application of Adhesives	339950	Sign Manufacturing (Gluer, Floor Manager, Painter, Laminator, OSHA CSHO, Acrylic Production, Production, Industrial Hygienist, Sign Maker, Lettering)
Unknown / Other Uses	327991	Cut Stone and Stone Product Manufacturing (Carpenter, Postform)
	321211	Hardwood Veneer and Plywood Manufacturing (Lamination, Operator, CSHO)
	321911	Wood Window and Door Manufacturing (stripper)
	321999	All Other Miscellaneous Wood Product Manufacturing (Floater: stripper and refinisher, Fabricator)
	337110	Wood Kitchen Cabinet and Countertop Manufacturing (Glue Sprayer, CSHO, Cabinet Assembler, Spray Painter, Fabricator)
	337212	Custom Architectural Woodwork and Millwork Manufacturing (Shop worker)
	423930	Recyclable Material Merchant Wholesalers (Fingers)
	339999	All Other Miscellaneous Manufacturing (Glass decorator)
	423810	Construction and Mining (except Oil Well) Machinery and Equipment Merchant Wholesalers (Technician)
	424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers (Fabricator)
	424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers (Plant Worker)
	443112	Radio, Television, and Other Electronics Stores (2007 NAICS - 2012 is 443142 Electronic Stores) (Press Operator)
	443141	Household Appliance Stores (Metal Shop Worker)
	322121	Paper (except Newsprint) Mills (Operators, Mechanics)
	485410	School and Employee Bus Transportation (Service Worker)
	532299	All Other Consumer Goods Rental (Warehouse Help, Industrial Hygienist)
	811490	Other Personal and Household Goods Repair and Maintenance (Laborer)

Table_Apx B-1 Mapping of Scenarios to Industry Sectors with Methylene Chloride Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2002 and 2016

Possible Release / Exposure Scenarios	NAICS	NAICS Description (Job Titles from OSHA)
N/A	926150	Regulation, Licensing, and Inspection of Miscellaneous Commercial Sectors (Compliance Officer, Industrial Hygienist, CSHO)

Table_Apx B-2 Mapping of Scenarios to Industry Sectors with Methylene Chloride Area Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2013 and 2016

Possible Release / Exposure Scenarios	NAICS	NAICS Description
Polyurethane foam blowing	326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing (Blue Zone, Adhesive Application)
Paint and Coating Application; Application of Adhesives	339950	Sign Manufacturing (Production Area)

NIOSH HHEs

EPA found a total of 122 HHEs that contained methylene chloride on NIOSH's website. Limiting the search to reports done since 2000 (~16 years) resulted in three HHEs. The following subsections provide summaries of the facilities inspected, the findings of the inspection, and any recommendations for using the data.

Federal Crime Lab, Unidentified Location (2016) (2012-0238-3257)

The Health Hazard Evaluation Program received a request from the health and safety director at a Federal Bureau of Investigation (FBI) crime laboratory (lab) to evaluate workplace health hazards. Inspectors sampled employees in the Operational Projects Unit, which builds crime scene models to display in court hearings. Activities included woodcutting, spray painting, laser cutting of plastics, assembling plastics parts, and 3-dimensional printing. The inspectors used Dräger direct-reading colorimetric detector tubes to evaluate employee exposures to methylene chloride during the following tasks:

1. Manually transferring methylene chloride from a 1-quart container to a 30-mL squeeze bottle in the paint spray booth. This task took approximately 2 minutes and was done 1–2 times per month.
2. Hand assembling Plexiglas® parts without local exhaust ventilation. A small amount of methylene chloride was squeezed from a 30-mL container onto the parts. The employee then held the pieces together for a few seconds.

Employees voluntarily wore lab coats, Sperian® N95 filtering facepiece respirators, ear plugs or earmuffs, and nitrile gloves. No methylene chloride was detected during sampling activities (< 20 ppm).

EPA notes that these exposure data may be compared with alternative data that are available for the risk evaluation before use. The methodology and results for this study are limited, and/or may not be representative of typical occupational use.

Woodworking Studio, Brooklyn College, Brooklyn, New York (2009) (HETA 2007-0167-3078)

NIOSH received a confidential employee request for an HHE at Brooklyn College in Brooklyn, New York, to investigate health and safety concerns in the sculpture studios, including the ceramic, woodworking, and metalworking studios. In the woodworking studio, the inspectors observed methylene chloride being used as an adhesive for plexiglass bonding and being applied using a 4-ounce squeeze bottle. The inspectors performed PBZ air sampling for VOCs, but methylene chloride was not measurable at quantifiable levels (LOD unknown). The inspectors recommended that the college substitute a less toxic plastics adhesive for methylene chloride.

EPA notes that these exposure data be compared with alternative data that are available for the risk evaluation before use. The methodology and results for this study are limited, and/or may not be representative of typical occupational use.

Human Performance International, Inc., Charlotte, North Carolina (2001) (HETA 2000-0110-2849)

The Hazard Evaluation and Technical Assistance Branch (HETAB) of the National Institute for Occupational Safety and Health (NIOSH) collaborated with the Division of Applied Research and Technology (DART) within NIOSH to conduct a pilot research study evaluating occupational exposure to noise and potential ototoxic agents, such as solvents, metals, and asphyxiants, among a stock car racing team.

Methylene chloride was present in the lacquer thinner used to clean the paint guns. In between each coat of primer, sealer, or paint that is applied, the painter leaves the paint booth to clean the paint gun in a lacquer thinner bath that is located directly adjacent to the paint booth. After cleaning, the primer or paint is mixed and poured into the paint gun. Coveralls and an organic vapor cartridge half-face respirator are worn inside the paint booth. The respirator is removed when the painter exits the paint booth, and is not worn while the paint gun is cleaned, or while the paint is mixed. The painter reported that the respirator filters are changed every two months and the respirator is discarded when it gets dirty. It was not cleaned on a daily basis after use. A chemical solutions glove was occasionally worn while cleaning the paint gun in the lacquer thinner bath and while mixing paint.

Full-shift area samples were taken in the paint booth, outside the paint booth door, in the paint storage and mixing area, and the body shop area. Concentrations of methylene chloride were non-detectable (LOD = 0.045 ppm).

This use of methylene chloride as a paint thinner used to clean paint guns may be a previously unidentified activity that occurs in automotive refinishing shops. Paint stripping in automotive refinishing shops was previously assessed in EPA’s 2014 risk assessment.

Table_Apx B-3 summarizes information from the NIOSH HHEs described above.

Table_Apx B-3 Summary of NIOSH HHEs Since 2000

Exposure/Release Scenario	Facility Description	Number of Exposure Samples	Minimum of Exposure Values (ppm)	Maximum of Exposure Values (ppm)	Comments	Data Source
Manual adhesive application	Model Building Shop	Unknown	ND	ND	PBZ samples; LOD = 20 ppm	(NIOSH, 2016)
Manual adhesive application	Woodworking Studio	Unknown	ND	ND	PBZ samples; LOD unknown	(NIOSH, 2009)
Paint and coating (use of paint thinner to clean paint guns may be a not-previously identified activity in auto refinish shops)	Race Shop – Paint Booth, Paint Mixing, Body Shop	Unknown	ND	ND	Area samples; LOD = 0.045 ppm	(Gwin et al., 2001)

B.3 Sources Containing Potentially Relevant Data or Information

Some sources of information and data related to releases and worker exposure were found during the systematic review literature search. Sources of data or information identified in the Analysis Plan Sections 2.6.1.1 Environmental Releases and 2.6.1.5 Occupational Exposures are shown in the four tables below. The data sources identified are based on preliminary results to date of the full-text screening step of the systematic review process. Further screening and quality evaluation are on-going. These sources will be reviewed to determine the utility of the data and information in the Risk Evaluation.

Table_Apx B-4 Potentially Relevant Data Sources for Information Related to Process Description

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Table_Apx B-5 Potentially Relevant Data Sources for Measured or Estimated Release Data

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Appendix C SUPPORTING TABLE FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES CONCEPTUAL MODEL

Table_Apx C-1 Industrial and Commercial Activities and Uses Conceptual Model Supporting Table
(Note that rows shaded in gray are not proposed for further analysis)

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
Manufacturing	Domestic Manufacture	Domestic Manufacture	Manufacture of methylene chloride	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29 CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Manufacturing	Import	Import	Repackaging of Import Containers	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Processing	Processing as a reactant	Intermediate in industrial gas manufacturing (e.g. manufacture of fluorinated gases used as refrigerants); Intermediate for pesticide, fertilizer, and other agricultural chemical manufacturing; CBI function for petrochemical manufacturing; Intermediate for other chemicals	Industrial gas manufacturing; Agricultural chemical manufacturing; Petrochemical manufacturing; Chemical manufacturing	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Processing	Incorporated into formulation, mixture, or reaction product	Solvents[3]; Propellants and blowing agents; Paint additives and coating additives; Laboratory chemicals; Processing aid,	Formulation of: • chemical mixtures; • cleaning fluids; • Paints and Coatings; • laboratory chemicals;	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical

[3] Solvents (for cleaning or degreasing), Solvents (which become part of product formulation or mixture); Propellants and blowing agents for all other chemical product and preparation manufacturing; and Propellants and blowing agents for plastics product manufacturing; Paint additives and coating additives; Laboratory chemicals for all other chemical product and preparation manufacturing; Processing aid, not otherwise listed for petrochemical manufacturing; Adhesive and sealant chemicals in adhesive manufacturing; Unknown function for oil and gas drilling, extraction, and support

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
		not otherwise listed; Adhesive and sealant chemicals in adhesive manufacturing; Unknown function for oil and gas drilling, extraction, and support activities	• petrochemical products; • adhesives; • oil and gas drilling and extraction products; Use of blowing agents in chemical product manufacturing and plastics product manufacturing;	Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Processing	Repackaging	Solvents (which become part of product formulation or mixture) for all other chemical product and preparation manufacturing; Laboratory chemicals; CBI functions for all other chemical product and preparation manufacturing;	Repackaging	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Processing	Recycling	Recycling	Process solvent recycling	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Distribution in commerce	Distribution	Distribution	Distribution of bulk shipments of methylene chloride; Distribution of formulated products	Liquid Contact, Vapor	Dermal/ Inhalation	Workers, ONU	No	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.
Industrial, commercial and consumer uses	Solvents (for cleaning or degreasing)	Batch vapor degreaser (e.g., open-top, closed-loop) In-line vapor degreaser (e.g., conveyorized, web cleaner)	Open top vapor degreasing (OTVD); OTVD with enclosures; Airtight closed-loop degreasing system; Airless vacuum drying degreasing system; Airless vacuum-to-vacuum degreasing system Conveyorized vapor degreasing; Cross-rod and ferris wheel vapor degreasing; Web vapor degreasing	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Industrial, commercial and consumer uses	Solvents (for cleaning or degreasing)	Cold cleaner; Aerosol spray degreaser/ cleaner	Spray use in cold cleaning - maintenance (manual spray; spray sink; dip tank); Aerosol degreasing/ cleaning by contractors	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	Yes	EPA will further analyze to determine whether mist generation is applicable.
Industrial, commercial and consumer uses	Adhesives and sealants	Single component glues and adhesives and sealants and caulks	Manual non-spray (paste/roller/brush) application	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Industrial, commercial and consumer uses	Adhesives and sealants	Single component glues and adhesives and sealants and caulks	Manual spray application	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	Yes	Public comments indicate aerosol spray application occurs.

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
Industrial, commercial and consumer uses	Paints and coatings including paint and coating removers for furniture stripping	Paints and coatings removers for furniture stripping	Paint and coating remover application and removal	Liquid Contact Vapor Mist	Dermal Inhalation	Workers ONU	No	EPA intends to finalize the methylene chloride rulemaking addressing paint stripping uses of methylene chloride, scenarios already assessed in the 2014 risk assessment will not be re-evaluated and will rely on the in the 2014 risk evaluation (U.S. EPA, 2014b) (https://www.epa.gov/newsreleases/epa-announces-action-methylene-chloride)
Industrial, commercial and consumer uses	Paints and coatings	Paints and coatings use	Manual spray application	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded.
				Mist	Dermal/Inhalation	Workers, ONU	Yes	EPA will further analyze to determine whether mist generation is applicable.
Industrial, commercial and consumer uses	Paints and coatings	Paints and coatings use	Manual non-spray (paste/roller/brush) application	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Industrial, commercial and consumer uses	Adhesives and sealants including adhesives and sealants removers	Adhesive/caulk removers	Adhesive/caulk removal by contractors	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	Yes	EPA will further analyze to determine whether mist generation is applicable.
Industrial, commercial and consumer uses	Metal products not covered elsewhere	Degreasers – aerosol and non-aerosol degreasers and cleaners e.g., coil cleaners	Spray use in cold cleaning - maintenance (manual spray; spray sink)	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
				Mist	Dermal/Inhalation	Workers, ONU	Yes	EPA will further analyze to determine whether mist generation is applicable.
Industrial, commercial and consumer uses	Metal products not covered elsewhere	Degreasers – aerosol and non-aerosol degreasers and cleaners e.g., coil cleaners	Dip tank use in cold cleaning - manufacturing (dip tank)	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Industrial, commercial and consumer uses	Fabric, textile and leather products not covered elsewhere	Textile finishing and impregnating/ surface treatment products e.g. water repellant	Fabric finishing	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	Yes	EPA will further analyze to determine whether mist generation is applicable.
Industrial, commercial and consumer uses	Automotive care products	Functional fluids for air conditioners: refrigerant,	Charging air conditioners during automotive original equipment	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
		treatment, leak sealer; Interior car care – spot remover; Degreasers: gasket remover, transmission cleaners, carburetor cleaner, brake quieter/cleaner; Degreasers: gasket remover, transmission cleaners, carburetor cleaner, brake quieter/cleaner	manufacture; Servicing automotive air conditioners (refrigerant, leak sealer); Commercial interior car care; Commercial automotive servicing; Commercial brake servicing	Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	Yes	Automotive Care Products are generally used in aerosol form.
Industrial, commercial and consumer uses	Apparel and footwear care products	Post-market waxes and polishes applied to footwear e.g. shoe polish	Commercial shoe care	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded.
				Mist	Dermal/Inhalation	Workers, ONU	Yes	EPA will further analyze to determine whether mist generation is applicable.
Industrial, commercial and consumer uses	Laundry and dishwashing products	Spot remover for apparel and textiles	Spot cleaning at commercial dry cleaners	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	Yes	EPA will further analyze to determine whether mist generation is applicable.
Industrial, commercial and consumer uses	Lubricants and greases	Liquid and spray lubricants and greases; Degreasers – aerosol and non-aerosol degreasers and cleaners		Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded.
				Mist	Dermal/Inhalation	Workers, ONU	Yes	EPA will further analyze to determine whether mist generation is applicable.
Industrial, commercial and consumer uses	Building/ construction materials not covered elsewhere	Cold pipe insulation		Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	Yes	EPA will further analyze to determine whether mist generation is applicable.

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
Industrial, commercial and consumer uses	Solvents (which become part of product formulation or mixture)	All other chemical product and preparation manufacturing	Unspecified chemical product manufacturing	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Industrial, commercial and consumer uses	Processing aid not otherwise listed	In multiple manufacturing sectors		Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Industrial, commercial and consumer uses	Propellants and blowing agents	Flexible polyurethane foam manufacturing	Polyurethane foam blowing	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected
Industrial, commercial and consumer uses	Other Uses	Other non-aerosol uses, e.g. Laboratory chemicals - all other chemical product and preparation manufacturing; Electrical equipment, appliance, and component manufacturing; Plastic and rubber products; Oil and gas drilling, extraction, and support activities; Functional fluids (closed systems) in pharmaceutical and medicine manufacturing; Carbon remover, lithographic printing cleaner, wood floor cleaner, brush cleaner	Laboratory use; Electrical equipment, appliance, and component manufacturing; Plastic product manufacturing (compounding and converting); Use in oil and gas drilling, extraction, and support activities; Pharmaceutical product manufacturing; Use as carbon remover, lithographic printing cleaner, wood floor cleaner, brush cleaner	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected

Life Cycle Stage	Category	Subcategory	Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
Industrial, commercial and consumer uses	Other Uses	Other aerosol uses, e.g. Anti-adhesive agent - anti-spatter welding aerosol	Use as anti-adhesive agent - anti-spatter welding aerosol	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	Yes	EPA will further analyze to determine whether mist generation is applicable.
Disposal	Waste Handling, Treatment and Disposal	Disposal of methylene chloride wastes	Worker handling of wastes	Liquid Contact	Dermal	Workers	Yes	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected however occluded exposures may significantly contribute to total exposure. Occluded exposures will be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
				Vapor	Dermal	Workers, ONU	No	Based on OSHA standard (29CFR 1910.1052) workers are required to be protected and exposure to vapors are not expected to be occluded. Furthermore, vapor dermal exposures are expected to be much smaller than concurrent inhalation exposures for workers and ONU
				Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected

Appendix D SUPPORTING TABLE FOR CONSUMER ACTIVITIES AND USES CONCEPTUAL MODEL

Table_Apx D-1 Consumer Activities and Uses Conceptual Model Supporting Table
(Note that rows shaded in gray are not proposed for further analysis)

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
Solvents for Cleaning and Degreasing	Brush Cleaner	Liquid	Liquid Contact	Dermal contact with liquid product on the skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Evaporation from the surface	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
Solvents for Cleaning and Degreasing	Carbon Remover	Aerosol	Liquid Contact	Dermal contact with liquid product on the skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature,
						Bystander		

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
								inhalation pathway will be further analyzed.
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Evaporation from the surface	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
Solvents for Cleaning and Degreasing	Coil Cleaner	Aerosol	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Evaporation from the surface	Inhalation	Consumers	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystanders		
Solvents for Cleaning and Degreasing	Degreaser	Liquid	Liquid Contact	Dermal contact with liquid product on the skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Evaporation from the surface	Inhalation	Consumer		Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
		Aerosol	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
								dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Evaporation from the surface	Inhalation	Consumers	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystanders		
Adhesives and Sealants	Single component glues and adhesives and sealants and caulks	Liquid	Liquid Contact	Dermal contact with liquid product on the skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
								exposures may be higher.
			Vapor/Mist	Evaporation from the surface	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
Adhesives and Sealants	Sealant	Aerosol	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
				Evaporation from the surface	Inhalation	Consumers	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystanders		
Paints and Coatings including removers	Adhesive Remover	Liquid	Liquid Contact	Dermal contact with liquid product on the skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Evaporation from the surface	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
Metal Products							No	None of the uses are for consumers
Fabric, Textile, and Leather Products	Textile Treatment	Liquid primarily					No	None of the uses are for consumers
Automotive care products	Function fluids for air conditioners: refrigerant,	Aerosol	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
	treatment, leak sealer							chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Inhalation of gas as comes through A/C	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
Automotive care products	Interior car care, spot remover	Liquid	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumers	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
						Bystanders		

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
			Vapor/Mist	Evaporation from the surface	Inhalation	Consumers	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystanders		
Automotive Care Products	Auto Products - Engine Cleaner/ Degreaser	Aerosol	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Evaporation from the surface	Inhalation	Consumers	Yes	Due to high volatility (VP = 435 mmHg) at room
						Bystanders	Yes	

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
								temperature, inhalation pathway will be further analyzed.
Automotive Care Products	Auto Products - Brake Cleaner	Aerosol	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Evaporation from the surface	Inhalation	Consumers	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystanders		

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
Automotive Care Products	Auto Products - Carburetor Cleaner	Aerosol	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Evaporation from the surface	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
Automotive Care Products	Auto Products - Fuel system cleaner	Unclear on product form	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
								dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Evaporation from the surface	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
Automotive Care Products	Auto Products - Gasket Remover	Aerosol	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
								exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Evaporation from the surface	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
Apparel and Footwear Care Products	Textile Treatment						No	None of the listed products are consumer products
Laundry and Dishwashing Products							No	None of the listed products are consumer products
Lubricants and Greases	Lubricant	Aerosol or Liquid					No	None of the listed products are

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
								consumer products
Other Uses	Cold Pipe Insulation Spray	Aerosol	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Evaporation from the surface	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
Other Uses	Weld Spatter Protectant	Aerosol	Liquid Contact	Dermal contact with liquid product on skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.
			Vapor/Mist	Spray application (stationary)	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		
					Oral	Consumer	No	Based on physical chemical properties, mists of methylene chloride will likely be rapidly absorbed in the respiratory tract or evaporate
						Bystander		
				Evaporation from the surface	Inhalation	Consumer	Yes	Due to high volatility (VP = 435 mmHg) at room temperature, inhalation pathway will be further analyzed.
						Bystander		

Category	Subcategory	Form	Exposure Pathway / Media	Exposure Scenario	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale for Further Analysis / no Further Analysis
Solvents for Cleaning and Degreasing	Brush Cleaner	Liquid	Liquid Contact	Dermal contact with liquid product on the skin	Dermal	Consumer	Yes	Based on conditions of use, consumers may have direct dermal contact with methylene chloride. Occluded exposures may be higher.

Appendix E SUPPORTING TABLE FOR ENVIRONMENTAL RELEASES AND WASTES CONCEPTUAL MODEL

Table_Apx E-1 Environmental Releases and Wastes Conceptual Model Supporting Table

Life Cycle Stage	Use Category	Category	Release	Exposure Pathway	Receptor	Further Analysis?	Rationale for Further Analysis / no Further Analysis
Disposal	Disposal	Wastewater or Liquid Wastes	Industrial WWT operations	Water, Sediment	Aquatic Species	Yes	Aquatic species may be exposed to MC in water and sediment pore water at hazardous concentrations.
					Terrestrial Species	No	Terrestrial species exposures to MC in water are orders of magnitude below hazardous concentrations.
			Industrial wastewater pre treatment operations, then transfer to POTW	Water, Sediment	Aquatic Species	Yes	EPI Suite STP model estimates 43% of MC in wastewater will not be removed during treatment and will be present in the WWTP effluent. The Henry's Law constant of MC (3.25E-3 atm-m^3/mol) indicates that MC will volatilize from water. Aquatic species may be exposed to MC in water and sediment pore water at hazardous concentrations.
					Terrestrial Species	No	Terrestrial species exposures to MC in water are orders of magnitude below hazardous concentrations.
			Publicly owned treatment works (POTW)	Water, Sediment	Aquatic Species	Yes	EPI Suite STP model estimates 43% of MC in wastewater will not be removed during treatment and will be present in the WWTP effluent. Aquatic species may be exposed to MC in water and sediment pore water at hazardous concentrations.

Life Cycle Stage	Use Category	Category	Release	Exposure Pathway	Receptor	Further Analysis?	Rationale for Further Analysis / no Further Analysis
					Terrestrial Species	No	Terrestrial species exposures to MC in water are orders of magnitude below hazardous concentrations.
			Biosolids and land disposal to soil	Migration from biosolids via soil deposition	Terrestrial Species	No	Terrestrial species exposures to MC in water are orders of magnitude below hazardous concentrations.

Appendix F INCLUSION AND EXCLUSION CRITERIA FOR FULL TEXT SCREENING

Appendix F contains the eligibility criteria for various data streams informing the TSCA risk evaluation: environmental fate; engineering and occupational exposure; exposure to consumers; and human health hazard. The criteria are applied to the *on-topic* references that were identified following title and abstract screening of the comprehensive search results published on June 22, 2017.

Systematic reviews typically describe the study eligibility criteria in the form of PECO statements or a modified framework. PECO stands for Population, Exposure, Comparator and Outcome and the approach is used to formulate explicit and detailed criteria about those characteristics in the publication that should be present in order to be eligible for inclusion in the review. EPA/OPPT adopted the PECO approach to guide the inclusion/exclusion decisions during full text screening.

Inclusion and exclusion criteria were also used during the title and abstract screening, and documentation about the criteria can be found in the *Strategy for Conducting Literature Searches* document published in June 2017 along with each of the TSCA Scope documents. The list of *on-topic* references resulting from the title and abstract screening is undergoing full text screening using the criteria in the PECO statements. The overall objective of the screening process is to select the most relevant evidence for the TSCA risk evaluation. As a general rule, EPA is excluding non-English data/information sources and will translate on a case by case basis.

The inclusion and exclusion criteria for ecotoxicological data have been documented in the ECOTOX SOPs. The criteria can be found at https://cfpub.epa.gov/ecotox/help.cfm?helptabs=tab4) and in the *Strategy for Conducting Literature Searches* document published along with each of the TSCA Scope documents.

F.1 Inclusion Criteria for Data Sources Reporting Environmental Fate Data

EPA/OPPT developed a generic PESO statement to guide the full text screening of environmental fate data sources. PESO stands for Pathways and Processes, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the PESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental fate assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PESO statement.

Assessors seek information on various chemical-specific fate endpoints and associated fate processes, environmental media and exposure pathways as part of the process of developing the environmental fate assessment (Table_Apx F-2). Those that will be the focus of the environmental fate assessment for methylene chloride have been indicated in Table_Apx F-2. The PESO statement and information in Table_Apx F-1 will be used when screening the fate data sources to ensure complete coverage of the processes, pathways and data relevant to the fate of the chemical substance of interest.

Table_Apx F-1. Inclusion Criteria for Data Sources Reporting Environmental Fate Data	
PESO Element	**Evidence**
<u>P</u>athways and **<u>P</u>**rocesses	• Environmental fate, transport, partitioning and degradation behavior across environmental media to inform exposure pathways of the chemical substance of interest • Media of interest may include: – Surface water Please refer to the conceptual models for more information about the exposure pathways included in the TSCA risk evaluation.
<u>E</u>xposure	• Environmental exposure of ecological receptors (i.e., aquatic organisms) to the chemical substance of interest and/or its degradation products and metabolites Please refer to the conceptual models for more information about the ecological and human receptors included in the TSCA risk evaluation.
<u>S</u>etting or **<u>S</u>**cenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (e.g., wastewater treatment facilities) that would expose ecological receptors (i.e., aquatic organisms)
<u>O</u>utcomes	• Fate properties which allow assessments of exposure pathways: o Abiotic and biotic degradation rates, mechanisms, pathways, and products o Bioaccumulation magnitude and metabolism rates o Partitioning within and between environmental media (see Pathways and Processes)

Table_Apx F-2. Fate Endpoints and Associated Processes, Media and Exposure Pathways Considered in the Development of the Environmental Fate Assessment		
Fate Data Endpoint	**Associated Process(es)**	**Associated Media/Exposure Pathways**
		Surface water, Sediment
Abiotic reduction rates or half-lives	Abiotic reduction, Abiotic dehalogenation	X
Aerobic biodegradation rates or half-lives	Aerobic biodegradation	X
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	X
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	X
Bioconcentration factor (BCF), Bioaccumulation factor (BAF)	Bioconcentration, Bioaccumulation	X
Hydrolysis rates or half-lives	Hydrolysis	X
K_{AW}, Henry's Law constant, and other volatilization information	Volatilization	X
K_{OC} and other sorption information	Sorption, Mobility	X
Abiotic transformation products	Hydrolysis, Photolysis	X
Aerobic biotransformation products	Aerobic biodegradation	X
Anaerobic biotransformation products	Anaerobic biodegradation	X
Biomagnification and related information	Trophic magnification	X
Desorption information	Sorption, Mobility	X
Wastewater treatment removal information	Wastewater treatment	X

F.2 Inclusion Criteria for Data Sources Reporting Release and Occupational Exposure Data

EPA/OPPT developed a generic RESO statement to guide the full text screening of release and occupational exposure literature (Table_Apx F-3). RESO stands for Receptors, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the RESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria specified in the RESO statement will be eligible for inclusion, considered for evaluation, and possibly included in the environmental release and occupational exposure assessments, while those that do not meet these criteria will be excluded.

The RESO statement should be used along with the engineering and occupational exposure data needs table (Table_Apx F-4) when screening the literature.

Table_Apx F-3. Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data

RESO Element	Evidence
Receptors	• **Humans:** Workers, including occupational non-users • **Environment:** Aquatic ecological receptors (relevant release estimates input to Exposure) Please refer to the conceptual models for more information about the ecological and human receptors included in the TSCA risk evaluation.
Exposure	• Worker exposure to and relevant occupational environmental releases of the chemical substance of interest o Dermal and inhalation exposure routes (as indicated in the conceptual model) o Surface water (as indicated in the conceptual model) Please refer to the conceptual models for more information about the routes and media/pathways included in the TSCA risk evaluation.
Setting or Scenario	• Any occupational setting or scenario resulting in worker exposure and relevant environmental releases (includes all manufacturing, processing, use, disposal indicated in Table_Apx F-4 below.
Outcomes	• Quantitative estimates* of worker exposures and of relevant environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*

* Metrics (e.g., mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering, Release and Occupational Exposure Data Needs (Table_Apx F-4) provides a list of related and relevant general information.

Table_Apx F-4. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments	
Objective Determined during Scoping	**Type of Data**
General Engineering Assessment (may apply for either or both Occupational Exposures and / or Environmental Releases)	1. Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (e.g., each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. {Tags: Life cycle description, Life cycle diagram} [a] 2. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. {Tags: Production volume (PV), Import volume, Use volume, Percent PV} [a] 3. Description of processes, equipment, unit operations, and material flows and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). {Tags: Process description, Process material flow rate, Annual operating days, Annual batches, Weight fractions (for each of above, manufacture, import, processing, use)} [a] 4. Basic chemical properties relevant for assessing exposures and releases, e.g., molecular weight, normal boiling point, melting point, physical forms, and room temperature vapor pressure. {Tags: Molecular weight, Boiling point, Melting point, Physical form, Vapor pressure, Water solubility} [a] 5. Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations. {Tags: Numbers of sites (manufacture, import, processing, use), Site locations} [a]
Occupational Exposures	6. Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. {Tags: Worker activities (manufacture, import, processing, use)} [a] 7. Potential routes of exposure (e.g., inhalation, dermal). {Tags: Routes of exposure (manufacture, import, processing, use)} [a] 8. Physical form of the chemical(s) of interest for each exposure route (e.g., liquid, vapor, mist) and activity. {Tags: Physical form during worker activities (manufacture, import, processing, use)} [a] 9. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). {Tags: Personal Breathing Zone (PBZ) measurements (manufacture, import, processing, use)} [a] 10. Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). {Tags: Area measurements (manufacture, import, processing, use)} [a] 11. For solids, bulk and dust particle size characterization data. {Tags: Particle Size Distribution (PSD) measurements (manufacture, import, processing, use)} [a] 12. Dermal exposure data. {Tags: Dermal measurements (manufacture, import, processing, use)} 13. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). {Tags: Worker exposure modeling data needs (manufacture, import, processing, use)} [a] 14. Exposure duration (hr/day). {Tags: Worker exposure durations (manufacture, import, processing, use)} [a] 15. Exposure frequency (days/yr). {Tags: Worker exposure frequencies (manufacture, import, processing, use)} [a] 16. Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. {Tags: Numbers of workers exposed (manufacture, import, processing, use)} [a] 17. Personal protective equipment (PPE) types employed by the industries within scope. {Tags: Worker PPE (manufacture, import, processing, use)} [a] 18. Engineering controls employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions. {Tags: Engineering controls (manufacture, import, processing, use), Engineering control effectiveness data} [a]

Table_Apx F-4. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments	
Objective Determined during Scoping	**Type of Data**
Environmental Releases (to relevant environmental media)	19. Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. {Tags: Release sources (manufacture, import, processing, use)} [a] 20. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (water) and treatment and disposal methods (POTW), including releases per site and aggregated over all sites (annual release rates, daily release rates) {Tags: Release rates (manufacture, import, processing, use)} [a] 21. Release or emission factors. {Tags: Emission factors (manufacture, import, processing, use)} [a] 22. Number of release days per year. {Tags: Release frequencies (manufacture, import, processing, use)} [a] 23. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). {Tags: Release modeling data needs (manufacture, import, processing, use)} [a] 24. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions. {Tags: Treatment/ emission controls (manufacture, import, processing, use), Treatment/ emission controls removal/ effectiveness data} [a]
Note: [a] These are the tags included in the full text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.	

F.3 Inclusion Criteria for Data Sources Reporting Exposure Data on Consumers and Ecological Receptors

EPA/OPPT developed PECO statements to guide the full text screening of exposure data/information for human (i.e., consumers, potentially exposed or susceptible subpopulations) and ecological receptors. Subsequent versions of the PECO statements may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PECO statement are eligible for inclusion, considered for evaluation, and possibly included in the exposure assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PECO statement. The methylene chloride-specific PECO is provided in Table_Apx F-5.

Table_Apx F-5. Inclusion Criteria for the Data Sources Reporting Methylene Chloride Exposure Data on Consumers and Ecological Receptors	
PECO Element	**Evidence**
Population	**Human:** Consumers (i.e., receptors who use a product directly) and bystanders in the home (i.e., receptors who are non-product users that are incidentally exposed to the product or article); including PESS such as children; infants; pregnant women; lactating women, do it yourself (DIY) or consumers with high-end exposure.
	Ecological: Aquatic biota.
Exposure	**Expected Primary Exposure Sources, Pathways, Routes:** • Sources: Consumer uses in the home producing releases to air and dermal contact; industrial and commercial activities involving non-closed systems producing releases to surface water • Pathways: Indoor air and dermal contact in consumer products; surface water • Routes of Exposure: Inhalation exposure via indoor air (consumer and bystander populations) and dermal exposure via direct contact with consumer products containing methylene chloride including occluded exposures; exposure to aquatic species via surface water

Table_Apx F-5. Inclusion Criteria for the Data Sources Reporting Methylene Chloride Exposure Data on Consumers and Ecological Receptors	
PECO Element	**Evidence**
Comparator (Scenario)	**Human:** Consumer and bystander exposure via use of methylene chloride containing consumer products in the home.
	Ecological: Aquatic species exposure via contact with surface water
Outcomes for Exposure Concentration or Dose	**Human:** Acute, subchronic, and/or chronic external dose estimates (mg/kg/day); acute, subchronic, and/or chronic air and water concentration estimates (mg/m^3 or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered.
	Ecological: A range of ecological receptors will be considered (range dependent on available ecotoxicity data) using surface water concentrations.

F.4 Inclusion Criteria for Data Sources Reporting Human Health Hazards

EPA/OPPT developed a methylene chloride-specific PECO statement (Table_Apx F-6) to guide the full text screening of the human health hazard literature. Subsequent versions of the PECOs may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the criteria specified in the PECO statement will be eligible for inclusion, considered for evaluation, and possibly included in the human health hazard assessment, while those that do not meet these criteria will be excluded according to the exclusion criteria.

In general, the PECO statements were based on (1) information accompanying the TSCA Scope document, and (2) preliminary review of the health effects literature from authoritative sources cited in the TSCA Scope documents. When applicable, these authoritative sources (e.g., IRIS assessments, EPA/OPPT's Work Plan Problem Formulations or risk assessments) will serve as starting points to identify PECO-relevant studies.

Table_Apx F-6. Inclusion Criteria for Data Sources Reporting Human Health Hazards Related to Methylene Chloride [a]

PECO Element	Evidence Stream	Papers/Features Included	Papers/Features Excluded

Population [b]	*Human*	• Any population
		• All lifestages
		• Study designs:
		  o Controlled exposure, cohort, case-control, cross-sectional, case-crossover for all endpoints
		  o Case studies and case series only related to deaths and respiratory distress from acute exposure
			• Case studies and case series for all endpoints ***other than*** death and respiratory distress from acute exposure

	Animal	• All non-human whole-organism mammalian species • All lifestages	• Non-mammalian species
Exposure	*Human*	• Exposure based on administered dose or concentration of methylene chloride, biomonitoring data (e.g., urine, blood or other specimens), environmental or occupational-setting monitoring data (e.g., air, water levels), job title or residence • Primary metabolites of interest (e.g., COHb) as identified in biomonitoring studies	

Table_Apx F-6. Inclusion Criteria for Data Sources Reporting Human Health Hazards Related to Methylene Chloride [a]

		• Exposure identified as ***<u>or presumed to be</u>*** from oral, dermal, inhalation routes • Any number of exposure groups • Quantitative, semi-quantitative or qualitative estimates of exposure • Exposures to multiple chemicals/mixtures only if methylene chloride or related metabolites were independently measured and analyzed	• Route of exposure ***<u>not</u>*** by inhalation, oral or dermal type (e.g., intraperitoneal, injection) • Multiple chemical/mixture exposures with no independent measurement of or exposure to methylene chloride (or related metabolite)
	Animal	• A minimum of 2 quantitative dose or concentration levels of methylene chloride plus a negative control group[a] • Acute, subchronic, chronic exposure from oral, dermal, inhalation routes • Exposure to methylene chloride only (no chemical mixtures)	• Only 1 quantitative dose or concentration level in addition to the control • Route of exposure ***<u>not</u>*** by inhalation, oral or dermal type (e.g., intraperitoneal, injection) • No duration of exposure stated • Exposure to methylene chloride in a chemical mixture
Comparator	*Human*	• A comparison population [not exposed, exposed to lower levels, exposed below detection] for endpoints ***<u>other than</u>*** death or respiratory distress Any or no comparison for exposures associated with death or respiratory distress	• No comparison population for endpoints other than death or respiratory distress from acute exposure
	Animal	• Negative controls that are vehicle-only treatment and/or no treatment	• Negative controls ***<u>other than</u>*** vehicle-only treatment or no treatment
Outcome	*Human* *Animal*	• Endpoints described in the methylene chloride scope document [c]: o Acute toxicity (neurotoxicity and lethality) o Liver toxicity o Neurotoxicity o Irritation o Cancer • Other endpoints (e.g., immunotoxicity, reproductive/developmental toxicity) [d]	
General Considerations		**Papers/Features Included**	**Papers/Features Excluded**
		• Written in English [e] • Reports primary data • Full text available • Reports both methylene chloride exposure ***<u>and</u>*** a health outcome	• Not written in English • Reports secondary data (e.g., review papers) • No full text available (e.g., only a study description/abstract, out-of-print text) • Reports a methylene chloride-related exposure ***<u>or</u>*** a health outcome, but not both (e.g. incidence, prevalence report)

[a] Some of the studies that are excluded based on the PECO statement may be considered later during the systematic review process. For methylene chloride, EPA will evaluate studies related to susceptibility and may evaluate, toxicokinetics and physiologically based pharmacokinetic models after other data (e.g., human and animal data identifying adverse health outcomes) are reviewed. EPA may need to evaluate mechanistic data (especially related to immunotoxicity, CNS depression, lethality) depending on the review of health effects data. Finally, EPA may also review other data as needed (e.g., animal studies using one concentration, review papers) when analyzing evidence during the data integration phase of the systematic review process.

[b] Mechanistic data are excluded during the full text screening phase of the systematic review process but may be considered later (see footnote *a*).

[c] EPA will review key and supporting studies in the IRIS assessment (U.S. EPA, 2011b) that were considered in the dose-response assessment for non-cancer and cancer endpoints as well as studies published after the IRIS assessment (U.S. EPA, 2011b).

[d] EPA may screen for hazards other than those listed in the scope document if they were identified in the updated literature search that accompanied the scope document.

[e] EPA may translate studies as needed.