

Scope of the Risk Evaluation for Carbon Tetrachloride (Methane, Tetrachloro-)

CASRN: 56-23-5



June 2017

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This report was developed by the United States Environmental Protection Agency (U.S. EPA), Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT).

Acknowledgements

The OPPT Assessment Team gratefully acknowledges participation or input from EPA's Office of General Counsel, Office of Research and Development, Office of Air and Radiation, and assistance from EPA contractors CSRA LLC (Contract No. CIO-SP3, HHSN316201200013W), ERG (Contract No. EP-W-12-006), ICF (Contract No. EP-C-14-001) and SRC (Contract No. EP-W-12-003).

Docket

Supporting information can be found in public docket: <u>EPA-HQ-OPPT-2016-0733</u>.

Disclaimer

Reference herein to any specific commercial products, process or service by trade name, trademark, manufacturer or otherwise does not constitute or imply its endorsement, recommendation or favoring by the U.S. Government.

ABBREVIATIONS

°C	Degrees Celsius
AAL	Allowable Ambient Levels
atm	Atmosphere(s)
ATSDR	Agency for Toxic Substances and Disease Registries
AWQC	Ambient Water Quality Criteria
BCF	Bioconcentration Factor
BUN	Blood Urea Nitrogen
CAA	Clean Air Act
CASRN	Chemical Abstract Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFC	Chlorofluorocarbon
cm ³	Cubic Centimeter(s)
CNS	Central Nervous System
COC	Concentration of Concern
Corap	Community Rolling Action Plan
CPCat	Chemical and Product Categories
CPSC	Consumer Product Safety Commission
CS ₂	Carbon Disulfide
CSATAM	Community-Scale Air Toxics Ambient Monitoring
CSCL	Chemical Substances Control Law
CYP450	Cytochrome P450
CWA	Clean Water Act
DNA	Deoxyribonucleic Acid
DT50	Dissipation Time for 50% of the compound to dissipate
EC	European Commission
ECHA	European Chemicals Agency
EDC	Ethylene Dichloride
EG	Effluent Guidelines
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
FHSA	Federal Hazardous Substance Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
g	Gram(s)
GI	Gastrointestinal
НАР	Hazardous Air Pollutant
HCFC	Hydrochlorofluorocarbons
HCI	Hydrochloric Acid
HFC	Hydrofluorocarbon

HFO	Hydrofluoroolefin
HPV	High Production Volume
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
km	Kilometer(s)
L	Liter(s)
lb	Pound
log K _{oc}	Logarithmic Soil Organic Carbon:Water Partitioning 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
mPa∙s	Millipascal(s)-Second
MSDS	Material Safety Data Sheet
NAICS	North American Industrial Classification System
NATA	National Air Toxics Assessment
NATTS	National Air Toxics Trends Stations
NEI	National Emissions Inventory
NESHAP	National Emission Standards
NHANES	National Health and Nutrition Examination Survey
NIH	National Institute of Health
NIOSH	National Institute of Occupational Safety and Health
NPDWR	National Primary Drinking Water Regulations
NTP	National Toxicology Program
NWQMC	National Water Quality Monitoring Council
OCSPP	Office of Chemical Safety and Pollution Prevention
ODS	Ozone Depleting Substance
OECD	Organisation for Economic Co-operation and Development
OELs	Occupational Exposure Limits
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
OW	Office of Water
PCE	Perchloroethylene
PEL	Permissible Exposure Level
POD	Point of Departure
POTW	Publicly Owned Treatment Works
ppm	Part(s) per Million
QC	Quality Control
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RCRA	Resource Conservation and Recovery Act
REI	Reactive Ion Etching

SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SIAP	Screening Information Dataset Initial Assessment Profile
SIDS	Screening Information Dataset
SDWA	Safe Drinking Water Act
STEL	Short-term Exposure Limit
STORET	STORage and RETrieval
TCCR	Transparent, Clear, Consistent and Reasonable
TCLP	Toxicity Characteristic Leaching Procedure
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TURA	Toxic Use Reduction Act
TWA	Time-Weighted Average
UATMP	Urban Air Toxics Monitoring Program
U.S.	United States
USGS	United States Geological Survey
UV	Ultraviolet
VOC	Volatile Organic Compounds
WHO	World Health Organisation
WQP	Water Quality Portal

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 (<u>81 FR 91927</u>), as required by TSCA § 6(b)(2)(A). Carbon tetrachloride was one of these chemicals.

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

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

In the case of carbon tetrachloride, legacy uses and associated legacy disposals will be excluded from the scope of the risk evaluation. EPA is excluding these uses because EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on current and prospective uses, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of *conditions of use* in that context.

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

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

Carbon tetrachloride is a high production volume solvent. The Montreal Protocol and Title VI of the Clean Air Act (CAA) Amendments of 1990 called for a complete phase-out of carbon tetrachloride

production for non-feedstock uses by 2000 and the Consumer Product Safety Commission (CPSC) banned the use of carbon tetrachloride in consumer products (excluding unavoidable residues not exceeding 10 ppm atmospheric concentration) in 1970. Currently, carbon tetrachloride is used a feedstock in the production of hydrochlorofluorocarbons (HCFCs), hydrofluorocarbons (HFCs) and hydrofluoroolefins (HFOs) and in the manufacturing of other chlorinated compounds, agricultural products and petrochemicals. EPA has identified information on several other uses that may still exist including solvents for laboratory uses, degreasing and cleaning, adhesives, sealants, paints, coatings, rubber, cement and asphalt formulations.

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

This document presents the occupational scenarios in which workers and occupational non-users may be exposed carbon tetrachloride during a variety of conditions of use, such as manufacturing of refrigerants or chlorinated compounds and using solvents for machinery cleaning. For carbon tetrachloride, EPA believes that workers, consumers, and bystanders as well as certain other groups of individuals may experience greater exposures than the general population. EPA will evaluate whether other groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) or have greater susceptibility than the general population, and should therefore be considered relevant potentially exposed or susceptible subpopulations for purposes of this risk evaluation.

Exposures to the general population may occur from industrial releases. Most of the reported environmental releases for carbon tetrachloride were air emissions (fugitive and point source air emissions). Other reported releases include land disposal, ground injection and water releases. EPA expects to consider these releases as they relate to exposures to occupational, consumer and general populations.

Carbon tetrachloride has been the subject of numerous health hazard reviews including EPA's Integrated Risk Information System (IRIS) Toxicological Review and Agency for Toxic Substances and Disease Registry's (ATSDR's) Toxicological Profile. Any existing assessments will be a starting point as EPA will conduct a systematic review of the literature, including new literature since the existing assessments, as available in *Carbon tetrachloride (CASRN 56-23-5) Bibliography: Supplemental File for the TSCA Scope Document*, <u>EPA-HQ-OPPT-2016-0733</u>. Human health hazards of carbon tetrachloride have been identified by EPA previously and include liver toxicity, renal toxicity and cancer. Carbon tetrachloride hazards to fish, aquatic invertebrates, aquatic plants, sediment invertebrates and amphibians have previously been assessed by EPA or other organizations. These hazards will be evaluated based on the specific exposure scenarios identified.

The initial analysis plan describes EPA's plan for conducting systematic review of readily available information and identification of assessment approaches to be used in conducting the risk evaluation

for carbon tetrachloride. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the risk evaluation of carbon tetrachloride.

1 INTRODUCTION

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

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

TSCA § 6(b)(4) requires the 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). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. On February 14, 2017, EPA convened a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of the risk evaluations under development for the 10 chemical substances designated in December 2016 for risk evaluations pursuant to TSCA. EPA provided the public an opportunity to identify information, via oral comment or by submission to a public docket, specifically related to the conditions of use for the 10 chemical substances. EPA used this information in developing this scope document, which fulfills the TSCA § 6(b)(4)(D) requirement for carbon tetrachloride.

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

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

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

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

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

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

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

1.1 Regulatory History

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

Federal Laws and Regulations

Carbon tetrachloride 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.

State Laws and Regulations

Carbon tetrachloride 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.

Laws and Regulations in Other Countries and International Treaties or Agreements

Carbon tetrachloride 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.

1.2 Assessment History

EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations—information useful to EPA in preparing this scope for risk evaluation. Table 1-1 shows the assessments that have been conducted. In addition to using this information, EPA intends to conduct a full review of the data collected (see *Carbon tetrachloride (CASRN 56-23-5) Bibliography: Supplemental File for the TSCA Scope Document,* <u>EPA-HQ-OPPT-2016-0733</u>) using the literature search strategy (see *Strategy for Conducting Literature Searches for Carbon Tetrachloride: Supplemental File for the TSCA Scope Document,* <u>EPA-HQ-OPPT-2016-0733</u>) to ensure that EPA is considering information that has been made available since these assessments were conducted.

Authoring Organization	Assessment	
EPA assessments		
U.S. EPA, Office of Water (OW)	Update of Human Health Ambient Water Quality Criteria: Carbon Tetrachloride 56-23-5, EPA-HQ- OW-2014-0135-0182 (2015b)	
U.S. EPA, Integrated Risk Information System (IRIS)	Toxicological Review of Carbon Tetrachloride In Support of Summary Information on IRIS (2010)	
U.S. EPA, Office of Drinking Water	Carbon Tetrachloride Health Advisory, Office of Drinking Water US Environmental Protection Agency (1987)	
Other U.Sbased organizations		
Agency for Toxic Substances and Disease Registry (ATSDR)	Toxicological Profile for Carbon Tetrachloride (2005)	
California Environment Protection Agency, Office of Environmental Health Hazard Assessment	Public Health Goal for Carbon Tetrachloride (2000)	
International		
Health Canada	<u>Guidelines for Canadian Drinking Water Quality,</u> <u>Guideline Technical Document, Carbon</u> <u>Tetrachloride</u> (2010)	
Organisation for Economic Co-operation and Development 's Screening Information Dataset (OECD SIDS), Co-CAM, 10-12	SIDS SIAP for Carbon Tetrachloride (2011)	
World Health Organisation (WHO)	Carbon Tetrachloride in Drinking Water, Background document for development of WHO Guidelines for Drinking -water Quality (2004)	

Table 1-1. Assessment History of Carbon Tetrachloride

1.3 Data and Information Collection

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

Data Collection: Data Search

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

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments and the National Toxicology Program's (NTP) *Report on Carcinogens,* to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. The *Strategy for Conducting Literature Searches for Carbon Tetrachloride: Supplemental File for the TSCA Scope Document, EPA-HQ-OPPT-2016-0733* provides details about the data sources and search terms that were used in the initial search.

Data Collection: Data Screening

Following the data search, references were screened and categorized using selection criteria outlined in the *Strategy for Conducting Literature Searches for Carbon Tetrachloride: Supplemental File for the TSCA Scope Document,* <u>EPA-HQ-OPPT-2016-0733</u>. 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; 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 exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard), but within each data set, there are two broad categories or data tags: (1) *on-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. *Off-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. The Strategy for Conducting Literature Searches for Carbon Tetrachloride: Supplemental File for the TSCA Scope Document, EPA-HQ-OPPT-2016-0733 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 *Strategy for Conducting Literature Searches for Carbon Tetrachloride: Supplemental File for the TSCA Scope Document*, <u>EPA-HQ-OPPT-2016-0733</u> 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 *Carbon tetrachloride (CASRN 56-23-5) Bibliography: Supplemental File for the TSCA Scope Document*, <u>EPA-HQ-OPPT-2016-0733</u>. This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and the initial categorization for *on-topic* and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *off-topic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for modeling); hence, additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

2 SCOPE OF THE EVALUATION

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

2.1 Physical and Chemical Properties

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

Property	Value ^a	References
Molecular formula	CCl ₄	
Molecular weight	153.82	
Physical form	Colorless liquid, sweet, aromatic and ethereal odor resembling chloroform	<u>Merck (1996); U.S. Coast</u> <u>Guard (1985)</u>
Melting point	-23°C	<u>Lide (1999)</u>
Boiling point	76.8°C	<u>Lide (1999)</u>
Density	1.46 g/cm ³ at 20°C	<u>Boublík et al. (1984)</u>
Vapor pressure	115 mm Hg at 25°C	<u>Lide (1999)</u>
Vapor density	5.32 (relative to air)	<u>Boublík et al. (1984)</u>
Water solubility	793 mg/L at 25°C	<u>Horvath (1982)</u>
Octanol:water partition coefficient (log K _{ow})	2.83	<u>Hansch et al. (1995)</u>
Henry's Law constant	0.0276 atm m ³ /mole	Leighton and Calo (1981)
Flash point	None	U.S. Coast Guard (1985)
Autoflammability	Not readily available	
Viscosity	2.03 mPa·s at -23°C	Daubert and Danner (1989)
Refractive index	1.4607 at 20°C	Merck (1996)

Table 2-1. Physical and Chemical Properties of Carbon Tetrachloride

Property	Value ^a	References
Diaelectric constant	2.24 at 20°C	Norbert and Dean (1967)
^a Measured unless otherwise noted.		

2.2 Conditions of Use

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

2.2.1 Data and Information Sources

As the first step in preparing these scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. As further described in this document, EPA searched a number of available data sources (e.g., Use and Market Profile for Carbon Tetrachloride, EPA-HQ-OPPT-2016-0733). 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: Carbon Tetrachloride, EPA-HQ-OPPT-2016-0733-0003) prior to a February 2017 public meeting on scoping efforts for risk evaluation convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public and stakeholder meetings has been incorporated into this scope document to the extent appropriate, as indicated in Table 2-3. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseen activities associated with the subject chemicals, based on reasonably available information. The documents do not, in most cases, specify whether activity under discussion is intended, known, or reasonably foreseen, in part due to the time constraints in preparing these documents. As further described in this document, EPA searched a number of available data sources (e.g., Use and Market Profile for Carbon Tetrachloride, EPA-HQ-OPPT-2016-0733).

2.2.2 Identification of Conditions of Use

As part of the scope, an initial life cycle diagram is provided (Figure 2-1) depicting the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer; when distinguishable), distribution in commerce and disposal. The information is grouped according to Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, 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 of use may be grouped under multiple CDR categories.

For the purposes of this scope, CDR definitions were used. CDR 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, 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 (<u>U.S. EPA, 2017b</u>, <u>2016b</u>), when the volume was not claimed confidential business information (CBI). The 2016 CDR reporting data for carbon tetrachloride are provided in Table 2-2 for carbon tetrachloride from EPA's CDR database (<u>U.S. EPA, 2017b</u>).

Table 2-2. Production Volume of Carbon	Tetrachloride in Chemical Data Reporting (CDR) Reporting
Period (2012 to 2015) ^a	

Reporting Year	2012	2013	2014	2015		
Total Aggregate Production Volume (Ibs)	129,145,698	116,658,281	138,951,153	142,582,067		
^a <u>U.S. EPA (2017b)</u> . Internal communication. The CDR data for the 2016 reporting period is available via ChemView (<u>https://java.epa.gov/chemview</u>) (<u>U.S. EPA, 2016b</u>). Because of an ongoing CBI substantiation process required by amended TSCA, the CDR data available in the scope document is more specific than currently in ChemView.						

Figure 2-1 depicts the initial life cycle diagram of carbon tetrachloride from manufacture to the point of disposal. This diagram does not distinguish among most industrial, commercial and consumer uses; EPA will further investigate and define the differences between these uses during the risk evaluation. It should be noted that the Montreal Protocol and Title VI of the Clean Air Act (CAA) Amendments of 1990 called for a complete phase-out of carbon tetrachloride production for non-feedstock uses by 2000 and the Consumer Product Safety Commission (CPSC) banned the use of carbon tetrachloride in consumer products (excluding unavoidable residues not exceeding 10 ppm atmospheric concentration) in 1970. During preliminary data gathering, EPA has identified use as a feedstock as the main use for carbon tetrachloride. However, there are several industrial/commercial/consumer uses that may still exist including: catalyst regeneration, as a processing aid and as an additive in petrochemical manufacturing; in the manufacturing of agricultural products; as a solvent for degreasing and cleaning, in adhesives, sealants, paints, coatings, rubber cement and asphalt formulations and for laboratory procedures (i.e., extraction solvent) [EPA-HQ-OPPT-2016-0733-0003 (U.S. EPA, 2017c)]. EPA expects that some commercial products containing carbon tetrachloride are also available for purchase by consumers, such that many products are used in both commercial and consumer applications. Most of the products EPA identified that contain carbon tetrachloride as a cleaning solvent or as a solvent in formulation have less than 1% by weight carbon tetrachloride. For instance, there are public comments, EPA-HQ-OPPT-2016-0733-0005 and EPA-HQ-OPPT-2016-0733-0017, stating that carbon tetrachloride may be present in a limited number of industrial products with chlorinated ingredients at a concentration of less than 0.003% by weight. EPA will further investigate carbon tetrachloride use in these products during the risk evaluation process.

Due to CBI claims in the 2016 CDR, EPA cannot provide the volumes associated with each life cycle stage (U.S. EPA, 2016b).



Figure 2-1. Initial Carbon Tetrachloride Life Cycle Diagram

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

^a Due to CBI claims, EPA cannot differentiate between manufacturing and import sites.

^b See Table 2-3 for additional uses not mentioned specifically in this diagram.

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

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR (U.S. EPA, 2016b) and included in the life cycle diagram are summarized below. The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacture, 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).

For the uses, the **"Petrochemical and Agricultural Products Manufacturing"** category encompasses chemical substances used for a variety of purposes at petrochemical and agricultural products manufacturing sites. This category includes the use of carbon tetrachloride for catalyst regeneration, as a processing aid and as an additive.

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 carbon tetrachloride in vapor degreasing, cold cleaning and in industrial and commercial aerosol degreasing products.

The **"Adhesives and Sealants"** category encompasses chemical substances contained in adhesive and sealant products used to fasten other materials together. EPA anticipates that the primary subcategory to be the use of carbon tetrachloride in rubber cement, asphalt and other solvent-based adhesives and sealants. This category covers industrial, commercial and consumer uses of adhesives and sealants.

The **"Paints and Coatings"** category encompasses chemical substances contained in paints, lacquers, varnishes and other coating products that are applied as a thin continuous layer to a surface. Coating may provide protection to surfaces from a variety of effects such as corrosion and ultraviolet (UV) degradation; may be purely decorative; or provide other functions. EPA anticipates that the primary subcategory to be the use of carbon tetrachloride in solvent-based paints or other coatings. This category covers industrial, commercial and consumer uses of paints and coatings.

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

Table 2-3. Categories and Subcategories of Conditions of Use for Carbon Tetrachloride

Life Cycle Stage	Category ^a	Subcategory ^b	References
Manufacture	Domestic manufacture	Domestic manufacture	<u>U.S. EPA (2016b)</u>
	Import	Import	<u>U.S. EPA (2016b)</u>
Processing	Processing as a reactant/ intermediate	Hydrochlorofluorocarbons (HCFCs), Hydrofluorocarbon (HFCs) and Hydrofluoroolefin (HFOs)	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> Public comments, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> 0007, <u>EPA-HQ-OPPT-</u> 2016-0733-0008 and <u>EPA-HQ-OPPT-2016-</u> 0733-0016; <u>U.S. EPA</u> (2016b)
		Perchloroethylene (PCE)	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> Public comments, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> <u>0007 and EPA-HQ-OPPT-</u> <u>2016-0733-0008; U.S.</u> <u>EPA (2016b)</u>
		Inorganic chlorinated compounds	Public comment, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> <u>0027</u>
		Chlorinated paraffins	Public comment, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> 0024
	Processing - incorporation into formulation, mixture or reaction product	Petrochemicals manufacturing	<u>U.S. EPA (2016b)</u> ; Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u> ; <u>U.S. EPA (2016a)</u>
Processing	Processing - incorporation into formulation, mixture or reaction product	Agricultural products manufacturing	U.S. EPA (2016b); Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> Public comments, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> <u>0007</u> and <u>EPA-HQ-OPPT-</u> <u>2016-0733-0008</u>

Life Cycle Stage	Category ^a	Subcategory ^b	References
		Solvents for cleaning and degreasing	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> Public comment, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> <u>0011, EPA-HQ-OPPT-</u> <u>2016-0733-0012</u> and <u>EPA-HQ-OPPT-2016-</u> <u>0733-0015</u>
		Adhesives and sealants	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> Public comment, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> <u>0011,</u>
		Paints and coatings	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u>
	Processing - incorporation into article	Incorporation into article	<u>U.S. EPA (2016a)</u>
	Processing - repackaging	Repackaging	<u>U.S. EPA (2016a)</u>
	Recycling	Recycling	<u>U.S. EPA (2016b), U.S.</u> EPA (2016a)
Distribution in commerce	Distribution	Distribution in commerce	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u>
Industrial Use	Petrochemical manufacturing	Catalyst regeneration	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u>
Industrial Use	Petrochemical manufacturing	Processing aid	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> <u>U.S. EPA (2016b)</u>
		Additive	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> Public comment, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> <u>0012; U.S. EPA (2016a)</u>
	Agricultural products manufacturing	Fertilizers and other agricultural products manufacturing	<u>U.S. EPA (2016b)</u> , Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u> ; Public comments, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u>

Life Cycle Stage	Category ^a	Subcategory ^b	References
			0007 and EPA-HQ-OPPT- 2016-0733-0008
Industrial/commercial/ consumer use	Solvents for cleaning and degreasing	Machinery cleaning	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> Public comment, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> <u>0011</u>
		Textile cleaning	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u>
		Brake cleaning	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u>
	Adhesives and sealants	Rubber cement	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u>
		Arts and crafts	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> Public comment, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> <u>0015</u>
		Asphalt	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u>
Industrial/commercial/ consumer use	Adhesives and sealants	Industrial adhesives	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> Public comments, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> <u>0011, EPA-HQ-OPPT-</u> <u>2016-0733-0012</u> , and <u>EPA-HQ-OPPT-2016-</u> <u>0733-0015</u>
	Paints and coatings	Paints and coatings	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u>

Life Cycle Stage	Category ^a	Subcategory ^b	References			
	Laboratory chemicals	Laboratory chemical	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> <u>U.S. EPA (2016b)</u> , Public comments, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0007</u> and <u>EPA-HQ-OPPT-</u> <u>2016-0733-0013</u>			
	Other uses	Reactive ion etching	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003</u>			
		Processing aid (e.g., metal recovery, nitrogen trichloride removal in chlor- alkali production).	Use document, <u>EPA-HQ-</u> <u>OPPT-2016-0733-0003;</u> Public comments, <u>EPA-</u> <u>HQ-OPPT-2016-0733-</u> <u>0007</u> and <u>EPA-HQ-OPPT-</u> <u>2016-0733-0027</u>			
Disposal	Emissions to air	Emissions to air	<u>U.S. EPA (2016a)</u>			
	Wastewater	Wastewater	<u>U.S. EPA (2016a)</u>			
	Liquid wastes	Liquid wastes	<u>U.S. EPA (2016a)</u>			
	Solid wastes	Solid wastes	<u>U.S. EPA (2016a)</u>			
^a These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes and broadly represent						

^a These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes and broadly represent conditions of use of carbon tetrachloride in industrial and/or commercial settings. ^b These subcategories reflect more specific uses of carbon tetrachloride.

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 carbon tetrachloride. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use of carbon tetrachloride 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 carbon tetrachloride.

2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and environmental receptors EPA expects to consider in the risk evaluation.

Table 2-4 provides environmental fate data that EPA has identified and considered in developing the scope for carbon tetrachloride.

Property or Endpoint	Value ^a	References					
Direct photodegradation	Minutes (atmospheric -stratospheric)	OECD (2011)					
Indirect photodegradation	>330 years (atmospheric)	<u>OECD (2011)</u>					
Hydrolysis half-life	7000 years at 1 ppm	<u>OECD (2011)</u>					
Biodegradation	6 to 12 months (soil) 7 days to 12 months (aerobic water, based on multiple studies)	OECD (2011) ECHA (2012) ATSDR (2005) HSDB (2005)					
	3 days to 4 weeks (anaerobic water, based on multiple studies)						
Bioconcentration factor (BCF)	30 bluegill sunfish 40 rainbow trout	<u>OECD (2011)</u>					
Bioaccumulation factor (BAF)	19 (estimated)	<u>U.S. EPA (2012b)</u>					
Soil organic carbon:water	1.69-2.16	ECHA (2012)					
partition coefficient (log K _{oc})	2.06 (weighted mean of two soils-silt loam and sandy loam)	<u>OECD (2011)</u>					
^a Measured unless otherwise noted.							

 Table 2-4. Environmental Fate Characteristics of Carbon Tetrachloride

Carbon tetrachloride shows minimal susceptibility towards indirect photolysis by hydroxyl radicals in the troposphere, where it's estimated tropospheric half-life exceeds 330 years. Ultimately, carbon tetrachloride diffuses upward into the stratosphere where it is photodegraded to form the trichloromethyl radical and chlorine atoms (OECD, 2011). Further, carbon tetrachloride is efficiently degraded by direct photolysis under stratospheric conditions and the DT₅₀ (Dissipation Time for 50% of the compound to dissipate) value is in the order of minutes. However, the troposphere to the stratosphere migration of carbon tetrachloride is very long and this migration time limits the dissipation. The rate of photodegradation increases at altitudes >20 km and beyond.

Carbon tetrachloride dissolved in water does not photodegrade or oxidize in any measurable amounts, with a calculated hydrolysis half-life of 7,000 years based on experimental data at a concentration of 1 ppm (<u>OECD, 2011</u>). Removal mechanisms from water could include volatilization due to the Henry's law constant and anaerobic degradation in the sediment.

Based on the available environmental fate data, carbon tetrachloride is likely to biodegrade slowly under aerobic conditions with pathways that are environment- and microbial population-dependent. Anaerobic degradation has been observed to be faster than aerobic degradation under some conditions with acclimated microbial populations. Anaerobic biodegradation is expected to be a significant degradation mechanism in soil and ground water. Estimated and measured BCF and BAF values ranging from 19 – 40 indicates that carbon tetrachloride has no significant bioaccumulation potential in plants and animals (U.S. EPA, 2012b; OECD, 2011).

2.3.2 Releases to the Environment

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

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

Table 2-5 provides production-related waste managed data (also referred to as waste managed) for carbon tetrachloride reported by industrial facilities to the TRI program for 2015 (<u>U.S. EPA, 2017d</u>). Table 2-6 provides more detailed information on the quantities released to air or water or disposed of on land.

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

Number of Facilities	Recycling	Energy Recovery	Treatment	Releases ^{a,b}	Total Production Related Waste
47	5,954,066	5,638,154	15,196,739	151,690	26,940,648

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.

In 2015, 47 facilities reported a total of 27 million pounds of carbon tetrachloride waste managed. Of this total, nearly 6 million pounds were recycled, 5.6 million pounds were recovered for energy, 15 million pounds were treated, and almost 152 thousand pounds were released into the environment.

Of these releases, the largest releases of nearly 105 thousand pounds were to air (fugitive and point source air emissions), a little under 500 pounds were released to water (surface water discharges), 50 thousand pounds were released to land (of which disposal to Resource Conservation and Recovery Act (RCRA) Subtitle C landfills is the primary disposal method), and under 200 pounds were released in other forms such as indefinite storage.

Table 2-6. Summary of Carbor	Tetrachloride TRI Releases	to the Environment in 2015 (lbs
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		Air Re	leases		Land Releases				
	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 Releases ^b
Subtotal		69,897	34,941		19,608	27,300	401		
Totals	47	104	,838	468		47,309		164	152,780

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. While production-related waste managed shown in Table 2-5 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), release quantities shown in Table 2-6 include both production-related and non-routine quantities (TRI section 5 and 6 data). As a result, release quantities may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (<u>U.S. EPA, 2016a</u>).

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

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 carbon tetrachloride. Though carbon tetrachloride's use has significantly decreased from a peak in the 1970's, it's long halflife and previous ubiquitous use and disposal has resulted in the continued presence in various environmental media (ATSDR, 2005). Carbon tetrachloride is listed as a Hazardous Air Pollutant (HAP) and is included in several multi-year monitoring programs, with data collected across the nation in both urban and rural locations (U.S. EPA, 2017a, 1996). For example, carbon tetrachloride is included in all three ambient air monitoring programs, collectively known as the National Monitoring Programs: National Air Toxics Trends Stations (NATTS) network, Community-Scale Air Toxics Ambient Monitoring (CSATAM) Program and Urban Air Toxics Monitoring Program (UATMP). NATTS sites are based on preliminary air toxics programs such as the 1996 National Air Toxics Assessment (NATA).

According to the 2015 National Air Toxics Inventory, ambient air monitoring trends from 2003 to 2013 have shown that of the eight hazardous air pollutants monitored, only carbon tetrachloride average concentrations have slightly increased in the atmosphere over the 10-year period. This is likely primarily due to its extremely long half-life in the troposphere (U.S. EPA, 2015a).

Carbon tetrachloride is specifically regulated under the Safe Drinking Water Act (SDWA). Therefore, under the National Primary Drinking Water Regulations, Carbon tetrachloride is designated as a volatile organic compound (VOC) contaminant and is monitored in drinking water (<u>U.S. EPA, 2009</u>).

The U.S. Geological Survey (USGS) monitors organic compounds in ground water and has detected carbon tetrachloride in community water systems (<u>USGS</u>, 2007). The U.S. EPA provides the public with storage and retrieval (STORET) data that maps monitoring sites and allows for download of sampling data of surface water monitoring sites. These data are searchable via the Water Quality Portal (WQP), a cooperative service sponsored by the USGS, the EPA and the National Water Quality Monitoring Council (NWQMC) (<u>NWQMC</u>, 2017). The portal contains data collected by over 400 state, federal, tribal and local agencies.

Biomonitoring data on carbon tetrachloride are collected in the National Health and Nutrition Examination Survey (NHANES) (<u>CDC, 2017</u>).

2.3.4 Environmental Exposures

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

2.3.5 Human Exposures

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

2.3.5.1 Occupational Exposures

EPA expects to consider worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2. In addition, EPA expects to consider exposure to occupational non-users, who do not directly handle the chemical but perform work in an area where the chemical is present. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment have on occupational exposure levels.

Workers and occupational non-users may be exposed to carbon tetrachloride when performing activities associated with the conditions of use described in Section 2.2, including, but not limited to:

- Unloading and transferring carbon tetrachloride to and from storage containers to process vessels.
- Using carbon tetrachloride in process equipment.
- Applying formulations and products containing carbon tetrachloride onto substrates (e.g., spray applying coatings or adhesives containing carbon tetrachloride).
- Cleaning and maintaining equipment.
- Sampling chemical, formulations or products containing carbon tetrachloride for quality control (QC).
- Repackaging chemical, formulations or products containing carbon tetrachloride.
- Handling, transporting and disposing waste containing carbon tetrachloride.
- Use of carbon tetrachloride in laboratories.
- Performing other work activities in or near areas where carbon tetrachloride is used.

Based on these activities, EPA expects to consider inhalation exposure to vapor and mists and dermal exposure, including skin contact with liquids and vapors for workers and occupational non-users. EPA also expects to consider potential worker exposure through mists that deposit in the upper respiratory tract and are swallowed.

The United States has several regulatory and non-regulatory exposure limits for carbon tetrachloride: including an OSHA Permissible Exposure Limit (PEL) of 10 ppm time-weighted average (TWA) and 25 ppm ceiling and a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL) of 2 ppm (12.6 mg/m³) 60-minute Short-term Exposure Limit (STEL). Also, NIOSH

indicates that carbon tetrachloride has an immediately dangerous to life and health (IDLH) value of 200 ppm based on acute inhalation toxicity data in humans, and provides a notation that carbon tetrachloride is considered a potential occupational carcinogen. The influence of these exposure limits on occupation exposures will be considered in the occupational exposure assessment.

Key data that inform occupational exposure assessment and which EPA expects to consider include: the OSHA Chemical Exposure Health Data (CEHD) and NIOSH Health Hazard Evaluation (HHE) program data. OSHA data are workplace monitoring data from OSHA inspections. The inspections can be random or targeted, or can be the result of a worker complaint. OSHA data can be obtained through the OSHA Integrated Management Information System (IMIS) at <u>https://www.osha.gov/oshstats/index.html</u>. Table Apx B-1 in Appendix B provides a summary of industry sectors with carbon tetrachloride personal monitoring air samples obtained from OSHA inspections conducted between 2013 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 <u>https://www.cdc.gov/niosh/hhe/</u>. During the problem formulation, EPA will review these data and evaluate their utility in the risk evaluation.

2.3.5.2 Consumer Exposures

Carbon tetrachloride can be found in consumer products and/or commercial products that are readily available for public purchase at common retailers [EPA-HQ-OPPT-2016-0733-0003, sections 3 and 4, (U.S. EPA, 2017c)], which can therefore result in exposures to consumers.

Exposures routes for consumers using carbon tetrachloride-containing products may include inhalation of vapors and aerosols (spray applications), dermal exposure to products. Although unlikely given the physical-chemical properties, EPA also expects to consider incidental ingestion due to eating and/or drinking during and immediately after product use.

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

2.3.5.3 General Population Exposures

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

Inhalation

The volatility of carbon tetrachloride makes inhalation exposures a likely exposure pathway when it is released (via air or as a result of waste disposal) during industrial, commercial or consumer uses (see Figure 2-4). Inhalation of carbon tetrachloride, due to its volatilization, during household use of contaminated water (e.g., during bathing/showering, dishwashing) could be a source of exposure to the general population.

Vapor intrusion is an additional source of exposure in indoor environments. VOCs such as carbon tetrachloride can migrate upwards toward the ground surface and into overlying buildings through gaps and cracks in foundation slabs or basement walls. This route from a subsurface source to the air inside a building is referred to as the vapor intrusion pathway (U.S. EPA, 2012a). Although unlikely

given the conditions of use, EPA expects to consider vapor intrusion as a pathway of exposure for the general population.

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

Oral

Oral ingestion pathways may include exposure to contaminated drinking water or breast milk. EPA also expects to consider ingestion via the oral route such as from incidental ingestion of carbon tetrachloride residue on the hand/body.

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

Dermal

Dermal exposure via water could occur through contact, such as washing and bathing with household water contaminated with carbon tetrachloride. The source of the contaminated water could either be contaminated surface or ground waters.

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

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

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

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

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

- Workers and occupational non-users.
- Consumers and bystanders associated with consumer use. Carbon tetrachloride has been identified as being used in products available to consumers; however, only some individuals within the general population may use these products. Therefore, those who do use these products are a potentially exposed or susceptible subpopulation due to greater exposure.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in

releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, use or disposal sites).

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

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

2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of carbon tetrachloride, as described in the *Strategy for Conducting Literature Searches for Carbon Tetrachloride: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0733). Based on initial screening, EPA expects to consider the hazards of carbon tetrachloride identified in this scope document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every hazard identified in the scope will be considered for every exposure scenario.

2.4.1 Environmental Hazards

For scoping purposes, EPA consulted the following sources of environmental hazard data for carbon tetrachloride: <u>ECHA (ECHA, 2017</u>) and <u>OECD SIDS Initial Assessment Profile (SIAP) (OECD, 2011)</u>. However, EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for carbon tetrachloride (*Carbon tetrachloride (CASRN 56-23-5) Bibliography: Supplemental File for the TSCA Scope Document*, <u>EPA-HQ-OPPT-2016-0733</u>).

EPA expects to consider the hazards of carbon tetrachloride to aquatic organisms including fish, aquatic invertebrates, aquatic plants, sediment invertebrates and amphibians exposed to relevant media under acute and chronic exposure conditions. In 2011, the OECD SIDS SIAP for carbon tetrachloride summarized acute toxicity to fish and aquatic invertebrates from carbon tetrachloride, based on mortality and immobilization, respectively. Chronic toxicity to aquatic invertebrates (growth and reproduction) was observed when exposed to carbon tetrachloride. Aquatic plant toxicity was observed, based on growth rate, when exposed to carbon tetrachloride. Embryo-larval mortality was observed in different species of amphibians when exposed acutely to carbon tetrachloride.

EPA expects to consider the hazards of carbon tetrachloride to terrestrial organisms including soil invertebrates and mammals exposed to relevant media under acute and chronic exposure conditions

(see Carbon tetrachloride (CASRN 56-23-5) Bibliography: Supplemental File for the TSCA Scope Document, <u>EPA-HQ-OPPT-2016-0733</u>).

2.4.2 Human Health Hazards

Carbon tetrachloride has an existing EPA IRIS Assessment (U.S. EPA, 2010) and an ATSDR Toxicological Profile (ATSDR, 2005); hence, many of the hazards of carbon tetrachloride have been previously compiled and systematically reviewed. EPA has relied heavily on these comprehensive reviews in preparing this scope. EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for carbon tetrachloride (*Carbon tetrachloride (CASRN 56-23-5) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0733). EPA expects to consider all potential hazards associated with carbon tetrachloride. Based on reasonably available information, the following are the hazards that have been identified in previous government documents and that EPA currently expects will likely be the focus of its analysis.

2.4.2.1 Non-Cancer Hazards

Acute Toxicity

Following acute exposures, human case reports identify liver as a primary target organ of toxicity and the kidney as an additional primary target organ of toxicity (U.S. EPA, 2010). Neurotoxicity indicated central nervous system (CNS) depression is another primary effect of carbon tetrachloride in humans following acute exposures, with examples of neurotoxic effects including drowsiness, headache, dizziness, weakness, coma and seizures (U.S. EPA, 2010). GI symptoms such as nausea and vomiting, diarrhea and abdominal pain are considered another initial acute effect.

Liver Toxicity

Liver toxicity has consistently been demonstrated following human and animal exposures to carbon tetrachloride (U.S. EPA, 2010). Suggestive evidence of an effect of occupational exposure on serum enzymes indicative of hepatic effects was reported in a cross-sectional epidemiology study. Similar to humans, data from acute, subchronic and chronic animal studies suggest that the liver is the major target organ for carbon tetrachloride toxicity (U.S. EPA, 2010).

Kidney Toxicity

Renal toxicity is generally delayed relative to hepatotoxicity and effects include oliguria, elevated blood urea nitrogen (BUN) and histopathological changes (e.g., nephrosis, degeneration and interstitial inflammation in fatal cases). In animals, renal toxicity was observed in inhalation (but not oral) studies. In subchronic studies, renal toxicity generally occurred at higher concentrations than those producing liver damage. In contrast, chronic exposures resulted in comparable sensitivity of the kidney and liver in rodents (U.S. EPA, 2010).

Irritation/Sensitization

Following dermal exposures, primary irritation was observed in rabbits and guinea pigs (<u>ATSDR, 2005</u>). Guinea pigs also exhibited degenerative change in epidermal cells and edema (<u>ATSDR, 2005</u>). In the murine local lymph node assay, carbon tetrachloride showed weak dermal sensitization potential (<u>OECD, 2011</u>).

2.4.2.2 Genotoxicity and Cancer Hazards

The IRIS Assessment for carbon tetrachloride evaluated data for genotoxicity and cancer hazard. Carbon tetrachloride has been extensively studied for its genotoxic and mutagenic effects. Overall, results are largely negative. There is little direct evidence that carbon tetrachloride induces intragenic or point mutations in mammalian systems. The mutagenicity studies that have been performed using transgenic mice have yielded negative results, as have the vast majority of the mutagenicity studies that have been conducted in bacterial systems. The weight of evidence suggests that carbon tetrachloride is more likely an indirect mutagenic agent (i.e., lipid peroxidation, protein modifications) rather than a direct mutagen (deoxyribonucleic acid [DNA] modifications) (<u>U.S. EPA, 2010</u>).

In the IRIS carcinogenicity assessment, carbon tetrachloride is considered "likely to be carcinogenic to humans" by all routes of exposure based on inadequate evidence of carcinogenicity in humans, and sufficient evidence in animals by oral and inhalation exposure. The animal evidence shows that carbon tetrachloride is a liver carcinogen in rats, mice and hamsters following oral and inhalation exposure in eight bioassays. Carbon tetrachloride also induced pheochromocytomas in mice exposed by the oral and inhalation routes of exposure.

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).

EPA's IRIS assessment identified the following as factors that might influence susceptibility to carbon tetrachloride: age (e.g., childhood, senescence), gender, nutritional status, disease status and exposure to other chemicals (U.S. EPA, 2010, 2006). The IRIS assessment noted that because metabolism of carbon tetrachloride to reactive metabolites by cytochrome P450 (CYP450) enzymes is hypothesized to be a key event in the toxicity of this compound, variability in CYP450 levels due to age-related differences or other factors such as exposure to other chemicals that either induce or inhibit microsomal enzymes may impact an individual's response to carbon tetrachloride. In addition, variability in nutritional status, alcohol consumption and/or underlying diseases (e.g., diabetes) may alter metabolism or antioxidant protection systems and thereby also alter susceptibility to carbon tetrachloride (U.S. EPA, 2010). EPA expects to consider these factors, and others that may be identified from more current literature, in the risk evaluation for carbon tetrachloride.

2.5 Initial Conceptual Models

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

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

Figure 2-2 presents the initial conceptual model for human receptors from industrial and commercial activities and uses of carbon tetrachloride. EPA expects that workers and occupational non-users may be exposed to carbon tetrachloride via inhalation and dermal routes. EPA expects to consider potential worker exposure through mists that deposit in the upper respiratory tract and are swallowed.



(See Figure 2-4)

Figure 2-2. Initial Carbon Tetrachloride 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 carbon tetrachloride.

^a Some products are used in both commercial and consumer applications. Additional uses of carbon tetrachloride are included in Table 2-3.

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

^c Includes possible vapor intrusion into industrial or commercial facility from carbon tetrachloride contaminated soil and/or ground water.

^d Exposure through mists that deposit in the upper respiratory tract and are swallowed.

^e Receptors include potentially exposed or susceptible subpopulations.

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

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

Figure 2-3 presents the initial conceptual model for human receptors from consumer uses of carbon tetrachloride. Similar to Figure 2-2, EPA expects that consumers and bystanders may be exposed via inhalation, dermal and oral routes, with inhalation of vapor and mist and dermal exposures being the most likely exposure routes. It should be noted that some consumers may purchase and use products primarily intended for commercial use. It also shows liquid and solid wastes containing carbon tetrachloride.



Figure 2-3. Initial Carbon Tetrachloride 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 carbon tetrachloride.

^a Some products are used in both commercial and consumer applications. Additional uses of carbon tetrachloride are included in Table 2-3.

^b EPA expects to consider potential exposure through mists that deposit in the upper respiratory tract and are swallowed. Although unlikely given the physical-chemical properties, EPA also expects to consider oral ingestion via oral route such as from incidental ingestion of carbon tetrachloride residue on the hand/body. ^c Receptors include potentially exposed or susceptible subpopulations.

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

As shown in Figure 2-4, EPA anticipates that general populations living near industrial and commercial facilities using carbon tetrachloride may be exposed via inhalation of outdoor air. In addition, aquatic and terrestrial life may be exposed to carbon tetrachloride-contaminated water, sediment and soil. Exposures to ecological species from releases of carbon tetrachloride to environmental media and disposal of wastes containing carbon tetrachloride are depicted in Figure 2-4.



Figure 2-4. Initial Carbon Tetrachloride 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 carbon tetrachloride.

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

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

- ^c Volatilization from or liquid contact with tap water in the home during showering, bathing, washing, etc. represents another potential in-home exposure pathway.
- ^d Presence of mist is not expected; dermal and oral exposure are negligible.

^e Receptors include potentially exposed or susceptible subpopulations.

2.6 Initial Analysis Plan

The initial analysis plan will be used to develop the eventual problem formulation and final analysis plan for the risk evaluation. While EPA has conducted a search for readily available data and information from public sources as described in Section 1.3, EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations.

The analysis plan outlined here is based on the conditions of use of carbon tetrachloride, as described in Section 2.2 of this scope. The analysis plan may be refined as EPA proceeds with the systematic review of the information in the *Carbon tetrachloride (CASRN 56-23-5) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0733). The analysis plan will be expanded if EPA identifies additional hazards, exposures, conditions of use or potentially exposed or susceptible subpopulations that are relevant to this risk evaluation. EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent.

2.6.1 Exposure

2.6.1.1 Environmental Releases

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

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

2.6.1.2 Environmental Fate

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

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

2.6.1.3 Environmental Exposures

EPA expects to consider the following in developing its environmental exposure assessment of carbon tetrachloride:

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

2.6.1.4 Occupational Exposures

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

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

2.6.1.5 Consumer Exposures

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

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

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

2.6.1.6 General Population

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

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

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

EPA will conduct an environmental hazard assessment of carbon tetrachloride as follows:

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

2.6.2.2 Human Health Hazards

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

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

2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in the *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 Risk Evaluation Framework Rule.

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APPENDICES

Appendix A REGULATORY HISTORY

A.1 Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations	·	·
TSCA - Section 6(b)	EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	Carbon tetrachloride 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.	Carbon tetrachloride manufacturing (including importing), processing and use information is reported under the CDR Rule (76 FR 50816, August 16, 2011).
TSCA - Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed, or imported in the United States.	Carbon tetrachloride was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5 (60 FR 16309, March 29, 1995).
TSCA - Section 8(d)	Provides EPA with authority to issue rules requiring producers, importers and (if specified) processors of a chemical substance or mixture to submit lists and/or copies of health and safety studies.	Two submissions received (1947- 1994) (U.S. EPA, ChemView. Accessed April 13, 2017).
TSCA - Section 8(e)	Manufacturers (including imports), 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.	Three submissions received (1992- 2010) (U.S. EPA, ChemView. Accessed April 13, 2017).
TSCA - Section 4	Provides EPA with authority to issue rules and orders requiring	Seven section 4 notifications received for carbon tetrachloride:

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation		
	manufacturers (including importers) and processors to test chemical substances and mixtures.	two acute aquatic toxicity studies, one bioaccumulation report and four monitoring reports (1978-1980) (U.S. EPA, ChemView. Accessed April 13, 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.	Carbon tetrachloride is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.		
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - Sections 3 and 6	FIFRA governs the sale, distribution and use of pesticides. Section 3 of FIFRA generally requires that pesticide products be registered by EPA prior to distribution or sale. Pesticides may only be registered if, among other things, they do not cause "unreasonable adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either (1) the pesticide, labeling, or other material does not comply with FIFRA; or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	Use of carbon tetrachloride as a grain fumigant was banned under FIFRA in 1986 (51 FR 41004, November 12, 1986).		
Federal Food, Drug, and Cosmetic Act (FFDCA) - Section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to set tolerances (rules that establish maximum allowable residue limits), or exemptions from the requirement of a tolerance, for all residues of a pesticide (including both active and inert ingredients) that are in or on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the tolerance or exemption is "safe." Sections 408(b) and (c) of the FFDCA define "safe" to mean the Agency has a	EPA removed carbon tetrachloride from its list of pesticide product inert ingredients used in pesticide products in 1998 (63 FR 34384, June 24, 1998).		

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	reasonable certainty that no harm will result from aggregate exposures to the pesticide residue, including all dietary exposure and all other exposure (e.g., non-occupational exposures) for which there is reliable information. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation. In the absence of a tolerance or an exemption from tolerance, a food containing a pesticide residue is considered adulterated and may not be distributed in interstate commerce.	
CAA - Section 112(b)	This section lists 189 HAPs that must be addressed by EPA and includes authority for EPA to add or delete pollutants. EPA may, by rule, add pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects.	Lists carbon tetrachloride as a HAP (70 FR 75047, December 19, 2005).
CAA - Section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of major sources and area sources of HAPs. The standards must require the maximum degree of emission reduction that 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 carbon tetrachloride, including: Rubber tire manufacturing (67 FR 45588, July 9, 2002) Chemical Manufacturing Area Sources (74 FR 56008, October 29, 2009) Use of carbon tetrachloride as a dilutent for NCl3 (59 FR 19402, April 22,1994), Halogenated solvent cleaning operations (59 FR 61801, December 2, 1994) Wood Furniture Manufacturing Operations (60 FR 62930, December 7,1995) Group 1 Polymers and Resins (61 FR 46906, September 5, 1996)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		Plywood and Composite Wood Products (69 FR 45944, July 30, 2004)
CAA - Section 604	Establishes a mandatory phase-out of ozone depleting substances.	The production and import of most Class I Ozone Depleting Substances (ODS), including carbon tetrachloride, was banned in 1996 (58 FR 65018, December 10, 1993). However, this ban does not apply to production and import of amounts that are transformed. 40 CFR 82.4. "Transform" is defined as "to use and entirely consume (except for trace quantities) a controlled substance in the manufacture of other chemicals for commercial purposes." 40 CFR 82.3.
CWA - Section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA published updated AWQC for carbon tetrachloride, including recommendations for "water + organism" and "organism only" human health criteria for states and authorized tribes to consider when adopting criteria into their water quality standards.
CWA – Sections 301(b), 304(b), 306, and 307(b)	Requires establishment of Effluent Limitations Guidelines and Standards for conventional, toxic, and non-conventional pollutants. For toxic and non-conventional 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.	
CWA - Section 307(a)	Establishes a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR 401.15. The "priority pollutants" specified by those families are listed in	Carbon tetrachloride is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such is subject to effluent limitations per section 1317 of the Clean Water Act.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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, see section 301(b), 304(b), 307(b), 306, or on a case-by-case best professional judgment basis in NPDES permits. CWA 402(a)(1)(B).	
SDWA - Section 1412	Requires EPA to publish a non- enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgment 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.	Carbon tetrachloride is subject to National Primary Drinking Water Regulations (NPDWR) under SDWA and EPA has set a MCLG of zero and an enforceable MCL of 0.005 mg/L (56 FR 3526 January 30, 1991).
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) - Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they	Carbon tetrachloride is a hazardous substance under CERCLA. Releases of carbon tetrachloride in excess of 10 pounds must be reported (40 CFR 302.4).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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.	Carbon tetrachloride is included on the list of hazardous wastes pursuant to RCRA 3001. Two categories of carbon tetrachloride wastes are considered hazardous: discarded commercial chemicals (U211) (40 CFR 261.31(a)), and spent degreasing solvent (F001) (40 CFR 261.33(f)) (45 FR 33084 May 19, 1980). RCRA solid waste that leaches
		0.5 mg/L or more carbon tetrachloride when tested using the TCLP leach test is RCRA hazardous (D019) under 40 CFR 261.24 (55 FR 11798 March 29, 1990).
		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 (40 CFR 261.4(a)(26)) (78 FR 46447, July 31, 2013).
Other Federal Regulations		
Federal Hazardous Substance Act (FHSA)	Requires precautionary labeling on the immediate container of hazardous household products and allows the Consumer Product Safety Commission (CPSC) to ban certain products that are so dangerous or the nature of the hazard is such that required labeling is not adequate to protect consumers.	Use of carbon tetrachloride in consumer products was banned in 1970 by the CPSC (16 CFR 1500.17).
FFDCA	Provides the U.S. Food and Drug Administration (FDA) with authority to	The FDA regulates carbon tetrachloride in bottled water. The maximum permissible level of

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	oversee the safety of food, drugs and cosmetics.	carbon tetrachloride in bottled water is 0.005 mg/L (21 CFR 165.110). All medical devices containing or manufactured with carbon tetrachloride must contain a warning statement that the compound may destroy ozone in the atmosphere (21 CFR 801.433). Carbon tetrachloride is also listed as an "Inactive Ingredient for approved Drug Products" by FDA (FDA Inactive Ingredient Database. Accessed April 13, 2017).
OSHA	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.	In 1970, OSHA issued occupational safety and health standards for carbon tetrachloride that included a PEL of 10 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1000).
	Under the Act, OSHA can issue occupational safety and health standards including such provisions as PELs, exposure monitoring, engineering and administrative control measures, and respiratory protection.	OSHA prohibits all workplaces from using portable fire extinguishers containing carbon tetrachloride (29 CFR 1910.157(c)(3)).
Atomic Energy Act	The Atomic Energy Act authorizes the Department of Energy to regulate the health and safety of its contractor employees.	10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for carbon tetrachloride is 5 ppm (8hr Time Weighted Average) and 10 ppm Short Term Exposure Limit (STEL).

A.2 State Laws and Regulations

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
State agencies of interest	
State permissible exposure limits	California PEL: 12.6 mg/L (Cal Code Regs. Title 8, section 5155), Hawaii PEL: 2 ppm (Hawaii Administrative Rules section 12-60-50).
State Right-to-Know Acts	Massachusetts (454 Code Mass. Regs. section 21.00), New Jersey (8:59 N.J. Admin. Code section 9.1), Pennsylvania (34 Pa. Code section 323).
State air regulations	Allowable Ambient Levels (AAL): Rhode Island (12 R.I. Code R. 031-022), New Hampshire (RSA 125-I:6, ENV- A Chap. 1400).
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).
Other	In California, carbon tetrachloride was added to the Proposition 65 list in 1987 (Cal. Code Regs. Title 27, section 27001). Carbon tetrachloride is on the MA Toxic Use Reduction Act (TURA) list of 1989 (301 Code Mass. Regs. section 41.03).

A.3 International Laws and Regulations

Table Apx A-3. Regulatory Actions by Other Governments and Tribes

Country/Organization	Requirements and Restrictions
Regulatory Actions by oth	er Governments and Tribes
Montreal Protocol	Carbon tetrachloride is considered an ODS and its production and use are controlled under the 1987 Montreal Protocol on Substances That Deplete the Ozone Layer and its amendments (Montreal Protocol Annex B – Group II).

Country/Organization	Requirements and Restrictions	
Canada	Carbon tetrachloride is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). Other regulations include: Federal Halocarbon Regulations, 2003 (SOR/2003-289). ODS Regulations, 1998 (SOR/99-7).	
European Union (EU)	Carbon tetrachloride was evaluated under the 2012 Community rolling action plan (CoRAP) under regulation (European Commission [EC]) No 1907/2006 - REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) ECHA database. Accessed April 18, 2017). Carbon tetrachloride is restricted by regulation (EC) No 2037/2000 on	
	substances that deplete the ozone layer.	
Australia	Carbon tetrachloride was assessed under Environment Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP), and there have been no reported imports of the chemical as a feedstock in the last 10 years (National Industrial Chemicals Notification and Assessment Scheme, NICNAS, 2017, <i>Environment Tier II Assessment for Methane,</i> <i>Tetrachloro</i> Accessed April, 18 2017).	
Japan	 Carbon tetrachloride is regulated in Japan under the following legislation: Industrial Safety and Health Act (ISHA) 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 Poisonous and Deleterious Substances Control Act Act on the Protection of the Ozone Layer through the Control of Specified Substances and Other Measures 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 13, 2017). 	
Australia, Austria, Belgium, Canada, Denmark, EU, Finland, France, Germany, Ireland, Israel, Japan, Latvia, New Zealand, People's Republic of China, Poland, Singapore, South	Occupational exposure limits (OELs) for carbon tetrachloride. (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2017).	

Country/Organization	Requirements and Restrictions
Korea, Spain, Sweden, Switzerland, United Kingdom	
Basel Convention	Halogenated organic solvents (Y41) are listed as a category of waste under the Basel Convention-Annex I. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporter.
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.

Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for carbon tetrachloride.

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 for consideration.

B.1.1 Manufacture (Including Import)

B.1.1.1 Domestic Manufacture

Carbon tetrachloride was previously produced solely through the chlorination of carbon disulfide (CS₂); however, in the 1950s chlorination of hydrocarbons became popular (<u>Holbrook, 2000</u>). Currently, most Carbon tetrachloride is manufactured using one of three methods: chlorination of hydrocarbons or chlorinated hydrocarbons; oxychlorination of hydrocarbons; or CS₂ chlorination (<u>Holbrook, 2000</u>).

- Chlorination of hydrocarbons or chlorinated hydrocarbons The chlorination of hydrocarbons involves a simultaneous breakdown of the organics and chlorination of the molecular fragments at pyrolytic temperatures and is often referred to as chlorinolysis) (Holbrook, 2000). A variety of hydrocarbons and chlorinated hydrocarbon waste streams can be used as feedstocks; however, methane is the most common (Holbrook, 2000). PCE is formed as a major byproduct of this process with small volumes of hexachloroethane, hexachlorobutadiene and hexachlorobenzene also produced (Holbrook, 2000).
- **Oxychlorination of hydrocarbons** The oxychlorination of hydrocarbons involves the reaction of either chlorine or hydrochloric acid (HCl) and oxygen with a hydrocarbon feedstock in the presence of a catalyst (<u>Marshall and Pottenger, 2016</u>; <u>Holbrook, 2000</u>). This process can be

utilized to convert HCl produced as a byproduct during the manufacture of chlorinated hydrocarbons into useful products (<u>Marshall and Pottenger, 2016</u>).

• **CS₂ Chlorination** - The chlorination of CS₂ involves the continuous reaction of CS₂ with chlorine in an annular reaction (Holbrook, 2000). The carbon tetrachloride produced is distilled to have a CS₂ content of 0 to 5 ppm. This process produces disulfur dichloride as a byproduct that is reduced with hydrogen without a catalyst or with a ferric chloride catalyst (Holbrook, 2000).

Based on EPA's knowledge of the chemical industry, worker activities at manufacturing facilities may involve manually adding raw materials or connecting/disconnecting transfer lines used to unload containers into storage or reaction vessels, rinsing/cleaning containers and/or process equipment, collecting and analyzing QC samples, manually loading carbon tetrachloride product or connecting/disconnecting transfer lines used to load carbon tetrachloride product into containers.

B.1.1.2 Import

EPA has identified activities related to the import of carbon tetrachloride through comments submitted in public docket <u>EPA-HQ-OPPT-2016-0733</u>. Based on EPA's knowledge of the chemical industry, imported chemicals are often stored in warehouses prior to distribution for further processing and use. In some cases, the chemicals may be repackaged into differently sized containers, depending on customer demand, and QC samples may be taken for analyses.

B.1.2 Processing and Distribution

B.1.2.1 Reactant or Intermediate

Processing as a reactant or intermediate is the use of carbon tetrachloride as a feedstock in the production of another chemical product via a chemical reaction in which carbon tetrachloride is consumed to form the product. In the past, carbon tetrachloride was mainly used as feedstock for the manufacture chlorofluorocarbons (CFCs) (<u>Marshall and Pottenger, 2016</u>). However, due to the discovery that CFCs contribute to stratospheric ozone depletion, the use of CFCs was phased-out by the year 2000 to comply with the Montreal Protocol (<u>Holbrook, 2000</u>).

Currently, carbon tetrachloride is used as a feedstock to produce a variety of products including HCFCs, HFCs, HFOs, vinyl chloride, ethylene dichloride (EDC), PCE, chloroform, hafnium tetrachloride, thiophosgene and methylene chloride (EPA-HQ-OPPT-2016-0733-0003) (U.S. EPA, 2017c; Marshall and Pottenger, 2016; Weil et al., 2006; Holbrook, 2003a, b). The specifics of the reaction process (e.g., use and types of catalysts, temperature conditions, etc.) will vary depending on the product being produced; however, a typical reaction process would involve unloading carbon tetrachloride from containers and feeding into the reaction vessel(s), where carbon tetrachloride would either fully or partially react with other raw materials to form the final product. Following the reaction, the product may or may not be purified to remove unreacted carbon tetrachloride (if any exists). Reacted carbon tetrachloride is assumed to be destroyed and thus not expected to be released or cause potential worker exposure.

EPA has not identified specific worker activities related to the processing of carbon tetrachloride as a reactant or intermediate at this time. However, based on EPA's knowledge of the chemical industry, worker activities are expected to be similar to that at manufacturing facilities including unloading and loading activities, rinsing/cleaning activities and collecting and analyzing QC samples.

B.1.2.2 Incorporation into a Formulation, Mixture or Reaction Products

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 carbon tetrachloride that may require incorporation into a formulation include adhesives, sealants, paints, coatings, additives and asphalt. Carbon tetrachloride specific formulation processes were not identified; however, several ESDs published by OECD and Generic Scenarios published by EPA have been identified that provide general process descriptions for these types of products.

The formulation of paints and coatings typically involves dispersion, milling, finishing and filling into final packages (<u>OECD</u>, 2009b). Adhesive formulation involves mixing together volatile and non-volatile chemical components in sealed, unsealed or heated processes (<u>OECD</u>, 2009a). Sealed processes are most common for adhesive formulation because many adhesives are designed to set or react when exposed to ambient conditions (<u>OECD</u>, 2009a).

Process descriptions for formulation of sealants, additives and asphalt were not identified at this time. However, the processes are expected to be similar to those described above and typically involve unloading formulation components from transport containers, either directly into the mixing equipment or into an intermediate storage vessel, mixing of components either a batch or continuous system, QC sampling and final packaging of the formulation in to containers. Depending on the product, formulation products may be filtered prior to packaging. Transfer from transport containers into storage or mixing vessels may be manual or automated, through the use of a pumping system. If automated, an automated dispenser may be used to feed the components into the mixing vessel to ensure that precise amounts are added at the proper time during the mixing process. Final packaging occurs either through manual dispensing from transfer lines or through utilization of an automatic system.

There is significant overlap in worker activities across the various formulation processes. The activities are expected to be similar to manufacturing activities and include unloading and loading activities, rinsing/cleaning activities and collecting and analyzing QC samples (<u>OECD, 2009a</u>, <u>b</u>).

B.1.2.3 Incorporation into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) that is distributed for industrial, trade or consumer use. Exact process operations involved in the incorporation of carbon tetrachloride are dependent on the article. EPA will further investigate the potential use of carbon tetrachloride in this type of process during the risk evaluation.

B.1.2.4 Repackaging

Typically, 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. Based on EPA's knowledge of the chemical industry, worker activities at repackaging sites may involve manually unloading carbon tetrachloride from bulk containers into the smaller containers for distribution or connecting/disconnecting transfer lines used to transfer carbon tetrachloride product between containers and analyzing QC samples. EPA will further investigate the potential use of carbon tetrachloride in this type of process during the risk evaluation.

B.1.2.5 Recycling

TRI data from 2015 indicate that some sites ship carbon tetrachloride 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). Worker activities are expected to be unloading of waste solvents and loading of reclaimed solvents. Figure_Apx B-1 illustrates a typical solvent recovery process flow diagram (U.S. EPA, 1980).



Figure_Apx B-1. General Process Flow Diagram for Solvent Recovery Processes

Source: U.S. EPA (1980)

B.1.3 Uses

In this document, EPA has grouped uses based on CDR categories and identified examples within these categories as subcategories of use. 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 Petrochemical Manufacturing

EPA has identified uses of carbon tetrachloride as a processing aid and in catalyst regeneration at petrochemical manufacturing facilities [EPA-HQ-OPPT-2016-0733-0003 (U.S. EPA, 2017c)]. EPA has also identified a patent which indicates a potential use of carbon tetrachloride as a fuel additive.

B.1.3.2 Agricultural Products Manufacturing

EPA has identified uses of carbon tetrachloride in the manufacturing of fertilizers and other agricultural products [EPA-HQ-OPPT-2016-0733-0003 (U.S. EPA, 2017c)].

B.1.3.3 Solvents for Cleaning and Degreasing

Carbon tetrachloride has been identified in a variety of cleaning products including brake cleaners, machinery cleaning products and textile cleaning products [EPA-HQ-OPPT-2016-0733-0003 (U.S. EPA, 2017c)]. Due to the Montreal Protocol and Title VI of the CAA Amendments, use of carbon tetrachloride in these types of products has been phased-out. Because most of the products identified by EPA in the *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Carbon Tetrachloride* [EPA-HQ-OPPT-2016-0733-0003 (U.S. EPA, 2017c)] contain less than 1% by weight carbon tetrachloride and CAA regulations, EPA expects carbon tetrachloride is only present in these products as an impurity rather than serving a specific function.

Brake Cleaning

Brake cleaners are typically aerosol degreasing products in which an aerosolized solvent spray, typically applied from a pressurized can, is used to remove residual contaminants from fabricated parts. General aerosol degreasing processes, including brake cleaning, have been previously described in EPA's 1-BP Draft Risk Assessment (U.S. EPA, 2016c). Brake cleaning products may also be purchased and used by consumers.

Textile Cleaning

Textile cleaning typically refers to the use as a solvent in dry cleaning machines or in products used to spot clean garments. 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>EPA's 1-BP Draft Risk Assessment (U.S. EPA, 2016c</u>).

Machinery Cleaning

Machinery cleaning could fall under a variety of degreasing operations that are used to remove dirt, grease and surface contaminants from the substrate. Degreasing operations can involve batch processes, continuous processes or aerosol degreasing (similar to that of brake cleaning); actual operation can include vapor-phase and/or liquid-phase degreasing (e.g. cold cleaning) <u>EPA's 1-BP Draft</u> <u>Risk Assessment (U.S. EPA, 2016c)</u>.

B.1.3.4 Adhesive and Sealants

Carbon tetrachloride has been identified as a component in several adhesive and sealant products and in asphalt [EPA-HQ-OPPT-2016-0733-0003 (U.S. EPA, 2017c)]. Similar to cleaning and degreasing solvents, the use of carbon tetrachloride in these products was phased-out and most of the products identified by EPA contain less than 1% by weight carbon tetrachloride. Therefore, EPA expects carbon tetrachloride is only present in these formulations as an impurity rather than serving a specific function (EPA-HQ-OPPT-2016-0733).

The OECD ESD for Use of Adhesives provides general process descriptions and worker activities for industrial uses of adhesives. In industrial processes, liquid adhesives are unloaded from containers into the coating reservoir, applied to a flat or three-dimensional substrate and the substrates are then joined and allowed to cure (OECD, 2013). The majority of adhesive applications include spray, roll, curtain, syringe or bead application (OECD, 2013). For solvent-based adhesives, the volatile solvent evaporates during the curing stage (OECD, 2013). Worker activities include unloading activities, container and equipment cleaning activities, and manual applications of adhesive (OECD, 2013). EPA did not identify any process information for use in sealants or asphalt. EPA will gather additional information in expanded literature searches in subsequent phases of the risk evaluation process. Note: Based on EPA's knowledge of the industry, EPA expects an overlap in process descriptions, worker activities and application methods for use of sealant products.

EPA has also identified several sealant and adhesive products that contain carbon tetrachloride that could be purchased for commercial uses or purchased online by consumers [EPA-HQ-OPPT-2016-0733-0003 (U.S. EPA, 2017c)]. Based on EPA's knowledge of the industry, the likely application methods for commercial and consumer uses include spray, brush, syringe, eyedropper, roller and bead applications.

B.1.3.5 Paints and Coatings

Carbon tetrachloride has been identified as a component in paint and coating products such as swimming pool paints and traffic paints [EPA-HQ-OPPT-2016-0733-0003 (U.S. EPA, 2017c)]. Similar to cleaning and degreasing solvents, the use of carbon tetrachloride in these products was phased-out and most of the products identified by EPA contain less than 1% by weight carbon tetrachloride. Therefore, EPA expects carbon tetrachloride is only present in these formulations as an impurity rather than serving a specific function.

Several OECD ESDs and EPA generic scenarios provide general process descriptions and worker activities for industrial and commercial uses od paints and coatings. Typical 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, 2009a, b). Worker activities are expected to include unloading activities, container and equipment cleaning activities, and manual applications of coatings.

B.1.3.6 Laboratory Chemicals

Carbon tetrachloride is used in laboratories as a chemical reagent, extraction solvent and a reference material or solvent in analytical procedures, such as spectroscopic measurements [EPA-HQ-OPPT-2016-0733-0003 (U.S. EPA, 2017c)].

B.1.3.7 Other Uses

Carbon tetrachloride may also be used in a variety of other uses including reactive ion etching (RIE), laboratory chemicals, processing aid and metal recovery. RIE involves ion bombardment to achieve directional etching and a reactive gas, such as carbon tetrachloride, to selectively maintain etched layers [EPA-HQ-OPPT-2016-0733-0003 (U.S. EPA, 2017c)].

B.1.4 Disposal

Table 2-5 and Table 2-6 present the production-related waste managed data for carbon tetrachloride reported to the TRI program for 2015. Waste containing carbon tetrachloride is classified as hazardous waste (see Table_Apx A-1). Facilities generating waste containing carbon tetrachloride must comply with EPA regulations for treatment, storage, and disposal.

B.2 Occupational Exposure Data

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

Table_Apx B-1 summarizes OSHA CEHD data by all of the North American Industry Classification Systems (NAICS) codes.

NAICS North American Industrial Classification System	NAICS Description
322121	Paper (except newsprint) mills
331512	Steel investment foundries
332439	Other metal container manufacturing
336111	Automobile manufacturing
926150	Regulation, licensing and inspection of miscellaneous commercial sectors

Table_Apx B-1. Summary of Industry Sectors with Carbon Tetrachloride Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2013 and 2016