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Draft Scope of the Risk Evaluation for Formaldehyde

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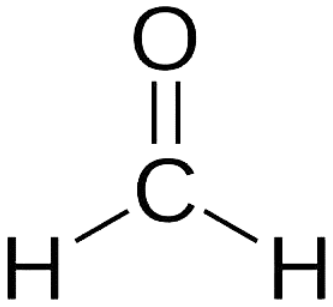

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Docket
Supporting information can be found in public docket: EPA-HQ-OPPT-2018-0438.

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 United States Government.

ABBREVIATIONS AND ACRONYMS

°C	Degrees Celsius
µg	Microgram(s)
µg/L	Micrograms per Liter
AAL	Acceptable or Allowable Ambient Levels
ACC	American Chemistry Council
ACGIH	American Conference of Governmental Industrial Hygienists
ADME	Absorption, distribution, metabolism, and excretion
AEGL	Acute Exposure Guideline Level
AERMOD	AMS (American Meteorological Society)/EPA Regulatory Model
Apx	Appendix
AQS	Air Quality System
atm	atmosphere(s)
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	Ambient Water Quality Criteria
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BSER	Best System of Emission Reduction
BW	Body weight
$BW^{3/4}$	Body weight scaling to the 3/4 power
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL	Contaminant Candidate List
CDC	Centers for Disease Control
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEM	Consumer Exposure Model
CEPA	Canadian Environmental Protection Act
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
ChemSTEER	Chemical Screening Tool for Exposure and Environmental Releases
CHIRP	Chemical Risk Information Platform
CI	Confidence interval
cm^3	Cubic Centimeter(s)
COC	Concentration of Concern
CoRAP	Community Rolling Action Plan
COU	Conditions of Use
CPCat	Chemical and Product Categories
CPSC	Consumer Product Safety Commission
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DMR	Discharge Monitoring Report
DOE	Department of Energy
DOT	Department of Transportation
EC	European Commission
EC	Engineering Control

ECHA	European Chemicals Agency
E-FAST	Exposure and Fate Assessment Screening Tool
EHC	Environmental Health Criteria
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
EPI Suite™	Estimation Program Interface Suite™
ESD	Emission Scenario Document
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
FHSA	Federal Hazardous Substance Act
FIAM	Formaldehyde Indoor Air Model
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register
FYI	For Your Information
g	Gram(s)
g/cm^3	Grams per cubic centimeters
g/mol	Grams per Unit-Molar Mass
GACT	Generally Available Control Technology
GS	Generic Scenario
HAP	Hazardous Air Pollutant
HE	High-end
HERO	Health and Environmental Research Online
HHE	Health Hazard Evaluation
HMTA	Hazardous Materials Transportation Act
HSDB	Hazardous Substances Data Bank
IA	Indoor air
IARC	International Agency for Research on Cancer
IDLH	Immediately Dangerous to Life and Health
IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones
IPCS	International Programme on Chemical Safety
IRIS	Integrated Risk Information System
ISHA	Industrial Safety and Health Act
kg	Kilogram(s)
km	Kilometer(s)
K_{oa}	Octanol:Air Partition Coefficient
K_{oc}	Organic Carbon:Water Partition Coefficient
K_{ow}	Octanol:Water Partition Coefficient
L	Liter(s)
lb	Pound
LC50	Lethal Concentration of 50% test organisms
LD50	Lethal Dose at which 50% of test organisms die
LEV	Local exhaust ventilation
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
Log K_{oc}	Logarithmic Organic Carbon:Water Partition Coefficient

Log K_{ow}	Logarithmic Octanol:Water Partition
m	Meter(s)
m^2	Square meter(s)
m^3	Cubic Meter(s)MA Model-averaging
MACT	Maximum Achievable Control Technology
MCCEM	Multi-Chamber Concentration and Exposure Model
MFG	Manufacture
mg	Milligram(s)
mg/kg-bw	Milligram(s) per kilogram body weight
mg/L	Milligram(s) per Liter
mg/m^3	Milligram(s) per cubic meter
mg/mL	Milligram(s) per milliliter
min	Minute(s)
MOA	Mode of Action
MP	Melting Point
MSDS	Material Safety Data Sheet
MSW	Municipal Solid Waste
MSWLF	Municipal Solid Waste Landfill(s)
MW	Molecular weight
N/A	Not Applicable
NAAQS	National Ambient Air Quality Standards
NAICS	North American Industry Classification System
ND	Non-detect (value is < analytical detection limit)
NEI	National Emissions Inventory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NHANES	National Health and Nutrition Examination Survey
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIH	National Institute of Health
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NPL	National Priorities List
NPRI	National Pollutant Release Inventory
NSPS	New Source Performance Standards
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEHHA	Office of Environmental Health Hazard Assessment
OEL	Occupational Exposure Limit
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
OW	Office of Water
P	Persistence
PBPK	Physiologically Based Pharmacokinetic

PBPK/PD	Physiologically-based pharmacokinetic / pharmacodynamic
PBT	Persistent, Bioaccumulative, Toxic
PECO	Population, Exposure, Comparator and Outcome
PEL	Permissible Exposure Limit
PESS	Potentially Exposed or Susceptible Subpopulation
PF	Phenol-formaldehyde
POD	Point of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
ppm	Part(s) per million
PV	Production Volume
PWS	Public Water System
QA	Quality Assurance
QC	Quality Control
RAD	Risk Assessment Division
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
RegDet	Regulatory Determination
REL	Recommended Exposure Limit
SD	Standard deviation
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SIDS	Screening Information Dataset
STEL	Short-term Exposure Limit
STORET	STORage and RETrieval
TCCR	Transparent, Clear, Consistent and Reasonable
TCLP	Toxicity Characteristic Leaching Procedure
TIAB	Title and Abstract
TLV	Threshold Limit Value
TMF	Technical, Managerial, Financial
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TURI	Toxics Use Reduction Institute (Massachusetts)
TWA	Time-weighted average
U.S.	United States
U.S.C.	United States Code
UIC	Underground Injection Control
UNEP	United Nations Environment Programme
U.S. EPA	United States Environmental Protection Agency
USGS	United States Geological Survey
VOC	Volatile Organic Compound
VP	Vapor Pressure
WHO	World Health Organization
WQP	Water Quality Portal
WQX	Water Quality Exchange

EXECUTIVE SUMMARY

In December 2019, EPA designated formaldehyde (CASRN 50-00-0) as a high-priority substance for risk evaluation following the prioritization process as required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR 702) (Docket ID: EPA-HQ-OPPT-2018-0438). The first step of the risk evaluation process is the development of the scope document and this document fulfills the TSCA regulatory requirement to issue a draft scope document as required in 40 CFR 702.41(c)(7). This draft scope for formaldehyde includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA plans to consider in this risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

General Information: Formaldehyde is a highly water-soluble (4.0×10^5 mg/L) gas with a vapor pressure of 3,886 mm Hg.

Reasonably Available Information. EPA leveraged the data and information sources already described in the document supporting the High-Priority Substance designation for formaldehyde to inform the development of this draft scope. To further develop this draft scope, EPA conducted a comprehensive search to identify and screen multiple evidence streams (i.e., chemistry, fate, release and engineering, exposure, and hazard) and the search and screening results are provided in Section 2.1. Searches were conducted for formaldehyde. Screening of literature from publicly available databases is currently in progress; detailed information will be provided in Section 2.1.2 once screening has concluded. EPA is seeking public comment on this draft scope document and will consider additional information identified following publication of this draft scope document, as appropriate, in developing the final scope document. EPA is using the systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a) to guide the process of searching for and screening reasonably available information, including information already in EPA's possession, for use and inclusion in the risk evaluation. EPA is applying these systematic review methods to collect reasonably available information regarding hazards, exposures, PESS, and conditions of use that will help inform the risk evaluation for formaldehyde.

Conditions of Use. EPA plans to evaluate manufacturing, including importing; processing; distribution in commerce; industrial, commercial, and consumer uses; and disposal of formaldehyde in risk evaluation. Formaldehyde is used in several processing activities, including use as a reactant, incorporation into articles, and incorporation into a formulation, mixture, or reaction product-for various industrial, commercial, and consumer applications. Formaldehyde is widely used in industrial, commercial, and consumer applications such as textiles, foam bedding/seating, semiconductors, resins, glues, composite wood products, paints, coatings, plastics, rubber, resins, construction materials (including insulation and roofing), furniture, toys, and various adhesives and sealants. EPA identified these conditions of use from information reported to EPA through CDR and TRI reporting, published literature, and consultation with stakeholders both for uses currently in production and uses whose production may have ceased. In addition, EPA plans to analyze distribution in commerce and disposal as part of the risk evaluation. Section 2.2 provides details about the conditions of use within the scope of the risk evaluation.

Conceptual Model. The conceptual model for formaldehyde is presented and discussed in Section 2.6. Conceptual models are graphical depictions of the actual or predicted relationships of conditions of use, exposure pathways (media), exposure routes (e.g., inhalation, dermal, oral), hazards and receptors throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, to release or disposal. EPA plans to focus the risk evaluation for formaldehyde on the following exposures, hazards and receptors, however, EPA also plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.

- *Exposures (Pathways and Routes), Receptors and PESS:* EPA plans to analyze both human and environmental exposures resulting from the conditions of use to formaldehyde that EPA plans to consider in the risk evaluation. Exposures to formaldehyde are discussed in Section 2.3. Additional information gathered through systematic review searches will also inform expected exposures.

  EPA's plan as to evaluate environmental exposure pathways in the draft scope document considers whether and how other EPA-administered statutes and regulatory programs address the presence of formaldehyde in media pathways falling under the jurisdiction of those authorities. Section 2.6.3 discusses those pathways that may be addressed pursuant to other Federal laws. In Section 2.6.4, EPA presents the conceptual model describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of formaldehyde within the scope of the risk evaluation.

  Preliminarily, EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.
  - *Occupational exposures associated with industrial and commercial conditions of use:* EPA plans to evaluate exposures to workers and/or occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of formaldehyde (Section 2.3.5).
  - *Consumer and bystander exposures associated with consumer conditions of use:* EPA plans to evaluate consumer exposure via inhalation and dermal routes (Section 2.3.6). EPA plans to evaluate inhalation routes of exposure for the consumer user and consumer bystander. EPA plans to evaluate dermal routes of exposure for only consumer users (bystanders are not expected to have dermal exposure) via direct dermal contact and vapor to skin contact. Additionally, dermal exposure will only be evaluated for select conditions of use where there is a constant supply of product against the skin and evaporation of product during use is inhibited due to a barrier (rag) or if there is immersion of a body part into a pool of material.
  - *General population exposures:* EPA plans to evaluate general population exposure to formaldehyde via the inhalation route for co-located and co-residing individuals due to off-gassing from building materials used or installed in a residential setting. ,(Section 2.3.7).

  - *Receptors and PESS:* EPA plans to include children, women of reproductive age (e.g., pregnant women), workers and consumers as receptors and PESS in the risk evaluation.
  - *Environmental exposures:* EPA plans to evaluate exposure to formaldehyde for aquatic and terrestrial receptors.

- *Hazards:* Hazards for formaldehyde are discussed in Section 2.4. EPA completed preliminary reviews of information from peer-reviewed assessments and databases to identify potential environmental and human health hazards for formaldehyde as part of the prioritization process. EPA identified environmental hazard information during the prioritization process and information collected through systematic review methods and public comments may identify additional environmental hazards that warrant the inclusion of the environmental hazard assessment in the risk evaluation. Environmental hazard effects were identified for aquatic and terrestrial organisms.

  EPA plans to identify and evaluate the environmental, epidemiological and toxicological literature for formaldehyde using EPA's systematic review process. Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-response assessment. EPA plans to evaluate all the potential human health hazards for formaldehyde identified during prioritization. The broad health effect categories include irritation/corrosion of the skin, dermal and respiratory sensitization, reproductive/developmental toxicity and carcinogenicity in experimental animal studies.

Analysis Plan. The analysis plan for formaldehyde is presented in Section 2.7. The analysis plan outlines the general science approaches that EPA plans to use for the various evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of formaldehyde to date which includes a partial, but ongoing, review of identified information submitted as described in Section 2.1. EPA plans to continue to consider new information submitted by the public. EPA may update its analysis plan in the final scope document if additional data or approaches become reasonably available.

EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for formaldehyde, including the methods for assessing the quality of data and information and the approach for evidence synthesis and evidence integration supporting the exposure and hazard assessments. The details will be provided in a supplemental document that EPA anticipates releasing for public comment prior to the finalization of the scope document.

Peer Review. The draft risk evaluation for formaldehyde will be peer reviewed. Peer review will be conducted in accordance with relevant and applicable methods for chemical risk evaluations using EPA's Peer Review Handbook and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45).

1 INTRODUCTION

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

TSCA § 6(b) and 40 CFR Part 702, Subpart A require the Environmental Protection Agency (EPA) to designate chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at the time, and upon designating a chemical substance as a high-priority substance, initiate a risk evaluation on the substance. TSCA § 6(b)(4) directs EPA, in conducting risk evaluations for existing chemicals, 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 PESS identified as relevant to the risk evaluation by the Administrator, under the conditions of use."

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and PESS that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high priority substances for risk evaluations (84 FR 71924), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. Formaldehyde is one of the chemicals designated as a high priority substance for risk evaluation.

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information[1] to support the development of this draft scope document for formaldehyde. EPA leveraged the data and information sources already identified in the document supporting the high-priority substance designation. In addition, EPA searched for additional data and information on physical and chemical properties, environmental fate, engineering, exposure, and environmental and human health hazards that could be obtained from the following general categories of sources:

1. Databases containing publicly available, peer-reviewed literature;
2. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases.
3. Data and information submitted under TSCA Sections 4, 5, 8(e), and 8(d), as well as “for your information” (FYI) submissions.

Following the comprehensive search, EPA performed a title and abstract screening to identify information potentially relevant for the risk evaluation process. This step also classified the references

[1] *Reasonably available information* means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA Section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA Section 14 (40 CFR 702.33).

into useful categories or tags to facilitate the sorting of information through the systematic review process. The search and screening process were conducted based on EPA's general expectations for the planning, execution and assessment activities outlined in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). EPA plans to publish supplemental documentation on the systematic review methods supporting the formaldehyde risk evaluation to explain the literature and screening process presented in this document in the form of literature inventory trees. Please note that EPA focuses on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the TSCA scope document, whereas the data evaluation and integration stages will occur during the development of the draft risk evaluation and thus are not part of the scoping activities described in this document.

The subsequent sections summarize the data collection activities completed up to date for the general categories of sources and topic areas (or disciplines) using systematic review methods. EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for formaldehyde upon publication of the supplemental documentation of those methods.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 262 search results relevant to EPA's risk assessment needs for formaldehyde. Appendix A lists the gray literature sources that yielded 262 discrete data or information sources relevant to formaldehyde. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, environmental hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

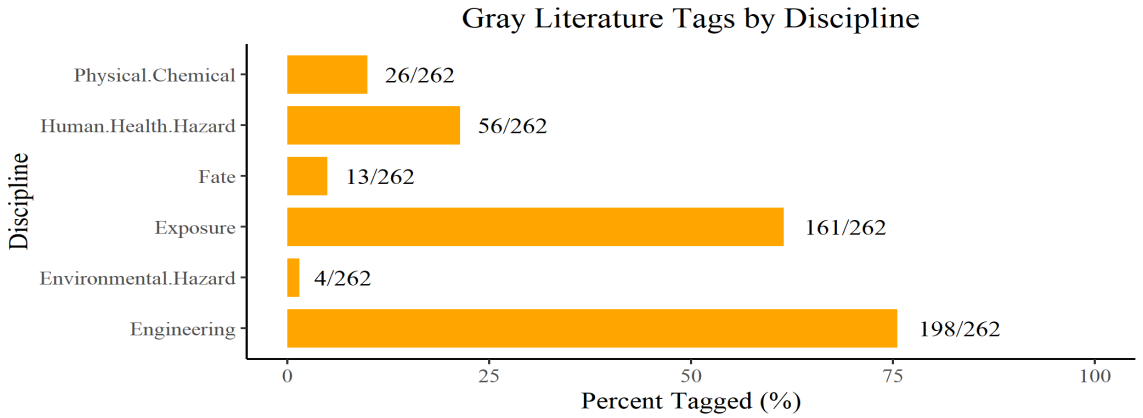

Figure 2-1 Gray Literature Tags by Discipline for Formaldehyde
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

2.1.2 Search of Literature from Publicly Available Databases (Peer-reviewed Literature)

EPA is currently conducting a systematic review of the reasonably available literature. This includes performing a comprehensive search of the reasonably available peer review literature on physical-

[2] Gray literature is defined as the broad category of data/information sources not found in standard, peer reviewed literature or databases (e.g., PubMed and Web of Science). Gray literature includes data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites, and other databases.

chemical (p-chem) properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of formaldehyde. Eligibility criteria were applied in the form of PECO (population, exposure, comparator, outcome) statements. Included references will meet the PECO criteria, whereas excluded references will not meet the criteria (i.e., not relevant), and supplemental material will be considered as potentially relevant. EPA plans to analyze the reasonably available information identified for each discipline during the development of the risk evaluation. EPA is in the process of screening the identified literature for the different disciplines; the search results are not yet ready for review. The literature inventory trees depicting the number of references that were captured and those that were included, excluded, or tagged as supplemental material during the screening process for each discipline area will be shown in Figure 2-2 through Figure 2-6. "TIAB" in these figures refers to "title and abstract screening". Note that the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-categories may be smaller than the main category because some studies may not be depicted in the sub-categories if their relevance to the risk evaluation was unclear.

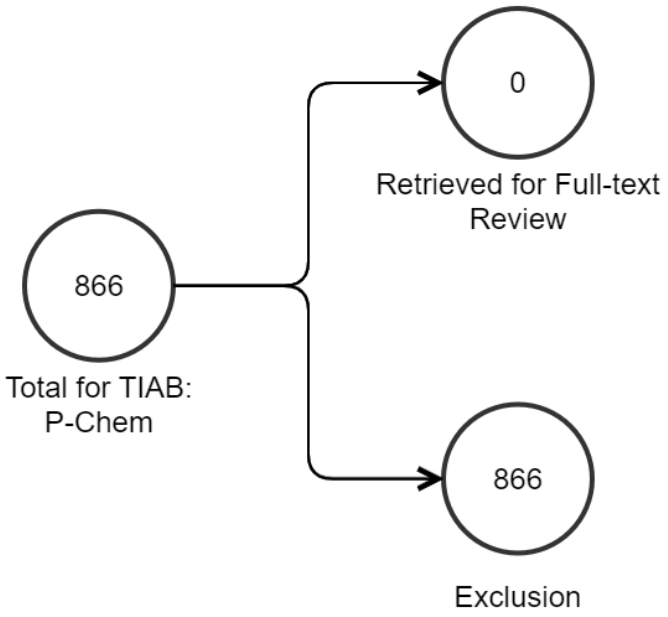

Figure 2-2 Peer-Reviewed Literature - Physical-Chemical Properties Search Results for Formaldehyde

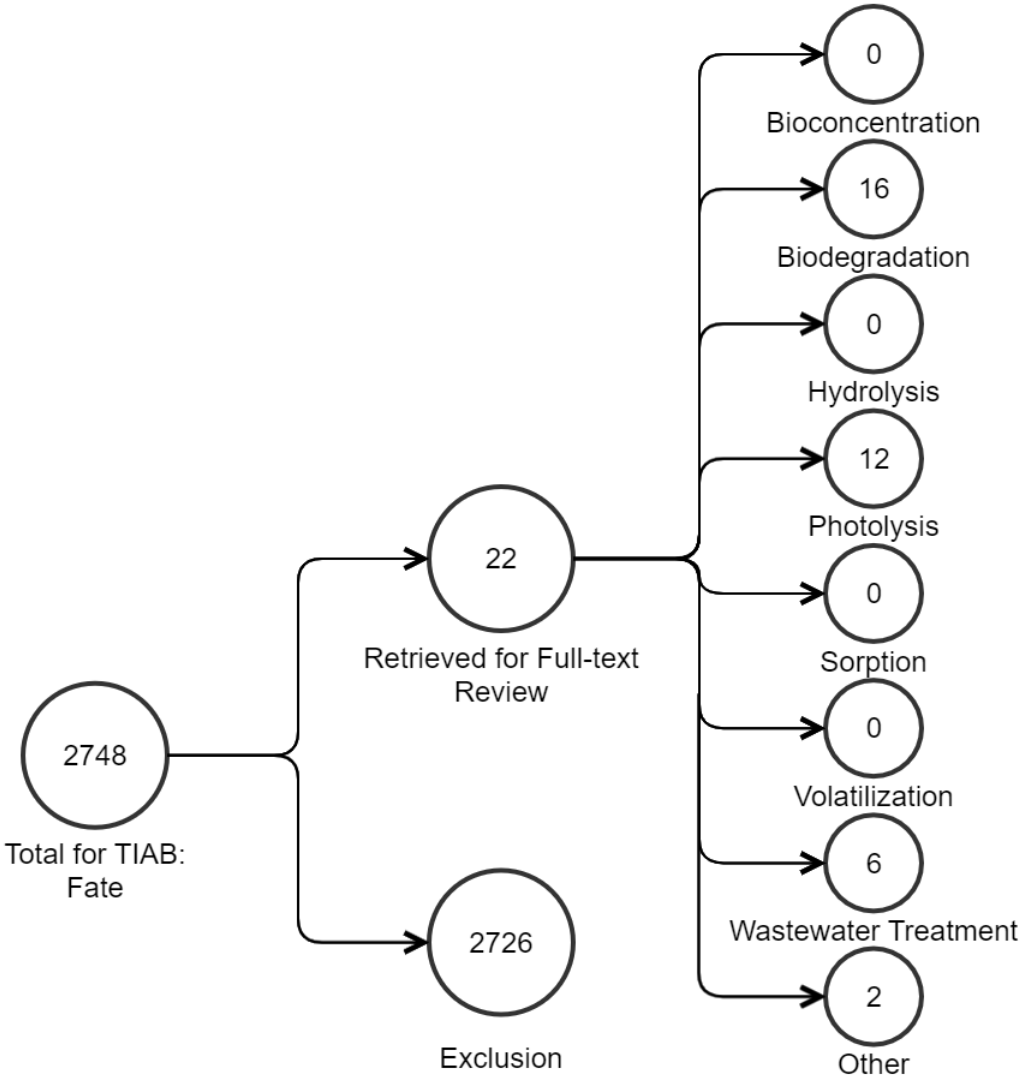

Figure 2-3 Peer-reviewed Literature - Fate and Transport Search Results for Formaldehyde

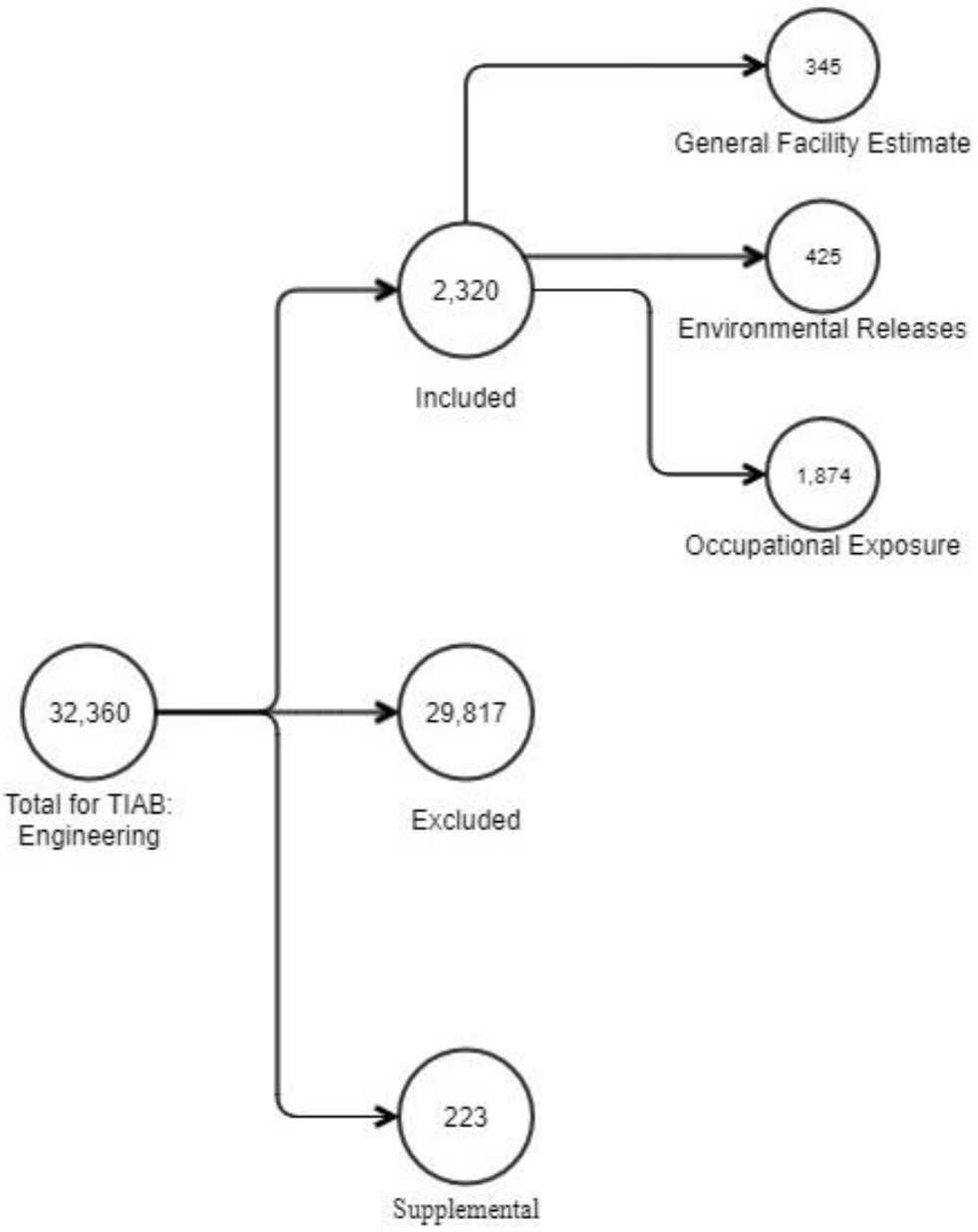

Figure 2-4 Peer-reviewed Literature - Engineering Search Results for Formaldehyde

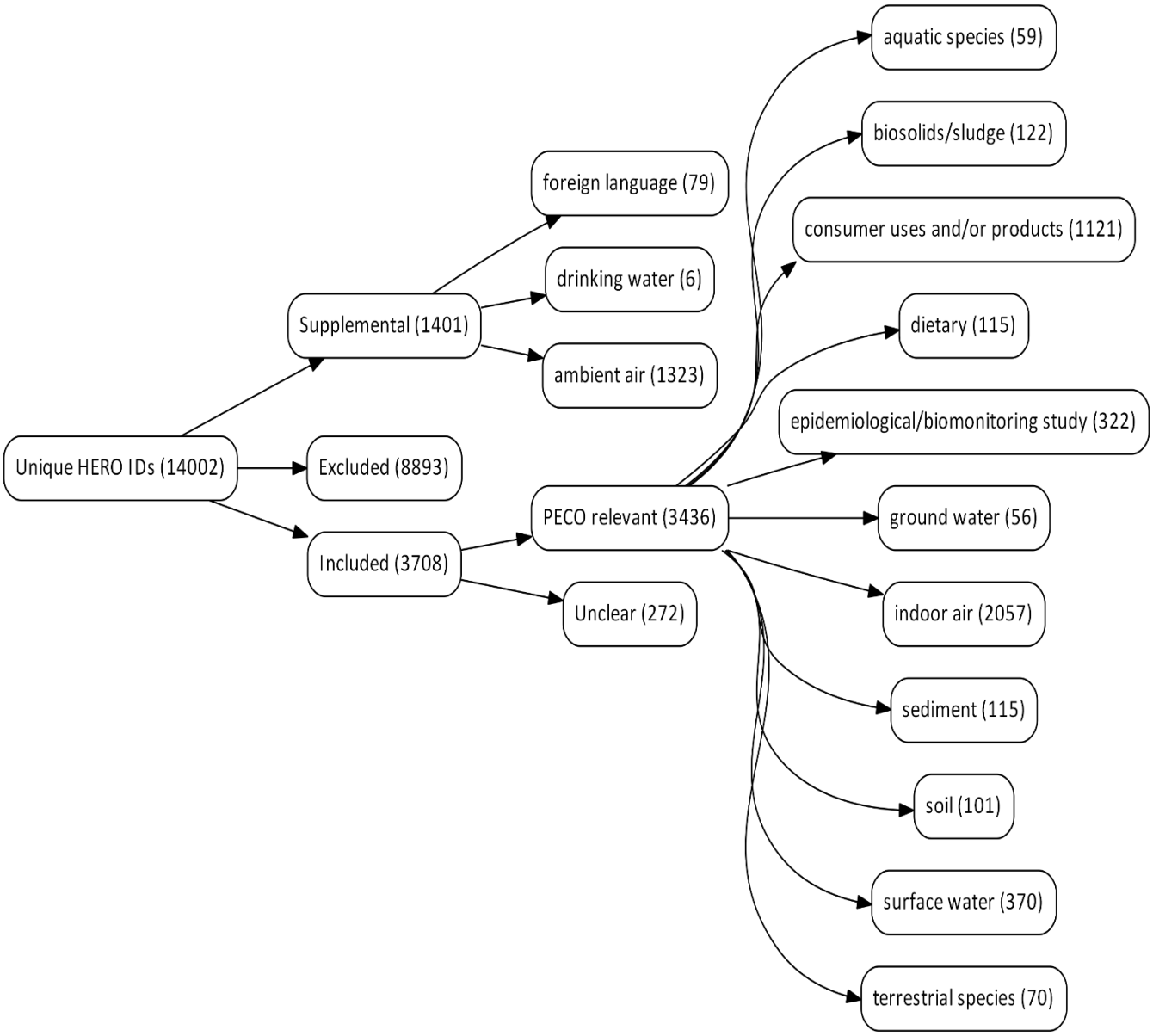

Figure 2-5 Peer-reviewed Literature - Exposure Search Results for Formaldehyde

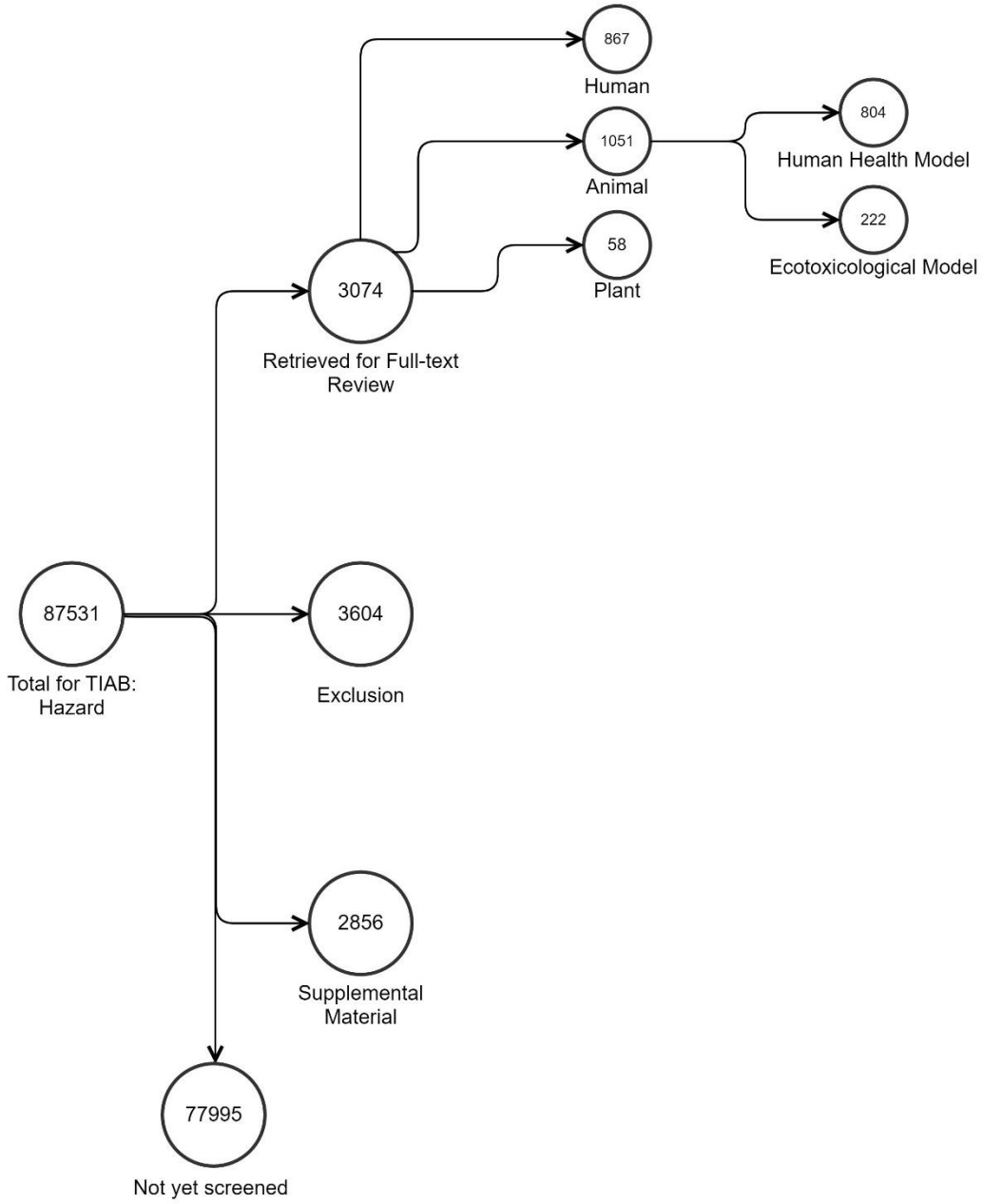

Figure 2-6. Peer-reviewed Literature - Hazard Search Results for Formaldehyde

For efficient screening, TIAB for hazard were screened in SWIFT ActiveScreener (https://www.sciome.com/swift-activescreener/), a specialized systematic review software application that uses "active" learning by which real time screening decisions are used to prioritize unscreened studies for relevance. By leveraging this active learning tool, EPA will not need to manually screen all of the 87,531 peer-reviewed human health and environmental hazards citations identified in its formaldehyde literature search. To date, EPA has only identified approx. 50% of the peer-reviewed data that are likely to be relevant to the formaldehyde risk analysis based on TIAB, therefore, the numbers presented in this diagram will change. TIAB screening will continue until SWIFT ActiveScreener indicates that it is likely that at least 95% of the relevant studies have been identified, a percent identification often used to evaluate the performance of machine learning applications and considered comparable to human error rates. In addition, the supplemental tagging details are unavailable at this stage of the draft scope document.

2.1.3 Search of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA screened a total of 191 submissions using inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document. EPA identified 116 submissions that met the inclusion criteria in these statements and identified 38 submissions with supplemental data. EPA excluded 37 submissions because the reports were identified as one of the following:

- Prepublication copy of a manuscript or letter regarding a draft manuscript that was later published and that would be identified via other peer or gray literature searches
- Summary of other reports
- Study of toxicity to bacteria
- Data not relevant to any discipline
- Submission on a different chemical
- Letter containing meeting notes
- Status or progress report
- Preliminary or interim report of a final available submitted report
- Record of telephone communication
- Annotated bibliography

EPA plans to conduct additional deduplication at later stages of the systematic review process (e.g., full text screening), when more information regarding the reports is reasonably available.

Table 2-1 Results of Title Screening of Submissions to EPA under Various Sections of TSCA

Discipline	Included	Supplemental
P-Chem Properties	0	0
Environmental Fate and Transport	2	0
Environmental and General Population Exposure	25	0
Occupational Exposure/Release Information	73	1
Environmental Hazard	1	4
Human Health Hazard	56	34

2.2 Conditions of Use

As described in the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), EPA assembled information from the CDR and TRI programs to determine conditions of use[3] or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of formaldehyde, including

[3] *Conditions of use* means 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 (15 U.S.C. § 2602(4)).

published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing formaldehyde, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) data, and other resources in which SDSs could be found. SDSs were cross-checked with company websites to make sure that each product SDS was current. In addition, and when applicable, EPA incorporated communications with companies, industry groups, environmental organizations, and public comments to supplement the use information.

After gathering the conditions of use, EPA identified those categories or subcategories of use activities for formaldehyde that the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These categories and subcategories are described in Section 2.2.1; Table 2-2.

Also, EPA identified and described the categories and subcategories of conditions of use that will be included in the scope of the risk evaluation (Section 2.2.1; Table 2-2). The conditions of use included in the scope are those reflected in the life cycle diagrams and conceptual models.

2.2.1 Conditions of Use Included in the Scope of the Risk Evaluation

Table 2-2 lists the conditions of use that are included in the scope of the risk evaluation.

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

Life Cycle Stage	Category	Subcategory	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019b)
	Importing	Importing	U.S. EPA (2019b)
Processing	Reactant	Adhesives and sealant chemicals in: Plastic and resin manufacturing; Wood product manufacturing; All other basic organic chemical manufacturing	U.S. EPA (2019b)
		Intermediate in: Pesticide, fertilizer, and other agricultural chemical manufacturing; Petrochemical manufacturing; Soap, cleaning compound, and toilet preparation manufacturing; All other basic organic chemical manufacturing; Plastic materials and resin manufacturing; Adhesive manufacturing; All other chemical product and preparation manufacturing; Paper manufacturing; Plastic products manufacturing; Wood product manufacturing; Construction; Agriculture, forestry, fishing, and hunting	U.S. EPA (2019b)

Life Cycle Stage	Category	Subcategory	Reference
		Functional fluid in: Oil and gas drilling, extraction, and support activities	U.S. EPA (2019b)
		Processing aids, specific to petroleum production in all other basic chemical manufacturing	U.S. EPA (2019b)
		Bleaching agent in wood product manufacturing	U.S. EPA (2019b)
		Agricultural chemicals in agriculture, forestry, fishing, and hunting	U.S. EPA (2019b)
	Incorporation into an article	Finishing agents in textiles, apparel, and leather manufacturing	U.S. EPA (2019b)
		Paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace)	U.S. EPA (2019b); AIA (EPA-HQ-OPPT-2018-0438-0006)
		Synthetic Rubber Manufacturing in transportation equipment manufacturing (tires)	USTM Meeting (2019)
		Adhesives and sealant chemicals in wood product manufacturing; plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction; paper manufacturing	U.S. EPA (2019b); AIA (EPA-HQ-OPPT-2018-0438-0006); ARMA (EPA-HQ-OPPT-2018-0438-0005)
	Incorporation into a formulation, mixture, or reaction product	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; all other basic organic chemical manufacturing	U.S. EPA (2019b); AIA (EPA-HQ-OPPT-2018-0438-0006); Everlube Meeting (2020)
		Asphalt, paving, roofing, and coating materials manufacturing	U.S. EPA (2019b); ARMA (EPA-HQ-OPPT-2018-0438-0005)
		Solvents (which become part of a product formulation or mixture) in paint and coating manufacturing	U.S. EPA (2019b)
		Processing aids, specific to petroleum production in: oil and gas drilling, extraction, and support activities and all	U.S. EPA (2019b); AIA (EPA-HQ-OPPT-2018-0438-0006); EDF

Life Cycle Stage	Category	Subcategory	Reference
		other basic inorganic chemical manufacturing	(EPA-HQ-OPPT-2018-0438-0017)
		Paint additives and coating additives not described by other categories in: paint and coating manufacturing and plastic material and resin manufacturing	U.S. EPA (2019b)
		Intermediate in: all other basic chemical manufacturing; all other chemical product and preparation manufacturing; plastic material and resin manufacturing; oil and gas drilling, extraction, and support activities; wholesale and retail trade	U.S. EPA (2019b)
		Other: Preservative in all other chemical product and preparation manufacturing	U.S. EPA (2019b)
		Solid separation agents in miscellaneous manufacturing	U.S. EPA (2019b)
		Agricultural chemicals (non-pesticidal) in: agriculture, forestry, fishing, and hunting; pesticide, fertilizer, and other agricultural chemical manufacturing	U.S. EPA (2019b)
		Surface active agents in plastic material and resin manufacturing	U.S. EPA (2019b)
		Ion exchange agents in adhesive manufacturing and paint and coating manufacturing	U.S. EPA (2019b)
		Lubricant and lubricant additive in adhesive manufacturing	U.S. EPA (2019b)
		Plating agents and surface treating agents in all other chemical product and preparation manufacturing	U.S. EPA (2019b)
		Functional fluids (closed system) in soap, cleaning compound, and toilet preparation manufacturing	U.S. EPA (2019b)
		Other: Laboratory chemicals	U.S. EPA (2019b)
		Adhesive and sealant chemical in adhesive manufacturing	U.S. EPA (2019b)
		Bleaching agents in textile, apparel, and leather manufacturing	U.S. EPA (2019b)

Life Cycle Stage	Category	Subcategory	Reference
	Repackaging	Sales to distributors for laboratory chemicals	U.S. EPA (2019b)
	Recycling	Recycling	U.S. EPA (2019b)
Industrial Use	Non-incorporative activities	Process aid in: Oil and gas drilling, extraction, and support activities (e.g., hydraulic fracking fluid)	U.S. EPA (2019b); EDF (EPA-HQ-OPPT-2018-0438-0017)
		Used in: construction and agriculture, forestry, fishing, and hunting	U.S. EPA (2019b)
Disposal	Disposal	Disposal	U.S. EPA (2019b)
Commercial Uses	Chemical substances in furnishing, treatment/care products	Floor coverings; Foam seating and bedding products; Furniture and furnishings not covered elsewhere; Cleaning and furniture care products; Fabric, textile, and leather products not covered elsewhere	U.S. EPA (2016); U.S. EPA (2019b); Certified Labs (1995); CPSC email (2019);
	Chemical substances in treatment products	Water treatment products	U.S. EPA (2019b); Mansfield Sanitary (1985); Chemetrics (1989); Calgon (1990)
	Chemical substances in treatment/care products	Laundry and dishwashing products; Personal care products	U.S. EPA (2019b)
	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; Paint and coatings	U.S. EPA (2019b) E.I. Dupont de Nemours & Co. (1989; 1995)
	Chemical substances in construction, paint, electrical, and metal products	Building/construction materials – wood and engineered wood products; Building/construction materials not covered elsewhere	U.S. EPA (2019b); U.S. EPA (2016)
	Chemical substances in electrical products	Electrical and electronic products (including semiconductors)	U.S. EPA (2019b); IPC Meeting (2019); Enthone-OMI, Inc. (1990)

Life Cycle Stage	Category	Subcategory	Reference
	Chemical substances in metal products	Metal products not covered elsewhere	U.S. EPA (2019b); Formica brand products (1988)
	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products	U.S. EPA (2019b); USTM Meeting (2019); Northern Labs, Inc (1990); Everlube Meeting (2020)
	Chemical substances in agriculture use products	Lawn and garden products	U.S. EPA (2019b)
	Chemical substances in outdoor use products	Explosive materials	U.S. EPA (2019b)
	Chemical substances in packaging, paper, plastic, and hobby products	Food packaging; Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	U.S. EPA (2019b); ACA Meeting (2019); ACC 2019 (EPA-HQ-OPPT-2018-0438-0018); Franklin International (1992); Enthone-OMI, Inc (1992)
	Chemical substances in hobby products	Arts, crafts, and hobby materials	U.S. EPA (2019b); Day-Glo Corporation (1993); Elmers (2012)
	Chemical substances in packaging, paper, plastic, hobby products	Ink, toner, and colorant products; Photographic supplies	U.S. EPA (2019b); Graphic Controls Industrial Products (1985); Eastman-Kodak (1996)
	Chemical substances in products not described by other codes	Laboratory Chemicals (e.g., specimen preservation, medical samples, mortuary science)	U.S. EPA (2019b); Dodge Chemical Co (1988); Pierce Chemicals (1988)
Consumer Uses	Chemical substances in	Floor coverings; Foam seating and bedding products; Cleaning and furniture	U.S. EPA (2019b); U.S. EPA (2016);

Life Cycle Stage	Category	Subcategory	Reference
	furnishing treatment/care products	care products; Furniture and furnishings not covered elsewhere	Keller-Reckitt & Colman Inc (1991)
		Fabric, textile, and leather products not covered elsewhere (clothing)	CPSC Email (2019)
	Chemical substances in treatment products	Water treatment products	U.S. EPA (2019b); Mansfield Sanitary (1985); Chemetrics (1989); Calgon (1990)
	Chemical substances in treatment/care products	Laundry and dishwashing products; Personal care products	U.S. EPA (2019b); Phoenix Brands (2007), Suavitel (2016); Colgate-Palmolive Company (2015); Softsoap (2016); Keller-Reckitt & Colman Inc (1991)
	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; Paint and coatings	U.S. EPA (2019b); Dexter Crown Metro Aerospace Inc (1992)
		Building/construction materials – wood and engineered wood products; Building/construction materials not covered elsewhere	U.S. EPA (2019b); U.S. EPA (2016)
	Chemical substances in electrical products	Electrical and electronic products (including semiconductors)	U.S. EPA (2019b); IPC Meeting (2019); Enthone-OMI, Inc. (1990)
	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products	U.S. EPA (2019b); USTM Meeting (2019); Northern Labs, Inc (1990); Everlube Meeting (2020)
	Chemical substances in agriculture use products	Lawn and garden products	U.S. EPA (2019b);
	Chemical substances in packaging, paper,	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	U.S. EPA (2019b); ACA Meeting (2019); ACC (EPA-HQ-OPPT-2018-0438-0018);

Life Cycle Stage	Category	Subcategory	Reference
	plastic, hobby products		Enthone-OMI, Inc. (1992)
	Chemical substances in hobby products	Arts, crafts, and hobby materials	U.S. EPA (2019b); Day-Glo Color Corporation (1993); Elmers (2012)
	Chemical substances in packaging, paper, and plastic	Ink, toner, and colorant products; Photographic supplies	U.S. EPA (2019b); Graphic Controls Industrial Products (1985); Franklin International (1992); Eastman Kodak Company (1996)

- Life Cycle Stage Use Definitions
  - "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
  - "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
  - "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule for Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, TSCA Section 6(b)(4)(D) requires EPA to identify "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider" in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33736, 33729; July 20, 2017). As a result, EPA plans to not include in this scope or in the risk evaluation the activities described below that the Agency has concluded do not constitute conditions of use.

EPA has determined that formaldehyde has several uses outside the scope of TSCA. Specifically, formaldehyde has several pesticidal uses in agriculture and as an antimicrobial pesticide. Formaldehyde is also used in personal care products, cosmetics, hair treatments, mouthwash, nail treatment, shaving cream, soap, shampoo, and deodorants. Miscellaneous non-TSCA uses include use of formaldehyde in food packaging adhesives and sugar refineries (Earthjustice (EPA-HQ-OPPT-2018-0438-0019)). These uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi). Activities and releases associated with these uses of formaldehyde are therefore not "conditions of use" (defined as circumstances associated with "a chemical substance[4]," TSCA § 3(4)) and will not be evaluated during

[4]*Chemical substance* means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical. Chemical substance does not include (1) any mixture; (2) any pesticide (as defined in the Federal

risk evaluation]. However, manufacturing, processing, and industrial uses of these products are covered by TSCA and will be considered a condition of use. Additionally, EPA has determined that three types of composite wood products in panel form only (hardwood plywood, particleboard, and medium density fiberboard [including thin-medium density fiberboard]) currently regulated under the Formaldehyde Emission Standards for Composite Wood Products final rule (i.e., 40 CFR 770) will not be included in the scope of this evaluation because these products are manufactured domestically and/or imported only after meeting the Congressionally mandated emission standards, which are verified through an actively managed EPA third-party certification program. EPA has determined that other non-TSCA Title VI regulated "composite," "engineered," or "pressed" wood products will be included in the scope of this evaluation.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), production volume of formaldehyde in 2015 was between 1 billion and 5 billion pounds (U.S EPA, 2017; Figure 2-1). EPA also reviews pre-2015 CDR production volume information, as detailed in the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) and will include future production volume information as it becomes available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-7 depicts the conditions of use that are considered within the scope of the risk evaluation for the various life cycle stages including manufacturing, processing, use (industrial, commercial, and consumer), distribution and disposal of formaldehyde. Section 2.2.1 summarizes the descriptions of the industrial, commercial and consumer use categories included in the life cycle diagram. The descriptions provide a brief overview of the use category. The activities that EPA determined are out of scope are not included in the life cycle diagram. Appendix E contains more detailed descriptions (e.g., process descriptions, worker activities) for each manufacture, processing, use and disposal category. The information in the life cycle diagram is grouped according to the 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)[5].

Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; (3) tobacco or any tobacco product; (4) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act); (5) any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by Section 4182 or 4221 or any other provision of such Code), and; (6) any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device

[5] The descriptions are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions and can be found in EPA's Instructions for Reporting 2016 TSCA Chemical Data Reporting.

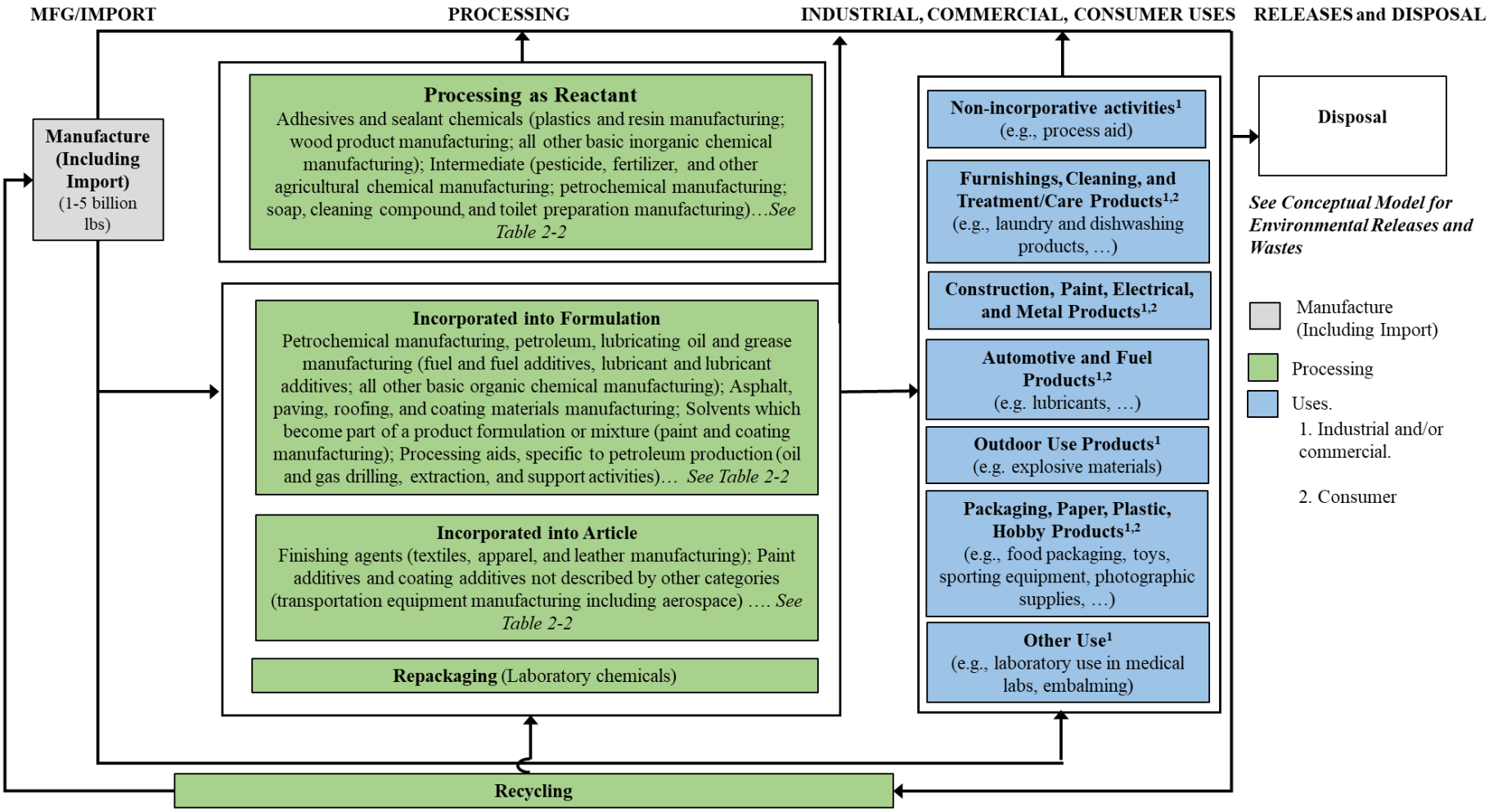

Figure 2-7. Formaldehyde Life Cycle Diagram

Please refer to Table 2-2 for the comprehensive list of processing activities and the relevant sub-categories for industrial, commercial, and consumers uses. Volume is not depicted in the life cycle diagram for processing and industrial and commercial uses as specific production volume is claimed as CBI or withheld pursuant to TSCA Section § 14.

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for formaldehyde. Release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including PESS, and environmental receptors. EPA plans to consider, where relevant, the duration, intensity (concentration), frequency, and number of exposures in characterizing exposures to formaldehyde.

2.3.1 Physical and Chemical (P-Chem) Properties

Consideration of p-chem properties is essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform other components of the risk evaluation, i.e., the hazard and exposure assessments. EPA plans to use the physical and chemical properties described in the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) to support the development of the risk evaluation for formaldehyde. The values for the physical and chemical properties (Appendix B) may be updated as EPA collects additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for formaldehyde. EPA plans to use the environmental fate characteristics described in the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) to support the development of the risk evaluation for formaldehyde. The values for the environmental fate properties (Appendix C) may be updated as EPA collects additional information through systematic review methods.

2.3.3 Releases to the Environment

Releases to the environment from conditions of use (e.g., manufacturing, industrial and commercial processes, commercial or consumer uses) are a 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 plans to evaluate are data reported to the Toxics Release Inventory (TRI) program. EPA's TRI database contains information on chemical waste management activities that are reported by industrial and federal facilities, including quantities released into the environment (i.e., to air, water, and disposed of to land), treated, burned for energy, recycled, or transferred off-site to other facilities for these purposes.

Under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) formaldehyde is a TRI-reportable substance effective January 1, 1987 (40 CFR 372.65). For TRI reporting[6], facilities in covered sectors in the United States are required to disclose releases and other waste management activity quantities of formaldehyde under the CASRN 50-00-0 if they manufacture (including import) or process more than 25,000 pounds or otherwise use more than 10,000 pounds of the chemical in a given year by July 1 of the following year.

[6] For TRI reporting criteria see https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting

Table 2-3 provides production-related waste management data for formaldehyde reported by facilities to the TRI program for reporting year 2018.[7] As shown in the table, 715 facilities reported a total of over 132 million pounds of formaldehyde production-related waste managed in 2018. Of this total, approximately 70 million pounds were treated, nearly 35 million pounds were recycled, over 20 million pounds were released or otherwise disposed of, and over 7 million pounds were burned for energy recovery. Of the 70 million pounds of formaldehyde that were treated, about 65 million pounds were treated on site and 5 million pounds were treated off site. Similarly, 99% of the formaldehyde waste that was recycled was recycled on site, and 93% of the formaldehyde waste that was used for energy recovery was combusted on site.

Table 2-3 Summary of Formaldehyde TRI Production-Related Waste Managed in 2018

Year	Number of Facilities	Recycled (lbs)	Recovered for Energy (lbs)	Treated (lbs)	Released[a,b,c] (lbs)	Total Production Related Waste (lbs)
2018	715	34,831,401	7,135,922	70,021,737	20,196,004	132,185,063

Data source: 2018 TRI Data (Updated November 2019)
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.
[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

Table 2-4 provides a summary of the quantities of formaldehyde released to the environment during 2018 as reported to TRI.[21] Of the more than 20 million pounds of formaldehyde that were disposed of or otherwise released to the environment during 2018, 19 million pounds were released or disposed of on site, and one million pounds were disposed of or released off site. Nearly ¾ of all the formaldehyde that was disposed of or released occurred to land, the majority of which (14.2 million pounds) was disposed of on-site to Class I underground injection wells and about 240,000 pounds was disposed of off-site to Class I underground injection wells. Over 4.6 million pounds of formaldehyde were released to air; 93% of which was in the form of point source air (stack) emissions. Releases to water and other releases not mentioned above accounted for small amounts of the total releases at just 1% and 2%, respectively.

Table 2-4 Summary of Releases of Formaldehyde to the Environment During 2018

Year	Number of Facilities	Air Releases		Water Releases (lbs)	Land Disposal			Other Releases [a] (lbs)	Total Releases [b, c] (lbs)
		Stack Air Releases (lbs)	Fugitive Air Releases (lbs)		Class I Under-ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal [a] (lbs)		
Totals 2018	715	4,277,398	333,355	214,861	14,478,154	178,228	308,328	371,471	20,161,796
		4,610,754			14,964,710				

Data source: 2018 TRI Data (Updated November 2019)
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] These release quantities do include releases due to one-time events not associated with production such as remedial actions or earthquakes.
[c] Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

[7] Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-3 were queried using TRI Explorer and uses the 2018 National Analysis data set (released to the public in November 2019). This dataset includes revisions for the years 1988 to 2018 processed by EPA.

The total production-related waste managed quantity shown in Table 2-3 does not include any quantities reported as catastrophic or one-time releases. It does include quantities transferred off site to receiving facilities for release or disposal and, if the receiving facilities are subject to the TRI reporting requirements, they would report these quantities as on-site releases and these same quantities would be included in the total release. This is referred to as "double counting", because the quantities are counted twice. That is, when a facility transfers a quantity of a chemical off site for disposal to another facility, the facility reports the quantity as transferred off site for disposal and the receiving facility reports the same quantity of the chemical as disposed of on site. This is done because total production-related waste values in the TRI database considers all instances of where and how the waste is managed (first as a quantity sent off site for disposal and next as a quantity disposed of on-site), and reflects both the off-site transfer and the on-site disposal quantities, as represented in Table 2-3. However, the TRI program recognizes that this is the same quantity of the chemical and therefore included it only once in the total release aggregation in Table 2-4. As a result, the total release quantities shown in the two tables differ slightly.

EPA plans to review these data in conducting the exposure assessment component of the risk evaluation for formaldehyde.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of formaldehyde can result in releases to the environment. Environmental exposures are informed by releases into the environment, overall persistence, degradation, and bioaccumulation within the environment, and partitioning across different media. EPA plans to identify and evaluate reasonably available environmental exposure data utilizing EPA's systematic review process for the risk evaluation.

EPA expects environmental exposure can occur as a result of releases of formaldehyde to the environment (via direct releases, indirect releases, or deposition from other media) and will review environmental exposure in the risk evaluation. EPA plans to identify and evaluate monitoring studies in peer reviewed literature as well as relevant and reliable monitoring data sources (e.g., discharge monitoring report (DMR) and water quality portal (WQP)) utilizing EPA's systematic review process to inform environmental exposure. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota will also be identified and evaluated utilizing EPA's systematic review process since such studies can provide evidence of exposure. Environmental exposure of terrestrial species to formaldehyde is a possible pathway and receptor. However, such exposure is limited to activities like plant ingestion. Formaldehyde is not expected to bioaccumulate in fish (U.S. EPA, 2019) and therefore environmental exposure of terrestrial species via fish ingestion is not expected.

Formaldehyde is expected to be present in the outdoor environment as a result of releases from multiple industrial and commercial conditions of use identified in Section 2.2. Chemical manufacturing, manufacturing of products containing formaldehyde) and use of formaldehyde in other chemical manufacturing processes could all cause releases to different media to the outdoor environment.

Disposal and waste treatment activities associated with formaldehyde and formaldehyde containing products are also expected to result in releases to the outdoor environment. EPA expects formaldehyde to be present in ambient air as a result of these releases. While data reported to TRI indicate releases of formaldehyde to surface water, ongoing presence of formaldehyde in surface water is expected to be limited due to the rapid and nearly complete hydration of formaldehyde to a gem-diol, methylene glycol, in water (WHO, 2002; Environment Canada, 2001).

2.3.5 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use (manufacturing, processing, industrial/commercial uses, and disposal) described in Section 2.2.1. In addition, EPA may analyze exposure to ONUs, workers who do not directly handle the chemical but perform work in an area where the chemical is present. EPA also expects to consider the effect(s) that engineering controls (EC) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

Worker Activities

Worker activities associated with the conditions of use within the scope of the risk evaluation for formaldehyde that EPA plans to analyze, include, but are not limited to:

- Unloading and transferring formaldehyde or formaldehyde solutions to and from storage containers and process vessels;
- Sampling chemicals, formulations, or products for quality control;
- Repackaging chemicals, formulations, or products containing formaldehyde;
- Applying formulations and products containing formaldehyde onto substrates (e.g., applying paints and coatings, thinners, and paint removers containing formaldehyde);
- Handling, transporting, and disposing waste containing formaldehyde; and
- Performing other work activities in or near areas where formaldehyde is used.

Additional key data that will inform occupational exposure assessment include: Occupational Safety and Health Administration (OSHA) Chemical Exposure Health Data (CEHD) and National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation (HHE) program data, presented in Appendix E.2.

Inhalation

EPA plans to analyze inhalation exposure for workers and ONUs for all conditions of use specified in Section 2.2. Formaldehyde has an OSHA standard OSHA 1910.1048 (OSHA, 2019). The Permissible Exposure Limit (PEL) is 0.75 parts per million (ppm) over an 8-hour workday, time weighted average (TWA) and a Short-Term Exposure Limit (STEL) of 2 ppm. The OSHA standard also includes, but not limited to requirements for exposure monitoring, recordkeeping, PPE if other ECs are not feasible, and hazard communication. This chemical also has a NIOSH Recommended Exposure Limit (REL) of 0.016 ppm TWA and 15 minute Ceiling limit of 0.1 ppm. NIOSH considers formaldehyde to be a potential occupational carcinogen with an Immediately Dangerous to Life or Health (IDLH) value of 20 ppm (NIOSH 2018). The American Conference of Governmental Industrial Hygienists (ACGIH) set the Threshold Limit Value (TLV) at 0.1 ppm TWA and 0.3 ppm STEL.

Oral

EPA generally does not evaluate occupational exposures through the oral route. Workers may inadvertently transfer chemicals from their hands to their mouths or ingest inhaled particles that deposit in the upper respiratory tract. The frequency and significance of this exposure route are dependent on several factors including the p-chem properties of the substance during expected worker activities, workers' awareness of the chemical hazards, the visibility of the chemicals on the hands while working, workplace practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). However, EPA will consider the oral exposure on a case by case basis.

Dermal

EPA plans to analyze dermal exposure to workers through liquid contact with formulations that contain formaldehyde. ONUs do not directly handle these formulations; therefore, liquid contact is not expected for ONUs. OSHA standard (1910.1048) requires that skin contact with 1 % or more of formaldehyde be prevented by chemical protective clothing and equipment.

2.3.6 Consumer Exposures

Consumer exposure to formaldehyde can occur via inhalation and dermal routes during and after using consumer products containing formaldehyde within a residence. Consumer exposure to formaldehyde can also occur via inhalation due to off-gassing from various products used or installed within a residence. Consumer exposure to formaldehyde via the oral (ingestion) route is not expected, since formaldehyde is highly volatile and not expected to absorb to dust or other particles within a residence which could then be ingested.

Consumer exposure to formaldehyde via the inhalation route is expected for both the consumer user and consumer bystander during and after use of a consumer product containing formaldehyde within a residence. The consumer user is the individual utilizing a consumer product containing formaldehyde within a residence within a specified room of use. The consumer bystander is one or more individuals located within a residence where a consumer product containing formaldehyde is used but is not within the room of use during product use.

Consumer exposure to formaldehyde via the dermal route is only expected for the consumer user during and immediately after use of a consumer product containing formaldehyde. A consumer bystander is not expected to come into direct dermal contact with a consumer product containing formaldehyde during or immediately after use.

Oral consumer exposure to formaldehyde will not be evaluated since it is highly volatile and not expected to sorb onto material within a residence which a consumer could ingest.

2.3.7 General Population Exposures

Environmental releases of formaldehyde from certain conditions of use identified in Section 2.2, such as manufacturing, processing, distribution, use and disposal, as well as off-gassing from installation and use of various building products (pressed wood products, carpets, etc.) (NICNAS 2006) in a residential setting, may lead to general population exposure.

Based on these environmental releases reported in Section 2.3.3, as well as P-Chem and fate properties of formaldehyde discussed in Section 2.3.2, Appendix B and Appendix C, EPA anticipates formaldehyde may be present in ambient air. While data reported to TRI indicate releases of formaldehyde to surface water, ongoing presence of formaldehyde in surface water is expected to be limited due to the rapid and nearly complete hydration of formaldehyde to a gem-diol, methylene glycol, in water (WHO, 2002; Environment Canada, 2001). Formaldehyde is not expected to bioaccumulate in fish (U.S. EPA, 2019a) and, given its low octanol/water partition coefficient, adsorption to soil is likely low (ATSDR 1999).

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for formaldehyde. EPA considers all the potential environmental hazards for formaldehyde identified during prioritization to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments, which may update the list of potential environmental hazards associated with formaldehyde exposure. If necessary, EPA plans to update the list of potential hazards in the final scope document of the formaldehyde. Based on information identified during prioritization, environmental hazard effects were identified for aquatic and terrestrial organisms.

EPA plans to conduct an environmental risk characterization of formaldehyde to determine whether there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of formaldehyde in environmental media (i.e., water, sediment, soil, and tissue). The data for environmental monitoring and toxicity will be used in this risk characterization to determine whether exposure to formaldehyde poses risk for adverse effects in aquatic and/or terrestrial organisms.

2.4.2 Human Health Hazards

As described in the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for formaldehyde. EPA considers all of the potential human health hazards for formaldehyde identified during prioritization to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. The preliminary literature survey identified studies reporting acute toxicity, repeated dose toxicity, genetic toxicity, reproductive and developmental toxicity, carcinogenicity, epidemiological or biomonitoring studies and absorption, distribution, metabolism, and excretion (ADME) of formaldehyde.

EPA has identified adverse effects for a number of the screened outcome domains during prioritization including inhalation toxicity and carcinogenicity. EPA is in the process of identifying additional reasonably available information through systematic review methods and public input, which may update the list of potential human health hazards under the scope of the risk evaluation. If necessary, EPA plans to update the list of potential hazards in the final scope document of the formaldehyde risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA § 6(b)(4) requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." TSCA §3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011a).

During the Prioritization process, EPA identified the following PESS based on CDR information and studies reporting developmental and reproductive effects: children, women of reproductive age (e.g., pregnant women), consumers and workers (U.S. EPA, 2019a). EPA plans to evaluate these PESS in the risk evaluation.

In developing exposure scenarios, EPA plans to analyze reasonably available information to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006a). Likewise, EPA plans to evaluate reasonably available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of formaldehyde. Pathways and routes of exposure associated with workers and ONUs are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes, including those pathways that may be addressed pursuant to other Federal laws are discussed and depicted in the conceptual model shown in Section 2.6.3. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that may be addressed pursuant to other Federal laws, are presented in the conceptual model shown in Section 2.6.4.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses that EPA plans to include in the risk evaluation. There is potential for exposures to workers and ONU via inhalation routes and exposures to workers via dermal routes. For industrial and commercial activities and uses, it is expected that potential routes of exposure are through vapor and/or mists and through liquid contact with formaldehyde containing solutions. Due to formaldehyde's high volatility, EPA expects the inhalation pathway to be most likely source of exposure to workers and ONUs.

Workers at waste management facilities may be exposed to formaldehyde via inhalation or dermal routes during waste handling, treatment or disposal. EPA plans to evaluate activities resulting in exposures associated with distribution in commerce (e.g., loading, unloading) throughout the various lifecycle stages and conditions of use (e.g., manufacturing, processing, industrial use, commercial use, and disposal) rather than a single distribution scenario. For each condition of use identified in Table 2-2, an initial determination was made as to whether or not each combination of exposure pathway, route, and receptor will be analyzed in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix F.

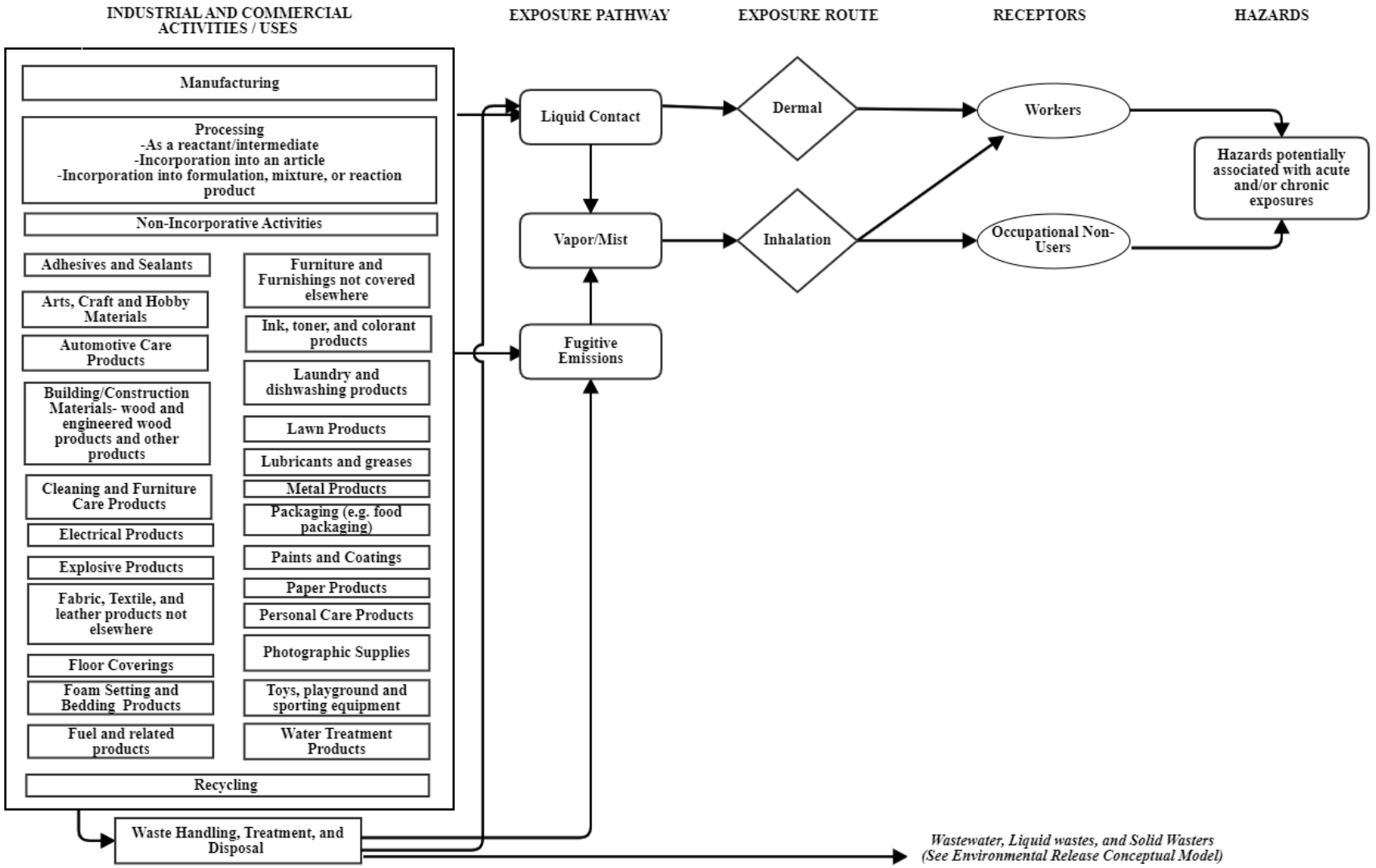

Figure 2-8 Formaldehyde Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

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

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-9 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of formaldehyde that EPA plans to include in the risk evaluation.

EPA plans to evaluate consumer exposure via inhalation and dermal routes resulting from use of formaldehyde containing consumer products within a residence. Consumer products may be in liquid or aerosol form. Formaldehyde is highly volatile and therefore not expected to be present in solid form during consumer use. Additionally, formaldehyde is not expected to adsorb to dust, particulate, or other materials which a consumer could ingest. Therefore, EPA does not plan to evaluate consumer exposure via any oral route. The results and supporting rationale are included in Appendix G.

Inhalation

Consumer exposure via the inhalation route is expected for both the consumer user and consumer bystander. Exposure via inhalation can occur through the inhalation of vapor or mist directly or indirectly from overspray of a consumer product. Both liquid and aerosol product forms can have an overspray fraction readily available for uptake by a consumer via inhalation. Exposure via inhalation can also occur as a result of offgassing from certain building products or components installed or utilized within a residence.

Consumer exposure via the inhalation route will be evaluated for both the consumer user and consumer bystander. EPA plans to evaluate inhalation exposure based on an overspray fraction of product during use and from offgassing from building products or components installed or utilized within a residence.

Dermal

Consumer exposure via the dermal route is expected for the consumer user. Consumer bystanders are not expected to experience direct or indirect dermal contact during product use since they are not within the room of use during product use. Therefore, EPA plans to only evaluate dermal exposure for the consumer user.

Exposure via the dermal route can occur through the deposition of liquid, vapor, or mist directly or indirectly onto the skin. Since vapor or mist in this context refers to overspray material which may redeposit onto the skin during use, it is included in the liquid contact pathway within the conceptual model presented in Figure 2-9.

EPA plans to evaluate dermal exposure based on the permeation of formaldehyde through the skin as well as vapor to skin. The evaluation of dermal exposure will be limited to select scenarios where evaporation of material from the skin is prohibited or limited due to a physical barrier (wet rag soaked with product) or where full immersion of a body part is expected during product use.

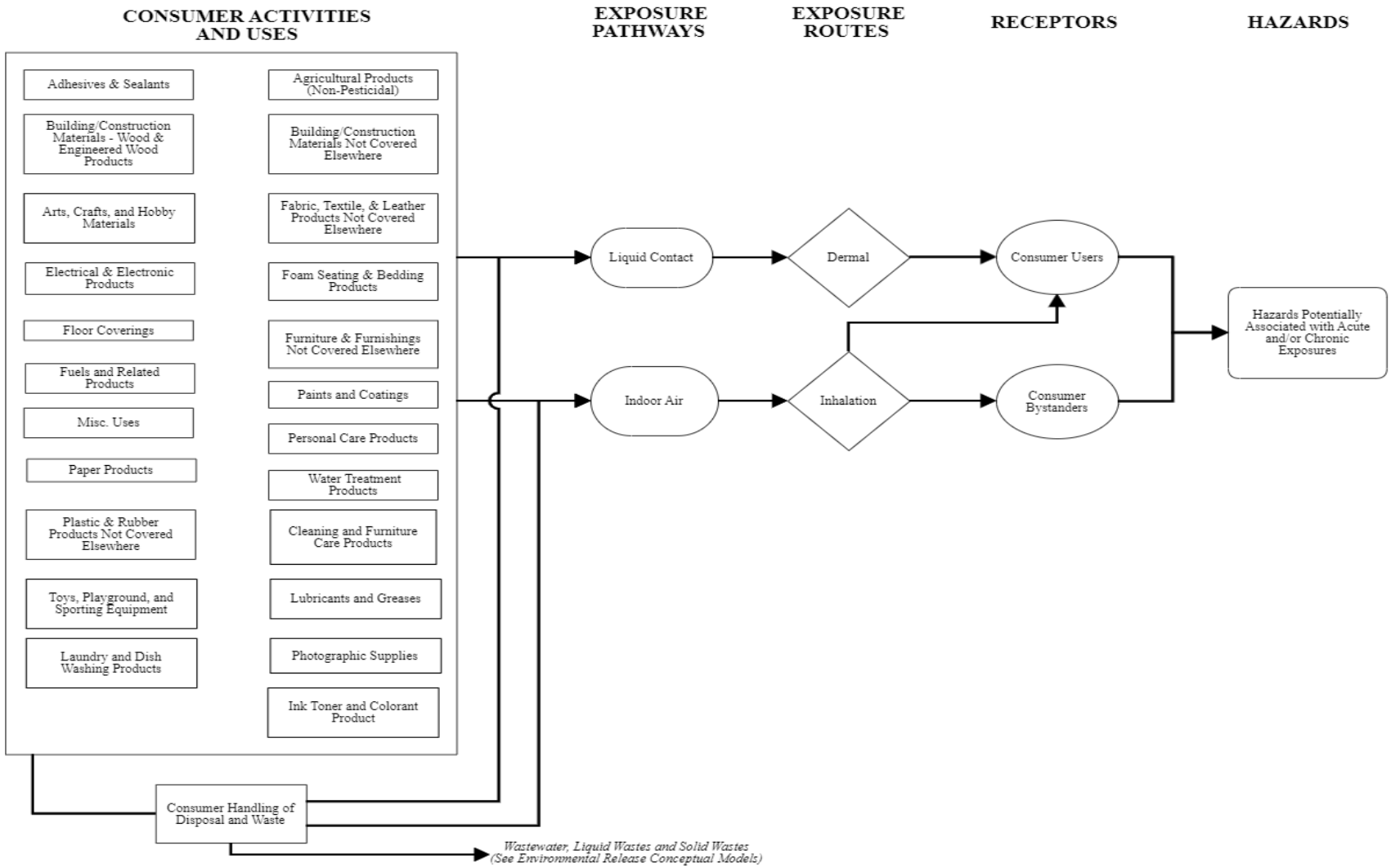

Figure 2-9 Formaldehyde Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards

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

[a] Receptors include PESS (see Section 2.5).

2.6.3 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards (Regulatory Overlay)

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of formaldehyde within the scope of the risk evaluation. It also discusses those pathways that may be addressed pursuant to other Federal laws.

In complying with TSCA, EPA plans to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, maximize scientific and analytical efforts, and meet the statutory deadline for completing risk evaluations. OPPT is working closely with the offices within EPA that administer and implement the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA), to identify how those statutes and any associated regulatory programs address the presence of formaldehyde in exposure pathways falling under the jurisdiction of these EPA statutes.

The conceptual model in Figure 2-10 presents the potential exposure pathways, exposure routes and hazards to human and environmental receptors from releases and waste streams associated with industrial, commercial, and consumer uses of formaldehyde. This figure includes overlays, labeled and shaded to depict the regulatory programs (e.g., CAA, SDWA, CWA, RCRA) and associated pathways that EPA considered in developing this conceptual model for the draft scope document. The pathways are further described in Section 2.6.3.1 through Section 2.6.3.4.

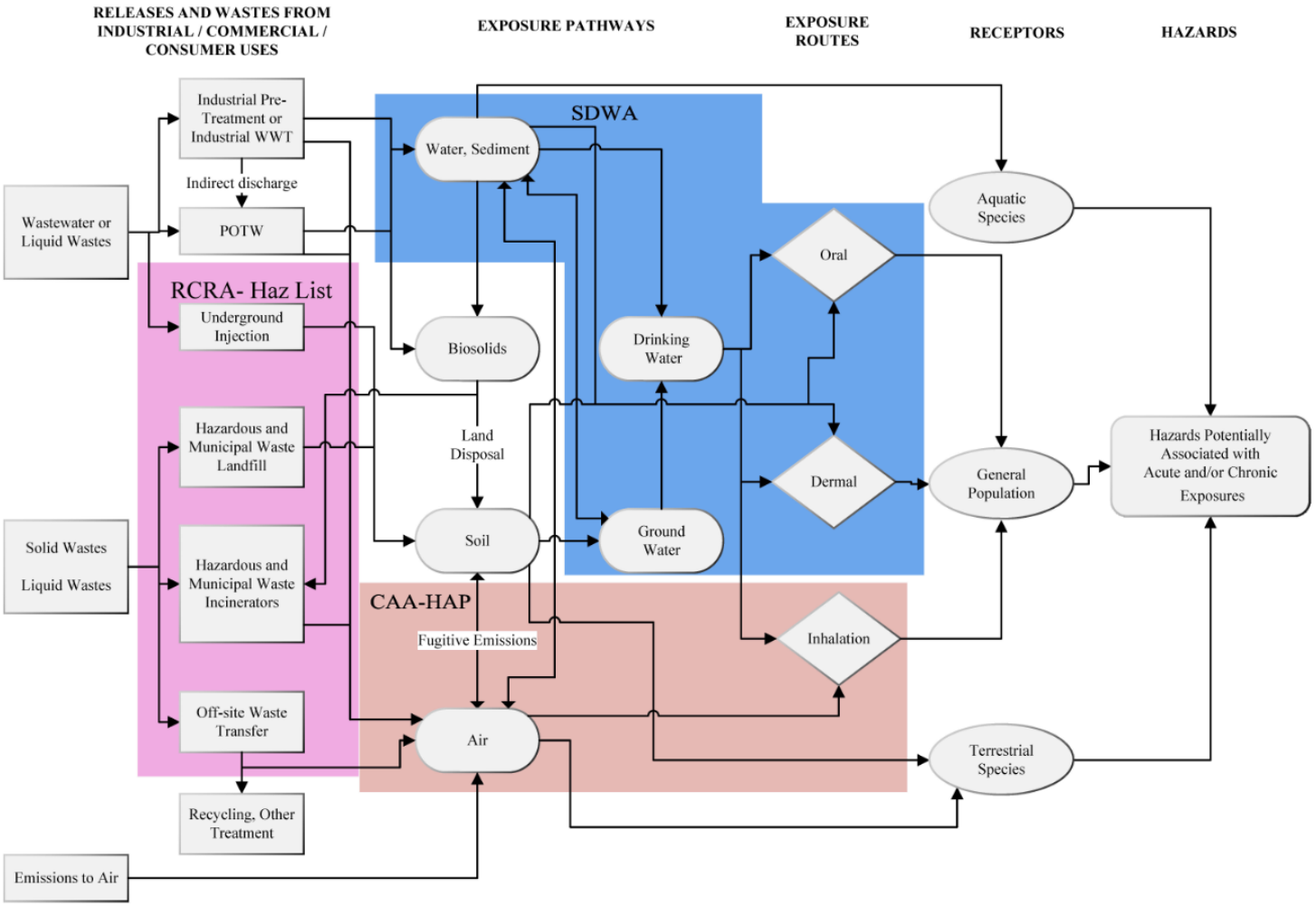

Figure 2-10 Formaldehyde Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of Formaldehyde including the environmental statutes covering those pathways.

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. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering.

b) Receptors include PESS (see Section 2.5).

c) For regulation of hazardous and municipal waste incinerators and municipal waste landfills CAA and RCRA may have shared regulatory authority.

2.6.3.1 Ambient Air Pathway

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

Emission pathways to ambient air from commercial and industrial stationary sources and associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation from stationary source releases of formaldehyde to ambient air are covered under the jurisdiction of the CAA. EPA's Office of Air and Radiation and Office of Pollution Prevention and Toxics will continue to work together to provide an understanding and analysis of the CAA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

2.6.3.2 Drinking Water Pathway

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

The Contaminant Candidate List (CCL) is a list of unregulated contaminants that are known or anticipated to occur in public water systems and that may require regulation. EPA must publish a CCL every 5 years and make Regulatory Determinations (RegDet) to regulate (or not) at least five CCL contaminants every 5 years. To regulate a contaminant EPA must conclude the contaminant may have adverse health effects, occurs or is substantially likely to occur in public water systems at a level of concern and that regulation, in the sole judgement of the Administrator, presents a meaningful opportunity for health risk reduction.

Once contaminants have been placed on the CCL, EPA identifies if there are any additional data needs, including gaps in occurrence data for evaluation under Regulatory Determination; if sufficient occurrence data is lacking, the contaminant may be considered for monitoring under the Unregulated Contaminant Monitoring Rule.

Formaldehyde is currently listed on EPA's Fourth Contaminant Candidate List (CCL 4). In accordance with EPA-OW's process, formaldehyde was evaluated under the fourth Regulatory Determination process under SDWA and did not make a regulatory determination at this time.

2.6.3.3 Ambient Water Pathway

EPA develops recommended water quality criteria under Section 304(a) of the CWA for pollutants in surface water that are protective of aquatic life or human health designated uses. EPA has not developed CWA Section 304(a) recommended water quality criteria for the protection of human or aquatic life for formaldehyde, so there are no national recommended criteria for this use available for adoption into state water quality standards and available for use in NPDES permits. EPA may publish CWA Section 304(a)

ambient water quality criteria and/or aquatic life criteria for formaldehyde in the future if it is identified as a priority under the CWA.

2.6.3.4 Disposal and Soil Pathway

Formaldehyde is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a listed waste on the U122, K009, K010, K038, K040, K156, K157 lists. The general standard in Section RCRA 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those "*necessary to protect human health and the environment*," RCRA 3004(a). The regulatory criteria for identifying "characteristic" hazardous wastes and for "listing" a waste as hazardous also relate solely to the potential risks to human health or the environment (40 CFR §§ 261.11, 261.21-261.24). RCRA statutory criteria for identifying hazardous wastes require EPA to "tak[e] into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics." Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion Maximum Achievable Control Technology (MACT)) or injected into Underground Injection Control (UIC) Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

Emissions to ambient air from municipal and industrial waste incineration and energy recovery units that form combustion by-products from incineration treatment of formaldehyde wastes may be subject to regulations, as would formaldehyde that is burned for energy recovery.

On-site releases to land that go to underground injection in the risk evaluation. TRI reporting in 2018 indicated 14,478,154 pounds released to underground injection to a Class I well. Environmental disposal of formaldehyde injected into Class I hazardous waste well types are presumed to be managed and prevented from further environmental release by RCRA and SDWA regulations. Therefore, disposal of formaldehyde via underground injection is not likely to result in environmental and general population exposures.

EPA has identified releases to land that go to RCRA Subtitle C hazardous waste landfills. Based on 2018 reporting, TRI land disposal includes Subtitle C landfills (178,228 pounds) and reported as transferred to "other landfills" both on-site and off-site (308,328 pounds reported in 2018). Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general population exposure in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

Formaldehyde is present in commercial and consumer products that may be disposed of in landfills, such as Municipal Solid Waste (MSW) landfills. On-site releases RCRA Subtitle D municipal solid waste landfills leading to exposures of the general population (including susceptible populations) or terrestrial species from such releases may occur based on current TRI releases (i.e., 308,328 lb in 2018) for

formaldehyde. While permitted and managed by the individual states, municipal solid waste landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lbs per month). Bulk liquids, such as free solvent, may not be disposed of at MSW landfills.

On-site releases to land from industrial non-hazardous and construction/demolition waste landfills may occur for formaldehyde. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under authorized state regulatory programs, but states must implement federal regulatory requirements for siting, groundwater monitoring, and corrective action, and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirements such as for liners, post-closure and financial assurance, but are not required to do so.

2.6.4 Conceptual Model for Environmental Releases and Wastes

As described in Section 2.6.3, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2 -11 presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of formaldehyde that EPA plans to consider in the risk evaluation. The exposure pathways, exposure routes and hazards presented in this conceptual model are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of formaldehyde in exposure pathways falling under the jurisdiction of these EPA statutes.

The diagram shown in Figure 2-11 includes releases from industrial, commercial and/or consumers uses and direct or indirect releases to ambient air resulting from consumer use or installation of building materials and products containing formaldehyde as well as land application of biosolids and soil from POTWs or Industrial WWTs that may lead to exposure to aquatic and terrestrial receptors and the general population.

Releases to water/sediment via direct and indirect discharges to water that may lead to exposure to aquatic and terrestrial receptors and general population from exposure to ambient water via recreational activities such as swimming or boating are not included due to the rapid and nearly complete hydration of formaldehyde to a gem-diol, methylene glycol in water. The supporting basis for general population and environmental pathways considered for formaldehyde are included in Appendix H.

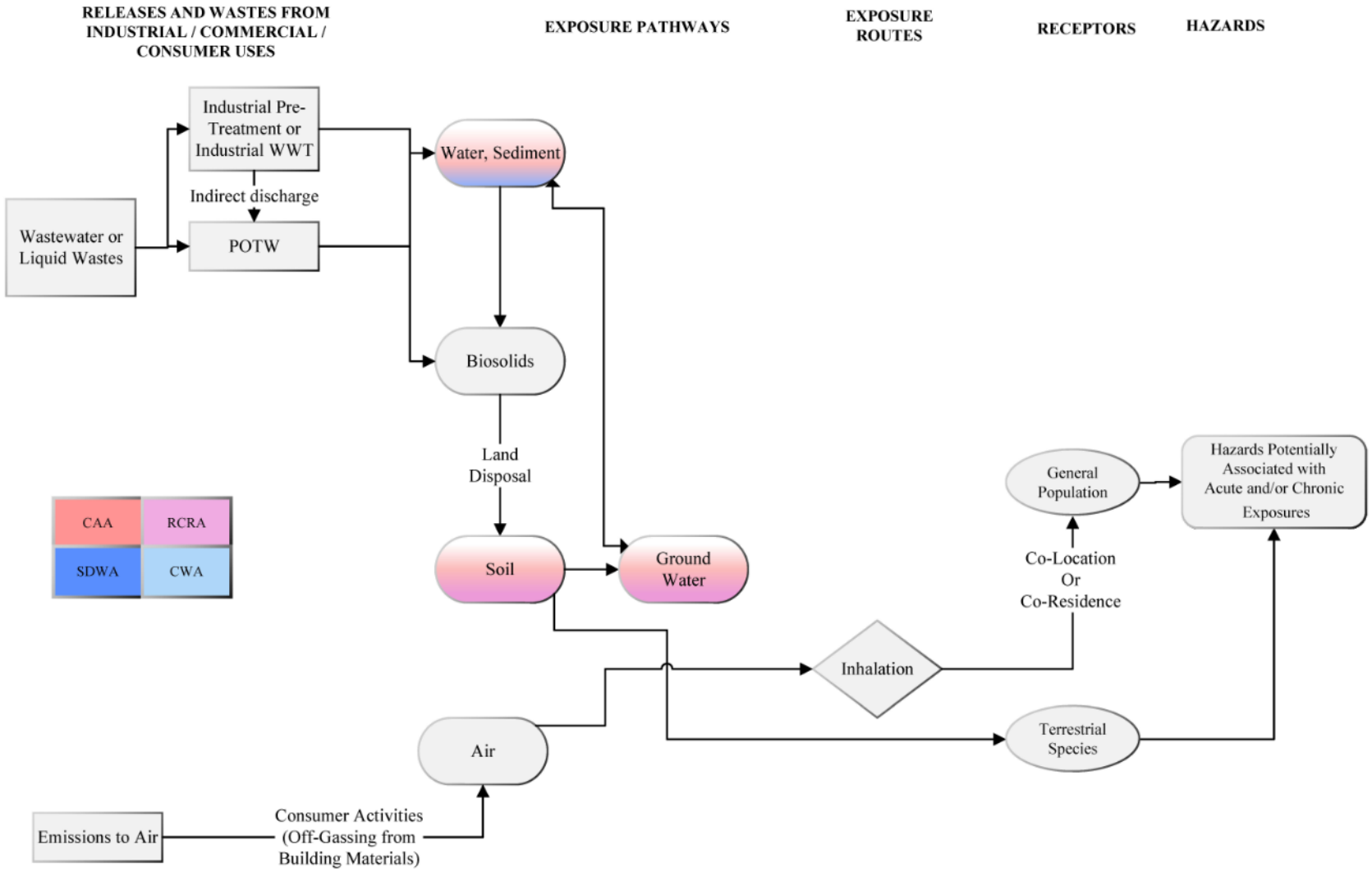

Figure 2-11 Formaldehyde Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of Formaldehyde that EPA plans to consider in the risk evaluation.

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 POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW.

b) Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of formaldehyde to date which includes a partial, but not complete review of identified information as described in Section 2.1. EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for further evaluating conditions of use, exposures, hazards and PESS during risk evaluation. Further, EPA may consider any relevant CBI in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. EPA plans to consider new information submitted by the public. EPA may update its analysis plan in the final scope document if additional data or approaches become reasonably available.

2.7.1 Physical/Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical (p-chem) properties and environmental fate and transport of formaldehyde as follows:

1) **Review reasonably available measured or estimated p-chem and environmental fate endpoint data collected using systematic review procedures and, where reasonably available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to review data and information collected through the systematic review methods and public comments about the p-chem properties (Appendix B) and fate endpoints (Appendix C), some of which appeared in the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) and in Appendices B and C. All sources cited in EPA's analysis will be evaluated according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will likely be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

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.**
   Measured data and, where necessary, model predictions of physical/chemical properties and environmental fate endpoints will be used to characterize the persistence and movement of formaldehyde within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in soil and sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

3) **Conduct a weight of the scientific evidence evaluation of environmental fate data, including qualitative and quantitative sources of information.**
   During risk evaluation, EPA plans to evaluate and integrate the physical/chemical and environmental fate evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, ambient air (consumer activities affecting co-located/co-residence populations), sediment, soil, and terrestrial biota associated to exposure to formaldehyde. EPA has not yet determined the exposure levels in these media or how they may be used in the risk evaluation. EPA plans to analyze scenario-specific exposures. Based on their p-chem properties, expected sources, and transport and transformation within the outdoor and indoor environment, chemical substances can be more prevalent in some media and less prevalent in other media. Exposure level(s) of formaldehyde can be characterized through a combination of reasonably available monitoring data and modeling approaches.

2.7.2.1 Environmental Releases

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.**
   EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is presented in Appendix A. EPA plans to continue to review data sources identified during risk evaluation using the evaluation strategy in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Potential sources of environmental release data are summarized in Table 2-5.

Table 2-5 Potential Categories and Sources of Environmental Release Data

U.S. EPA TRI Data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
Discharge Monitoring Report (DMR) surface water discharge data for formaldehyde from NPDES-permitted facilities

2) **Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies).**
   EPA has reviewed key release data sources including the Toxics Release Inventory (TRI), and the data from this source is summarized in Section 2.3.3. EPA plans to continue to review relevant data sources as identified during risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

   Additionally, for conditions of use where no measured data on releases are reasonably available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Occupational Exposures and Releases ChemSTEER (U.S. EPA, 2016).

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.**
   EPA plans to review literature sources identified and if surrogate data are found, EPA plans to match these data to applicable conditions of use for potentially filling data gaps.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.**
This item will be performed after completion of #2 and #3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt or apply models for specific conditions of use (and corresponding release scenarios). EPA has identified information from various EPA statutes (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to release estimation. EPA plans to further consider relevant regulatory requirements in estimating releases during risk evaluation.

5) **Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.**
EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the 2009 ESD on Plastics Additives and the 2011 ESD on Chemical Industry may be useful. EPA plans to need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed.

EPA Generic Scenarios are all available at the following: https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios

The following Generic Scenarios contain information related to the potential uses of formaldehyde:

- EPA's *Formulation of Waterborne Coatings Revised Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (June 2014);
- EPA's *Additives in Plastics Processing (Compounding) – Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (May 2004);
- EPA's *Additives in Plastics Processing (Converting) – Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (May 2004);
- EPA's Leather Tanning – *Revised Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (June 2001);
- EPA's *Leather Dyeing – Revised Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (September 2000);
- EPA's *Fabric Finishing – Final Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (September 1994);
- EPA's *Generic Scenario – Final Application of Chemicals in Enhanced Oil Recovery Steam Stimulation, Steam Flooding, and Polymer/Surfactant Flooding* (1994);
- EPA's *Generic Scenario – Final Application of Waterborne Wood Preservatives Using Pressure Treatment* (1994);
- EPA's *Generic Scenario – Final Water Treatment Disinfectants – Application* (1994); and
- EPA's *Generic Scenario – Material Fabrication Processes for Manufacture of Printed Circuit Boards* (1994).

OECD Emission Scenario Documents are available at the following:
http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm

The following ESD contain information related to the potential uses of formaldehyde:

http://www.oecd.org/chemicalsafety/emissionscenariodocuments.htm

- OECD's *Complementing Document to the ESD On Plastic Additives: Plastic Additives During the Use of End Products* (May 2019);
- OECD's *ESD on the Use of Textile Dyes* (February 2017);
- OECD's *Complementing Document for ESD on Coating Industry: Application of Paint Solvents for Industrial Coating* (December 2015);
- OECD's *ESD on the Industrial Use of Adhesives* (April 2015);
- OECD's *ESD on Chemicals Used in Oil Well Production* (June 2013);
- OECD's *ESD on the Use of Metalworking Fluids* (October 2011);
- OECD's *ESD on the Chemical Industry* (September 2011);
- OECD's *ESD on Coating Application via Spray Painting in the Automotive Refinishing Industry* (July 2011);
- OECD's *ESD on the Blending of Fragrance Oils into Commercial and Consumer Products* (September 2010);
- OECD's *ESD on the Formulation of Radiation Curable Coatings, Inks and Adhesives* (January 2010);
- OECD's *ESD on Plastic Additives* (July 2009);
- OECD's *ESD on Coating Industry (Paint, Lacquers, and Varnishes)* (July 2009);
- OECD's *ESD on Adhesive Formulation* (April 2009); and
- OECD's *ESD on Lubricants and Lubricant Additives* (November 2004).

EPA was not able to identify ESDs or GSs corresponding to several conditions of use including recycling of formaldehyde. EPA plans to perform additional targeted research to understand those conditions of use which may inform identification of release scenarios. EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. If ESDs and GSs are not reasonably available, other methods may be considered.

6) **Map or group each condition of use to a release assessment scenario(s).**
EPA has identified release scenarios and mapped (i.e., grouped) them to relevant conditions of use as shown in Appendix F. EPA was not able to identify release scenarios corresponding to some conditions of use (e.g., recycling). EPA plans to perform targeted research to understand those uses, which may inform identification of release scenarios. EPA may further refine the mapping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and release sources and usage rates of formaldehyde and formulations containing formaldehyde, or professional judgment) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the scientific evidence of environmental release data.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.2 Environmental Exposures

EPA plans to conduct the following to develop its environmental exposure assessment of formaldehyde:

1) **Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.**
   EPA plans to evaluate environmental exposure for the following environmental media sediment and to a limited extent soil. Nutrient uptake and air intake of formaldehyde by terrestrial plant species from sediment and soil can lead to environmental exposure to terrestrial species through ingestion of the terrestrial plant species. Depending on the information identified and evaluated through EPA's systematic review process related to these pathways, routes, species, and biota, EPA plans to develop and build out relevant exposure scenarios to evaluate environmental exposure.

   Formaldehyde is not expected to bioaccumulate in fish (U.S. EPA, 2019a) and therefore EPA does not plan to evaluate environmental exposure through oral routes via fish ingestion. Given formaldehyde's low octanol/water partition coefficient, adsorption to soil is likely low (ATSDR, 1999) and therefore EPA does not plan to evaluate environmental exposure through oral routes via soil and dust ingestion for larger terrestrial species. Depending on information identified and evaluated through EPA's systematic review process, exposure through oral and dermal routes via soil may be considered for smaller soil dwelling terrestrial species such as earthworms.

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.**
   Reasonably available environmental exposure models that meet the TSCA Section 26(h) and (i) Science Standards and that estimate environmental concentrations will be considered for use in this evaluation alongside reasonably available environmental monitoring data identified and evaluated through EPA's systematic review process to characterize environmental exposures. Modeling approaches to estimate environmental concentrations of the chemical substance of interest generally consider the following inputs: direct environmental releases indirect environmental releases (i.e., air deposition), fate and transport (partitioning within media) and characteristics of the environment (e.g., river flow, volume of lake, meteorological data). Release data can be obtained from various databases and is being developed as part of the environmental release assessment discussed in 2.7.2.1. Some models which may be considered for this evaluation include the Exposure and Fate Assessment Screening Tool (E-FAST) and PWC.

3) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
   Information identified and evaluated through EPA's systematic review process that is relevant to the exposure levels to be evaluated will be reviewed to determine how representative they are of current conditions, behaviors, uses, and use patterns. Sampling and analysis methodologies will also be reviewed to determine representativeness. These reviews add an additional layer of review and effort, but are necessary because of changes to knowledge,

understanding, methodologies, technology, sensitivity, levels of detection, uses, and use patterns.

Information and data identified and evaluated through EPA's systematic review process will be integrated throughout the risk evaluation process. The specific means by which information and data gets integrated depends on the context under which it is found and the relevancy to the exposure levels to be evaluated. monitoring data may be utilized to develop a trend analysis which can help inform the risk evaluation. Monitoring data may also be utilized to inform representativeness of modeled estimates, sensitivity of models used, or to provide further comparisons between monitored and modeled data. Information and data may also be integrated to inform inclusion or exclusion of certain environmental media, pathways, or exposure routes. It may also be used to inform model inputs or how EPA builds out various exposure scenarios.

4) **Group each condition(s) of use to environmental assessment scenario(s).**
Refine and finalize exposure scenarios for environmental receptors by considering combinations of sources (use descriptors), exposure pathways including routes, and populations exposed. For formaldehyde, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:
    - Estimates of environmental concentrations near industrial point sources based on reasonably available monitoring data.
    - Modeling inputs for release into the media of interest, fate and transport and characteristics of the environment.
    - Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
    - Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are reasonably available, and characterize exposed aquatic and terrestrial populations.
    - Weight of the scientific evidence of environmental occurrence data and modeled estimates.

5) **Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.**
Information and data identified and evaluated through EPA's systematic review process will receive a data quality rating (score) representing high, medium, low, or unacceptable quality based on a series of metrics developed and incorporated into the review process. The metrics will provide a base from which EPA plans to begin to apply a weight of the scientific evidence to each piece of information or data. The weight of the scientific evidence will, in turn, inform if and how the various pieces of information or data can or will be integrated into the risk evaluation process. The data quality rating and weight of the scientific evidence will be utilized to develop scientifically supported conclusions regarding exposure levels, as well as confidence and uncertainty surrounding the exposure levels found.

2.7.2.3 Occupational Exposures

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

1) **Review reasonably available exposure monitoring data for specific condition(s) of use.**
   EPA plans to review exposure data including workplace monitoring data collected by government agencies such as the OSHA and the NIOSH, and monitoring data found in published literature. These workplace monitoring data include personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures).

   EPA has preliminarily reviewed reasonably available monitoring data collected by OSHA and NIOSH and will match these data to applicable conditions of use. EPA has also identified additional data sources that may contain relevant monitoring data for the various conditions of use. EPA plans to review these sources and extract relevant data for consideration and analysis during risk evaluation. The following are some data sources identified thus far:

   Table 2-6 Potential Sources of Occupational Exposure Data

1999 ATSDR Toxicological Profile for Formaldehyde
OSHA Chemical Exposure Health Data (CEHD) program data
NIOSH Health Hazard Evaluation (HHE) Program reports

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to formaldehyde.**
   EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps.

3) **For conditions of use where data are limited or not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.**
   EPA has identified potentially relevant OECD ESDs and EPA GS corresponding to some conditions of use. Section 2.7.2.1 provides details on the relevant OECD ESDs and EPA GS that corresponding to some formaldehyde conditions of use. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA was not able to identify ESDs or GS's corresponding to some conditions of use, including recycling of formaldehyde. EPA plans to perform additional targeted research to understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.**
   This step will be performed after Steps #2 and #3 are completed. Based on information developed from Steps #2 and #3, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models developed by EPA/OPPT, other government agencies, or reasonably available in the scientific literature, or EPA may elect to develop additional models to assess specific condition(s) of use. Inhalation exposure models may be simple box models or two-zone (near-field/far-field)

models. In two-zone models, the near-field exposure represents potential inhalation exposures to workers, and the far-field exposure represents potential inhalation exposures to ONUs.

5) **Consider and incorporate applicable EC and/or PPE into exposure scenarios.**
EPA plans to review potentially relevant data sources on ECs and PPE to determine their applicability and incorporation into exposure scenarios during risk evaluation. EPA plans to assess worker exposure pre- and post-implementation of ECs, using reasonably available information on control technologies and control effectiveness. For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

6) **Map or group each condition of use to occupational exposure assessment scenario(s).**
EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use as shown in Appendix F. As presented in the fourth column of Table_Apx F-1, EPA has grouped the conditions of use into release/exposure scenarios which EPA plans to analyze. EPA may further refine the mapping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

EPA plans to analyze consumer exposure to formaldehyde resulting from use of products containing formaldehyde within a residence. Consumer exposure will be evaluated for both the consumer user and consumer bystander as described below.

1) **Group each condition of use to consumer exposure assessment scenario(s).**
Consumer exposure scenarios will be built out based on the conditions of use and on products containing formaldehyde available for consumer use identified in Section 2.2.1. Consumer exposure will be evaluated for inhalation and dermal routes.

   Consumer exposure via the inhalation route will be evaluated for both the consumer user and consumer bystander. Consumer inhalation exposure will be evaluated for liquid and aerosol product use as well as exposure resulting from offgassing from consumer products installed or used within a residence.

Consumer exposure via the dermal route will only be evaluated for the consumer user as a consumer bystander, as defined in this evaluation, is not expected to receive a dermal exposure. Additionally, due to the high volatility of formaldehyde, dermal exposure will only be evaluated for select conditions of use where there is a constant supply of product against the skin and evaporation of product during use is inhibited due to a barrier (rag) or full immersion of a body part into a pool of material occurs.

When evaluating consumer exposure, EPA plans to evaluate the methodologies to be used based on information identified and evaluated as part of EPA's systematic review process. Information EPA plans to utilize consumer use pattern information (amount of a product used and duration of product use) and product specific information (amount of chemical in products (weight fraction)). Other information like room of use will depend on the intended use of products and where it is most likely to be used. Such information may be found in published literature and consumer use surveys. Building parameters like size of building, volume of room where use occurs, air exchange rates, ventilation rates, and similar parameters are expected to be relatively consistent across residences and will rely on default values within models or data from EPA's exposure factors handbook. EPA plans to consider a range of values when evaluating exposure and will vary specific parameters to which the selected model(s) is(are) sensitive.

2) **Evaluate the relative potential of indoor exposure pathways based on reasonably available data.**
Exposure pathways associated with inhalation and dermal routes are expected to be the predominant exposure pathways to be evaluated for consumer exposure to formaldehyde. This is based on p-chem properties, fate properties, expected chemical behaviors associated with the conditions of use identified in Section 2.2.1, and product use patterns. The high volatility of formaldehyde indicates inhalation exposure can result from evaporation of products used on a surface (furniture, counter tops, floors, etc.), aerosolization of product during application, and offgassing from products containing formaldehyde. The high volatility of formaldehyde also indicates that formaldehyde in liquid products applied to a surface may rapidly volatize leading to an inhalation exposure rather than a dermal exposure. Dermal exposure may occur during use of a liquid product (or possibly an aerosol product applied to a surface), however, the high volatility of formaldehyde indicates dermal exposure may be limited to certain scenarios where evaporation is prohibited, or full immersion into a product occurs. Once in the vapor phase, formaldehyde is expected to remain in the vapor phase and is not expected to adsorb to particles or dust, therefore EPA does not plan to evaluate exposure via an oral pathway (ingestion of dust, mouthing, etc.).

3) **Review existing indoor exposure models that may be applicable in estimating indoor air, indoor dust concentrations, or indoor dust surface loadings.**
Consumer inhalation exposure can be evaluated utilizing several different models including Consumer Exposure Model (CEM), Multi-Chamber Concentration and Exposure Model (MCCEM), and for off-gassing IECCU or FIAM. Selection of the appropriate EPA model depends on a fit-for-purpose analysis of the conditions of use, products available, and relevant, pre-defined scenarios within the various models.

Consumer dermal exposure will be evaluated utilizing CEM, since MCCEM, IECCU, and FIAM do not have dermal components. Other consumer models, like CONSEXPO, may have a dermal component, but are not EPA models. While we are not excluding the use of non-EPA models, use of such models require a more thorough review of the model, model components, peer review background, and other aspects prior to use. Dermal exposure can vary depending on the methodology used within a given model. EPA plans to utilize a permeability approach with respect to dermal exposure due to the scenarios to be evaluated (prohibited evaporation due to a barrier or full immersion into a product during use). Within CEM, the permeability approach is more representative of these consumer scenarios because it does not consider evaporation. The fraction absorbed approach within CEM considers evaporation and therefore may not be representative of the scenarios EPA plans to evaluate.

4) **Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available.**
The information and data identified and evaluated under EPA's systematic review process may include certain empirical data which may be used to develop, adapt, or apply certain exposure models. Empirical data can also be used for comparison purposes to identify trends, similarities, or differences between approaches or models. Where differences are identified, EPA may consider the underlying parameters and assumptions to identify why differences may exist.

   Empirical information and data can also help inform inputs for certain exposure models used for this evaluation. EPA plans to evaluate the reasonably available information involving permeability coefficients associated with formaldehyde in multiple product mixtures (aqueous, solvent, or mixture). The absence of empirical information and data can inform revisions to approaches or methodologies currently included for this evaluation.

5) **Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with each other and with indoor monitoring data reporting formaldehyde in specific media (e.g., dust or indoor air).**
The information and data identified and evaluated under EPA's systematic review process may include consumer exposure information for specific consumer products, consumer uses, or consumer use locations. This information can be used to identify trends as well as compare or contrast results in different locations. It can also be used to inform modeling methodologies and approaches utilized by EPA for this evaluation. Some challenges arise with product specific consumer exposure information since it may not align adequately with a specific condition of use analyzed in this evaluation.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further refined.**
The information and data identified and evaluated under EPA's systematic review process may include exposure information for PESS. This information can include exposure factors or activity patterns not captured in other information and data source categories. Use of PESS specific information can be used to inform approaches and methodologies necessary to adequately consider PESS in this evaluation. The expected methodologies and approaches

described for consumer exposure in this evaluation indirectly capture PESS in the evaluation. Consumer users are defined for this evaluation, and EPA plans to evaluate representative age groups which are expected to be intended users of formaldehyde containing consumer products. Considering PESS, consumer users for this evaluation may be men and women of reproductive age, individuals with pre-existing health conditions which could impact their ability to manage an exposure, or elderly individuals. However, an infant is not expected to be an intended consumer user for anticipated products identified for this evaluation and therefore would not be considered PESS as a user. At the same time, infants may fall into the category of consumer bystander as defined in this evaluation. Consumer bystanders can fall into any age group (infant to elderly) and therefore are considered as part of the consumer bystander exposure evaluation. Depending on the units associated with various health endpoints identified for this evaluation determines if PESS evaluations need to be expanded or refined. If a health endpoint is based on a concentration, then PESS is addressed alongside all other age groups since concentration at a given receptor point is independent of an individual's surface area, body weight, inhalation rates, etc. If a health endpoint is based on a dose, then to adequately consider PESS, some additional analysis or refinement may be necessary.

7) **Evaluate the weight of the scientific evidence of consumer exposure estimates based on different approaches.**
   Information and data identified and evaluated through EPA's systematic review process will receive a data quality rating (score) representing high, medium, low, or unacceptable quality based on a series of metrics developed and incorporated into the review process. The metrics will provide a base from which EPA plans to begin to apply a weight of the scientific evidence to each piece of information or data. The weight of the scientific evidence will, in turn, inform if and how the various pieces of information or data can or will be integrated into the risk evaluation process. The data quality rating and weight of the scientific evidence will be utilized to develop scientifically supported conclusions regarding exposure levels, as well as confidence and uncertainty surrounding the exposure levels found.

2.7.2.5 General Population

EPA plans to analyze general population exposures via the inhalation route as a result of off-gassing for co-location and co-residence populations. Co-location, for purposes of this evaluation, refers to an individual living very near a separate residence where one or more consumer products from which formaldehyde is expected to off-gas for an extended period of time are utilized and installed. Co-residence, for purposes of this evaluation, refers to an individual living adjacent to (immediately above or next to) a separate residence where one or more consumer products from which formaldehyde is expected to off-gas for an extended period of time are utilized and installed.

1) **Refine and finalize exposure scenarios for general population by considering combinations of sources and uses, exposure pathways including routes, and exposed populations.**
   General population exposure scenarios will be built out based on the information and data identified and evaluated as part of EPA's systematic review process. General population exposure for co-located and co-residence scenarios may consist of one or more distances very near a residence (co-location) or one or more building configurations (co-residence).

2) **Review reasonably available environmental and biological monitoring data for exposure pathways and media to which general population exposures are expected.**
Information and data identified and evaluated as part of EPA's systematic review process will be utilized to inform decisions about exposure pathways and media to which general population exposures may occur.

3) **For exposure pathways where empirical data is not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.**
General population exposure levels can be estimated utilizing a variety of EPA models. Co-location scenarios can be modeled using AERMOD since it allows a user to model concentrations at very small distances from an emission source. Co-residence scenarios can be modeled using IECCU since it is an indoor air pollutant transport model capable of modeling multiple zones and multiple building configurations based on user defined inputs.

4) **Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling approaches.**
General population exposure for co-located and co-residence scenarios resulting from off-gassing may need to consider variable emission rates due to the promulgation of regulations under TSCA which limits formaldehyde content in certain composite wood products (as defined by the regulation). The regulation was promulgated in 2016, so consideration of off-gassing products before and after this date may need to be evaluated separately since off-gassing can be ongoing for more than 4 years. Screening level analysis may be applicable in this situation to identify if off-gassing after 4 years can lead to acute or chronic exposure levels or concerns. Further consideration of this approach will be reviewed throughout the risk evaluation process.

5) **Review reasonably available exposure modeled estimates. For example, existing models developed for a previous formaldehyde chemical assessment may be applicable to EPA's assessment.**
The information and data identified and evaluated as part of EPA's systematic review process may include modeled estimates of formaldehyde concentrations associated with general population exposure. This information can be used to inform approaches and methodologies utilized by EPA for this evaluation. The degree to which this information is used depends on a variety of factors including comparability of different models used, model parameters utilized to derive modeled estimates, and comparability of such modeled scenarios and results.

6) **Review reasonably available information about population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further defined (e.g., early life and/or puberty as a potential critical window of exposure).**
The information and data identified and evaluated under EPA's systematic review process may include exposure information for PESS. This information can include exposure factors or activity patterns not captured in other information and data source categories. Use of PESS specific information can be used to inform approaches and methodologies necessary to adequately consider PESS in this evaluation. The expected methodologies and approaches described for general population in this evaluation indirectly capture PESS in the evaluation. Individuals within the general population can fall into any age group (infant to elderly) and therefore are considered part of the general population evaluated for exposure in this

evaluation. Depending on the units associated with various health endpoints identified for this evaluation determines if PESS evaluations need to be expanded or refined. If a health endpoint is based on a concentration, then PESS is addressed alongside all other age groups since concentration at a given receptor point is independent of an individual's surface area, body weight, inhalation rates, etc. If a health endpoint is based on a dose, then to adequately consider PESS, some additional analysis or refinement may be necessary.

7) **Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.**
Information and data identified and evaluated through EPA's systematic review process will receive a data quality rating (score) representing high, medium, low, or unacceptable quality based on a series of metrics developed and incorporated into the review process. The metrics will provide a base from which EPA plans to begin to apply a weight of the scientific evidence to each piece of information or data. The weight of the scientific evidence will, in turn, inform if and how the various pieces of information or data can or will be integrated into the risk evaluation process. The data quality rating and weight of the scientific evidence will be utilized to develop scientifically supported conclusions regarding exposure levels, as well as confidence and uncertainty surrounding the exposure levels found

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

EPA plans to conduct an environmental hazard assessment of formaldehyde 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).**
EPA plans to analyze the hazards of formaldehyde to aquatic and/or terrestrial organisms, including plants, invertebrates (e.g., insects, arachnids, mollusks, and crustaceans), and vertebrates (e.g., mammals, birds, amphibians, fish, and reptiles) across exposure durations and conditions if potential environmental hazards are identified through public comments and the results of the systematic search and screening of the literature. Additional types of environmental hazard information will also be considered (i.e., analogue and read-across data) when characterizing the potential hazards of formaldehyde to aquatic and/or terrestrial organisms.

   EPA plans to evaluate environmental hazard data using the environmental toxicity data quality criteria outlined in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The study evaluation results will be documented in the risk evaluation phase and data from suitable studies will be extracted and integrated in the risk evaluation process.

   Hazard endpoints (e.g., mortality, growth, immobility, and reproduction) will be evaluated, while considering data availability, relevance and quality.

2) **Derive hazard thresholds for aquatic and/or terrestrial organisms.**
Depending on the robustness of the evaluated data for a particular organism or taxa (e.g., aquatic invertebrates), environmental hazard values (e.g., EC_x, LC_x, NOEC, LOEC) may be derived and used to further understand the hazard characteristics of formaldehyde to aquatic and/or terrestrial species. Identified environmental hazard thresholds may be used to derive concentrations of concern (COC), based on endpoints that may affect populations of organisms or taxa analyzed

3) **Evaluate the weight of the scientific evidence of environmental hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

4) **Consider the route(s) of exposure, based on reasonably available monitoring and modeling data, and other reasonably available approaches to integrate exposure and hazard assessments.**
EPA plans to consider aquatic (e.g., water and sediment exposures) and terrestrial pathways in the formaldehyde conceptual model. These organisms may be exposed to formaldehyde via a number of environmental pathways (i.e., surface water, sediment, soil, and diet).

5) **Conduct an environmental risk characterization of Formaldehyde.**
EPA plans to conduct a risk characterization of formaldehyde to identify if there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of formaldehyde in environmental media (i.e., water, sediment, and soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk.

6) **Consider a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of Formaldehyde.**
EPA may consider assessing the persistence, bioaccumulation, and toxic (PBT) potential of formaldehyde after reviewing relevant p-chem properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (BAF/BCF) of formaldehyde. In addition, EPA plans to integrate traditional environmental hazard endpoint values (e.g., LC_{50} and LOEC) and exposure concentrations (e.g., surface water concentrations, tissue concentrations) for formaldehyde with the fate parameters (e.g., BAF, BCF, BMF, and TMF).

2.7.3.2 Human Health Hazards

EPA plans to 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).**
EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for formaldehyde. EPA plans to publish the systematic review documentation prior to finalizing the scope document.

Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods, in silico and high throughput screening. The association between acute and chronic exposure scenarios to formaldehyde and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

2) **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 identified human health hazard endpoints.**
EPA plans to identify human health hazards from acute and chronic exposures by evaluating the human and animal data that meet the systematic review data quality criteria described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (oral, dermal, inhalation) and by cancer and noncancer endpoints.

Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011b, 1994). Dose-response analyses may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints are not reasonably available or would not alter the analysis.

The cancer mode of action (MOA) determines how cancer risks can be quantitatively evaluated. Carcinogenic hazards have been identified for formaldehyde as noted in the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a). EPA plans to evaluate information on genotoxicity and the mode of action for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005).

3) **In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.**
Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to formaldehyde hazard(s). Susceptibility of particular human receptor groups to formaldehyde will be determined by evaluating information on factors that influence susceptibility.

EPA has reviewed some sources containing hazard information associated with susceptible populations and lifestages such as pregnant women and infants. Pregnancy (i.e., gestation) and childhood are potential susceptible lifestages for formaldehyde exposure. The European Chemicals Agency 2017 document Investigation Report: Formaldehyde and Formaldehyde Releasers (ECHA, 2017) contains a list of studies that will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to formaldehyde's hazard(s). EPA plans to review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

4) **Derive points of departure (PODs) where appropriate for the routes and durations of exposure; conduct benchmark dose modeling depending on the reasonably available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.**
Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with the EPA's *Benchmark Dose Technical Guidance Document*. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

   EPA plans to evaluate whether the reasonably available PBPK and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD, or for extrapolation of the POD to standard exposure durations (e.g., lifetime continuous exposure). If application of the PBPK model is not possible, oral PODs may be adjusted by $BW^{3/4}$ scaling in accordance with U.S. EPA (2011), and inhalation PODs may be adjusted by exposure duration and chemical properties in accordance with U.S. EPA (1994).

5) **Evaluate the weight of the scientific evidence of human health hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

6) **Consider the route(s) of exposure (e.g., oral, inhalation, dermal), reasonably available route-to-route extrapolation approaches; biomonitoring data; and approaches to correlate internal and external exposures to integrate exposure and hazard assessment.**
At this stage of review, EPA believes there will be sufficient data to conduct dose-response analysis and/or benchmark dose modeling for the oral route of exposure for formaldehyde. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to formaldehyde, which could be important for worker, consumer, and general population risk analysis. Reasonably available data will be assessed to determine whether or not a point of departure can be identified for the dermal and inhalation routes. This may include using route-to-route extrapolation methods where appropriate depending on the nature of the reasonably available data.

   If sufficient toxicity studies are not identified in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation exposures. Without an adequate PBPK model, the approaches described in the EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004a) could be applied to extrapolate from oral to dermal exposure. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure. Similar methodology may also be used for assessing inhalation exposures

2.7.4 Summary of Risk Approaches for Characterization

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

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

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45). As explained in the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. The draft risk evaluation for formaldehyde will be peer reviewed.

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APPENDICES

Appendix A GRAY LITERATURE SOURCES

Table_Apx A-1. Gray Literature Sources that Yielded Results for Formaldehyde

Source/ Agency	Source Name	Source Type	Source Category
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document
Australian Government : Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Cancer Potency Information	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Reference Exposure Levels (RELs)	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer	Other US Agency Resources	Assessment or Related Document
ECHA	ECHA Documents	International Resources	Assessment or Related Document
ECHA	Annex XV Restriction Report	International Resources	Assessment or Related Document
Env Canada	Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment	International Resources	Assessment or Related Document
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document

Source/ Agency	Source Name	Source Type	Source Category
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and Water Quality Exchange (WQX)	U.S. EPA Resources	Database
EPA	Office of Air: Air Emission Factors	U.S. EPA Resources	Regulatory Document or List
EPA	Office of Air: TRI	U.S. EPA Resources	Database
EPA	Office of Air: AQS, Annual	U.S. EPA Resources	Database
EPA	TSCA Hazard Characterizations	U.S. EPA Resources	Assessment or Related Document
EPA	IRIS Summary	U.S. EPA Resources	Assessment or Related Document
EPA	Support document for AEGLS	U.S. EPA Resources	Assessment or Related Document
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	U.S. EPA Resources	Database
EPA	Office of Air: National Emissions Inventory (NEI) - Additional Documents	U.S. EPA Resources	Assessment or Related Document
EPA	EPA Pesticide Chemical Search (assessment)	U.S. EPA Resources	Assessment or Related Document
EPA	Other EPA: Misc sources	U.S. EPA Resources	General Search
EPA	EPA: AP-42	U.S. EPA Resources	Regulatory Document or List
EPA	TRI: Envirofacts Toxics Release Inventory 2017 Updated Dataset	U.S. EPA Resources	Database

Source/ Agency	Source Name	Source Type	Source Category
EPA	EPA: Generic Scenario	U.S. EPA Resources	Assessment or Related Document
EPA	EPA Discharge Monitoring Report Data	U.S. EPA Resources	Database
EPA	EPA Ambient Monitoring Technology Information Center – Air Toxics Data	U.S. EPA Resources	Database
EPA	Office of Water: CFRs	U.S. EPA Resources	Regulatory Document or List
EPA	Office of Air: CFRs and Dockets	U.S. EPA Resources	Regulatory Document or List
IARC	IARC Monograph	International Resources	Assessment or Related Document
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Pocket Guides	Other US Agency Resources	Database
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document
NLM	National Library of Medicine’s HazMap	Other US Agency Resources	Database

Source/ Agency	Source Name	Source Type	Source Category
NTP	RoC Monographs	Other US Agency Resources	Assessment or Related Document
NTP	Additional NTP Reports	Other US Agency Resources	Assessment or Related Document
OECD	OECD Substitution and Alternatives Assessment	International Resources	Assessment or Related Document
OECD	OECD SIDS	International Resources	Assessment or Related Document
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document
OECD	OECD: General Site	International Resources	General Search
OSHA	OSHA Chemical Exposure Health Data	Other US Agency Resources	Database
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other US Agency Resources	Database
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document
RIVM	Probit Function Technical Support Document	International Resources	Assessment or Related Document
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document

Appendix B PHYSICAL AND CHEMICAL PROPERTIES

This appendix provides p-chem information and data found in preliminary data gathering for formaldehyde. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* (EPA-HQ-OPPT-2018-0438).

Table_Apx B-1. Physical and Chemical Properties of Formaldehyde

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	CH_2O	NA	NA
Molecular weight	30.026 g/mol	NA	NA
Physical state	Colorless gas	Rumble, 2018	High
Physical properties	Clear, water-white, very slightly acid, gas or liquid; pungent, suffocating odor	NLM, 2019	High
Melting point	-118.3 to -92°C	Elsevier, 2019	High
Boiling point	-19.5 °C at 760 mm Hg	O'Neil, 2013	High
Density	0.815 g/cm^3 at -20°C	Rumble, 2018	High
Vapor pressure	3890 mm Hg at 25°C	NLM, 2019	High
Vapor density	1.067 (air = 1)	NLM, 2019	High
Water solubility	4×10^5 mg/L at 20°C	NLM, 2019	High
Log Octanol/water partition coefficient (Log Kow)	0.35	NLM, 2019	High
Henry's Law constant	3.37×10^{-7} atm·m^3/mol at 25°C	NLM, 2019	High

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Flash point	NA[b]		
Auto flammability	ca. 300 °C	O'Neil, 2013	High
Viscosity	Not available		
Refractive index	1.3746	NLM, 2019	High
Dielectric constant	Not available		

[a]Measured unless otherwise noted; [b]Selected value for gas state; NA = not applicable

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

Table_Apx C-1. Environmental Fate and Transport Properties of Formaldehyde

Property or Endpoint	Value[a]	Reference
Direct Photodegradation	$t_{½}$ = 6 hours in simulated sunlight	ATSDR (1999); Su (1979)
	$t_{½}$ = 1.6–19 hours in sunlight; degradation products H_2, CO, H^+, HCO^-	ATSDR (1999) citing Lewis (1993)
Indirect Photodegradation	45 hours (based on ^{-}OH reaction rate constant 8.5×10^{-12} cm^3/molecule-second at 25 ºC) 57 days (based on nitrate radicals reaction rate constant 5.6×10^{-16} cm^3/molecule-second at 25 ºC)	HSDB (2015); Atkinson (1992); NIST (2013)
Hydrolysis	Not expected; however, in an aqueous environment, formaldehyde will be fully hydrated to the gem-diol, methylene glycol	OECD (2002) citing Betterton (1992); HSDB (2015); ATSDR (1999)
Biodegradation (Aerobic)	Water: 100%/30 hours (die-away test) in stagnant lake water	HSDB (2015); ATSDR (1999) citing U.S. EPA (1976)
	Sediment: 90%/28 days (OECD 301D) with non-acclimated inoculum	OECD (2002) citing Gerike (1990); HSDB (2015)
Biodegradation (Anaerobic)	Water: 100%/48 hours (die-away test) in stagnant lake water	HSDB (2015); ATSDR (1999)
Wastewater Treatment	Removal/secondary treatment: 57–99%, removal percentages based upon data from a semi- continuous sewage and continuous activated sludge biological treatment simulator	Howard (1991)
	94% total removal (93% by biodegradation, 0.28% by sludge, 0% by volatilization to air; estimated)[b]	U.S. EPA (2012b)
Bioconcentration Factor	Not expected; based on a lack of evidence of bioaccumulation in a variety of fish and shrimp and a log K_{OW} of 0.35; studies suggest that formaldehyde is rapidly metabolized	OECD (2002); Hose and Lightner (1980); Sills and Allen (1979)
	3.2 (estimated)[b]	U.S. EPA (2012b)
Bioaccumulation Factor	1.1 (estimated)[b]	U.S. EPA (2012b)

Property or Endpoint	Value[a]	Reference
Soil organic Carbon:Water Partition Coefficient (Log K_{OC})	Absorbs to clay minerals; used as a soil fumigant	HSDB (2015); SYKE (2018) citing De and Chandra (1978)
	0 (K_{OC} = 1; MCI method); 0.89 (K_{OC} = 7.8; K_{OW} method) (estimated)[b]	U.S. EPA (2012b)

[a]Measured unless otherwise noted; [b] EPI Suite™ physical property inputs: Log K_{OW} = 0.35, BP = −19.5 ºC, MP = −92 ºC, VP = 3,890 mm Hg, WS = 4 × 105 mg/L, HLC = 3.37 × 10-7(atm-m3/mole), BIOP = 4, BioA = 1 and BioS = 1 SMILES: O=C; □OH = hydroxyl radical; K_{OC} = organic carbon-water partitioning coefficient; K_{OW} = octanol-water partition coefficient

Appendix D REGULATORY HISTORY

The chemical substance, formaldehyde, is subject to federal and state laws and regulations in the United States (Table_Apx D-1 and Table_Apx D-2). Regulatory actions by other governments, tribes and international agreements applicable to formaldehyde are listed in Table_Apx D-3.

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to Formaldehyde. Appendix D contains the compiled information from available federal, state, international and other government sources. EPA evaluated and considered the impact of these existing laws and regulations (e.g., regulations on landfill disposal, design and operations) during scoping to determine what, if any, further analysis might be necessary as part of the risk evaluation. Consideration of the nexus between these existing regulations and TSCA uses may additionally be made as detailed/specific conditions of use and exposure scenarios are developed in conducting the analysis phase of the risk evaluation.

D.1 Federal Laws and Regulations

Table_Apx D-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Formaldehyde is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of formaldehyde as high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	Formaldehyde is 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).
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	23 risk reports received for formaldehyde, or containing information related to formaldehyde were received between 1989 and 2011. (U.S. EPA, ChemView. Accessed April 3, 2019). Link to the 8(e) submission crosswalk HERE:

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Toxic Substances Control Act (TSCA) – Subchapter 6	TSCA Title VI sets formaldehyde emission standards for composite wood products (i.e., hardwood plywood, medium density fiberboard, and thin-medium density fiberboard) and requires that any component parts or finished goods fabricated with composite wood products use compliant panels that have met the emission standards and been tested/certified by an EPA recognized TSCA Title VI third party certifier. The TSCA Title VI program also has provisions for labeling, recordkeeping, import certification, and accreditation/third party certification oversight and annual reporting on the regulated composite wood products manufactured by mills.	TSCA Title VI sets formaldehyde emission standards for composite wood products (i.e., hardwood plywood, medium density fiberboard, and thin-medium density fiberboard) and requires third party certification, oversight, and annual reports to be submitted to EPA annually on all panel manufacturing under the TSCA Title VI program both domestically and internationally (81 FR 89674).
Emergency Planning and Community Right-To-Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (e.g., quantities recycled, treated, combusted) and pollution prevention activities (under Section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (i.e., air, land and water).	Formaldehyde 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	Formaldehyde was registered as an antimicrobial, conventional chemical on January 25, 1967. In June 2008 EPA published a reregistration eligibility decision for formaldehyde and paraformaldehyde (Case 0556; EPA Document 739-R-08-004). Formaldehyde is currently under registration

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	review, and the final work plan has been published (EPA-HQ-OPP-2015-0739).
Federal Food, Drug, and Cosmetic Act (FFDCA) –Section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to set tolerances (rules that establish maximum allowable residue limits), or exemptions from the requirement of a tolerance, for pesticide residues (including inert ingredients) on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the pesticide residues permitted under the action are "safe." Section 408(b) of the FFDCA defines "safe" to mean a reasonable certainty that no harm will result from aggregate, nonoccupational exposures to the pesticide. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation under FFDCA Section 408(d) or (e). In the absence of a tolerance or an exemption from tolerance, a food containing a pesticide residue is considered adulterated and may not be distributed in interstate commerce.	Formaldehyde is no longer exempt from the requirement of a tolerance (the maximum residue level that can remain on food or feed commodities under 40 CFR Part 180, Subpart D).
Clean Air Act (CAA) – Section 111(b)	Requires EPA to establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution, which may reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction (BSER) which (taking into account the cost of achieving reductions and environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	Formaldehyde is subject to the NSPS for equipment leaks of volatile organic compounds (VOCs) in the synthetic organic chemicals manufacturing industry for which construction, reconstruction or modification began after January 5, 1981 and on or before November 7, 2006 (40 CFR Part 60, Subpart VV).
Clean Air Act (CAA) – Section 112(b)	Defines the original list of 189 hazardous air pollutants (HAPs). Under 112(c) of the	Formaldehyde is listed as a HAP (42 U.S.C 7412).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA Section 112(d). CAA Section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	
Clean Air Act (CAA) – Section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). For major sources 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). For area sources, the standards must require generally achievable control technology (GACT) though may require MACT.	EPA has established NESHAPs for a number of source categories that emit formaldehyde to air. See https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9. Formaldehyde is also listed within the definition of *Total hazardous air pollutant emissions* which sums the emissions of six compounds: (acetaldehyde, acrolein, formaldehyde, methanol, phenol, and propionaldehyde). 40 CFR Subpart DDDD
Clean Air Act (CAA) – Section 183(e)	Section 183(e) requires EPA to list the categories of consumer and commercial products that account for at least 80 percent of all VOC emissions in areas that violate the National Ambient Air Quality Standards (NAAQS) for ozone and to issue standards for these categories that require "best available controls." In lieu of regulations, EPA may issue control techniques guidelines if the guidelines are determined to be substantially as effective as regulations.	Formaldehyde is listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). Formaldehyde has a reactivity factor of 8.97 g O3/g VOC.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Safe Drinking Water Act (SDWA) – Section 1412(b)	Every 5 years, EPA must publish a list of contaminants that: (1) are currently unregulated, (2) are known or anticipated to occur in public water systems (PWSs) and (3) may require regulations under SDWA. EPA must also determine whether to regulate at least five contaminants from the list every 5 years.	Formaldehyde was identified on both the Third (2009) and Fourth (2016) Contaminant Candidate Lists (CCL) (74 FR 51850, October 8, 2009) and (81 FR 81099, November 17, 2016).
Resource Conservation and Recovery Act (RCRA) – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Formaldehyde is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U122 (40 CFR 261.33). Formaldehyde is also listed as part of various groups of chemicals in Appendix VII to Part 261 – Basis for Listing Hazardous Waste as K009, K010, K038, K040, K156, and K157 (40 CFR Appendix VII to Part 261). Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the AutoAlliance International, Inc. of Flat Rock Michigan and DamlierChrysler Corporation, Jefferson North Assembly Plant, Detroit Michigan entries which permit a TCLP extraction sample not-to-exceed limit of 84.2 mg/L of formaldehyde in their leachate extract, and a total concentration of formaldehyde not to exceed 689 mg/kg, and a maximum allowable groundwater concentration (µg/L) of 1,380.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Eastman Chemical Company – Texas Operations which permits a bottom ash leachable concentration at 347 mg/L. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company Dearborn Assembly Plant which permits a TCLP extraction sample not to exceed 80 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 700 mg/kg, and a total concentration of formaldehyde not to exceed 689 mg/kg, and a maximum allowable groundwater concentration (µg/L) of 1,400. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company, Kansas City Assembly Plant which permits a TCLP extraction sample not to exceed 343 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 6880 mg/kg.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company, Michigan Truck Plant and Wayne Integrated Stamping and Assembly Plant which permits a TCLP extraction sample not to exceed 84.2 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 689 mg/kg, and a maximum allowable groundwater concentration (µg/L) of 1,380. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company, Wixom Assembly Plant which permits a TCLP extraction sample not to exceed 84.2 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 689 mg/kg. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation Assembly Plant which permits a TCLP extraction sample not to exceed 84 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 700 mg/kg, and a maximum

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		allowable groundwater concentration (µg/L) of 1,390. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation, Flint Truck and Hamtramck facilities which permit TCLP extraction samples not to exceed 63 mg/L of formaldehyde in their leachate extract and total concentrations of formaldehyde not to exceed 535 mg/kg. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation, Hamtramck which permits a TCLP extraction sample not to exceed 63 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 535 mg/kg. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation Janesville Truck Assembly Plant which permits a TCLP extraction sample not to exceed 43 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 540 mg/kg, and a maximum

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		allowable groundwater concentration (mg/L) of 0.950. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation Lansing Car Assembly – Body Plant which permits a TCLP extraction sample not to exceed 672 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 2100 mg/kg. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation Pontiac East – Body Plant which permits a TCLP extraction sample not to exceed 63 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 535 mg/kg. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Trigen/Cinergy-USFOS of Lansing LLC at General Motors Corporation, Lansing Grand River which permits a TCLP extraction sample not to exceed 84.2 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 689 mg/kg.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	Formaldehyde is a hazardous substance under CERCLA. Releases of formaldehyde in excess of 100 pounds must be reported (40 CFR 302.4).
Superfund Amendments and Reauthorization Act (SARA) –	Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program and provides new enforcement authorities and settlement tools.	Formaldehyde is listed 224 scoring 605 points on SARA, an amendment to CERCLA and the CERCLA Priority List of Hazardous Substances. This list includes substances most commonly found at facilities on the CERCLA National Priorities List (NPL) that have been deemed to pose the greatest threat to public health.
Other Federal Regulations		
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics.	The FDA regulates formaldehyde as a fumigant under its food additive and GRAS regulations (21 CFR 174.340, 175.105, 175.210, 175.300, 176.170, 176.180, 176.200, 177.1200, 177.2410, and 178.3120). Formaldehyde is also listed as an adhesive used in food packaging at 21 CFR 175.105. Formaldehyde is also listed as an “Inactive Ingredient for approved Drug

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		Products" by FDA with an established limit of 0.2% W/W on the amount of formaldehyde that can be present a solution, and 0.27% W/W on the amount of formaldehyde that can be present in an emulsion or cream (FDA Inactive Ingredient Database. Accessed April 10, 2019.
Federal Hazardous Substance Act (FHSA)	Requires precautionary labeling on the immediate container of hazardous household products and allows the Consumer Product Safety Commission (CPSC) to ban certain products that are so dangerous or the nature of the hazard is such that labeling is not adequate to protect consumers.	Under the Federal Hazardous Substance Act, Section 1500.83(a)(31), formaldehyde and products containing 1% or more formaldehyde are listed as "strong sensitizer" substances by CPSC (16 CFR 1500.13).
Occupational Safety and Health Act (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 (29 U.S.C Section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.	In 2013, OSHA issued occupational safety and health standards for formaldehyde that included a PEL of 0.75 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1048(c)(1)). OSHA has separate sections of the CFR for formaldehyde PELs for shipyard and construction employment; however, those sections reference the generic formaldehyde PEL at 1910.1048(c)(1),
Atomic Energy Act	The Atomic Energy Act authorizes the Department of Energy (DOE) 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 formaldehyde is [value of the TLV] ppm (8hr Time Weighted Average) and

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		[value] ppm Short Term Exposure Limit (STEL).
Federal Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to: • Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. • Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	The Department of Transportation (DOT) has designated Formaldehyde solutions as a hazardous material, and there are special requirements for marking, labeling and transporting it (49 CFR 172.101(g)).

D.2 State Laws and Regulations

Table_Apx D-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels (AAL) of Formaldehyde in New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants) is 1.3 (µg/m³) for a 24-hour AAL, 0.88 (µg/m³) for an annual AAL, 0.015 lbs/day for a 24-hour de-minimis, and 5.6 lbs/year for an annual de-minimis. Acceptable Ambient Levels (AAL) of Formaldehyde in Rhode Island is 50 (µg/m³) for a 1-hour AAL, 40 (µg/m³) for a 24-hour AAL, and 0.08 lbs/year for an annual (Air Pollution Regulation No. 22). As well, the requirement for registration has a threshold of 9 lbs/year as a minimum quantity for air emissions of formaldehyde; any exceedance of this minimum would trigger a reporting requirement the following year (Air Pollution Regulation No. 22.4.2(c)).
State Drinking Water Standards and Guidelines	Formaldehyde is listed in the groundwater: residential and nonresidential part 201 generic cleanup criteria and screening levels in Michigan with the following levels: residential drinking water criteria of 1,300 ppm, nonresidential drinking water criteria of 3,800 ppm, groundwater surface water interface criteria of 120 ppm, residential groundwater volatilization to indoor air inhalation criteria of 63,000 ppm, nonresidential groundwater volatilization to indoor air inhalation criteria of 360,000 ppm, and a water solubility of 550,000,000 ppm (Mich. Admin. Code r.299.44 and r.299.49, 2017),
State PELs	California (PEL of 0.75 ppm and a STEL of 2 (Cal Code Regs. Title 8, § 5155 and Cal Code Regs. Title 8, § 5217) Hawaii PEL: 0.75 ppm and a STEL of 2 for 15 minutes (Hawaii Administrative Rules Section 12-60-50 which refer to 29 CFR § 1910.1048 as a proxy for formaldehyde).
State Right-to-Know Acts	Formaldehyde is found in the following State Right to-Know Acts: Massachusetts (105 Code Mass. Regs. § 670.000 Appendix A), New Jersey (8:59 N.J. Admin. Code § 9.1) and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323).]
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing Formaldehyde, including Maine (38 MRSA Chapter 16-D), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A § 1776) and Washington State (Wash. Admin. Code 173-334-130).

State Actions	Description of Action
Volatile Organic Compound (VOC) Regulations for Consumer Products	Many states regulate Formaldehyde as a VOC. These regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. Regulated products vary from state to state, and could include composite wood products, aerosol coating products, as well as antiperspirant and deodorant (among other products). Composite Wood Products and Aerosol Coating Product in California (Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Article 3 and 17 CCR 93120), Antiperspirant and Deodorant in Delaware (Adm. Code Title 7, 1141), Antiperspirant and Deodorant in Illinois (35 Adm Code 223), Antiperspirant and Deodorant in New Hampshire (Env-A 4100) all have VOC regulations or limits for consumer products. Some of these states also require emissions reporting.
Other	California listed formaldehyde on Proposition 65 in 1988 due to cancer. (Cal Code Regs. Title 27, § 27001). Formaldehyde is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253). California issued a Health Hazard Alert for formaldehyde (Hazard Evaluation System and Information Service, 2016). Massachusetts designated formaldehyde as a Higher Hazard Substance requiring reporting starting in 2012 (301 CMR 41.00).

D.3 International Laws and Regulations

Table_Apx D-3. Regulatory Actions by other Governments, Tribes, and International Agreements

Country/ Organization	Requirements and Restrictions
Canada	Formaldehyde is on the Canadian List of Toxic Substances (CEPA, 1999 Schedule 1). A Priority Substances List (PSL) Assessment determined that formaldehyde is primarily used in the production of resins and fertilizers and enters the Canadian environment from direct human sources such as automotive and other fuel combustion and industrial on-site uses. Secondary formation occurs by the oxidation of natural and anthropogenic organic compounds present in air. The PSL Assessment report for formaldehyde determined that formaldehyde contributes to photochemical formation of ground-level ozone; and therefore, continued and improving monitoring at sites likely to release formaldehyde is desirable; especially those sites with industrial uses for resins and for fertilizers as well as releases from pulp and paper mills. The PSL assessment also

Country/ Organization	Requirements and Restrictions
	recommended continued investigation into options to reduce indoor air exposure to formaldehyde (EC ISBN 0-0662-29447-5, 1999). Other regulations include: • Canada's National Pollutant Release Inventory (NPRI). • Off Road Compression-Ignition Engine Emission Regulations (SOR/2005-32). • CCPA and Governments of Canada, Ontario, and Alberta Memorandum of Understanding for Environmental Protection Through Action Under CCPA Responsible Care (MOU, August 14, 2013). • Environmental Emergency Regulations (SOR/2003-307). • On-Road Vehicle and Engine Emission Regulations (SOR/2003-2). • Off-Road Small Spark-Ignition Engine Emission Regulations (SOR/2003-355).
European Union	Formaldehyde is listed on the ECHA Inventory (EC Number 200-001-8) and the EU: CLP Harmonized Classification (index number 605-001-00-5). Formaldehyde was evaluated under the 2013 Community rolling action plan (CoRAP) under regulation (EC) No1907/2006 - REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) ECHA database. Accessed April 19, 2019).
Australia	Formaldehyde was assessed under a Priority Existing Chemical designation (designated March 5, 2002) in response to occupational and public health concerns. The main industrial use of formaldehyde is for the manufacture of formaldehyde-based resins, which are widely used in a variety of industries, predominantly the wood industry. Formaldehyde is also used directly or in formulations in a number of industries including medicine-related industries (such as forensic/hospital mortuaries and pathology laboratories), embalming in funeral homes, film processing, textile treatments, leather tanning, and a wide range of personal care and consumer products. The concentrations of formaldehyde in these products range from 40%, such as in embalming and film processing solutions, to < 0.2%, such as in the majority of cosmetics and consumer products (NICNAS, 2006, *Priority Existing Chemical Assessment Report No. 28 for Formaldehyde-*. Accessed April 18, 2019*).*
Japan	Formaldehyde is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL)

Country/ Organization	Requirements and Restrictions
	• Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof • Industrial Safety and Health Act (ISHA) • Air Pollution Control Law • Water Pollution Control Law • Act on the Control of Household Products Containing Harmful Substances • Poisonous and Deleterious Substances Control Act (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP]. (Accessed April 18, 2019).
Basel Convention	B3010 (urea, phenol, and melamine formaldehyde resins) are listed as a category of waste under the Basel Convention. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters.
OECD Control of Transboundary Movements of Wastes Destined for Recovery Operations	B3010 (urea, phenol, and melamine formaldehyde resins) are listed as a category of waste subject to The Amber Control Procedure under Council Decision C (2001) 107/Final.
World Health Organization (WHO)	WHO has not established a tolerable daily intake for formaldehyde; however, did note that the average daily intake of formaldehyde is 0.02 mg/day for outdoor air; 0.05-2 mg/day for indoor conventional buildings, < 1-10 mg/day for buildings without sources of formaldehyde, 0.2-0.8 mg/day for workplaces without occupational use of formaldehyde, 4 mg/day for work places using formaldehyde, and 0-1 mg/day for environmental tobacco smoke (smoking 20 cigarettes a day corresponds with an intake of 1 mg/day of formaldehyde). The average daily intake of formaldehyde in drinking water is generally 0.2 mg/day and the quantity of formaldehyde generally ingested in food (contingent on the meal composition) may range from 1.5 to 14 mg/day. (Environmental Health Criteria (EHC) Monograph 89, 1989).
Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Japan, Latvia	Occupational exposure limits for formaldehyde (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. (Accessed April 18, 2019).

Country/ Organization	Requirements and Restrictions
New Zealand, People's Republic of China, Poland, Romania, Singapore, South Korea, Spain, Sweden, Switzerland, the Netherlands, U.S.A, and the United Kingdom	

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

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

E.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.

E.1.1 Manufacture (Including Import)

The 2016 CDR reported that, in 2015, 30 facilities domestically manufactured formaldehyde, four facilities imported formaldehyde, one facility both domestically manufactured and imported formaldehyde, and the manufacture/import activity for six facilities was claimed as CBI or withheld (U.S. EPA, 2019b).

E.1.1.1 Manufacture

Currently, most formaldehyde is manufactured using one of two methods using methanol and air as feedstocks: a silver-catalyst-based process and a metal-oxide-catalyst-based process. Both processes mix preheated air with vaporized methanol, feed the gaseous mixture into a reactor, cool the reactor products, and then separate the products to recover an aqueous formaldehyde solution. The silver-catalyst-based process uses a feed that is rich in methanol and completely converts the oxygen while the metal-oxide-based process uses a feed that is lean in methanol and completely converts the methanol. Both processes must keep the mixture of methanol and oxygen outside of the flammable range. Approximately 70% of newly installed formaldehyde production capacity uses the metal oxide process (Gerberich et al., 2013).

The silver-catalyst-based process operates the reactor at approximately atmospheric pressure and a temperature of 600 to 650 °C. The separation process uses absorption, distillation, and anion exchange to produce a product of aqueous formaldehyde solution that is up to 55 wt% formaldehyde and less than 1.5% methanol. This process can achieve an overall yield of 86 to 90% on a methanol basis (Gerberich et al., 2013).

The metal-oxide-based process uses metal oxide catalysts such as vanadium oxide and iron oxide-molybdenum oxide. The reactor operates at approximately atmospheric pressure and a temperature of 300 to 400 °C. The separation process uses absorption and ion exchange to produce a product of aqueous formaldehyde solution that is up to 55 wt% formaldehyde and less than 1% methanol. This process can achieve an overall yield of 88 to 92% on a methanol basis (Gerberich et al., 2013).

New production processes are in development, including the partial oxidation of methane and the dehydrogenation of methanol, but no units are commercial (Gerberich et al., 2013).

Manufacturers sell the commercial product as formaldehyde as an aqueous solution with concentrations from 25 to 56 wt%. Common formaldehyde grades include formulations of 37, 44, 50, and 56 wt% (Gerberich et al., 2013). In the 2016 CDR, all 31 facilities that reported domestically manufacturing formaldehyde in 2015 reported manufacturing formaldehyde in liquid form. Formaldehyde was reported

to be manufactured at concentrations of 30 to 60 wt% by 30 facilities and at a concentration of 90 wt% or greater by one facility (U.S. EPA, 2019b).

Liquid solutions of formaldehyde are unstable. Methanol can be added as an inhibitor to minimize polymerization. Both low-methanol and methanol-added grades of formaldehyde solution are available for sale. Formaldehyde solutions are shipped in stainless steel or lined carbon steel storage vessels. The shipping and storage of formaldehyde must consider the shelf life of the solution, which is a function of temperature and the composition of the solution. Manufacturers recommend minimum temperatures for storing the formaldehyde solution, which is a function of the weight percent of both formaldehyde and methanol inhibitor (Gerberich et al., 2013).

E.1.1.2 Import

Commodity chemicals such as formaldehyde may be imported into the United States in bulk via water, air, land, and intermodal shipments (Tomer, 2015). These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and intermodal tank containers. Chemicals shipped in bulk containers may be repackaged into smaller containers for resale, such as drums or bottles. Domestically manufactured commodity chemicals may be shipped within the United States in liquid cargo barges, railcars, tank trucks, tank containers, intermediate bulk containers (IBCs)/totes, and drums. Both imported and domestically manufactured commodity chemicals may be repackaged by wholesalers for resale; for example, repackaging bulk packaging into drums or bottles. The type and size of container will vary depending on customer requirements. In some cases, QC samples may be taken at import and repackaging sites for analyses. Some import facilities may only serve as storage and distribution locations, and repackaging/sampling may not occur at all import facilities.

In the 2016 CDR, of the four facilities that reported importing formaldehyde in 2015, one reported importing formaldehyde as a liquid at a concentration of 30 to 60 wt%, one reported the form as a liquid at a concentration of 1 to 30 wt%, one reported the form as a liquid at a concentration of less than 1 wt%, and one reported the form as a solid or liquid at a concentration of 1 to 30 wt% (U.S. EPA, 2019b).

E.1.2 Processing and Distribution

E.1.2.1 Processing as a Reactant or Intermediate

Processing as a reactant or intermediate is the use of formaldehyde as a feedstock in the production of another chemical via a chemical reaction in which formaldehyde is consumed to form the product. According to the 2016 CDR, formaldehyde is used as a reactant or intermediate in the production of the following products (U.S. EPA, 2016):

- Adhesive and sealant chemicals;
- Plastic materials and resins;
- Pesticide, fertilizer, and other agricultural chemicals;
- Petrochemicals;
- Soap, cleaning compound, and toilet preparation chemicals;
- Functional fluids; and
- Other organic chemicals.

Exact operations for all of the uses of formaldehyde as a reactant to produce other chemicals are not known at this time. For using a chemical as a reactant, operations would typically involve unloading the chemical from transport containers and feeding the chemical into a reaction vessel(s), where the

chemical would react either fully or to a lesser extent. Following completion of the reaction, the produced substance may be purified further, thus removing unreacted formaldehyde (if any exists). Some formaldehyde-derived chemicals, such as formaldehyde-based resins, may decompose to re-form formaldehyde during the chemical's use or over the lifespan of articles produced using these chemicals. Therefore, EPA plans to consider the exposure potential to formaldehyde of formaldehyde-derived chemicals that may generate formaldehyde during the chemical's use even if the formaldehyde is reacted to completion during the production of the chemical.

A significant use of formaldehyde as a reactant is in the production of formaldehyde-based resins. The following formaldehyde-based resins are the most common (Gerberich et al., 2013).

Amino resins are thermosetting resins synthesized by reacting an aldehyde, such as formaldehyde, with an amino-functionalized chemical. Common amino compounds used are urea and melamine. The amino resins may be copolymerized with comonomers, such as using both urea and melamine or copolymerizing with phenol. The largest use of amino resins is as adhesives used to manufacture composite wood products. Other uses of amino resins include laminates for wood products, such as laminated wood beams, countertops, and parquet flooring; textile fabric finishes; tire adhesives; pre-impregnated papers; molding compounds; coatings; and curing agents for other resins (Williams, 2002; Binder et al., 2005).

Urea-formaldehyde (UF) and melamine-formaldehyde (MF) resins are manufactured by pumping aqueous formaldehyde and a strong base (caustic) into a heated reactor. Urea and/or melamine, which are solids, are fed into the reactor through hoppers. The reaction of formaldehyde with an amine proceeds via a two-step process. The first step is the methylolation or hydroxymethylation of the amine with formaldehyde. The second step is the polycondensation of monomer units to form polymer and release water. The reaction can be controlled to control the extent of reaction. The process may produce a stable syrup of methylols without proceeding through polycondensation to form the polymer. This methylol syrup may be packaged and shipped for use as an intermediate as an adhesive or molding compound. This intermediate may then subsequently be combined with an acid and heated to polymerize and cure the resin after its application. Instead of using the syrup as an intermediate, the process may alternatively blend the syrup with filler to form a molding compound. Fillers, such as cellulose or pulp may be conveyed through hoppers and into a mixer to blend with the syrup, and the syrup-filler blend may then be extruded, blended with other additives, milled into a powder and then packaged for sale. Another option is to spray dry the syrup, pulverize into a powder, and blend and package the spray-dried resin for sale (Williams, 2002; Binder et al., 2005).

Phenol-formaldehyde (PF) resins are synthesized by reacting phenol or a substituted phenol with formaldehyde. PF resins may be produced as thermoplastic or thermosetting polymers and may be liquids or solids. Liquid formulations include both dispersions and suspensions. PF resins are typically manufactured by adding formaldehyde and phenol or substituted phenol into a reactor, temperature is controlled using cooling water with the degree of polymerization monitored using samples (Kopf, 2003; EPA, 1991).

Polyacetal resin is the common term for the family of formaldehyde-based homopolymer and copolymer thermoplastics. Generally, the process includes generation of anhydrous formaldehyde from formaldehyde solution, polymerization, the final solid polymer product can be processed easily by

extrusion or injection molding. They can be reinforced with glass or fluorocarbon fibers and can be pigmented (Finnegan et al, 2000; Starr, 2000, EPA, 1991).

Formaldehyde is commonly reacted to form polyols. Several polyols made from formaldehyde include: pentaerythritol, made from acetaldehyde and formaldehyde; trimethylolpropane, made from n-butyraldehyde and formaldehyde; and neopentyl glycol, made from isobutyraldehyde and formaldehyde. These polyols have uses in synthetic lubricants industries. Pentaerythritol is used in a wide variety of paints, coatings, and varnishes and can be used to produce explosives (pentaerythritol tetranitrate). Trimethylolpropane is also used in urethane coatings, polyurethane foams, and multifunctional monomers. Neopentyl glycol is used in plastics and coatings (Gerberich et al., 2013; Hunter, 2000).

EPA plans to investigate processing uses of formaldehyde during risk evaluation.

E.1.2.2 Incorporated 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) for distribution in commerce. In the 2016 CDR, some submitters reported formaldehyde incorporated into an article. EPA has identified some uses of formaldehyde-based polymers that are used in an adhesive, coating, or textile finish that are then used in the manufacture of an article. Some example applications of formaldehyde-based polymers that may be incorporated into an article include:

- Formaldehyde-based resins used as wood product adhesives;
- Formaldehyde-based polymers used in coatings that are applied to articles;
- Formaldehyde-based resins used in fiberglass mats;
- Formaldehyde-based resins used in paper treating and coating;
- Formaldehyde-based resins used in pre-impregnated fiber composites;
- Formaldehyde-based resins used in textile finishing; and
- As paint additives and coating additives in transportation equipment manufacturing,
- and in plastic and resin manufacturing (U.S. EPA, 2019; USTMA Meeting Notes; AIA, 2019 (EPA-HQ-OPPT-2018-0438-0006); ARMA, 2019 (EPA-HQ-OPPT-2018-0438-0005))

According to the North American Insulation Manufacturers Association, formaldehyde-based resins are used in fiberglass, and rock and slag wool products. An example of the typical process involves spraying the fibers with aqueous solutions containing formaldehyde-based resins then curing to thermally set the binder. NAIMA reported typical weight concentrations of the binder at 3-6% (NAIMA, 2019). The aerospace industry uses epoxy and phenolic resins in pre-impregnated fiber composites (AIA, 2019). Tire manufacturing uses formaldehyde-based resins and textiles pretreated with resorcinol-formaldehyde latex dip (USTMA Meeting, 2019).

For use of adhesives reported under this code used in wood product and other articles, EPA expects processes to include applications by spray, brush, or roll coating of adhesive (OECD, 2013). For leather manufacturing, formalin has been reported to be used as a tanning agent in leather tanning (CPCat, 2015; NICNAS, 2006). For textile and apparel manufacturing, the general process for formaldehyde-based resins as finishing agents include three steps, pad/dry/cure, process that includes submerging the textile in a finishing solution containing formaldehyde-based resins, then drying and curing the textile (U.S. EPA, 1994; NICNAS, 2006).

In general, for plastic manufacturing, the final plastic article is produced in a conversion process that forms the compounded plastic into the finished products (U.S. EPA, 2004b; OECD, 2004a). The converting process is different depending on whether the plastic is a thermoplastic or a thermosetting material (U.S. EPA, 2004c). Thermoplastics converting involves the melting of the plastic material, forming it into a new shape and then cooling it (U.S. EPA, 2004c; OECD, 2004b). The converting of thermoplastics may involve extrusion, injection molding, blow molding, rotational molding or thermoforming (U.S. EPA, 2004c; OECD, 2004b).

Conversion of thermosetting materials involves using heat and pressure to promote curing, typically through cross-linking (OECD, 2004b). The primary conversion process for thermosetting materials is compression molding; however, fiber reinforced thermosetting plastics are converted using hand layup, spray molding and filament winding (OECD, 2004b). After the forming process, finishing operations such as filing, grinding, sanding, polishing, painting, bonding, coating and engraving are performed to complete the process (U.S. EPA, 2004c).

EPA plans to investigate processing uses where formaldehyde incorporated into an article during risk evaluation.

E.1.2.3 Incorporated into a Formulation, Mixture or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. In the 2016 CDR and in various public comments from industry and other companies, uses of formaldehyde that require incorporation into formulation, mixture, or reaction products were reported. In addition, EPA has identified formulated products that contained formaldehyde. Examples include coagulant aid (Calgon Corporation, 1990), lacquer thinner (E.I. Dupont de Nemours & Co.,1995), craft paint (Day-Glo Color Corporation, 1993), and wood glue (Franklin International,1992).

Formaldehyde-specific formulation processes were not identified from preliminary literature; however, several Emission Scenario Documents (ESDs) published by the OECD have been identified that provide general process descriptions for these types of processes. The formulation of coatings typically involves dispersion, milling, finishing and filling into final packages (OECD, 2009; U.S. EPA, 2014a). Adhesive formulations involve mixing together volatile and non-volatile chemical components in sealed, unsealed or heated processes (OECD, 2009). Sealed processes are most common for adhesive formulation because many adhesives are designed to set or react when exposed to ambient conditions (OECD, 2009). Lubricant formulation typically involves the blending of two or more components, including liquid and solid additives, together in a blending vessel (OECD, 2004b). The formulation step can involve compounding with additives and other raw materials to form a masterbatch in either open or closed blending processes (U.S. EPA, 2004b; OECD, 2009).

EPA plans to further investigate processing uses where formaldehyde incorporated into a formulation, mixture, or reaction product during risk evaluation.

E.1.2.4 Non-Incorporative Activities

Non-incorporative uses are those that use formaldehyde other uses such as a chemical processing aid or manufacturing aid. A processing aid is a chemical added to a chemical mixture that is used to improve the processing of the chemical mixture but does not become part of the reaction product and not intended to affect the function of a substance or article created. Examples include buffers, dehydrating agents, and sequestering agents (U.S. EPA, 2016).

The 2016 CDR reports a processing aid use of formaldehyde in oil and gas drilling, extraction, and support activities (U.S. EPA, 2019). Preliminary literature reported the use of formaldehyde as a corrosion inhibitor and hydrogen sulfide scavenger in oil production operations (Gerberich et al., 2013). The 2016 CDR also reports additional non-incorporative uses of formaldehyde for the agriculture, forestry, fishing and hunting industry, and construction industry (U.S. EPA, 2019).

E.1.3 Uses

E.1.3.1 Chemical substances in furnishings, cleaning, and treatment/care products

As stated in Section 2.2.1, formaldehyde is used to manufacture floor coverings, foam seating and bedding products, furniture and furnishings, cleaning and furniture care products, and fabric, textile, and leather products. The use of these products may require specialty installation, cutting, or other manipulation of the material for its use. The use of cleaning and treatment care products may include spray application.

Safety data sheets reported use of formaldehyde in water treatment products, the percent of formaldehyde in these formulations is unknown (Mansfield Sanitary, Inc., 1985; Chemetrics, 1989; Calgon, 1990). Formaldehyde has also been reported in laundry and dishwashing products and personal care products. EPA plans to evaluate these conditions of use during risk evaluation.

E.1.3.2 Chemical substances in construction, paint, electrical, and metal products

Adhesives and Sealants

As discussed during processing activities, formaldehyde-based resins (e.g., urea-formaldehyde resins, melamine-formaldehyde resin, etc.) are used as adhesives incorporated into wood and engineered wood products. Formaldehyde is incorporated as a hardener or an ion exchange agent in the production of acrylics, which are a class of structural adhesives (CPCat, 2015). EPA plans to evaluate this condition of use during risk evaluation.

Paint and Coatings

According to American Coating Association (ACA), formaldehyde is present in trace amounts in most raw materials used in paints and coatings such as latex resins and fluorescent pigments (ACA, 2019). EPA has identified formaldehyde used in lacquer thinner and cleaning solvent at 0.1% concentration (E.I. Dupont de Nemours & Co., 1995) and non-stick coating for metals at 1% concentration (E.I. Dupont de Nemours & Co., 1989). EPA plans to evaluate this condition of use during risk evaluation.

Building/construction materials- wood, engineered wood products and other materials not covered elsewhere

As stated in Appendix E.1.2.2, formaldehyde is heavily used for the production of binders used in the production of wood and engineered wood products. In addition, the formaldehyde resins (e.g., urea-formaldehyde resin) have been reported to be used in the manufacturing of fiber glass mats (discussed in Appendix E.1.2.2), these mats are then used to make different roofing products. Formaldehyde exposure can occur during this manufacturing as off-gassing of formaldehyde can occur when hot asphalt contacts the fiberglass mat that use formaldehyde-based resins as binders (ARMA, 2019). Formaldehyde is also reported in other construction material such as cement, laminates and other products (ECHA, 2019).

Electrical/electronic and Metal products not covered elsewhere

Molding compounds based on amino resins are used for parts of electrical devices (Williams, 2002). As stated for paints and coatings, formaldehyde is used in the surface coating of metal products. EPA has not identified specific process information for the use but EPA plans to evaluate this condition of use during risk evaluation.

E.1.3.3 Chemical substances in automotive and fuel products

AIA reports use of formaldehyde in the manufacture, operations, and maintenance of aerospace products in lubricants, including dry film lubricants, graphite paste, and lubricating oil (AIA, 2019). EPA has not identified specific process information for the use of these automotive and fuel products but EPA plans to evaluate this condition of use during risk evaluation.

E.1.3.4 Chemical substances in agriculture use products

Urea-formaldehyde is used in the manufacture of controlled-release fertilizers, which release nutrients at a constant rate. End users of controlled-release fertilizers include agricultural, horticultural, landscaping, and consumer markets (ECHA, 2019). EPA plans to evaluate this condition of use during risk evaluation.

E.1.3.5 Chemical substances in outdoor use products

EPA has not identified specific process information for the use of formaldehyde in explosive materials in the preliminary literature review but EPA plans to evaluate this condition of use during risk evaluation.

E.1.3.6 Chemical substances in packaging, paper, plastic and hobby products

Formaldehyde and formaldehyde resins are used in the manufacturing of pulp and paper manufacturing. Packaging products may contain formaldehyde from its use in adhesive, paper, and plastic manufacturing. The use of these products may involve cutting or other manipulation to suit the purpose of the products. EPA assumes that formaldehyde is in toys, playground, and sporting equipment through its use in adhesives and plastic materials. The installation and use of these toys and equipment would be reviewed for potential exposure to formaldehyde. Safety data sheets identified formaldehyde in craft paint and glue at less than 0.1% (Day-Glo Color Corporation, 1993; Elmers, 2012). EPA has not identified specific process information for the use of formaldehyde in these conditions of use in the preliminary literature review but EPA plans to evaluate this condition of use during risk evaluation.

Photographic Supplies

Preliminary literature identified the use of formaldehyde in products used for the processing of film. These products are mixed with other components, typically diluted with water in a bath, the film is placed into the bath for final processing, rinsed then dried. The concentration of formaldehyde in these products can be as high as 35% (NICNAS, 2006). EPA plans to evaluate this condition of use during risk evaluation.

E.1.3.7 Chemical substances in products not described by other codes

Embalming

Formaldehyde is a common chemical used in embalming at mortuary labs and funeral homes. Expected worker activities could include: handling concentrated formaldehyde solutions, preparing diluted solutions, arterial and cavity embalming, spray applications, and equipment cleaning (ECHA, 2019). The concentration of formaldehyde in these products can be as high as 40% (NICNAS, 2006). EPA plans to evaluate this condition of use during risk evaluation.

Other Laboratory Uses

Formaldehyde is also used for tissue preservation at other laboratories including medical labs to preserve samples (Sigma-Aldrich, 2019). EPA plans to evaluate this condition of use during risk evaluation.

E.1.4 Disposal

Each of the conditions of use of formaldehyde may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling. Industrial sites that treat or dispose onsite wastes that they themselves generate are assessed in each condition of use assessment. Similarly, point source discharges of formaldehyde to surface water are assessed in each condition of use assessment (point source discharges are exempt as solid wastes under RCRA). Wastes of formaldehyde that are generated during a condition of use and sent to a third-party site for treatment, disposal, or recycling may include the following:

- Wastewater: Formaldehyde may be contained in wastewater discharged to POTW or other, non-public treatment works for treatment. Industrial wastewater containing formaldehyde discharged to a POTW may be subject to EPA or authorized NPDES state pretreatment programs..

- Solid Wastes: Solid wastes are defined under RCRA as any material that is discarded by being: abandoned; inherently waste-like; a discarded military munition; or recycled in certain ways (certain instances of the generation and legitimate reclamation of secondary materials are exempted as solid wastes under RCRA). Solid wastes may subsequently meet RCRA's definition of hazardous waste by either being listed as a waste at 40 CFR §§ 261.30 to 261.35 or by meeting waste-like characteristics as defined at 40 CFR §§ 261.20 to 261.24. Solid wastes that are hazardous wastes are regulated under the more stringent requirements of Subtitle C of RCRA, whereas non-hazardous solid wastes are regulated under the less stringent requirements of Subtitle D of RCRA.

  Formaldehyde is a U-listed hazardous waste under code U122 under RCRA; therefore, discarded, unused pure and commercial grades of formaldehyde are regulated as a hazardous waste under RCRA (40 CFR § 261.33(f)).

- Wastes Exempted as Solid Wastes under RCRA: Certain conditions of use of formaldehyde may generate wastes of formaldehyde that are exempted as solid wastes under 40 CFR § 261.4(a). For example, the generation and legitimate reclamation of hazardous secondary materials of formaldehyde may be exempt as a solid waste.

2018 TRI reports 715 facilities managed, in total, over 132 million pounds of formaldehyde as waste. Of this total, approximately 70 million pounds were treated, nearly 35 million pounds were recycled, over 20 million pounds were released or otherwise disposed of, and over 7 million pounds were burned for energy recovery. Of the 70 million pounds of formaldehyde that were treated, about 65 million pounds were treated on site and 5 million pounds were treated off site. Similarly, 99% of the formaldehyde waste that was recycled was recycled on site, and 93% of the formaldehyde waste that was used for energy recovery was combusted on site.

Nearly three-quarters of the formaldehyde that was disposed of or released occurred to land, the majority of which (14.2 million pounds) was disposed of on-site to Class I underground injection wells and about

240,000 pounds was disposed of off-site to Class I underground injection wells. Over 4.6 million pounds of formaldehyde were released to air; 93% of which was in the form of point source air (stack) emissions. Releases to water and other releases not mentioned above accounted for small amounts of the total releases at just 1% and 2%, respectively {U.S. EPA, 2017, 5041148}.

E.2 Preliminary Occupational Exposure Data

EPA presents below an example of occupational exposure-related information obtained from preliminary data gathering. EPA plans to consider this information and data in combination with other data and methods for use in the risk evaluation.
Table_Apx E-1 summarizes NIOSH Health Hazard Evaluations identified during EPA's preliminary data gathering.

Table_Apx E-1. Summary of NIOSH HHEs with Monitoring for Formaldehyde[a]

Year of Publication	Report Number	Facility Description
2016	HHE-2016-0145-3292	Plastic bag manufacturer
2015	HHE-2015-0011-3253	Outpatient medical clinic (shared-use building)
2013	HHE-2013-0075-3264	Automotive parts manufacturer
2012	HHE-2012-0025-3207	Electrical cable accessory manufacturer
2012	HHE-2012-0135-3184	Medical examiner office
2010	HHE-2010-0001-3295	Insect rearing facility
2001	HETA-2001-0030-3020	Medical center – Charlotte, North Carolina
1999	HETA-99–0185-2787	Plastic injection molding e.g., corner guards for mattresses, pallet legs, diaper pales.
1999	HETA-99-0173-2856	Recreation – National wildlife refuge
1998	HETA-98-0279-2722	Furniture manufacturer
1998	HETA-98-0194-2721	Recreation – US fish and wildlife service
1997	HETA-97-0084-2669	Electrical product assembly – Printed circuit board
1997	HETA-97-0062-2662	Medical center – Anchorage, Alaska
1997	HETA-97–0049–2650	Medical center – Philadelphia, Pennsylvania
1997	HETA-97–0154–2693	Power generation services – Siemens
1983	HHE-83-156-1622	Automotive parts manufacturer – plastic
1982	NIOSH-108-17a	Wood product manufacturer – Medford, Oregon
1982	NIOSH-108-18a	Wood product manufacturer – Medford, Oregon
1981	NIOSH-108-19a	Wood product manufacturer – Springfield, Oregon

[a] Table includes HHEs identified to date.

Table_Apx E-2 summarizes the OSHA inspection monitoring data identified in the CEHD from 2010 to 2019 by North American Industry Classification System (NAICS) code.

Table_Apx E-2. Summary of Industry Sectors with Formaldehyde Monitoring Samples Available from OSHA Inspections Conducted Between 2010 and 2019.

NAICS	NAICS Description	Number of Data Points
No NAICS code reported		197

NAICS	NAICS Description	Number of Data Points
111411	Mushroom Production	2
112120	Dairy Cattle and Milk Production	13
112130	Dual-Purpose Cattle Ranching and Farming	5
112340	Poultry Hatcheries	17
112511	Finfish Farming and Fish Hatcheries	3
213112	Support Activities for Oil and Gas Operations	5
236118	Residential Remodelers	2
236220	Commercial and Institutional Building Construction	1
238160	Roofing Contractors	3
238310	Drywall and Insulation Contractors	18
238330	Flooring Contractors	2
238390	Other Building Finishing Contractors	4
311119	Other Animal Food Manufacturing	6
311412	Frozen Specialty Food Manufacturing	2
311812	Commercial Bakeries	10
311822	Flour Mixes and Dough Manufacturing from Purchased Flour	5
311830	Tortilla Manufacturing	8
313210	Broadwoven Fabric Mills	1
313310	Textile and Fabric Finishing Mills	3
313311	Broadwoven Fabric Finishing Mills	6
313312	Textile and Fabric Finishing (except Broadwoven Fabric) Mills	4
313320	Fabric Coating Mills	39
314911	Textile Bag Mills	4
314999	All Other Miscellaneous Textile Product Mills	5
315299	All Other Cut and Sew Apparel Manufacturing	4
316210	Footwear Manufacturing	7
316211	Rubber and Plastics Footwear Manufacturing	4
321113	Sawmills	6
321211	Hardwood Veneer and Plywood Manufacturing	2
321212	Softwood Veneer and Plywood Manufacturing	4
321213	Engineered Wood Member (except Truss) Manufacturing	9
321219	Reconstituted Wood Product Manufacturing	3
321911	Wood Window and Door Manufacturing	15
321912	Cut Stock, Resawing Lumber, and Planing	4
321918	Other Millwork (including Flooring)	40
321920	Wood Container and Pallet Manufacturing	3
321992	Prefabricated Wood Building Manufacturing	2
321999	All Other Miscellaneous Wood Product Manufacturing	16
322121	Paper (except Newsprint) Mills	4
322222	Coated and Laminated Paper Manufacturing	6
322299	All Other Converted Paper Product Manufacturing	2

NAICS	NAICS Description	Number of Data Points
323110	Commercial Lithographic Printing	4
323111	Commercial Printing (except Screen and Books)	7
323113	Commercial Screen Printing	4
323119	Other Commercial Printing	4
324121	Asphalt Paving Mixture and Block Manufacturing	2
324122	Asphalt Shingle and Coating Materials Manufacturing	1
325180	Other Basic Inorganic Chemical Manufacturing	5
325188	All Other Basic Inorganic Chemical Manufacturing	4
325193	Ethyl Alcohol Manufacturing	2
325199	All Other Basic Organic Chemical Manufacturing	6
325211	Plastics Material and Resin Manufacturing	19
325212	Synthetic Rubber Manufacturing	4
325314	Fertilizer (Mixing Only) Manufacturing	4
325412	Pharmaceutical Preparation Manufacturing	10
325510	Paint and Coating Manufacturing	9
325520	Adhesive Manufacturing	1
325611	Soap and Other Detergent Manufacturing	15
325620	Toilet Preparation Manufacturing	63
325991	Custom Compounding of Purchased Resins	3
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	38
326111	Plastics Bag and Pouch Manufacturing	32
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	17
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	7
326121	Unlaminated Plastics Profile Shape Manufacturing	3
326122	Plastics Pipe and Pipe Fitting Manufacturing	12
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	14
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	1
326199	All Other Plastics Product Manufacturing	127
326220	Rubber and Plastics Hoses and Belting Manufacturing	4
326299	All Other Rubber Product Manufacturing	56
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	1
327120	Clay Building Material and Refractories Manufacturing	19
327122	Ceramic Wall and Floor Tile Manufacturing	1
327125	Nonclay Refractory Manufacturing	15
327212	Other Pressed and Blown Glass and Glassware Manufacturing	8
327390	Other Concrete Product Manufacturing	3
327910	Abrasive Product Manufacturing	28
327993	Mineral Wool Manufacturing	37
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	13
331111	Iron and Steel Mills	4
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	3

NAICS	NAICS Description	Number of Data Points
331316	Aluminum Extruded Product Manufacturing	4
331419	Primary Smelting and Refining of Nonferrous Metal (except Copper and Aluminum)	6
331511	Iron Foundries	141
331513	Steel Foundries (except Investment)	88
331521	Aluminum Die-Casting Foundries	11
331522	Nonferrous (except Aluminum) Die-Casting Foundries	13
331524	Aluminum Foundries (except Die-Casting)	33
331525	Copper Foundries (except Die-Casting)	16
331528	Other Nonferrous Foundries (except Die-Casting)	16
332212	Hand and Edge Tool Manufacturing	3
332312	Fabricated Structural Metal Manufacturing	8
332313	Plate Work Manufacturing	5
332321	Metal Window and Door Manufacturing	8
332322	Sheet Metal Work Manufacturing	1
332410	Power Boiler and Heat Exchanger Manufacturing	5
332431	Metal Can Manufacturing	12
332439	Other Metal Container Manufacturing	25
332618	Other Fabricated Wire Product Manufacturing	2
332722	Bolt, Nut, Screw, Rivet, and Washer Manufacturing	4
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	29
332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	6
332994	Small Arms, Ordnance, and Ordnance Accessories Manufacturing	6
332996	Fabricated Pipe and Pipe Fitting Manufacturing	3
332997	Industrial Pattern Manufacturing	20
332998	Enameled Iron and Metal Sanitary Ware Manufacturing	4
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	26
333220	Plastics and Rubber Industry Machinery Manufacturing	4
333244	Printing Machinery and Equipment Manufacturing	3
333314	Optical Instrument and Lens Manufacturing	4
333411	Air Purification Equipment Manufacturing	6
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	2
333511	Industrial Mold Manufacturing	21
333992	Welding and Soldering Equipment Manufacturing	2
333994	Industrial Process Furnace and Oven Manufacturing	7
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	2
334310	Audio and Video Equipment Manufacturing	1
334412	Bare Printed Circuit Board Manufacturing	21
334419	Other Electronic Component Manufacturing	7
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing	4

NAICS	NAICS Description	Number of Data Points
334512	Automatic Environmental Control Manufacturing for Residential, Commercial, and Appliance Use	4
334515	Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals	2
334519	Other Measuring and Controlling Device Manufacturing	10
335122	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing	2
335311	Power, Distribution, and Specialty Transformer Manufacturing	2
335931	Current-Carrying Wiring Device Manufacturing	2
336111	Automobile Manufacturing	4
336112	Light Truck and Utility Vehicle Manufacturing	10
336211	Motor Vehicle Body Manufacturing	6
336212	Truck Trailer Manufacturing	1
336311	Carburetor, Piston, Piston Ring, and Valve Manufacturing	4
336322	Other Motor Vehicle Electrical and Electronic Equipment Manufacturing	5
336340	Motor Vehicle Brake System Manufacturing	11
336370	Motor Vehicle Metal Stamping	3
336399	All Other Motor Vehicle Parts Manufacturing	38
336411	Aircraft Manufacturing	2
336412	Aircraft Engine and Engine Parts Manufacturing	1
336413	Other Aircraft Parts and Auxiliary Equipment Manufacturing	3
336510	Railroad Rolling Stock Manufacturing	17
336612	Boat Building	8
337110	Wood Kitchen Cabinet and Countertop Manufacturing	62
337121	Upholstered Household Furniture Manufacturing	2
337122	Nonupholstered Wood Household Furniture Manufacturing	1
337127	Institutional Furniture Manufacturing	23
337211	Wood Office Furniture Manufacturing	16
337215	Showcase, Partition, Shelving, and Locker Manufacturing	7
339112	Surgical and Medical Instrument Manufacturing	30
339113	Surgical Appliance and Supplies Manufacturing	5
339920	Sporting and Athletic Goods Manufacturing	7
339932	Game, Toy, and Childrens Vehicle Manufacturing	5
339991	Gasket, Packing, and Sealing Device Manufacturing	25
339999	All Other Miscellaneous Manufacturing	24
423210	Furniture Merchant Wholesalers	3
423220	Home Furnishing Merchant Wholesalers	4
423310	Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers	9
423730	Warm Air Heating and Air-Conditioning Equipment and Supplies Merchant Wholesalers	4
423830	Industrial Machinery and Equipment Merchant Wholesalers	2
423930	Recyclable Material Merchant Wholesalers	8
423990	Other Miscellaneous Durable Goods Merchant Wholesalers	5
424120	Stationery and Office Supplies Merchant Wholesalers	4

NAICS	NAICS Description	Number of Data Points
424210	Drugs and Druggists' Sundries Merchant Wholesalers	3
424320	Men's and Boys' Clothing and Furnishings Merchant Wholesalers	8
424330	Women's, Children's, and Infants' Clothing and Accessories Merchant Wholesalers	7
424410	General Line Grocery Merchant Wholesalers	5
424470	Meat and Meat Product Merchant Wholesalers	2
424690	Other Chemical and Allied Products Merchant Wholesalers	20
442110	Furniture Stores	2
444130	Hardware Stores	3
444190	Other Building Material Dealers	2
445110	Supermarkets and Other Grocery (except Convenience) Stores	5
445210	Meat Markets	1
446120	Cosmetics, Beauty Supplies, and Perfume Stores	38
446199	All Other Health and Personal Care Stores	9
447110	Gasoline Stations with Convenience Stores	1
448110	Men's Clothing Stores	3
448120	Women's Clothing Stores	5
448140	Family Clothing Stores	4
448190	Other Clothing Stores	2
452112	Discount Department Stores	9
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores)	3
482111	Line-Haul Railroads	4
482112	Short Line Railroads	2
484121	General Freight Trucking, Long-Distance, Truckload	4
488210	Support Activities for Rail Transportation	1
493110	General Warehousing and Storage	5
493120	Refrigerated Warehousing and Storage	4
511120	Periodical Publishers	4
522110	Commercial Banking	2
524113	Direct Life Insurance Carriers	7
541330	Engineering Services	1
541410	Interior Design Services	2
541940	Veterinary Services	31
561210	Facilities Support Services	1
561422	Telemarketing Bureaus and Other Contact Centers	4
561720	Janitorial Services	7
562211	Hazardous Waste Treatment and Disposal	10
562219	Other Nonhazardous Waste Treatment and Disposal	2
562910	Remediation Services	3
611110	Elementary and Secondary Schools	4
611310	Colleges, Universities, and Professional Schools	40
611511	Cosmetology and Barber Schools	9

NAICS	NAICS Description	Number of Data Points
611519	Other Technical and Trade Schools	3
621111	Offices of Physicians (except Mental Health Specialists)	3
621112	Offices of Physicians, Mental Health Specialists	2
621210	Offices of Dentists	5
621320	Offices of Optometrists	12
621399	Offices of All Other Miscellaneous Health Practitioners	3
621491	HMO Medical Centers	5
621511	Medical Laboratories	170
621910	Ambulance Services	6
621999	All Other Miscellaneous Ambulatory Health Care Services	4
622110	General Medical and Surgical Hospitals	146
622310	Specialty (except Psychiatric and Substance Abuse) Hospitals	2
711310	Promoters of Performing Arts, Sports, and Similar Events with Facilities	6
713290	Other Gambling Industries	15
713990	All Other Amusement and Recreation Industries	1
721120	Casino Hotels	7
811111	General Automotive Repair	2
811121	Automotive Body, Paint, and Interior Repair and Maintenance	2
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	3
811420	Reupholstery and Furniture Repair	4
811490	Other Personal and Household Goods Repair and Maintenance	1
812111	Barber Shops	15
812112	Beauty Salons	515
812113	Nail Salons	7
812199	Other Personal Care Services	3
812210	Funeral Homes and Funeral Services	179
812220	Cemeteries and Crematories	2
812921	Photofinishing Laboratories (except One-Hour)	4
813990	Other Similar Organizations (except Business, Professional, Labor, and Political Organizations)	1
921130	Public Finance Activities	5
921190	Other General Government Support	5
922130	Legal Counsel and Prosecution	2
922190	Other Justice, Public Order, and Safety Activities	2
923140	Administration of Veterans' Affairs	10
926120	Regulation and Administration of Transportation Programs	3
926150	Regulation, Licensing, and Inspection of Miscellaneous Commercial Sectors	235
928110	National Security	4

Appendix F SUPPORTING INFORMATION: CONCEPTUAL MODEL FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES

Table_Apx F-1. Worker and Occupational Non-User Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Manufacture	Domestic Manufacture	Domestic Manufacture	Manufacturing of Formaldehyde	Liquid Contact	Dermal	Workers	Yes	Formaldehyde is expected to be manufactured and sold in aqueous formaldehyde solution. Therefore, dermal exposures to liquid is expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature). EPA plans to analyze inhalation exposures.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during manufacturing.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Import	Import	Repackaging of formaldehyde	Liquid Contact	Dermal	Workers	Yes	Formaldehyde may be imported in an aqueous solution; therefore, dermal exposure is expected for workers. However, exposure will only occur in the event the imported material is repackaged.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature). EPA plans to analyze inhalation exposures. However, exposure will only occur in the event the imported material is repackaged.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during repackaging of import containers.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	Reactant	Adhesives and sealant chemicals in: - Plastic and resin manufacturing - Wood product manufacturing - All other basic organic chemical manufacturing Intermediate in: - Pesticide, fertilizer, and other agricultural chemical manufacturing	Formaldehyde as a chemical intermediate for resin and other chemical production	Liquid Contact	Dermal	Workers	Yes	Workers are expected to handle aqueous solution containing formaldehyde; therefore, dermal exposure is expected to be a pathway.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		- Petrochemical manufacturing - Soap, cleaning compound, and toilet preparation manufacturing - All other basic organic chemical manufacturing - Plastic materials and resin manufacturing - Adhesive manufacturing - All other chemical product and preparation manufacturing - Paper manufacturing - Plastic products manufacturing - Wood product manufacturing - Construction - Agriculture, forestry, fishing, and hunting Functional fluid in: - Oil and gas drilling, extraction, and support activities Processing aids, specific to petroleum production in: - All other basic chemical manufacturing Bleaching agent in wood product manufacturing Agricultural chemicals in: agriculture, forestry, fishing, and hunting		Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature). EPA plans to evaluate inhalation exposures.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during processing.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Processing	Incorporation into an article	Finishing agent in: –Textiles, apparel, and leather manufacturing	Textile Finishing Leather Tanning	Liquid Contact	Dermal	Workers	Yes	Workers are expected to handle aqueous solution containing formaldehyde; therefore, dermal exposure is expected to be a pathway.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature). EPA plans to analyze inhalation exposures.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during processing.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	Incorporation into an article	Paint additives and coating additives not described by other categories in: –Transportation equipment manufacturing (including aerospace)	Application of paint and coatings in transportation equipment (including spray or roll coating)	Liquid Contact	Dermal	Workers	Yes	Workers are expected to handle aqueous solution containing formaldehyde; therefore, dermal exposure is expected to be a pathway.
				Vapor	Inhalation	Workers, ONU	Yes	Inhalation exposure from off gassing from the resin or vapor generated from use of formaldehyde containing solution may be possible. EPA plans to evaluate inhalation exposure.
				Mist	Inhalation	Workers, ONU	Yes	Mist generation may occur from spray coating application and will be analyzed.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	Incorporation into an article	Synthetic Rubber Manufacturing in: -Transportation Equipment Manufacturing (Tires)	Tire Manufacturing	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde may be possible, EPA plans to evaluate dermal exposure.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from off gassing of the resin and from the final article will be evaluated.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during processing.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	Incorporation into an article	Adhesives and sealant chemicals in: –Wood product manufacturing –Plastic material and resin manufacturing (including structural and fireworthy aerospace interiors) –Construction	Use of adhesive for wood product, plastic material, and general construction material manufacturing	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature) , inhalation exposure from off gassing of the resin and from the final article will be evaluated.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
			(spray, brush, or roll application of adhesive to, but not limited, to floors, plastic and wood furniture)	Mist	Inhalation	Workers, ONU	Yes	Mist generation can occur if adhesive is spray-applied.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	Incorporation into a formulation, mixture, or reaction product	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing. - Fuel and fuel additives - Lubricant and lubricant additives - all other basic organic chemical manufacturing Asphalt, Paving, Roofing, and Coating Materials Manufacturing. Solvents (which become part of a product formulation or mixture) in: –Paint and coating manufacturing Processing aids, specific to petroleum production in: - Oil and gas drilling, extraction, and support activities	Processing of formaldehyde into formulations, mixtures, or reaction products	Liquid Contact	Dermal	Workers	Yes	Formaldehyde may be handled in an aqueous solution form; therefore, EPA plans to evaluate for potential dermal exposure.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature). EPA plans to evaluate inhalation exposures
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during processing.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		- All other basic organic chemical manufacturing Paint additives and coating additives not described by other categories in: - Paint and coating manufacturing - Plastic material and resin manufacturing Intermediate in - All other basic chemical manufacturing - Plastic material and resin manufacturing - Oil and gas drilling, extraction, and support activities - Wholesale and retail trade Other: Preservative in all other chemical product and preparation manufacturing; Solid separation agents in miscellaneous manufacturing Agricultural chemicals (non-pesticidal); -Agriculture, forestry, fishing, and hunting - Pesticide, fertilizer, and other agricultural chemical manufacturing Surface active agents in plastic material and resin manufacturing		Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		Ion exchange agents in: - Adhesive manufacturing - Paint and coating manufacturing Lubricant and lubricant additive in adhesive manufacturing Plating agents and surface treating agents in all other chemical product and preparation manufacturing Functional fluids (closed system) in soap, cleaning compound, and toilet preparation manufacturing Laboratory chemicals: other Adhesive and sealant chemical in adhesive manufacturing Bleaching agents in textile, apparel, and leather manufacturing							
Processing	Repackaging	Laboratory chemical in other: sales to distributors	Repackaging	Liquid Contact	Dermal	Workers	Yes	Formaldehyde may be received in an aqueous solution; therefore, dermal exposure is expected for workers. However, exposure will only occur in the event the imported material is repackaged.
				Vapor	Inhalation	Workers, ONU	Yes	Due to its high volatility, inhalation exposures will be analyzed. However, exposure will only occur in the event the imported material is repackaged.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during repackaging of received containers.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Distribution in commerce	Distribution in commerce	Distribution in commerce	Distribution of formaldehyde, formaldehyde solutions, or products containing formaldehyde in commerce	Liquid Contact, Vapor	Dermal, Inhalation	Worker, ONU	Yes	EPA plans to analyze activities resulting in exposures associated with distribution in commerce (e.g. loading, unloading) throughout the various lifecycle stages and conditions of use (e.g. manufacturing, processing, industrial use, commercial use, disposal) rather than as a single distribution scenario.
Industrial Use	Non-incorporative activities	Processing aid in oil and gas drilling, extraction, and support activities (e.g., hydraulic fracking fluid)	Use of formaldehyde for oilfield well production	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during use.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Industrial Use	Non-incorporative activities	Construction; Agriculture, forestry, fishing and hunting	Industrial use of formaldehyde for construction and agriculture activities (e.g. processing aid)	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	Yes	Mist generation is not expected during use.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Chemical substances in furnishing treatment/care products	-Floor coverings -Foam seating and bedding products -Furniture and furnishings not covered elsewhere -Building/ construction materials (wood and engineered wood products)	Installation and demolition of formaldehyde-based furnishings and building/construction materials in residential, public and commercial buildings, and other structures	Liquid Contact	Dermal	Workers	No	Depending on products covered for this exposure scenario, dermal contact with liquid for workers is not expected for these finished articles.
				Vapor	Inhalation	Workers, ONU	Yes	Off-gassing of formaldehyde from these products is expected. EPA plans to evaluate inhalation exposure.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	Chemical substances in construction, paint, electrical, and metal products	-Building/ construction materials not covered elsewhere		Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during use.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Chemical substances in furnishing treatment/care products	-Cleaning and Furniture Care Products	Workers handling cleaning and furniture care products (spray application)	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	Yes	Depending on products, mist generation may occur from spray application and will be analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use		Fabric, textile, and leather products not covered elsewhere	Workers handling fabric, textile, and leather products	Liquid Contact	Dermal	Workers	No	Dermal contact with liquid for workers is not expected for these finished articles.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	Chemical substances in Furnishing, cleaning, and treatment/care products			Vapor	Inhalation	Workers, ONU	Yes	Depending on the product, vapor generation and/or off-gassing of formaldehyde is expected. EPA plans to evaluate inhalation exposure.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during use.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Chemical substances in treatment/care products	Water treatment products	Use of formulations containing formaldehyde for water treatment	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during use.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Commercial Use	Chemical substances in treatment/care products	Personal care products;	Workers handling formulations containing formaldehyde in personal care products	Liquid Contact	Dermal	Workers	Yes	Based off currently identified products, dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	Yes	Based off currently identified products, mist generation is not expected, but this may change as products are identified.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants Paint and coatings	Use of formulations containing formaldehyde for spray applications (e.g., spray or roll)	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	Yes	Mist generation may occur from spray coating application and will be analyzed.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Chemical substances in electrical products Chemical substances in metal products	Electrical and electronic products (including semiconductors) Metal products not covered elsewhere	Use of electronic and metal products	Liquid Contact	Dermal	Workers	No	Depending on identified products, products may be finished articles with no expected liquid contact with formaldehyde.
				Vapor	Inhalation	Workers, ONU	Yes	Depending on identified products, inhalation exposure from off-gassing or vapor generation will be evaluated.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during use.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Chemical substances in products	-Automotive care products -Lubricants and greases -Fuels and related products	Use of formulations containing formaldehyde in fuels, lubricants, and automotive care products.	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during use.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Chemical substances in agriculture use products	-Lawn and related products	Use of fertilizer containing formaldehyde in outdoors including lawns	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	Yes	Mist generation may occur from spray application and will be analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Chemical substances in outdoor products	-Explosive Materials	Use of explosive materials	Liquid Contact	Dermal	Workers	Yes	Depending on the material, EPA plans to evaluate dermal exposure to formaldehyde if applicable.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	No	Mist generation not expected for use.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Chemical substances in packaging, paper, plastic, hobby products	- Food packaging - Paper products - Plastic and rubber products - Toys, playground, and sporting equipment	Use of packaging, paper, and hobby products	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Inhalation exposure from vapor generation and off-gassing from articles will be evaluated.
				Mist	Inhalation	Workers, ONU	No	Mist generation not expected for use.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Commercial Use	Chemical substances in packaging, paper, plastic, hobby products	- Arts, crafts, and hobby materials - Ink, toner, and colorant products	Use of formulations containing formaldehyde in craft materials Use of printing ink, toner and colorant products containing formaldehyde	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during use.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Chemical substances in packaging, paper, plastic, hobby products	Photographic supplies	Photo processing using formulations containing formaldehyde	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during use.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Commercial Use	Other	Laboratory Use	Embalming General laboratory use	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.
				Mist	Inhalation	Workers, ONU	Yes	Mist generation may occur from spray application and will be analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Disposal	Waste Handling, Treatment and Disposal	Disposal of formaldehyde wastes	Worker handling of wastes	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature), inhalation exposure from vapor will be evaluated.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during use.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Appendix G SUPPORTING INFORMATION - CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USES

Table_Apx G-1. Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use	Air Care Products	Air Care Products	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Floor Coverings	Floor Coverings	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Off-gassing of formaldehyde from these products is expected. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Cleaning and Furniture Care Products	Cleaning and Furniture Care Products	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
	Lubricants and Greases	Lubricants and Greases	Direct contact through application or use of products using formaldehyde-based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.
			Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Arts, Crafts, and Hobby Materials	Arts, Crafts, and Hobby Materials	Direct contact through application or use of products using formaldehyde -based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.
			Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Toys, Playground, and Sporting Equipment	Toys, Playground, and Sporting Equipment	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Off-gassing of formaldehyde from these products is expected. Exposure via inhalation will be evaluated.

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Long-term emission/mass-transfer					
	Plastic & Rubber Products Not Covered Elsewhere	Plastic & Rubber Products Not Covered Elsewhere	Direct contact through application or use of products using formaldehyde-based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.
			Long-term emission/mass-transfer	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Off-gassing of formaldehyde from these products is expected. Exposure via inhalation will be evaluated.
	Paints and Coatings	Paints and Coatings	Direct contact through application or use of products using formaldehyde-based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.
			Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Ink, Toner, and Colorant Products	Ink, Toner, and Colorant Products	Direct contact through application or use of products using formaldehyde-based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.
			Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Off-gassing of formaldehyde from these products is expected. Exposure via inhalation will be evaluated.

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Long-term emission/mass-transfer					
	Photographic Supplies	Photographic Supplies	Direct contact through application or use of products using formaldehyde-based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.
			Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Foam Seating & Bedding Products	Foam Seating & Bedding Products	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Off-gassing of formaldehyde from these products is expected. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Fabric, Textile, & Leather Products Not Covered Elsewhere	Fabric, Textile, & Leather Products Not Covered Elsewhere	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Depending on the product, vapor generation and/or off-gassing of formaldehyde is expected. Exposure via inhalation will be evaluated.

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Long-term emission/mass-transfer					
	Furniture & Furnishings Not Covered Elsewhere	Furniture & Furnishings Not Covered Elsewhere	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Off-gassing of formaldehyde from these products is expected. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Building/Construction Materials - Wood & Engineered Wood Products	Building/Construction Materials - Wood & Engineered Wood Products	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Off-gassing of formaldehyde from these products is expected. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Building/Construction Materials Not Covered Elsewhere	Building/Construction Materials Not Covered Elsewhere	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Off-gassing of formaldehyde from these products is expected. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
	Electrical & Electronic Products	Electrical & Electronic Products	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Off-gassing of formaldehyde from these products is expected. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Fuels and Related Products	Fuels and Related Products	Direct contact through application or use of products using formaldehyde-based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.
			Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Paper Products	Paper Products	Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Off-gassing of formaldehyde from these products is expected. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Agricultural Products (Non-Pesticidal)	Agricultural Products (Non-Pesticidal)	Direct contact through application or use of products using formaldehyde-based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Water Treatment Products	Water Treatment Products	Direct contact through application or use of products using formaldehyde-based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.
			Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					
	Laundry and Dishwashing Products	Laundry and Dishwashing Products	Direct contact through application or use of products using formaldehyde-based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.
			Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
	Personal Care Products	Personal Care Products	Direct contact through application or use of products using formaldehyde-based products	Liquid	Dermal	Consumers	Yes	Evaporation of product from the skin may be limited or prohibited during use of liquid products. Exposure via dermal route will be evaluated.
			Direct contact through application or use of products using formaldehyde-based products	Indoor Air	Inhalation	Consumers and Bystanders	Yes	Vapor generation is expected during application. Exposure via inhalation will be evaluated.
			Long-term emission/mass-transfer					

Appendix H SUPPORTING INFORMATION - CONCEPTUAL MODEL FOR ENVIRONMENTAL RELEASES AND WASTES

Table_Apx H-1. General Population and Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[8]	Rationale
All	Emissions to Air	Emissions to Air (Industrial or Commercial)	Near facility ambient air concentrations	Inhalation	General Population	No	Formaldehyde is a HAP. Because stationary source releases of formaldehyde to ambient air are under the jurisdiction of the CAA.
			Indirect deposition to nearby bodies of water and soil catchments	Oral; Dermal	General Population	No	
				TBD	Aquatic and Terrestrial Receptors	No	
	Emissions to Air	Emissions to Air (Consumer Activities)	Near residence ambient air concentrations	Inhalation	General Population	Yes	Consumer use or installation of various building materials within a residence can lead to long-term off-gassing of formaldehyde from such materials. EPA plans to evaluate exposure to co-located and co-residence populations associated with off-gassing from consumer products used or installed in a residence.
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	No	Ongoing presence of formaldehyde in surface water is expected to be limited due to the rapid and nearly complete hydration of formaldehyde to a gem-diol, methylene glycol, in water.

[8] The exposure pathways, exposure routes and hazards EPA plans to evaluate are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of formaldehyde in exposure pathways falling under the jurisdiction of these EPA statutes.

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[8]	Rationale
			Direct release into surface water and partitioning to sediment	Oral Dermal and Inhalation	General Population	No	
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g., showering)	General Population	No	The drinking water exposure pathway for formaldehyde is currently addressed in the SDWA regulatory analytical process for public water systems.
			Biosolids: application to soil and/or migration to surface water	Oral (e.g., ingestion/ drinking surface water) Dermal (direct contact with surface water)	General Population	Yes	Although formaldehyde is a volatile chemical and not expected to sorb onto soil, EPA plans to analyze this pathway
				TBD	Aquatic and Terrestrial Receptors	Yes	
		Underground injection	Migration to groundwater, potential surface/drinking water	Oral Dermal Inhalation	General Population	No	Formaldehyde is released to Class I Underground Injection Wells which are covered by SDWA and RCRA.
				TBD	Aquatic and Terrestrial Receptors	No	
	Solid and Liquid Wastes	Hazardous, Municipal landfill and other land disposal	Leachate to soil, ground water and/or mitigation to surface water	Oral (e.g., ingestion) Dermal Inhalation	General Population	No	Formaldehyde is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33).
				TBD	Aquatic and Terrestrial Receptors	No	