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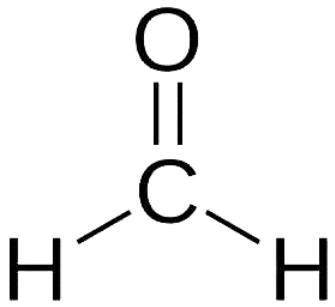
United States
Environmental Protection Agency

Final Scope of the Risk Evaluation for Formaldehyde

CASRN 50-00-0



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

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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
CSF	Cancer Slope Factor
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
IUR	Inhalation Unit Risk
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
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
OSF	Oral Slope Factor
OSHA	Occupational Safety and Health Administration
OW	Office of Water

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, Authorization and Restriction of Chemicals (European Union)
RegDet	Regulatory Determination
REL	Recommended Exposure Limit
RESO	Receptors, Exposure, Setting or Scenario, and Outcomes
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-2019-0131). The first step of the risk evaluation process is the development of the draft scope document. EPA published the *Draft Scope of the Risk Evaluation for Formaldehyde CASRN 50-00-0* (EPA Document No. EPA-740-D-20-014) c and provided a 45-day comment period on the draft scope per 40 CFR 702.41(c)(7). EPA has considered comments received (Docket ID: EPA-HQ-OPPT-2018-0438) during the public comment period to inform the development of this final scope document, and public comments received will continue to inform the development of the risk evaluation for formaldehyde. This document fulfills the TSCA requirement to issue a final scope document per TSCA Section 6(b)(4)(D) and as described in 40 CFR 702.41(c)(8). The 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 the 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.

General Information: Formaldehyde is a highly water-soluble (4.0×10^5 mg/L) gas with a vapor pressure of 3,886 mm Hg, (NLM, 2019). It has a molecular weight of 30.026 g/mol and the density of formaldehyde is 0.815 g/cm^3 at -20°C (Rumble, 2018). Consisting of carbon, hydrogen and oxygen, formaldehyde is a naturally occurring substance. It can be found in the living systems of both plants and animals and, in rural and urban environments.

Reasonably Available Information. EPA leveraged the data and information sources already described in the *Proposed Designation of formaldehyde (CASRN 50-0-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) document supporting the High Priority Substance designation for formaldehyde to inform the development of this scope document. Furthermore, EPA conducted a comprehensive search to identify and screen multiple evidence streams (*i.e.*, chemistry, fate, release and engineering, exposure, hazard) and the search and screening results are provided in Section 2.1. EPA used the systematic review process described in Appendix A to search for and screen reasonably available information, including information already in EPA's possession, for inclusion in the risk evaluation. This information includes the hazards, exposures, PESS, and conditions of use that may help inform the risk evaluation for formaldehyde. EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the risk evaluation and thus are not part of the scoping activities described in this document. EPA will consider additional information identified following publication of this scope document, as appropriate, in developing the risk evaluation, including the Chemical Data Reporting (CDR) information that the Agency will receive by the end of November 2020.

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. EPA revised the conditions of use in the final scope of the risk evaluation based on additional information and public comments (Docket ID EPA-HQ-OPPT-2018-0438) on the draft scope document for formaldehyde. Section 2.2 provides details about the conditions of use within the scope of the risk evaluation.

Conceptual Model. The conceptual models for formaldehyde are presented 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. EPA considered reasonably available information as well as public comments received on the draft scope document for formaldehyde in finalizing the exposure pathways, exposure routes, and hazards EPA plans to evaluate in the risk evaluation. As a result, EPA plans to focus the risk evaluation for formaldehyde on the following exposures, hazards and receptors:

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to evaluate releases to the environment as well as human and environmental exposures and releases to the environment resulting from the conditions of use of 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 for evaluating environmental exposure pathways in the scope of the risk evaluation considers whether and how other EPA administered statutes and regulatory programs cover formaldehyde in media pathways falling under the jurisdiction of those authorities. Section 2.6.3.1 discusses those pathways under the jurisdiction of other EPA-administered laws. In Section 2.6.3.2, 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.

  EPA considered reasonably available information and comments received on the draft scope for formaldehyde in determining the human and environmental exposure pathways, routes, receptors and PESS for inclusion in the final scope. EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation.

  - *Occupational exposure:* EPA plans to evaluate exposures to workers and 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.
  - *Consumer and bystander exposure:* EPA plans to evaluate consumer exposure via inhalation and dermal routes. EPA plans to evaluate inhalation routes of exposure for the consumer user and consumer bystander. EPA plans to evaluate dermal routes of exposure for consumer users only (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 (*e.g.*, rag) or if there is immersion of a body part into a pool of material.

  - *General population exposure:* EPA plans to evaluate general population exposures to formaldehyde from ingestion of fish and water, and from inhalation for co-located and co-residing individuals due to off-gassing from building materials used or installed in a residential setting.
  - *PESS:* EPA plans to include children, women of reproductive age (*e.g.*, pregnant women), workers and consumers as PESS in the risk evaluation.
  - *Environmental exposure:* EPA plans to evaluate exposure to formaldehyde for aquatic receptors.

- *Hazards.* Hazards for formaldehyde are identified in Section 2.4. EPA completed preliminary reviews of information (*e.g.*, federal and international government chemical assessments) to identify potential environmental and human health hazards for formaldehyde as part of the prioritization (U.S. EPA, 2019c) and scoping process (U.S. EPA, 2020c). EPA also considered reasonably available information collected through systematic review methods as outlined in Appendix A and public comments received on the draft scope for formaldehyde in determining the broad categories of environmental and human health hazard effects to be evaluated in the risk evaluation. EPA will use systematic review methods to evaluate the epidemiological and toxicological literature for formaldehyde.

  EPA plans to evaluate all potential environmental and human health hazard effects identified for formaldehyde in Sections 2.4.1 and 2.4.2, respectively. Identified through the data screening phase of systematic review, the potential environmental hazard effects and related information that EPA plans to consider for the risk evaluation include: ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory and skin and connective tissue for formaldehyde. Similarly, the potential human health hazard effects and related information identified through prioritization and the data screening phase of systematic review for formaldehyde that EPA plans to consider for the risk evaluation include: ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory and skin and connective tissue.

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 review of identified information submitted as described in Section 2.1. Should additional data or approaches become reasonably available, EPA may consider them for the risk evaluation.

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 (U.S. EPA, 2015b) and other methods consistent with Section 26 of TSCA (see 40 CFR 702.45).

1 INTRODUCTION

This document presents 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 TSCA on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

Under TSCA § 6(b), the Environmental Protection Agency (EPA) must 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 to conduct 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 nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use*."

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 (Docket ID: EPA-HQ-OPPT-2019-0131) (84 FR 71924, December 30, 2019), 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. On April 23, 2020, EPA published the *Draft Scope of the Risk Evaluation for Formaldehyde* (EPA Document No. 740-D-20-014) (85 FR 22733, April 23, 2020) (U.S. EPA, 2020c) for a 45-day public comment period. After reviewing and considering the public comments received (Docket ID: EPA-HQ-OPPT-2018-0438) on the draft scope document, EPA is now publishing this final scope document pursuant to 40 CFR 702.41(c)(8).

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 final 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;

[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).

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 into useful categories or tags to facilitate the sorting of information through the systematic review process.

Search terms were used to search each of the literature streams for gathering formaldehyde studies. These terms and the methods used to develop them are listed in Appendix A. The studies resulting from the search process were loaded into the EPA Health and Environmental Research Online (HERO) database and then prioritized to screen first the literature likely relevant for each of the disciplines: fate, physical and chemical properties, engineering, exposure and hazard. The tools and methods used to manage the screening process are also outlined in Appendix A. The studies resulting from the search underwent a title/abstract screening process, which tagged them by topic or category. Following this, a determination was made to move studies forward into full-text screening. The criteria used in the screening process for each discipline are found in the population, exposure, comparator, outcome (PECO) statements listed in Appendix A. The screening process results are presented in the form of literature inventory trees and evidence tables in Section 2.1.2. The screening process was conducted based on EPA's planning, execution and assessment activities outlined in Appendix A.

EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the 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.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 257 search results relevant to EPA's risk evaluation needs for formaldehyde. Appendix A.3.4 lists the gray literature sources that yielded 257 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 and chemical properties, environmental fate, ecological hazard, human health hazard, exposure, engineering), and the breakdown is shown in Figure 2-1. EPA will consider additional reasonably available information from gray literature if it becomes available during the risk evaluation phase.

[2] Gray literature is defined as the broad category of data/information sources not found in standard, peer-reviewed literature 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.

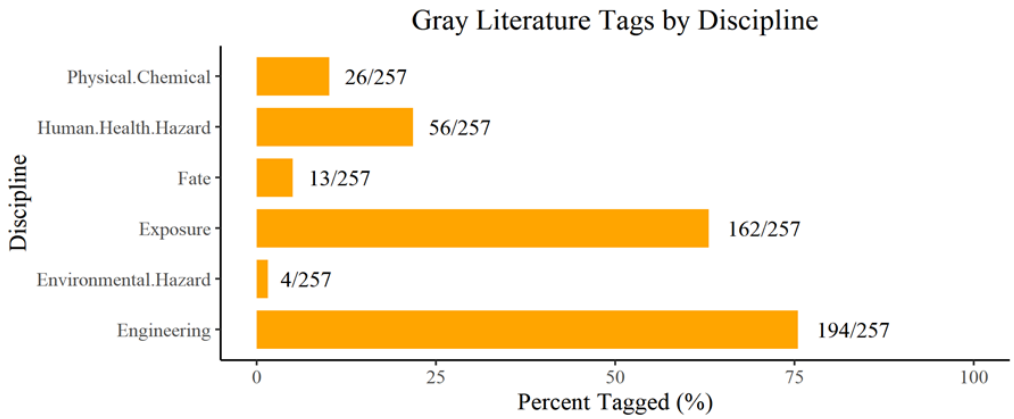

Figure 2-1. Gray Literature Tags by Discipline for Formaldehyde
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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

EPA has begun the systematic review process and has conducted searching and screening of the reasonably available literature using the process outlined in Appendix A. This includes performing a comprehensive search of the reasonably available peer review literature on physical and chemical 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 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 (see Section A.2). EPA plans to evaluate the reasonably available information identified for each discipline during the development of the risk evaluation.

EPA created literature inventory trees to graphically illustrate the flow of data and information sources following full-text screening (see Figure 2-2, Figure 2-3, Figure 2-4, Figure 2-6, Figure 2-8). EPA used the Health Assessment Workplace Collaborative (HAWC) tool to develop web-based literature inventory trees illustrating, through interactive links, studies that were included or excluded. These literature inventory trees enhance the transparency of the decisions resulting from the screening process described in Appendix A. For each of the corresponding disciplines, the literature was tagged to be included for evaluation during the risk evaluation process. Literature inventory trees for physical and chemical properties are provided as static diagrams (Figure 2-2). For all other disciplines, static screen captures are provided in addition to links within each figure's caption to the interactive trees. The links show individual studies that were tagged as included, excluded, or supplemental. Supplemental studies did not meet all inclusion criteria but may be considered during the risk evaluation as supporting information (see Appendix A). These studies can be accessed through the hyperlink provided in the associated caption below each figure. In some figures 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.

In addition, EPA tabulated the number and characteristics of the data and information sources included in the full-text screening process in the form of literature inventory heat maps for the engineering, exposure and hazard disciplines (see Figure 2-5, Figure 2-7, and Figure 2-9). For each of these four disciplines, a static image of the literature inventory heat map is provided, and a link to the interactive version presented in HAWC is included in the caption below each diagram.

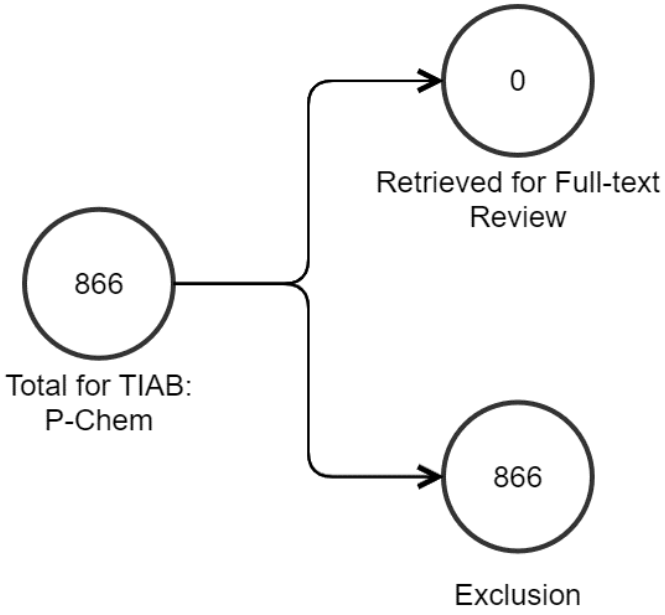

Figure 2-2. Peer-reviewed Literature Inventory Tree- Physical and chemical Properties Search Results for Formaldehyde

Data in this static figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. TIAB refers to "title and abstract" screening.

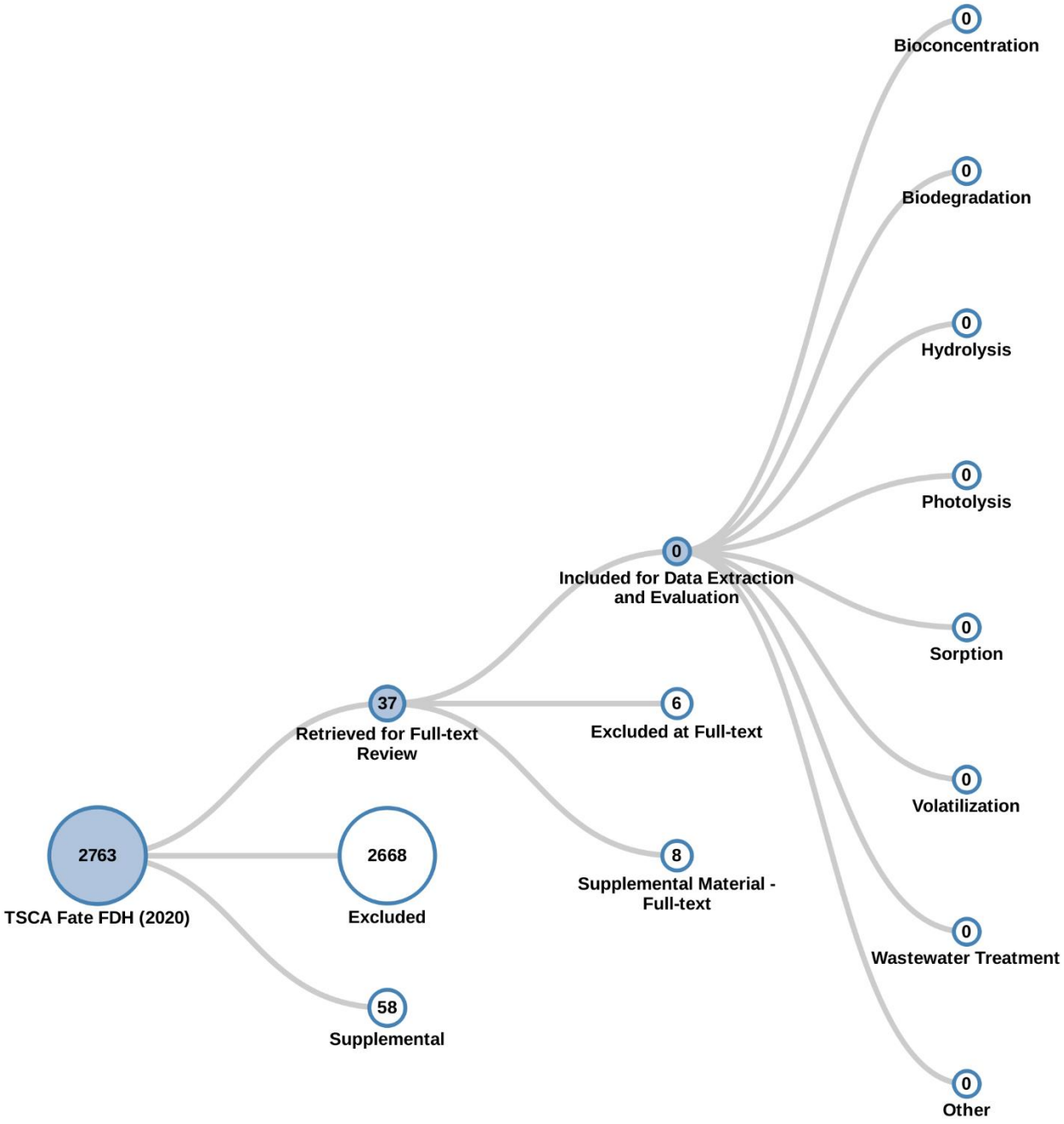

Figure 2-3. Peer-reviewed Literature Inventory Tree - Fate and Transport Search Results for Formaldehyde

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. No heatmap of fate references was created for formaldehyde because there were no fate references included for this chemical during full-text screening. Additional data may be added to the interactive version as they become available.

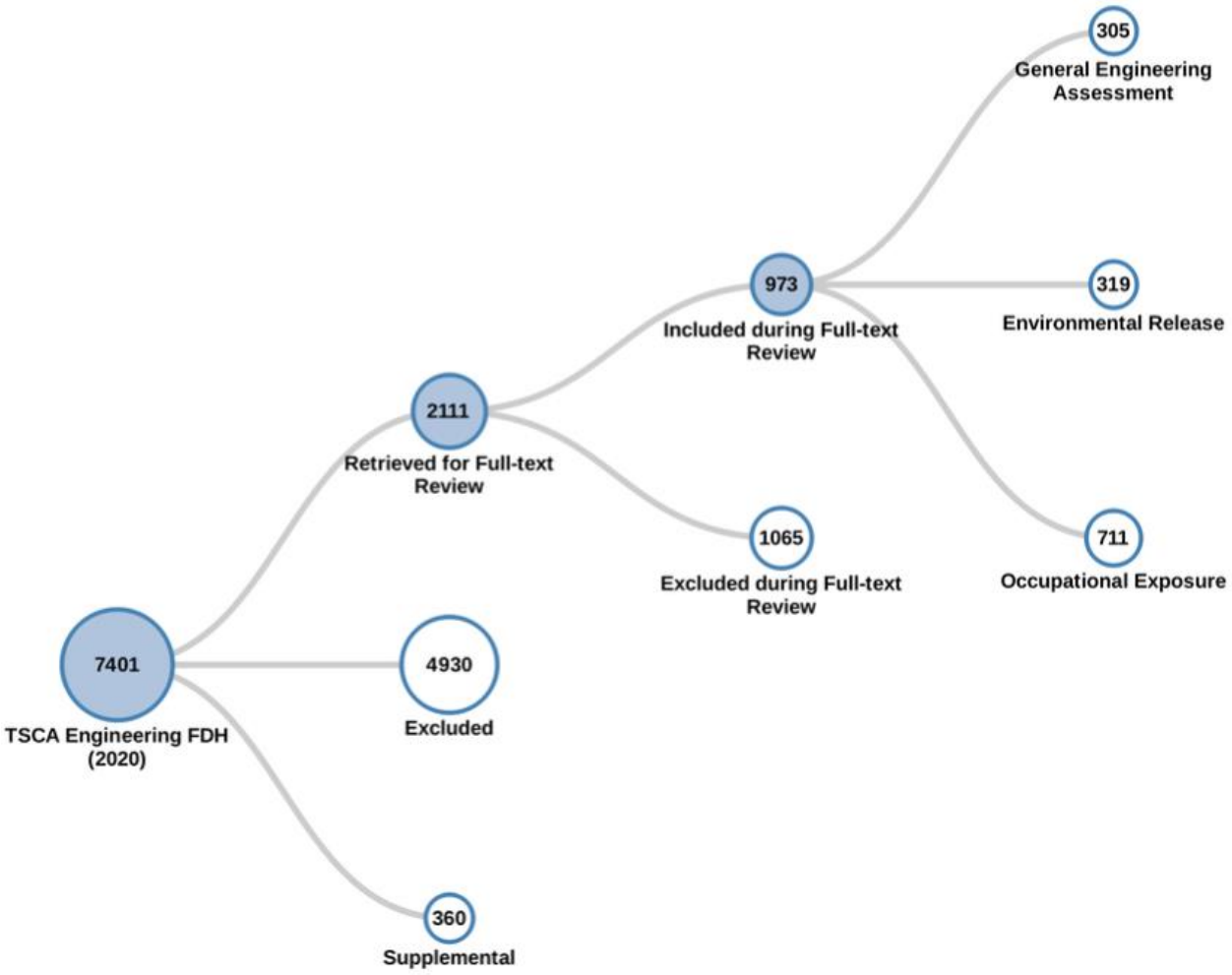

Figure 2-4. Peer-reviewed Literature Inventory Tree - Engineering Search Results for Formaldehyde

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. Additional data may be added to the interactive version as they become available. Due to the large number of references, this diagram does not reflect the 24,825 references considered not likely to be relevant by Swift-ActiveScreener (see Appendix A.2). Additional data may be added to the interactive version as they become available.

Data Type	Evidence Tags	
Environmental Releases	Description of release source	174
	No evidence tag	7
	Release frequency	14
	Release or emission factors	216
	Release quantity	135
	Waste treatment methods and pollution control	55
	Total	321
General Engineering Assessment	Chemical concentration	133
	Life cycle description	44
	No evidence tag	17
	Number of sites	28
	Process description	134
	Production, import, or use volume	90
	Throughput	30
	Total	305
Occupational Exposures	Area sampling data	516
	Dermal exposure data	26
	Engineering control	109
	Exposure duration	280
	Exposure frequency	130
	Exposure route	454
	No evidence tag	11
	Number of workers	214
	Particle size characterization	3
	Personal protective equipment	69
	Personal sampling data	340
	Physical form	244
	Worker activity description	389
	Total	711
Grand Total		975

Figure 2-5. Peer-reviewed Literature Inventory Heat Map - Engineering Search Results for Formaldehyde

Click here to view the interactive version for additional study details. Data in this interactive version represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. Additional data may be added to the interactive version as they become available.

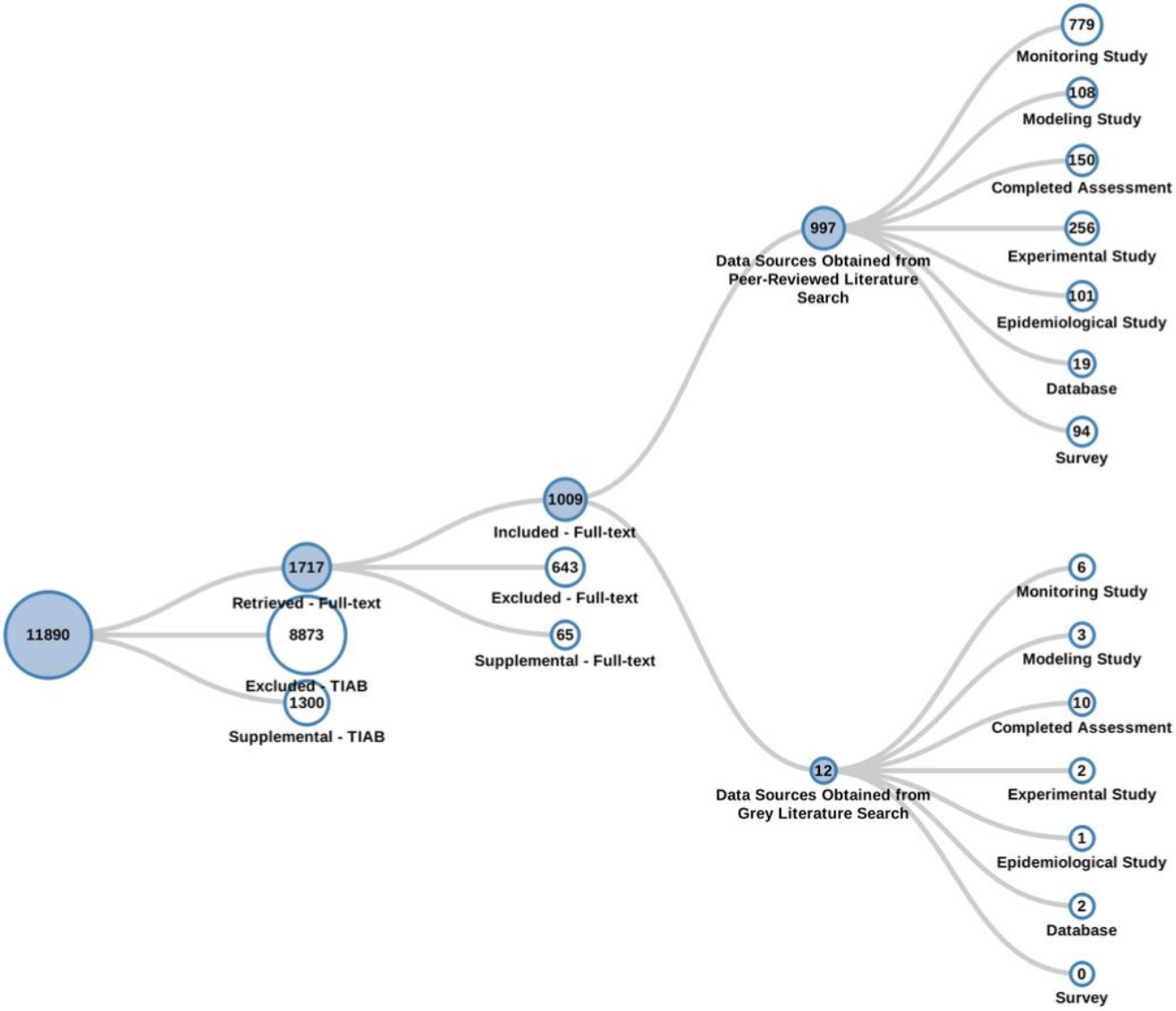

Figure 2-6. Peer-reviewed and Gray Literature Inventory Tree -Exposure Search Results for Formaldehyde

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2), and gray literature references search (see Appendix A.3) that were included during full-text screening as of July 31, 2020. Additional data may be added to the interactive version as they become available.

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Media (group)	Data Type: Monitoring Study	Modeling Study	Completed Assessment	Experimental Study	Epidemiological Study	Database	Survey	Grand Total
Ambient Air								
Biosolids/Sludge			1					1
Drinking Water								
Groundwater	2		2	1				3
Land Disposal/ Landfill								
Sediment	1	1	3					4
Soil	2	2	5	1				7
Surface Water	4	1	4	1	1	1		8
Wastewater	1		4					4
Aquatic Species	6	2	5					8
Terrestrial Species	3		4	4				6
Consumer	195	53	54	227	16	7	13	358
Dietary	20	2	14	3		1		26
Dust	9	2	4	1	1	1	3	10
Exposure Factors	30	19	23	15	8	4	3	57
Exposure Pathway	58	15	33	16	9	3	4	83
Human Biomonitoring	27	3	7	7	11		4	30
Indoor Air	744	97	131	208	87	15	92	911
Isomers	1		1		1			1
Use Information	18	5	13	7	4	3	1	33
No Evidence Type	2	1	2		1			2
Grand Total	785	111	160	258	102	21	94	1,009

Figure 2-7. Peer-reviewed and Gray Literature Inventory Heat Map –Exposure – Search Results for Formaldehyde

Click here to view the interactive version for additional study details. The column totals, row totals, and grand totals indicate total numbers of unique references, as some references may be included in multiple cells. The various shades of color visually represent the number of relevant references identified by exposure media or data type. The darker the color, the more references are available for a given exposure media or data type. Data in this figure represent all references obtained from the publicly available databases search (see Appendix A.1.2), and gray literature references search (see Appendix A.3) that were included during full-text screening as of July 31, 2020. Additional data may be added to the interactive version as they become available.

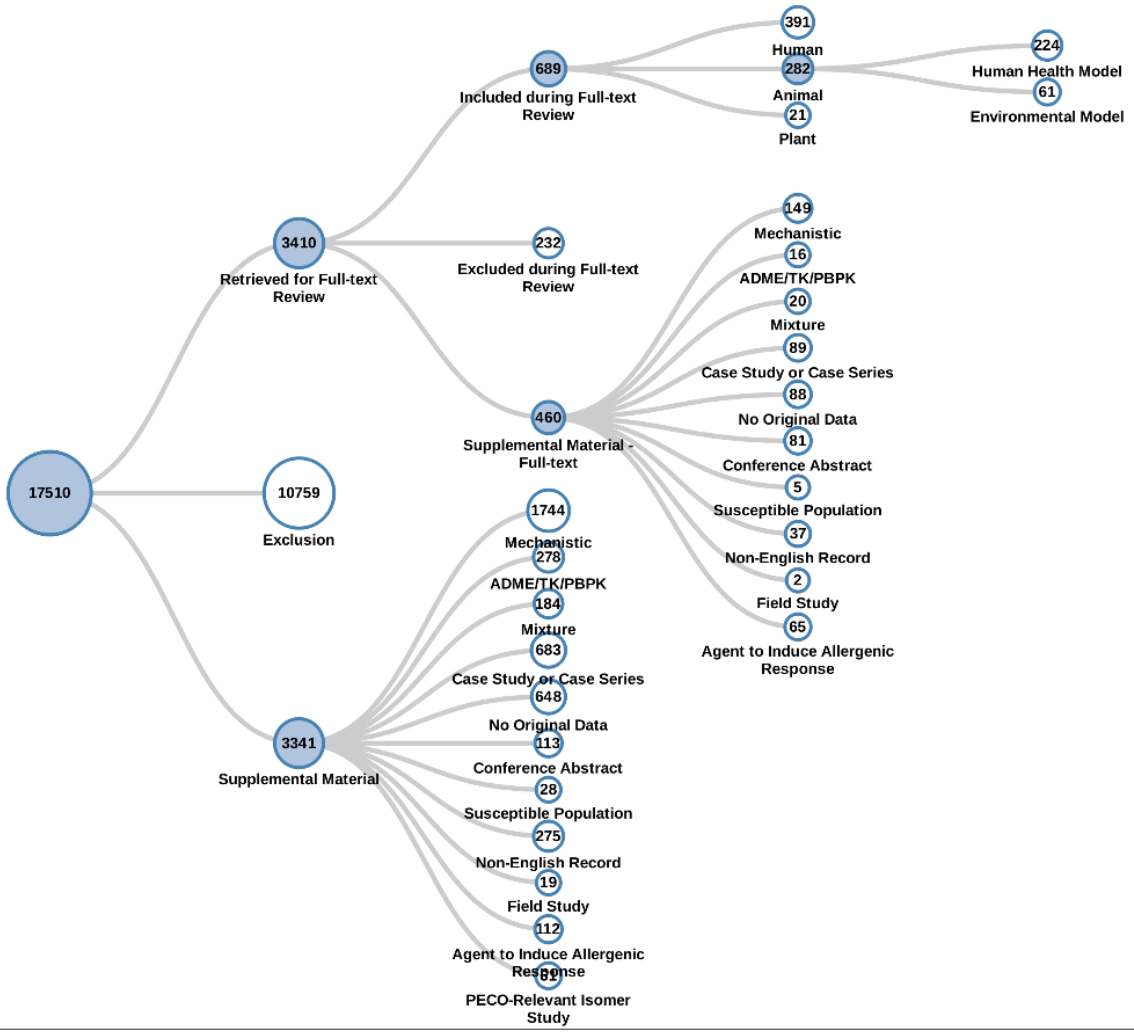

Figure 2-8. Peer-reviewed Literature Inventory Tree – Human Health and Environmental Hazards Search Results for Formaldehyde

Click here to view the interactive literature inventory tree. Data in this interactive version represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 07, 2020. Due to the large quantity of references, this diagram does not reflect the 69,979 references considered not likely to be relevant by Swift-ActiveScreener (see Appendix A.2). Additional data may be added to the interactive version as they become available.

	Evidence Type				
Health Outcomes	Human	Animal - Human Health Model	Animal - Environmental Model	Plant	Grand Total
ADME	31	83	11	5	128
Cancer	151	47	4		202
Cardiovascular	18	22	2		42
Developmental	70	59	17	7	152
Endocrine	12	32	5	2	50
Gastrointestinal	38	16	4	1	58
Hematological and Immune	138	61	17		214
Hepatic	9	22	5		36
Mortality	65	14	19	1	99
Musculoskeletal	18	61	5		84
Neurological	39	73	9		121
Nutritional and Metabolic	9	23	7	4	41
Ocular and Sensory	186	63	2		250
PBPK	1	1			2
Renal	14	9	3		26
Reproductive	27	38	5		70
Respiratory	267	110	6		383
Skin and Connective Tissue	88	28	4		119
No Tag	7	11	12	8	34
Grand Total	389	224	61	21	687

Figure 2-9. Peer-reviewed Literature Inventory Heat Map – Human Health and Environmental Hazards Search Results for Formaldehyde

Click here to view the interactive version for additional study details. The numbers indicate the number of studies with full-text keywords related to a particular health outcome, not the number of studies that observed an association with formaldehyde. Therefore, the studies examining multiple Health Outcomes and Evidence types, connections between health outcome, and evidence type may not be accurately represented. If a study evaluated multiple health outcomes or included multiple populations or study designs, it is shown here multiple times. Data in this figure represents references obtained from the publicly available databases search (See Appendix A.1.2) that were included during full-text screening as of August 03, 2020. Additional data may be added to the interactive version as they become available.

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. EPA screened a total of 191 submissions using PECO or similar statements that identify inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of

disciplines). The details about the criteria are presented in Appendix A.2.1. EPA identified 116 submissions that met the inclusion criteria in these statements and identified 38 submissions with supplemental data[3]. 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.

Table 2-1. Results of Title Screening of Submissions to EPA under Various Sections of TSCA[a]

Discipline	Included	Supplemental[b]
Physical and Chemical 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

[a]Individual submissions may be relevant to multiple disciplines.
[b]Included submissions may contain

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, 2019c), EPA assembled information from the CDR and TRI programs to determine conditions of use[4] or significant changes in conditions of use of the chemical substance. Once the 2020 CDR reporting period ends in November 2020, EPA will utilize the most recent CDR information. EPA also consulted a variety of other sources to identify uses of formaldehyde, including 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) (U.S. EPA, 2019b)

[3] EPA may further consider some supplemental or excluded references depending on the reasons for tagging as supplemental or excluded.
[4] *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 (TSCA § 3(4)).

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, EPA incorporated communications with companies, industry groups, environmental organizations, and public comments to supplement the use information.

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

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use, and disposal of formaldehyde, EPA identified those activities for formaldehyde the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These activities are described in Section 2.2.2.

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 [a]	Category [b]	Subcategory [c]	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019a)
	Importing	Importing	U.S. EPA (2019a)
Processing	Reactant	Adhesives and sealant chemicals in: Plastic and resin manufacturing; Wood product manufacturing; All other basic organic chemical manufacturing	U.S. EPA (2019a)
		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;	U.S. EPA (2019a)

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	Reference
		Agriculture, forestry, fishing, and hunting	
		Functional fluid in: Oil and gas drilling, extraction, and support activities	U.S. EPA (2019a)
		Processing aids, specific to petroleum production in all other basic chemical manufacturing	U.S. EPA (2019a)
		Bleaching agent in wood product manufacturing	U.S. EPA (2019a)
		Agricultural chemicals in agriculture, forestry, fishing, and hunting	U.S. EPA (2019a)
	Incorporation into an article	Finishing agents in textiles, apparel, and leather manufacturing	U.S. EPA (2019a); USTMA (EPA-HQ-OPPT-2018-0438-0054)
		Paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace)	U.S. EPA (2019a); AIA (EPA-HQ-OPPT-2018-0438-0006)
		Additive in rubber product manufacturing	USTMA (EPA-HQ-OPPT-2018-0438-0026); USTMA (EPA-HQ-OPPT-2018-0438-0054)
		Adhesives and sealant chemicals in wood product manufacturing; plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	U.S. EPA (2019a); AIA (EPA-HQ-OPPT-2018-0438-0006); ARMA (EPA-HQ-OPPT-2018-0438-0005); ARMA (EPA-HQ-OPPT-2018-0438-0051) USTMA (EPA-HQ-OPPT-2018-0438-0054)
	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 (2019a); AIA (EPA-HQ-OPPT-2018-0438-0006); Everlube (EPA-HQ-OPPT-2018-0438-0024)
		Asphalt, paving, roofing, and coating materials manufacturing	U.S. EPA (2019a); ARMA (EPA-HQ-OPPT-2018-0438-0005)

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	Reference
		Solvents (which become part of a product formulation or mixture) in paint and coating manufacturing	U.S. EPA (2019a)
		Processing aids, specific to petroleum production in: oil and gas drilling, extraction, and support activities and all other basic inorganic chemical manufacturing	U.S. EPA (2019a); AIA (EPA-HQ-OPPT-2018-0438-0006); EDF (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 (2019a)
		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 (2019a)
		Other: Preservative in all other chemical product and preparation manufacturing	U.S. EPA (2019a)
		Solid separation agents in miscellaneous manufacturing	U.S. EPA (2019a)
		Agricultural chemicals (non-pesticidal) in: agriculture, forestry, fishing, and hunting; pesticide, fertilizer, and other agricultural chemical manufacturing	U.S. EPA (2019a)
		Surface active agents in plastic material and resin manufacturing	U.S. EPA (2019a)
		Ion exchange agents in adhesive manufacturing and paint and coating manufacturing	U.S. EPA (2019a)
		Lubricant and lubricant additive in adhesive manufacturing	U.S. EPA (2019a)
		Plating agents and surface treating agents in all other chemical product and preparation manufacturing	U.S. EPA (2019a)

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	Reference
		Functional fluids (closed system) in soap, cleaning compound, and toilet preparation manufacturing	U.S. EPA (2019a)
		Other: Laboratory chemicals	U.S. EPA (2019a)
		Adhesive and sealant chemical in adhesive manufacturing	U.S. EPA (2019a)
		Bleaching agents in textile, apparel, and leather manufacturing	U.S. EPA (2019a)
	Repackaging	Sales to distributors for laboratory chemicals	U.S. EPA (2019a)
	Recycling	Recycling	U.S. EPA (2019a)
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Industrial Use	Non-incorporative activities	Process aid in: Oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing	U.S. EPA (2019a); EDF (EPA-HQ-OPPT-2018-0438-0017)
		Used in: construction and agriculture, forestry, fishing, and hunting	U.S. EPA (2019a)
		Oxidizing/reducing agent; processing aids, not otherwise listed (*e.g.*, electroless copper plating)	IPC (EPA-HQ-OPPT-2018-0438-0025); Enthone-OMI Inc. (1990); IPC (EPA-HQ-OPPT-0438-0050); SAI (EPA-HQ-OPPT-0438-0053)
	Chemical substances in industrial products	Paints and coatings; adhesives and sealants; lubricants	AIA (EPA-HQ-OPPT-2018-0438-0006)
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, 2020a); U.S. EPA (2019a); Certified Labs Certified Labs (Division of NCH Corporation) (1995); CPSC email (2019)
	Chemical substances in treatment products	Water treatment products	U.S. EPA (2019a); Mansfield Sanitary Inc. (1985); Chemetrics (1989); Calgon Corporation (1990)

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	Reference
	Chemical substances in treatment/care products	Laundry and dishwashing products; Personal care products (covered by TSCA)	U.S. EPA (2019a)
	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; Paint and coatings	U.S. EPA (2019a); E.I. Dupont de Nemours & Co. (1989); E.I. Dupont de Nemours & Co. (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 (2019a); (U.S. EPA, 2020a)
	Chemical substances in electrical products	Electrical and electronic products	U.S. EPA (2019a)
	Chemical substances in metal products	Metal products not covered elsewhere	U.S. EPA (2019a); Formica (1988)
	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products	U.S. EPA (2019a); USTMA (EPA-HQ-OPPT-2018-0438-0026); Northern Labs Inc. (1990); Everlube (EPA-HQ-OPPT-2018-0438-0024)
	Chemical substances in agriculture use products	Lawn and garden products	U.S. EPA (2019a)
	Chemical substances in outdoor use products	Explosive materials	U.S. EPA (2019a)

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	Reference
	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 (2019a); ACA (EPA-HQ-OPPT-2018-0438-0023); ACC (EPA-HQ-OPPT-2018-0438-0018); Franklin International (1992);
	Chemical substances in hobby products	Arts, crafts, and hobby materials	U.S. EPA (2019a); Day-Glo Color Corporation (1993); Elmer's (2012)
	Chemical substances in packaging, paper, plastic, hobby products	Ink, toner, and colorant products; Photographic supplies	U.S. EPA (2019a); Graphic Controls (1985); Eastman Kodak Company (1996)
	Chemical substances in products not described by other codes	Laboratory Chemicals (*e.g.*, specimen preservation, medical samples, mortuary science)	U.S. EPA (2019a); Dodge Chemical Co (1988); Pierce Chemicals (1988)
Consumer Uses	Chemical substances in furnishing treatment/care products	Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture and furnishings not covered elsewhere	U.S. EPA (2019a); (U.S. EPA, 2020a); Keller-Reckitt & Colman Inc. (1991b)
		Fabric, textile, and leather products not covered elsewhere (clothing)	CPSC Email (2019)
	Chemical substances in treatment products	Water treatment products	U.S. EPA (2019a); Mansfield Sanitary Inc. (1985); Chemetrics (1989); Calgon Corporation (1990)
	Chemical substances in treatment/care products	Laundry and dishwashing products; Personal care products (covered by TSCA)	U.S. EPA (2019a); Phoenix Brands (2007); Colgate-Palmolive Company (2016a, b, 2015); Keller-Reckitt & Colman Inc. (1991a)
	Chemical substances in construction,	Adhesives and Sealants; Paint and coatings	U.S. EPA (2019a); Dexter Crown Metro Aerospace Inc. (1992)

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	Reference
	paint, electrical, and metal products	Building/construction materials – wood and engineered wood products; Building/construction materials not covered elsewhere	U.S. EPA (2019a); (U.S. EPA, 2020a)
	Chemical substances in electrical products	Electrical and electronic products	U.S. EPA (2019a)
	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products	U.S. EPA (2019a); USTMA (EPA-HQ-OPPT-2018-0438-0026); Northern Labs Inc. (1990); Everlube (EPA-HQ-OPPT-2018-0438-0024)
	Chemical substances in agriculture use products	Lawn and garden products	U.S. EPA (2019a)
	Chemical substances in packaging, paper, plastic, hobby products	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	U.S. EPA (2019a); ACA (EPA-HQ-OPPT-2018-0438-0023); ACC (EPA-HQ-OPPT-2018-0438-0018)
	Chemical substances in hobby products	Arts, crafts, and hobby materials	U.S. EPA (2019a); Day-Glo Color Corporation (1993); Elmer's (2012)
	Chemical substances in packaging, paper, and plastic	Ink, toner, and colorant products; Photographic supplies	U.S. EPA (2019a); Graphic Controls (1985); Franklin International (1992); Eastman Kodak Company (1996)
Disposal	Disposal	Disposal	U.S. EPA (2019a)

a. Life Cycle Stage Use Definitions (40 CFR § 711.3)
- "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.
- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA Section 6(a)(5) to reach both.

Life-Cycle Stage [a]	Category [b]	Subcategory [c]	Reference

b. These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of formaldehyde in industrial and/or commercial settings.

c. These subcategories reflect more specific conditions of use of formaldehyde

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 82 FR 33726, July 20, 2017, TSCA Section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the PESS 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). TSCA Section 3(4) also grants EPA discretion to determine the circumstances that are appropriately considered to be conditions of use for a particular chemical substance[5]. As a result, EPA does not plan to include in this scope or in the risk evaluation activities described below that the Agency does not consider to be conditions of use or for which EPA is exercising discretionary authority provided by TSCA Section 6(b)(4)(D).

TSCA Section 3(2) also excludes from the definition of "chemical substance" "any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device" as well as "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide." EPA has determined that the following uses of formaldehyde are non-TSCA uses:

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 which would fall under the regulatory purview of the U.S. Food and Drug Administration. Miscellaneous non-TSCA uses include use of formaldehyde in sugar refineries (Earthjustice (EPA-HQ-OPPT-2018-0438-0019)). EPA has determined that the use of formaldehyde in sugar refining would be regulated under the FIFRA program. 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," TSCA § 3(4)) and will not be evaluated during risk evaluation].

[5] *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 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 (TSCA § 3(2).

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, 2020a). 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, 2019c) and will include more recent production volume information from the 2020 CDR reporting period in the risk evaluation to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

Figure 2-10 provides the lifecycle diagram for formaldehyde. The life cycle diagram is a graphical representation of the various life stages of the industrial, commercial and consumer use categories included within the scope of the risk evaluation. The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses). Appendix E contains additional descriptions (*e.g.*, process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use and disposal category.

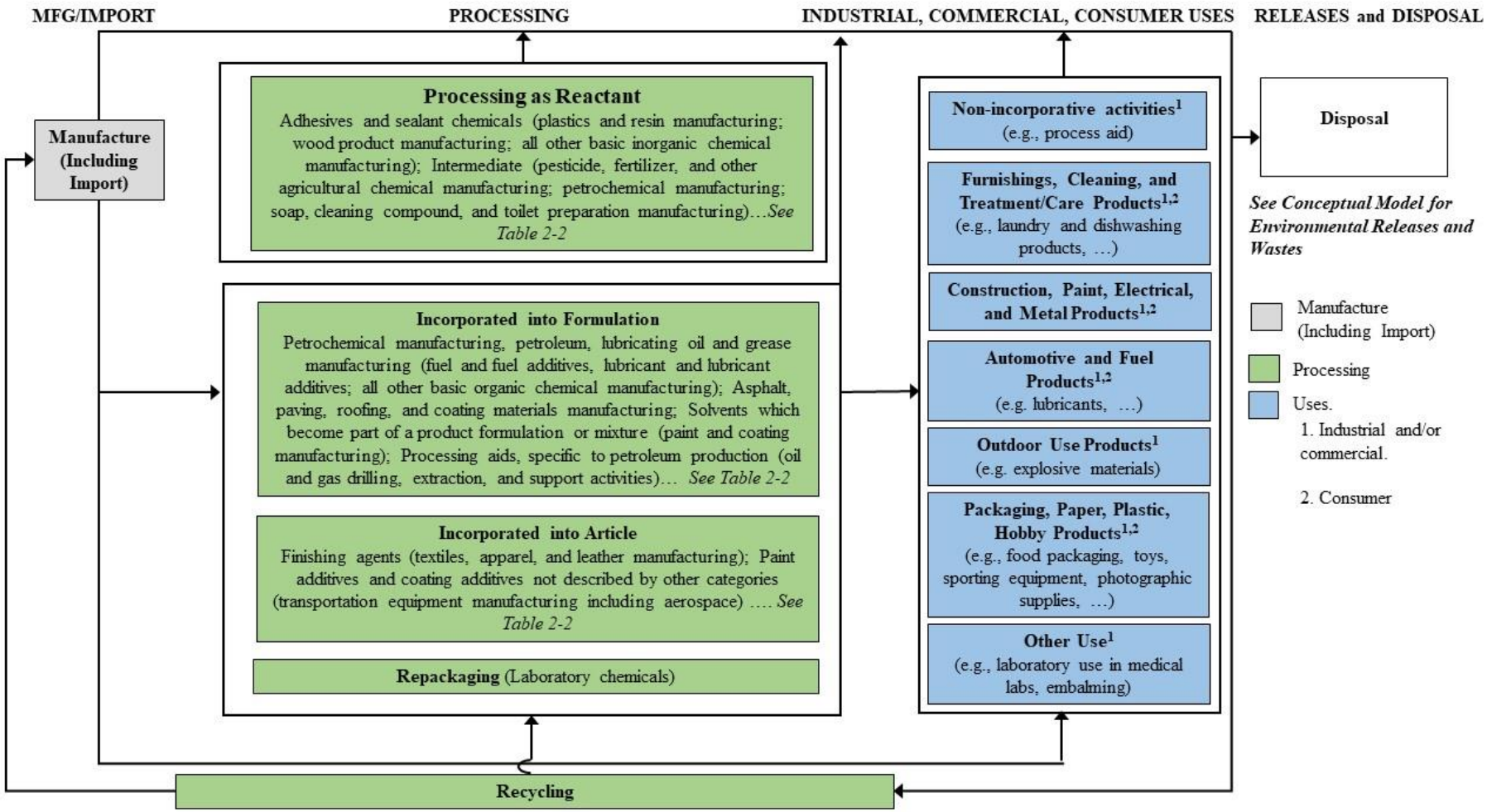

Figure 2-10. Formaldehyde Life Cycle Diagram

Please refer to Table 2-2 for the comprehensive list of processing activities and the relevant sub-categories for industrial, commercial, and consumers uses.

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze human and environmental exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for formaldehyde. In this section, the physical and chemical properties, environmental fate and transport properties and releases to the environment are described in addition to potential human and environmental exposures from TSCA conditions of use and from other possible or known sources. Release pathways and routes will be described in Section 2.6 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 Properties

Consideration of physical and chemical properties is essential for a thorough understanding or prediction of environmental fate (*i.e.*, transport and transformation) and the eventual environmental concentrations. It can also inform the hazard assessment. Table 2-3 summarizes the physical and chemical property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of June 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, 2019c) and may be updated as EPA continues to evaluate and integrate additional information through systematic review methods. Figure 2-11 summarizes the distribution of reported values for eight physical and chemical properties routinely used in existing chemical risk evaluations. Appendix B presents summary statistics for reported physical and chemical property values. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0438).

Table 2-3. 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
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		
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.
NA = Not applicable

Figure 2-11 displays a summary of the data collected as of June 2020 for eight physical and chemical values routinely used in TSCA existing chemical risk evaluations. The box and whisker plots for each endpoint illustrate the mean (average, indicated by the blue diamond) and the 10th, 25th, 50th (median), 75th, and 90th percentiles. All individual data points are indicated by black squares, and value preliminarily selected for use in the risk evaluation is overlaid (indicated by the orange circle) to provide context for where it lies within the distribution of the dataset. The number of unique primary data sources is indicated below each box and whisker plot. If multiple sources presented equivalent values and cited the same primary source, only one of those was included in the statistical calculations. As a result, the number of sources listed in Figure 2-11 may differ from the total number of data sources presented in Figure 2-2.

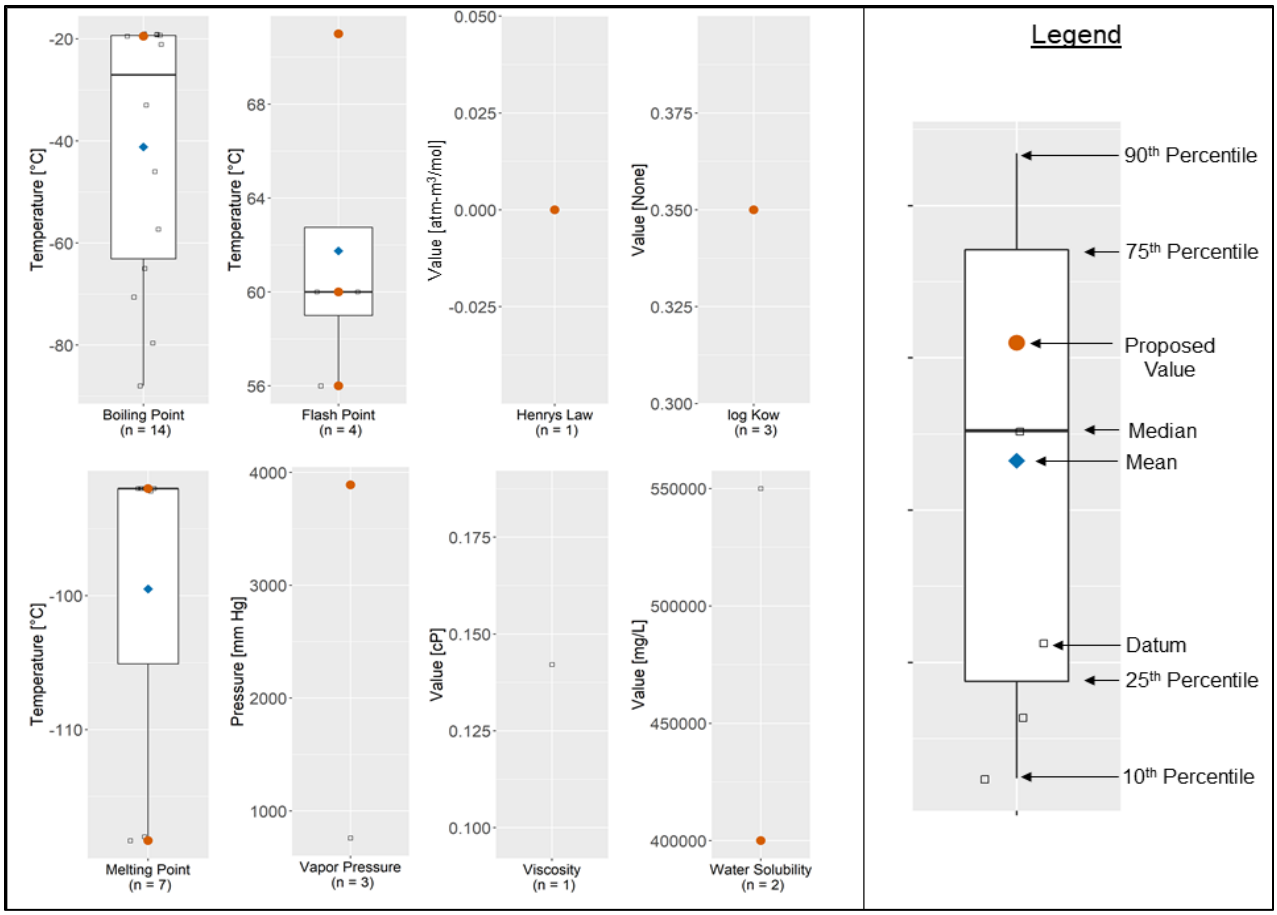

Figure 2-11. Box and Whisker Plots of Reported Physical and Chemical Property Values

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 Appendix C to support the development of the risk evaluation for formaldehyde. The values for the environmental fate properties may be updated as EPA evaluates and integrates additional information into the risk evaluation through systematic review methods.

2.3.3 Releases to the Environment

Releases to the environment from conditions of use 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.

Table 2-4 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 2-4. 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) U.S. EPA (2019d)
[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 2-5 provides a summary of the quantities of formaldehyde released to the environment during 2018 as reported to TRI. 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.

[6] For TRI reporting criteria see https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting
[7] Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-4 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.

Table 2-5. 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) (U.S. EPA, 2019d)
[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.

The total production-related waste managed quantity shown in Table 2-4 does not include any quantities reported as catastrophic or one-time releases not associated with production. 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 2-4. 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 2-5. 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 and exposure to aquatic and terrestrial receptors (biota). Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, and bioaccumulation within the environment, and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review reasonably available environmental monitoring data for formaldehyde.

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, 2019c) 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, 2000).

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 plans to consider the effect(s) that engineering controls (EC) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the risk evaluation.

Worker Activities

Examples of worker activities associated with the conditions of use within the scope of the risk evaluation for formaldehyde that EPA may 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 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

Formaldehyde is a gas with a vapor pressure of 3890 mm Hg at 25°C. 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. The American Conference of Governmental Industrial Hygienists (ACGIH) set the Threshold Limit Value (TLV) at 0.1 ppm TWA and 0.3 ppm STEL. 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).

EPA generally does not evaluate occupational exposures through the oral route. Workers and ONUs may inadvertently ingest inhaled particles that deposit in the upper respiratory tract. In addition, workers may transfer chemicals from their hands to their mouths. The frequency and significance of this exposure route are dependent on several factors including the physical and chemical properties of the substance during worker activities, the visibility of the chemicals on the hands while working, workplace training and practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). EPA will consider the relevance of this exposure route on a case-by-case basis, taking into consideration the aforementioned factors and any reasonably available information, and may assess oral exposure for workers for certain COUs and worker activities where warranted.

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.

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 physical and chemical

and fate properties of formaldehyde discussed in Section 2.3.1, 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, 2000). Formaldehyde is not expected to bioaccumulate in fish (U.S. EPA, 2019c) and, given its low octanol/water partition coefficient, adsorption to soil is likely low (ATSDR, 1999). The general population pathways in the scope of this evaluation are described in Sections 2.6.3 and 2.7.2.5

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

EPA considered reasonably available information (*e.g.,* federal and international government chemical assessments) on formaldehyde as well as public comments received on the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and draft scope for formaldehyde (U.S. EPA, 2020c) to identify potential environmental hazards. During prioritization, EPA identified environmental hazard effects for aquatic and terrestrial organisms.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following potential environmental hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory and skin and connective tissue (Figure 2-9). A summary of the references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-8). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the risk evaluation.

2.4.2 Human Health Hazards

EPA considered reasonably available information (*e.g.,* federal and international government chemical assessments) on formaldehyde as well as through comments received on the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and draft scope for formaldehyde (U.S. EPA, 2020c) to identify potential human health hazards. During prioritization, EPA identified the following potential human health hazards and related information: acute toxicity, repeated dose toxicity, genetic toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization and cancer.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following potential environmental hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculo-skeletal, neurological, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory and skin and connective tissue (Figure 2-9). A summary of the references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-8). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the 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).

EPA identified the following PESS based on CDR information, public comments received on the draft scope for formaldehyde (Docket ID: EPA-OPPT-2018-0438) and studies reporting developmental and reproductive effects: children, women of reproductive age (*e.g.*, pregnant women), workers, including ONUs and users, and consumers including users and bystanders (U.S. EPA, 2019c). EPA plans to evaluate these PESS in the risk evaluation. Following further evaluation of the reasonably available information, EPA may evaluate PESS in the general population as they relate to fence line communities.

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, 2006b) 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). Based on these analyses, EPA may update the list of PESS in the risk evaluation.

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 are under the jurisdiction of other EPA-administered, are discussed and depicted in the conceptual model shown in Section2.6.3.1. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that are under the jurisdiction of other EPA-administered, are presented in the conceptual model shown in Section 2.6.3.2.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-12 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 (including mists). 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, a determination was made as to whether or not EPA plans to evaluate each combination of exposure pathway, route, and receptor in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix F.

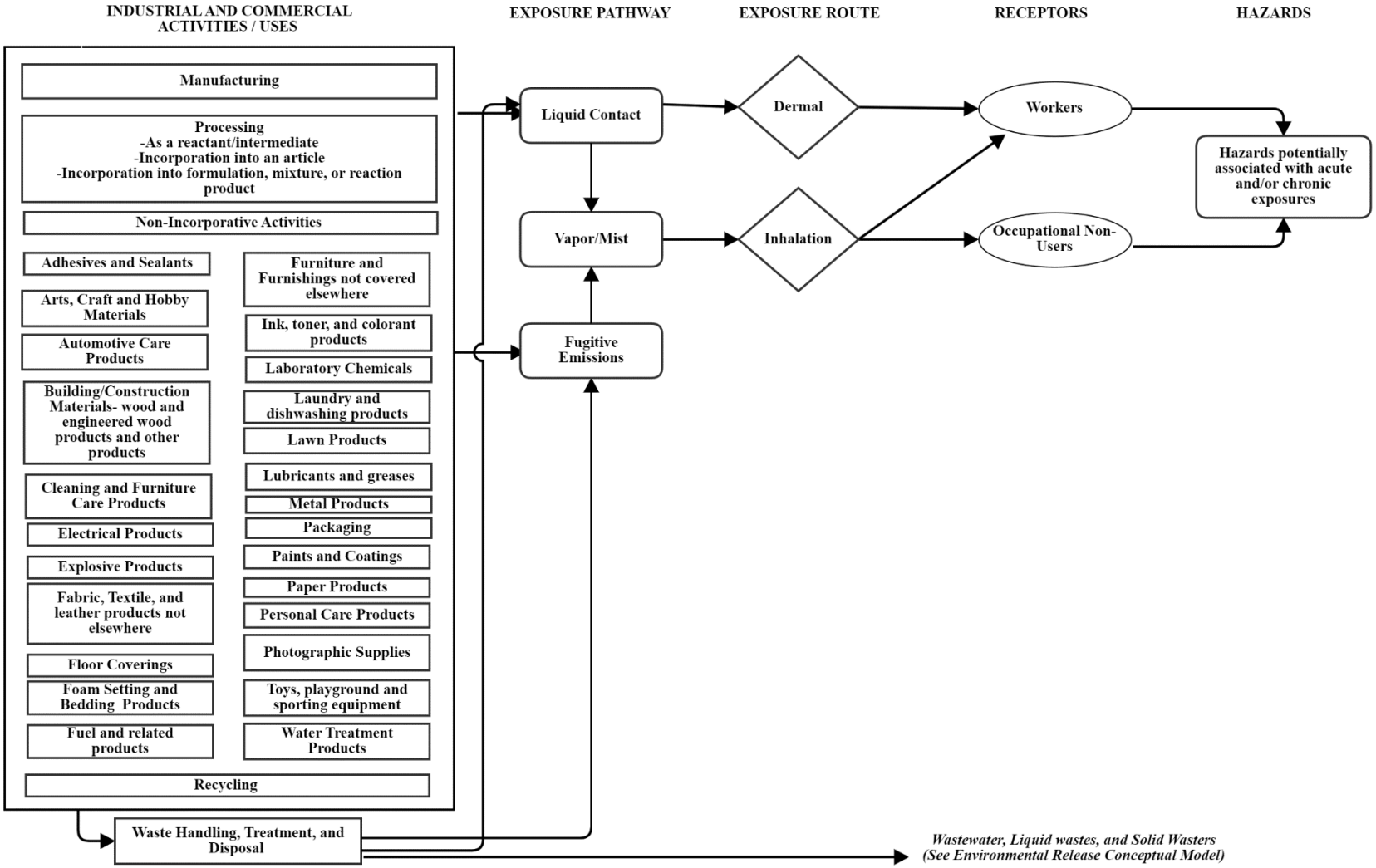

Figure 2-12. Formaldehyde Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

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 2-13 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.

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 off gassing 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 off gassing from building products or components installed or utilized within a residence.

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 2-13.

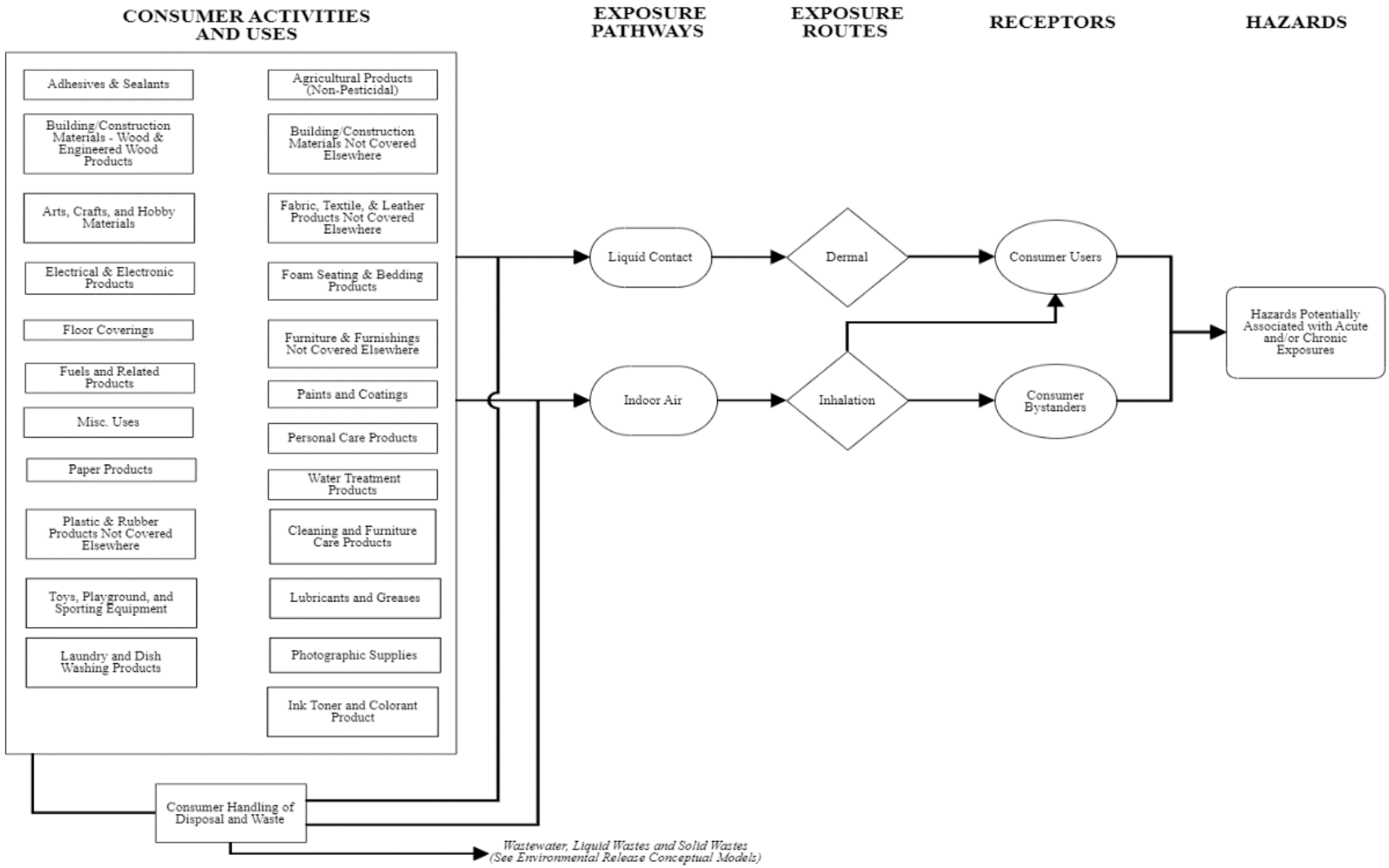

Figure 2-13. Formaldehyde Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of formaldehyde.
[a] Receptors include PESS (see Section 2.5).

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 from environmental releases and wastes) and hazards to general population and environmental receptors associated with the conditions of use of formaldehyde within the scope of the risk evaluation. This section also discusses those pathways that may be addressed pursuant to other EPA-administered laws.

The conceptual model in Figure 2-14 presents the potential exposure pathways, exposure routes and hazards to general population and environmental receptors from releases and waste streams associated with industrial, commercial, and consumer uses of formaldehyde. The conceptual model shows the overlays, labeled and shaded to depict the regulatory programs under EPA-administered statutes and associated pathways that EPA considered for the scope of the risk evaluation. The regulatory programs that cover these environmental releases and waste pathways are further described in Section 2.6.3.1

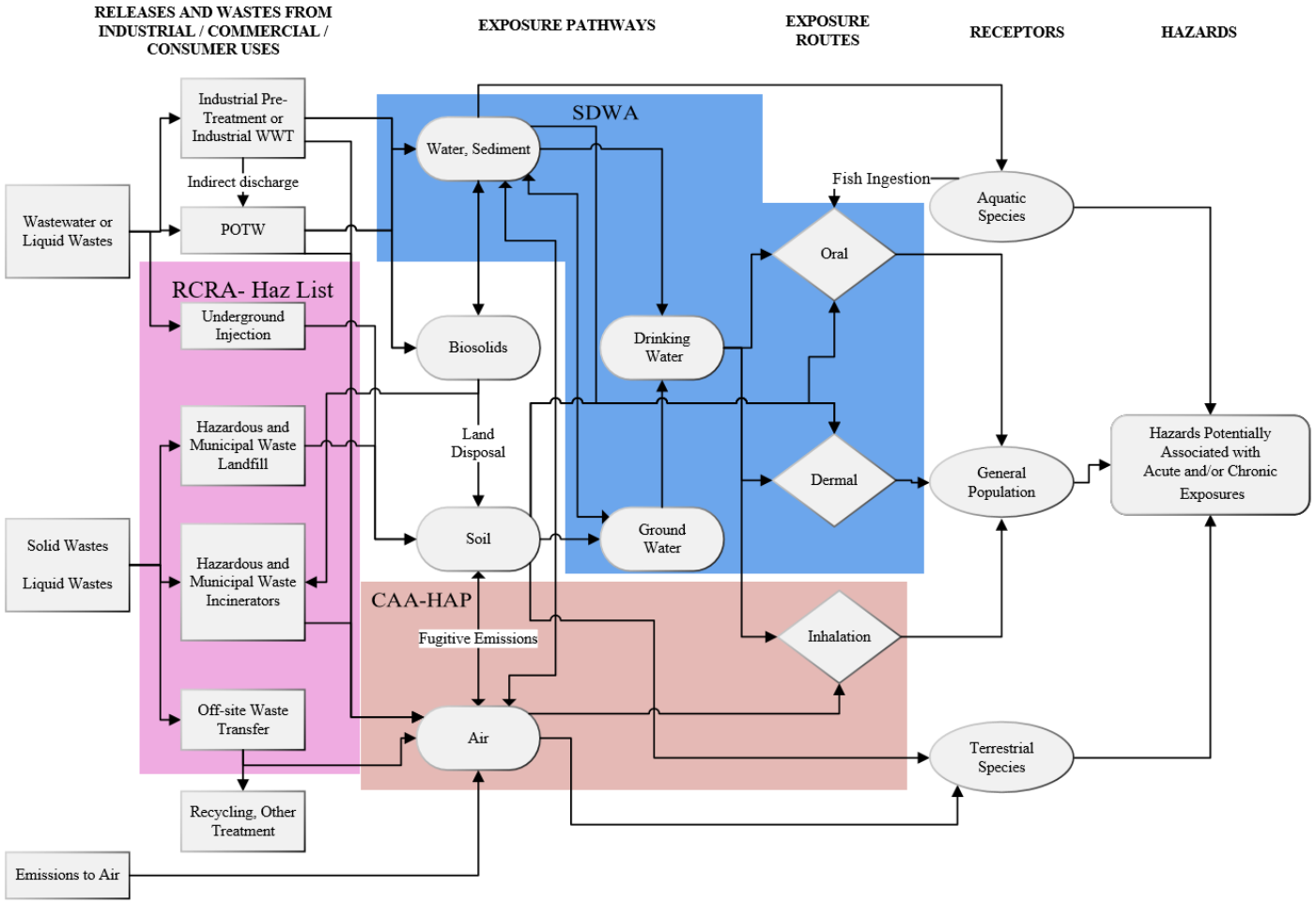

Figure 2-14. Formaldehyde Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

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).

2.6.3.1 Exposure Pathways and Risks Addressed by Other EPA Administered Statutes

In its TSCA Section 6(b) risk evaluations, EPA is coordinating action on certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. More specifically, EPA is exercising its TSCA authorities to tailor the scope of its risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered statutes or regulatory programs or risks that could be eliminated or reduced to a sufficient extent by actions taken under other EPA-administered laws. EPA considers this approach to be a reasonable exercise of the Agency's TSCA authorities, which include:

- TSCA Section 6(b)(4)(D): "The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider…"
- TSCA Section 9(b)(1): "The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this chapter."
- TSCA Section 9(e): "…[I]f the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency."
- TSCA Section 2(c): "It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this chapter."
- TSCA section 18(d)(1): "Nothing in this chapter, nor any amendment made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rule, standard of performance, risk evaluation, or scientific assessment implemented pursuant to this chapter, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, risk evaluation, scientific assessment, or any other protection for public health or the environment that— (i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law…"

These TSCA authorities supporting tailored risk evaluations and intra-agency referrals are described in more detail below:

TSCA Section 6(b)(4)(D)

TSCA Section 6(b)(4)(D) requires EPA, in developing the scope of a risk evaluation, to identify the hazards, exposures, conditions of use, and PESS the Agency "expects to consider" in a risk evaluation. This language suggests that EPA is not required to consider all conditions of use, hazards, or exposure pathways in risk evaluations. As EPA explained in the *Procedures for Chemical Risk Evaluation Under*

the Amended Toxic Substances Control Act (82 FR 33726, July 20, 2017) ("Risk Evaluation Rule"), "EPA may, on a case-by-case basis, tailor the scope of the risk evaluation "… in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination." 82 FR 33726, 33729 (July 20, 2017).

In the problem formulation documents for many of the first 10 chemicals undergoing risk evaluation, EPA applied the same authority and rationale to certain exposure pathways, explaining that "EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes." This is informed by the legislative history of the amended TSCA, which supports the Agency's exercise of discretion to focus the risk evaluation on areas that raise the greatest potential for risk. See June 7, 2016 Cong. Rec., S3519-S3520. Consistent with the approach articulated in the problem formulation documents, and as described in more detail below, EPA is exercising its authority under TSCA to tailor the scope of exposures evaluated in TSCA risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered, media-specific statutes and regulatory programs.

TSCA Section 9(b)(1)

In addition to TSCA Section 6(b)(4)(D), the Agency also has discretionary authority under the first sentence of TSCA Section 9(b)(1) to "coordinate actions taken under [TSCA] with actions taken under other Federal laws administered in whole or in part by the Administrator." This broad, freestanding authority provides for intra-agency coordination and cooperation on a range of "actions." In EPA's view, the phrase "actions taken under [TSCA]" in the first sentence of Section 9(b)(1) is reasonably read to encompass more than just risk management actions, and to include actions taken during risk evaluation as well. More specifically, the authority to coordinate intra-agency actions exists regardless of whether the Administrator has first made a definitive finding of risk, formally determined that such risk could be eliminated or reduced to a sufficient extent by actions taken under authorities in other EPA-administered Federal laws, and/or made any associated finding as to whether it is in the public interest to protect against such risk by actions taken under TSCA. TSCA Section 9(b)(1) therefore provides EPA authority to coordinate actions with other EPA offices without ever making a risk finding or following an identification of risk. This includes coordination on tailoring the scope of TSCA risk evaluations to focus on areas of greatest concern rather than exposure pathways addressed by other EPA-administered statutes and regulatory programs, which does not involve a risk determination or public interest finding under TSCA Section 9(b)(2).

In a narrower application of the broad authority provided by the first sentence of TSCA Section 9(b)(1), the remaining provisions of Section 9(b)(1) provide EPA authority to identify risks and refer certain of those risks for action by other EPA offices. Under the second sentence of Section 9(b)(1), "[i]f the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under [TSCA]." Coordination of intra-agency action on risks under TSCA Section 9(b)(1) therefore entails both an identification of risk, and a referral of any risk that could be eliminated or reduced to a sufficient extent under other EPA-administered laws to the

EPA office(s) responsible for implementing those laws (absent a finding that it is in the public interest to protect against the risk by actions taken under TSCA).

Risk may be identified by OPPT or another EPA office, and the form of the identification may vary. For instance, OPPT may find that one or more conditions of use for a chemical substance present(s) a risk to human or ecological receptors through specific exposure routes and/or pathways. This could involve a quantitative or qualitative assessment of risk based on reasonably available information (which might include, *e.g.*, findings or statements by other EPA offices or other federal agencies). Alternatively, risk could be identified by another EPA office. For example, another EPA office administering non-TSCA authorities may have sufficient monitoring or modeling data to indicate that a particular condition of use presents risk to certain human or ecological receptors, based on expected hazards and exposures. This risk finding could be informed by information made available to the relevant office under TSCA Section 9(e), which supports cooperative actions through coordinated information-sharing.

Following an identification of risk, EPA would determine if that risk could be eliminated or reduced to a sufficient extent by actions taken under authorities in other EPA-administered laws. If so, TSCA requires EPA to "use such authorities to protect against such risk," unless EPA determines that it is in the public interest to protect against that risk by actions taken under TSCA. In some instances, EPA may find that a risk could be sufficiently reduced or eliminated by future action taken under non-TSCA authority. This might include, *e.g.*, action taken under the authority of the Safe Drinking Water Act (SDWA) to address risk to the general population from a chemical substance in drinking water, particularly if the Office of Water has taken preliminary steps such as listing the subject chemical substance on the Contaminant Candidate List (CCL). This sort of risk finding, and referral could occur during the risk evaluation process, thereby enabling EPA to use more a relevant and appropriate authority administered by another EPA office to protect against hazards or exposures to affected receptors.

Legislative history on TSCA Section 9(b)(1) supports both broad coordination on current intra-agency actions, and narrower coordination when risk is identified and referred to another EPA office for action. A Conference Report from the time of TSCA's passage explained that Section 9 is intended "to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health and the environment." S. Rep. No. 94-1302 at 84. See also H. Rep. No. 114-176 at 28 (stating that the 2016 TSCA amendments "reinforce TSCA's original purpose of filling gaps in Federal law," and citing new language in Section 9(b)(2) intended "to focus the Administrator's exercise of discretion regarding which statute to apply and to encourage decisions that avoid confusion, complication, and duplication"). Exercising TSCA Section 9(b)(1) authority to coordinate on tailoring TSCA risk evaluations is consistent with this expression of Congressional intent.

Legislative history also supports a reading of Section 9(b)(1) under which EPA coordinates intra-agency action, including information-sharing under TSCA Section 9(e), and the appropriately positioned EPA office is responsible for the identification of risk and actions to protect against such risks. See, *e.g.*, Senate Report 114-67, 2016 Cong. Rec. S3522 (under TSCA Section 9, "if the Administrator finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, the Administrator should ensure that the relevant office of the EPA receives that information"); H. Rep. No. 114-176 at 28, 2016 Cong. Rec. S3522 (under Section 9, "if the Administrator determines that a risk to health or the environment associated with disposal of a chemical substance could be eliminated or reduced to a sufficient extent under the Solid Waste Disposal Act, the Administrator should use those authorities to protect against the risk"). Legislative history on Section

9(b)(1) therefore supports coordination with and referral of action to other EPA offices, especially when statutes and associated regulatory programs administered by those offices could address exposure pathways or risks associated with conditions of use, hazards, and/or exposure pathways that may otherwise be within the scope of TSCA risk evaluations.

TSCA Sections 2(c) and 18(d)

Finally, TSCA Section 2(c) supports coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs. Section 2(c) directs EPA to carry out TSCA in a "reasonable and prudent manner" and to consider "the environmental, economic, and social impact" of its actions under TSCA. Legislative history from around the time of TSCA's passage indicates that Congress intended EPA to consider the context and take into account the impacts of each action under TSCA. S. Rep. No. 94-698 at 14 ("the intent of Congress as stated in this subsection should guide each action the Administrator takes under other sections of the bill").

Section 18(d)(1) specifies that state actions adopted or authorized under any Federal law are not preempted by an order of no unreasonable risk issued pursuant to TSCA section 6(i)(1) or a rule to address unreasonable risk issued under TSCA section 6(a). Thus, even if a risk evaluation were to address exposures or risks that are otherwise addressed by other federal laws and, for example, implemented by states, the state laws implementing those federal requirements would not be preempted. In such a case, both the other federal and state laws, as well as any TSCA Section 6(i)(1) order or TSCA Section 6(a) rule, would apply to the same issue area. See also TSCA Section 18(d)(1)(A)(iii). In legislative history on amended TSCA pertaining to Section 18(d), Congress opined that "[t]his approach is appropriate for the considerable body of law regulating chemical releases to the environment, such as air and water quality, where the states have traditionally had a significant regulatory role and often have a uniquely local concern." Sen. Rep. 114-67 at 26.

EPA's careful consideration of whether other EPA-administered authorities are available, and more appropriate, for addressing certain exposures and risks is consistent with Congress' intent to maintain existing federal requirements and the state actions adopted to locally and more specifically implement those federal requirements, and to carry out TSCA in a reasonable and prudent manner. EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. This approach furthers Congressional direction and EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations.

EPA-administered statutes and regulatory programs that address specific exposure pathways and/or risks are listed as follows:

<u>TSCA Title VI</u>
EPA has determined that three types of composite wood products (hardwood plywood, particleboard, and medium density fiberboard [including thin-medium density fiberboard]), and laminated products 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. These panels will not be included in the scope of the evaluation in their panel form, or as these panels are

fabricated into component parts or finished goods. EPA is relying on the definition of a "panel[8]" "finished goods[9]", "component parts[10]", and "composite wood products[11]" from 40 CFR 770 to define these terms. 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.

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. See 42 U.S.C. 7412. 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. See 40 CFR part 63.

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. As such, EPA is not evaluating exposures to the general population from ambient air in the risk evaluation under TSCA. As such, EPA does not plan to evaluate exposures to the general population from ambient air in the risk evaluation under TSCA. This regulatory coverage is represented by the red shading in Figure 2-14.

Drinking Water Pathway

EPA has regular analytical processes to identify and evaluate unregulated drinking water contaminants of potential regulatory concern for public water systems under the SDWA. In addition, the SDWA requires EPA to 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 under the SDWA. EPA must publish a CCL every 5 years and make Regulatory Determinations (RegDet) to regulate (or not) at

[8] *Panel* means a thin (usually less than two inches thick), flat, usually rectangular piece of particleboard, medium-density fiberboard or hardwood plywood. Embossing or imparting of an irregular surface on the composite wood products by the original panel producer during pressing does not remove the product from this definition. Cutting a panel into smaller pieces, without additional fabrication, does not make the panel into a component part or finished good. This does not include items made for the purpose of research and development, provided such items are not sold, supplied, or offered for sale (40 CFR 770.3).

[9] *Finished Good* means any good or product, other than a panel, that contains hardwood plywood (with a veneer or composite core), particleboard, or medium-density fiberboard and that is not a component part or other part used in the assembly of a finished good. Site-built buildings or other site-built real property improvements are not considered finished goods (40 CFR 770.3).

[10] *Component part* means a platform for making hardwood plywood or laminated products that consists of particleboard and/or medium density fiberboard, or combination core (40 CFR 770.3).

[11] *Composite wood product* means hardwood plywood made with a veneer or composite core, medium-density fiberboard, and particleboard (40 CFR 770.3).

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.

Currently, EPA is evaluating formaldehyde through the SDWA statutory processes for developing a National Primary Drinking Water regulation. Formaldehyde is currently one of 109 contaminants listed on EPA's Fourth Contaminant Candidate List (CCL 4), see 81 FR 81099. Formaldehyde has a Lifetime Health Advisory level of 1 mg/L as found in the 2018 edition of the Drinking Water Standards and Health Advisory Tables using the following link: (https://www.epa.gov/sites/production/files/2018-03/documents/dwtable2018.pdf). Formaldehyde is currently listed on EPA's Fourth Contaminant Candidate List (CCL 4).

In February 2020, EPA published a Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, see 85 FR 14098. The Agency did not make a preliminary determination for formaldehyde. EPA plans to evaluate formaldehyde prior to making a regulatory determination. The Regulatory Determination 4 Support Document (USEPA, 2019a) (USEPA, 2019b) present additional information and analyses supporting the Agency's evaluation of formaldehyde.

EPA is coordinating actions for the purposes of TSCA Section 9(b). As announced February 20, 2020 in the Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List; formaldehyde has some finished water data and a health assessment. EPA continues to evaluate whether there is a meaningful opportunity to reduce health risk for persons served by public water systems from formaldehyde.[12] OCSPP has coordinated with the Office of Water regarding formaldehyde contamination in drinking water. EPA plans to evaluate formaldehyde through the SDWA on whether there is a meaningful opportunity to reduce health risk for persons served by public water systems. As described above, EPA has regular analytical processes to identify and evaluate drinking water contaminants of potential regulatory concern for public water systems under SDWA. OW evaluates the regulatory determination criteria under SDWA Section 1412(b)(1)(A) to determine whether or not to initiate the development of a National Primary Drinking Water Regulation. EPA promulgates National Primary Drinking Water Regulations (NPDWRs) under SDWA when the Agency concludes a 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. For each contaminant with NPDWRs, EPA sets an enforceable Maximum Contaminant Level (MCL) as close as feasible to a health

[12] EPA does not find that the science standards of TSCA Section 26(h) and (i) apply to this finding of risk, the Agency's determination that the risk could be eliminated or reduced to a sufficient extent by action under the CAA, or the corresponding tailoring of this risk evaluation. TSCA Sections 26(h) and (i) are triggered by EPA "decisions" made under TSCA Sections 4, 5, and 6, and the risk finding and associated determination described herein are both made pursuant to TSCA Section 9. Neither the finding of risk nor the subsequent determination implements TSCA Section 6. EPA will take appropriate action under SDWA in lieu of TSCA (absent a public interest finding described in TSCA Section 9(b), which EPA did not make). Thus, TSCA itself compels EPA to narrow the scope of the risk evaluation following the Agency's Section 9(b)(1) determination, and there is no separate EPA "decision" subject to TSCA Sections 26(h) and (i).

based, non-enforceable Maximum Contaminant Level Goals (MCLG). Feasibility refers to both the ability to treat water to meet the MCL and the ability to monitor water quality at the MCL, SDWA Section 1412(b)(4)(D), and public water systems are required to monitor for the regulated chemical based on a standardized monitoring schedule to ensure compliance with the maximum contaminant level (MCL). Under SDWA, EPA must also review existing drinking water regulations every 6 years, and if appropriate, revise them. SDWA, originally passed by Congress in 1974, thereby is the main federal statute to protect public health by regulating the nation's public drinking water supply and authorizing EPA to set national health-based standards and take other actions to protect against contaminants that may be found in drinking water.

EPA plans to evaluate formaldehyde under SDWA authorities to determine whether or not to regulate formaldehyde in drinking water from drinking water contaminated by formaldehyde as part of this risk evaluation, the information produced in the risk evaluation process will be considered by the Office of Water as part of the current SDWA actions.

As such, EPA does not plan to evaluate exposures to the general population from drinking water exposure in the risk evaluation. This regulatory coverage is represented by the dark blue shading in Figure 2-14.

Onsite Releases to Land Pathway

The Comprehensive Environmental Response, Compensation, and Liability Act, otherwise known as CERCLA, provides broad authority under the statute (generally referred to as Superfund) to clean up uncontrolled or abandoned hazardous-waste sites as well as accidents, spills, and other releases of hazardous substances, pollutants and contaminants into the environment. Through CERCLA, EPA was given authority to seek out those parties potentially responsible for the release of hazardous substances and either have them clean up the release or compensate the Federal government for undertaking the response action.

CERCLA Section 101(14) defines "hazardous substance" by referencing other environmental statutes, including toxic pollutants listed under CWA Section 307(a); hazardous substances designated pursuant to CWA Section 311(b)(2)(A); hazardous air pollutants listed under CAA Section 112; imminently hazardous substances with respect to which EPA has taken action pursuant to TSCA Section 7; and hazardous wastes having characteristics identified under or listed pursuant to RCRA Section 3001. See 40 CFR 302.4. CERCLA Section 102(a) also 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 within a 24-hour period must be reported (40 CFR 302.4, 302.6). The scope of this EPA TSCA risk evaluation does not include on-site releases to the environment of [chemical] at Superfund sites and subsequent exposure of the general population or non-human species.

Disposal and Soil Pathway

Formaldehyde is included on the list of hazardous wastes pursuant to the Resource Conservation and Recovery Act (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 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 SDWA)[13].

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 may occur for formaldehyde. 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 "all other land disposal" 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. See 40 CFR part 264. As a result, EPA does not plan to evaluate on-site releases to land from RCRA Subtitle C hazardous waste landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-14.

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

[13] This is not an exclusive list of Subtitle C authority, as it also covers, for example, disposal to surface impoundments, waste piles, and land treatment.

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. See 40 CFR part 258. As a result, EPA does not plan to evaluate on-site releases to land from RCRA Subtitle D municipal solid waste (MSW) landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-14.

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. See *e.g.*, RCRA Section 3004(c), 4007; 40 CFR part 257. As a result, EPA does not plan to evaluate on-site releases to land from industrial non-hazardous waste and construction/demolition waste landfills or associated exposures to the general population. This regulatory coverage is represented by the pink shading in Figure 2-14.

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

As described in Section 2.6.3.1, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-15 presents the exposure pathways, exposure routes and hazards to general population and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of formaldehyde that EPA plans to evaluate.

The diagram shown in Figure 2-15 presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes 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 receptors and the general population.

Releases to water/sediment via direct and indirect discharges to water that may lead to exposure to aquatic 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.

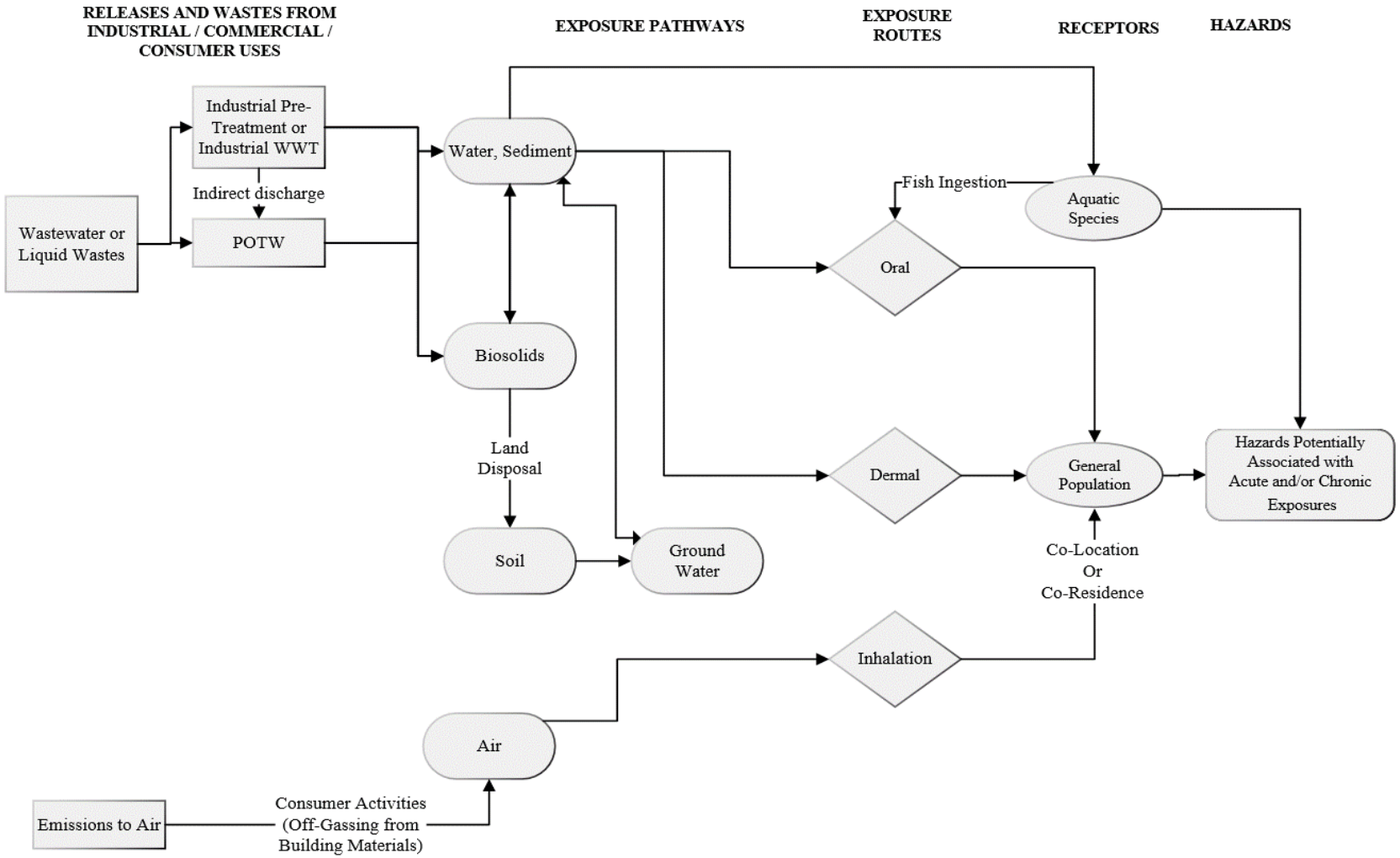

Figure 2-15. Formaldehyde Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

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 resulting from the full-text screening of reasonably available 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 evaluating conditions of use, exposures, hazards and PESS during risk evaluation. As discussed in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018), targeted supplemental searches during the analysis phase may be necessary to identify additional information (*e.g.*, commercial mixtures) for the risk evaluation of formaldehyde. For any additional data needs identified during the risk evaluation, EPA may use the Agency's TSCA authorities under Sections 4, 8 or 11, as appropriate.

2.7.1 Physical/Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical properties and environmental fate and transport of formaldehyde as follows:

1) **Review reasonably available measured or estimated physical and chemical and environmental fate endpoint data collected using systematic review procedures and, where reasonably available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to evaluate data and information collected through the systematic review methods and public comments about the physical and chemical 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, 2019c). All sources cited in EPA's analysis will be evaluated according to the procedures and metrics described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Where the systematic review process does not identify experimentally measured chemical property values of sufficiently high quality, testing will be requested under the TSCA Section 4 authority, or values will 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 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 *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, ambient air (consumer activities affecting co-located/co-residence populations), surface water, sediment, and aquatic biota associated with exposure

to formaldehyde. Based on its physical and chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment, formaldehyde is more likely to be present in some of these media and less likely to be present in others. EPA has not yet determined the exposure levels in these media. Exposure level(s) can be characterized through a combination of reasonably available monitoring data and estimated exposure levels from modeling approaches. Exposure scenarios are combinations of sources (uses), exposure pathways, and exposed receptors. Draft exposure scenarios corresponding to various conditions of use for formaldehyde are presented in Appendix F, Appendix G, and Appendix H. EPA plans to analyze scenario-specific exposures.

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 E. EPA plans to continue to review data sources identified during risk evaluation. Potential sources of environmental release data are summarized in Table 2-6.

Table 2-6. 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 will continue to consider additional reasonably available information and will evaluate it during development of the 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 Exposures and Environmental Releases (ChemSTEER) (U.S. EPA, 2015a).

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 and sources (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to consider for release estimation and environmental exposures. EPA plans to 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 (OECD, 2009a) and the 2011 ESD on Chemical Industry (OECD, 2011) 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:

- 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. If ESDs and GSs are not reasonably available, other methods may be considered. 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.

6) **Map or group each condition of use to a release assessment scenario(s).**
EPA has completed an initial mapping of release scenarios to relevant conditions of use as shown in Appendix F. EPA plans to refine the mapping/grouping of release scenarios based on factors (*e.g.*, process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use using reasonably available information. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop release scenarios.

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 *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). EPA plans to integrate the data using 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 analyze the following in developing its environmental exposure assessment of formaldehyde:

1) **Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.**
For formaldehyde, the environmental media which EPA plans to analyze is sediment. 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, 2019c) and therefore EPA does not plan to evaluate environmental exposure through oral routes via fish ingestion.

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.**
EPA plans to analyze and consider reasonably available environmental exposure models that meet the scientific standards under 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 surface water concentrations, and sediment concentrations may include 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 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.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

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 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 2-7. 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 may conduct industry outreach or perform supplemental targeted searches of peer-reviewed or gray literature to understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted supplemental searches 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 #2 and #3 are completed, and based on information developed from #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, 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. OSHA recommends employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly personal protective equipment (PPE). 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 completed an initial mapping of exposure scenarios to conditions of use. EPA plans to refine mapping or grouping 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. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop exposure scenarios.

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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018). EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. EPA plans to integrate the data using 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 both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

1) **Group each condition of use to consumer exposure assessment scenario(s).**
   Refine and finalize exposure scenarios for consumers by considering combinations of sources (ongoing consumer uses), exposure pathways including routes, and exposed populations.

   For formaldehyde, the following are noteworthy considerations in constructing consumer exposure scenarios:
   - Conditions of use
   - Duration, frequency and magnitude of exposure
   - Weight fraction of chemical in products
   - Amount of chemical used

   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 off gassing 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 potential of indoor exposure pathways based on reasonably available data.**
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 off gassing 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 exposures.**
Indoor exposure models that estimate emissions from use of consumer products are available. These models generally consider physical and chemical properties (*e.g.*, vapor pressure, molecular weight), product specific properties (*e.g.*, weight fraction of the chemical in the product), use patterns (*e.g.*, duration and frequency of use), user environment (*e.g.*, room of use, ventilation rates), and receptor characteristics (*e.g.*, exposure factors, activity patterns). The OPPT's Consumer Exposure Model (CEM) and other similar models can be used to estimate indoor air exposures from consumer products.

Models that estimate emission and migration of semi-volatile organic compounds (SVOCs) into the indoor environment models generally consider indoor fate and transport properties such as mass transfer as informed by the gas-phase mass transfer coefficient, the solid-phase diffusion coefficient and the material-air partition coefficient. These properties vary based on physical and chemical properties and properties of the material. The OPPT's Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) model and other similar models can be used to estimate indoor air and dust exposures from indoor sources.

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.**
For formaldehyde, EPA plans to evaluate exposure scenarios that involve PESS and plans to consider age-specific behaviors, activity patterns and exposure factors unique to those subpopulations. For some exposure scenarios related to consumer uses, EPA plans to consider whether exposures for adults may different from those of children due to different activities (*e.g.*, children may mouth certain products) or exposure factors (*e.g.*, inhalation rates).

7) **Evaluate the weight of the scientific evidence of consumer exposure estimates based on different approaches.**
EPA plans to rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the scientific evidence may include qualitative and quantitative sources of information. EPA plans to integrate the data using 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.

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

1) **Refine and finalize exposure scenarios for general population by considering sources conditions of use, exposure pathways, and routes.**
For formaldehyde, the following are noteworthy considerations in constructing exposure scenarios for the general population:

- Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
- For exposure pathways where data are not reasonably available, review existing exposure modeling approaches that may be applicable in estimating exposure levels.
- Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
- Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available and relevant.
- Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.

- Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need be further defined.
- Evaluate the weight of the scientific evidence of general population exposure data.
- Map or group each condition of use to general population exposure assessment scenario(s).
- Environmental Exposure pathways regulated by non-TSCA EPA laws and regulations will be excluded from analysis

EPA plans to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to inform exposure scenarios. EPA anticipates that there will be a wide range in the relative exposure potential of the exposure scenarios identified in Section 2.6.

After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on the conditions of use, exposure pathways and receptors. The number of scenarios is also dependent upon the reasonably available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is readily available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and include careful consideration of variability and uncertainty.

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.**
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.

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. In addition, another chemical's assessment may also be applicable if model parameter data are reasonably available.**
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 organisms, including plants, invertebrates (*e.g.*, insects, arachnids, mollusks, crustaceans), and vertebrates (*e.g.*, mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results and public comments. Additional types of environmental hazard information will also be considered (*e.g.*, analogue and read-across data) when characterizing the potential hazards of formaldehyde to aquatic organisms.

   EPA plans to evaluate environmental hazard data using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). The study evaluation results will be documented in the risk evaluation phase and data from acceptable studies will be extracted and integrated in the risk evaluation process.

   Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent 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) **Derive hazard thresholds for aquatic 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, and LOEC) may be derived and used to further understand the hazard characteristics of formaldehyde to aquatic 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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

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) pathways in the formaldehyde conceptual model. These organisms may be exposed to formaldehyde via a number of environmental pathways (*e.g.,* surface water, sediment, and diet).

5) **Consider a persistent, bioaccumulative, and toxic (PBT) assessment of formaldehyde**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of formaldehyde after reviewing relevant physical and chemical properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (*e.g.,* BAF, BCF) of formaldehyde. In addition, EPA plans to integrate traditional environmental hazard endpoint values (*e.g.,* LC_{50}, LOEC) and exposure concentrations (*e.g.,* surface water concentrations, tissue concentrations) for p-dichlorobenzene with the fate parameters (*e.g.*, BAF, BCF, BMF, TMF).

6) **Conduct an environmental risk estimation and characterization of formaldehyde.**
EPA plans to conduct a risk estimation and characterization of formaldehyde to identify if there are risks to the aquatic environments from the measured and/or predicted concentrations of formaldehyde in environmental media (*e.g.*, water, sediment). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982). Analysis of risk for characterization includes a confidence statement in risk estimation which qualitative judgment describing the certainty of the risk estimate considering the strength the evidence scores for hazard and exposure and the limitations, and relevance.

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 evaluate human health studies using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018) and updates to the epidemiological data quality criteria released with the first ten risk evaluations. EPA plans to include information developed from the draft IRIS hazard and dose response assessment. The study evaluation results will be documented in the risk evaluation phase and data from acceptable studies will be extracted and integrated in the risk evaluation process.

   Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent 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) **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 life stages such as pregnant women and infants. Pregnancy (*i.e.*, gestation) and childhood are potential susceptible life stages for formaldehyde exposure. EPA may quantify these differences in the risk evaluation following further evaluation of the reasonably available data and information.

3) **Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.**
Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018). Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (*e.g.*, oral, dermal, inhalation) and by the cancer and noncancer endpoints identified in Section 2.4.2.

Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011a, 1994) developing points of departure (POD) for either margins of exposure (MOEs), cancer slope factors (CSFs), oral slope factors (OSFs), and/or inhalation unit risks (IURs). 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) analyses determine the relevancy of animal data to human risk and how data can be quantitatively evaluated. If cancer hazard is determined to be applicable to formaldehyde EPA plans to evaluate information on genotoxicity and the MOA 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, 2005a). In accordance with EPA's *Supplemental Guidance for Assessing Susceptibility from Early-life Exposures to Carcinogens* (U.S. EPA, 2005b), EPA will determine whether age-dependent adjustment factors (ADAFs) are appropriate for formaldehyde for specific conditions of use based upon potential exposures to children.

4) **Derive points of departure (PODs) where appropriate; 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* (U.S. EPA, 2012a) . 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 BW3/4 scaling in accordance with U.S. EPA (2011b), 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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

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 reasonably available data to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure. 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.

   If sufficient reasonably available toxicity studies are not identified through the systematic review process to assess risks from inhalation or dermal exposure, then a route-to-route extrapolation may be needed. The preferred approach is to use a PBPK model (U.S. EPA, 2006a). Without an adequate PBPK model, considerations regarding the adequacy of data for route-to-route extrapolation are described in Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry (U.S. EPA, 1994). EPA may use these considerations when determining whether to extrapolate from the oral to the inhalation route of exposure. Similar approaches for oral-to-dermal route extrapolation are described in 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, 2004c).

   If there are acceptable inhalation data after completion of systematic review, EPA may also consider extrapolating from the inhalation to the dermal route if first-pass metabolism through the liver via the oral route is expected because in that case, use of data from the oral route is not recommended (U.S. EPA, 1994). EPA may also consider inhalation-to-dermal route extrapolation if an inhalation toxicity study with a sensitive hazard endpoint is used to evaluate risks. Based on these considerations, EPA extrapolated from the inhalation to the dermal route for several of the first ten risk evaluations under amended TSCA, including methylene chloride (U.S. EPA, 2020d) and carbon tetrachloride (U.S. EPA, 2020b).

7) **Conduct a human health risk estimation and characterization of formaldehyde.**
Analysis of risk for characterization includes a confidence statement in risk estimation. This confidence statement is based on qualitative judgment describing the certainty of the risk estimate considering the strength of the evidence scores for hazard and exposure along with their limitations and relevance. The lowest confidence evaluation for either hazard or exposure will drive the overall confidence estimate.

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 EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in EPA's Risk Characterization Policy, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers" (U.S. EPA, 2000). 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.

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 (U.S. EPA, 2000), and consistent with the requirements of the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017). As discussed in 40 CFR 702.43, risk characterization has a number of considerations. This is the step where EPA integrates the hazard and exposure assessments into risk estimates for the identified populations (including any PESS) and ecological characteristics and weighs the scientific evidence for the identified hazards and exposures. The risk characterization does not consider costs or other nonrisk factors, and takes into account, "where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use …." The risk characterization also summarizes the following considerations: (1) uncertainty and variability in each step of the risk evaluation; (2) data quality, and any applicable assumptions used; (3) alternative interpretations of data and analyses, where appropriate; and (4) any considerations for environmental risk evaluations, if necessary (*e.g.,* related to nature and magnitude of effects).

EPA plans to also be guided by EPA's Information Quality Guidelines (U.S. EPA, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA 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 (U.S. EPA, 2015b) 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 ABBREVIATED METHODS FOR SEARCHING AND SCREENING

A.1 Literature Search of Publicly Available Databases

A.1.1 Search Term Genesis and Chemical Verification

To develop the chemical terms for the subsequent literature search for formaldehyde, several online sources were queried.

- California Department of Pesticide Regulation: https://www.cdpr.ca.gov/docs/chemical/monster2.htm
- USEPA Chemistry Dashboard: https://comptox.epa.gov/dashboard
- University of Hertfordshire PPDB: Pesticide Properties Database: https://sitem.herts.ac.uk/aeru/ppdb/en/search.htm
- USEPA Reregistration Eligibility Decision (RED) documents: https://archive.epa.gov/pesticides/reregistration/web/html/status.html
- Office of Pesticide Programs Pesticide Chemical Search: https://ofmpub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1
- Food and Agriculture Organization of the United Nations: http://www.fao.org/home/en/
- PAN Pesticides Database: http://www.pesticideinfo.org/Search_Chemicals.jsp

Prior to inclusion in the search term string, all forms of chemical names were subjected to verification from several potential sources (*e.g.*, US EPA Chemistry Dashboard, STN International-CAS; see complete list of sources for chemical verification in Appendix A.1.2.1). From these sources, all chemical names, synonyms, CAS number(s), trade names, etc. were documented and used to generate terms for database searches.

Table_Apx A-1. Sources of Verification for Chemical Names and Structures

CHEMICAL SOURCE	CONTENTS	DOCUMENT LOCATION
Chemistry Dashboard (https://comptox.epa.gov/dashboard)	CAS Numbers, Synonyms, Structures, Properties, Environmental Fate and Transport.	Online
Dictionary of Chemical Names and Synonyms	Wide assortment of chemical compounds by chemical name and synonym, has CAS index and some structure data	ECOTOX
Farm Chemicals Handbook-1992	Pesticide information, CAS numbers and synonyms, some structure data ***Sometimes CAS number presented for a compound is for the main constituent only	ECOTOX
OPPT SMILES Verification Source	Structure Data	Electronic verification
RTECS (Registry of Toxic Effects of chemical substance, 1983-84 ed., 2 vols)	Chemical names, synonyms and CAS numbers	ECOTOX

CHEMICAL SOURCE	CONTENTS	DOCUMENT LOCATION
Sigma – Aldrich website58784 http://www.sigma-aldrich.com	Organic and inorganic Compounds by chemical name, has CAS index and some structure and Physical Property data	Online
STN International (CAS) 1994	***Most complete source of chemical name, synonym and structure information, no physical properties	Online
The Pesticide Manual 10th edition, 1994	Pesticide Compounds by chemical name, synonym, product code, has CAS index and some structure and Physical Property data	ECOTOX
TSCA (Toxic Substances Control Act Chemical Substance Inventory, 1985 ed., 5 vols)	Chemical names, synonyms and CAS numbers	ECOTOX
World Wide Web (misc. web sources) A copy of the verification page is saved to the Attachments tab of the chemical entry. This includes company MSDS sheets or Chemical Labels.	Chemical names, synonyms and CAS numbers	Online
California Department of Pesticide Regulation (http://www.cdpr.ca.gov/dprdatabase.htm)	Multiple databases containing chemicals, pesticides, companies, products, etc.	Online
PAN Pesticide Database (http://www.pesticideinfo.org/Search_Chemicals.jsp)	Pesticides searchable by name or CAS #. Includes CAS #, Name, synonyms, targets, toxicity data, related chemicals and regulatory information.	Online
US EPA Office of Pesticide Programs Pesticide Fate Database – No web access available. An electronic copy of the data file is located at the Contractor site: PFATE_37_Tables.mdb.	Multiple databases containing chemicals, pesticides, companies, products, etc.	Online

A.1.2 Publicly Available Database Searches

The databases listed below were searched for literature containing the chemical search terms. Database searching occurred during April and May of 2019 by an information specialist and the results were stored in the Health and Environmental Research Online (HERO) database and assigned a HERO reference identification number.[14] The present literature search focused only on the chemical name (including synonyms and trade names) with no additional limits. Full details of the search strategy for each database are presented in Appendix A.1.2.1.

After initial deduplication in HERO[15], these studies were imported into SWIFT Review software (Howard et al., 2016) to identify those references most likely to be applicable to each discipline area (*i.e.*, consumer, environmental, and general population exposure, occupational exposure and environmental releases, environmental hazards, human health hazards, and fate and physical chemistry).

A.1.2.1 Query Strings for the Publicly-Available Database Searches on Formaldehyde

Table_Apx A-2 presents a list of the data sources, the search dates and number of peer-reviewed references resulting from the searches for formaldehyde. The sources are found as online databases and

[14] EPA's HERO database provides access to the scientific literature behind EPA science assessments. The database includes more than 600,000 scientific references and data from the peer-reviewed literature used by EPA to develop its regulations.
[15] Deduplication in HERO involves first determining whether a matching unique ID exists (*e.g.*, PMID, WOSid, or DOI). If one matches one that already exists in HERO, HERO will tag the existing reference instead of adding the reference again. Second, HERO checks if the same journal, volume, issue and page number are already in HERO. Third, HERO matches on the title, year, and first author. Title comparisons ignore punctuation and case.

the resulting references were gathered and uploaded into the EPA Health and Environmental Research Online (HERO) database for literature screening.

Table_Apx A-2. Summary of Data Sources, Search Dates and Number of Peer-Reviewed Literature Search Results for Formaldehyde

Source	Date of Search	Number of References
Current Contents	04.29.19	25,408
WOS Core Collection	10.30.19	83,897
ProQuest CSA	05.01.19	33,035
Dissertation Abstracts	04.26.19	397
Science Direct	05.13.19	87,731
Agricola	05.16.19	7,048
TOXNET	05.04.19	16,899
PubMed	10.30.19	58,805
UNIFY	10.29.19	591
Totals:	04.29.19	313,811

General:

General search terms were compiled and used in the search strategies for each of the databases/sources listed below. Based upon the online search manuals for the respective databases/sources, it was necessary to construct searches as noted for each of the sources. The general search terms are the search terms compiled from the Chemical Report for WR011 OPPT RAD Formaldehyde 2019 to be used in the search strategies for each of the databases listed below. The search terms are listed below in full for each of the sources listed in Table_Apx A-2 and noted if the general search terms or other search terms were used.

"Caswell No. 465" OR "Chlodithan" OR "Chlodithane" OR "Fannoform" OR "F-gen" OR "Floguard 1015" OR "FM 282" OR "Fordor" OR "Formacide-B" OR "Formalaz" OR "formaldehido" OR "Formaldehyd" OR "Formaldehyde" OR "Formalin" OR "Formalin 40" OR "Formalin LM" OR "Formalin Taisei" OR "Formalina" OR "Formaline" OR "Formalith" OR "Formic aldehyde" OR "Formol" OR "Ivalon" OR "Karsan" OR "Lysoform" OR "Methaldehyde" OR "Methan 21" OR "Methanal" OR "Methanediol" OR "Methyl aldehyde" OR "Methylene glycol" OR "Methylene oxide" OR "Morbicid" OR "NCI-C02799" OR "NSC 298885" OR "Oplossingen" OR "Optilyse" OR "Oxomethane" OR "Oxymethylene" OR "Paracide-F" OR "Superlysoform" OR "Tetraoxy methylene"

CURRENT CONTENTS CONNECT:

Current Contents Connect may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking on the Current Contents Connect link or by copy and pasting (https://apps.webofknowledge.com).
(Maximum of 500 References per Download).

Date Searched: 04/29/19
Date Range of Search: 1998 to Present
N = 25,408

TS=("Caswell No. 465" OR "Chlodithan" OR "Chlodithane" OR "Fannoform" OR "F-gen" OR "Floguard 1015" OR "FM 282" OR "Fordor" OR "Formacide-B" OR "Formalaz" OR "formaldehido" OR "Formaldehyd" OR "Formaldehyde" OR "Formalin" OR "Formalin 40" OR "Formalin LM" OR "Formalin Taisei" OR "Formalina" OR "Formaline" OR "Formalith" OR "Formic aldehyde" OR "Formol" OR "Ivalon" OR "Karsan" OR "Lysoform" OR "Methaldehyde" OR "Methan 21" OR "Methanal" OR "Methanediol" OR "Methyl aldehyde" OR "Methylene glycol" OR "Methylene oxide" OR "Morbicid" OR "NCI-C02799" OR "NSC 298885" OR "Oplossingen" OR "Optilyse" OR "Oxomethane" OR "Oxymethylene" OR "Paracide-F" OR "Superlysoform" OR "Tetraoxy methylene")

N = 25,408

WOS Core Collection:

Web of Science Core Collection may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking on the Web of Science Link or copying and pasting (https://apps.webofknowledge.com).

Date Searched: 10/30/19
Date Range of Search: 1970 to Present
N = 83,897

TS=("Caswell No. 465" OR "Chlodithan" OR "Chlodithane" OR "Fannoform" OR "F-gen" OR "Floguard 1015" OR "FM 282" OR "Fordor" OR "Formacide-B" OR "Formalaz" OR "formaldehido" OR "Formaldehyd" OR "Formaldehyde" OR "Formalin" OR "Formalin 40" OR "Formalin LM" OR "Formalin Taisei" OR "Formalina" OR "Formaline" OR "Formalith" OR "Formic aldehyde" OR "Formol" OR "Ivalon" OR "Karsan" OR "Lysoform" OR "Methaldehyde" OR "Methan 21" OR "Methanal" OR "Methanediol" OR "Methyl aldehyde" OR "Methylene glycol" OR "Methylene oxide" OR "Morbicid" OR "NCI-C02799" OR "NSC 298885" OR "Oplossingen" OR "Optilyse" OR "Oxomethane" OR "Oxymethylene" OR "Paracide-F" OR "Superlysoform" OR "Tetraoxy methylene")

N = 83,897

PROQUEST Agricultural and Environmental Science Database:

ProQuest Agricultural and Environmental Science Database may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking on the Agricultural and Scientific Database link or copying and pasting (https://search.proquest.com/agricenvironm).
(Maximum of 500 References per Download).

Date Searched: 05/01/2019
Date Range of Search: 1900 to Present
N = 33,035

ALL("Caswell No. 465" OR "Chlodithan" OR "Chlodithane" OR "Fannoform" OR "F-gen" OR "Floguard 1015" OR "FM 282" OR "Fordor" OR "Formacide-B" OR "Formalaz" OR "formaldehido" OR "Formaldehyd" OR "Formaldehyde" OR "Formalin" OR "Formalin 40" OR "Formalin LM" OR "Formalin Taisei" OR "Formalina" OR "Formaline" OR "Formalith" OR "Formic aldehyde" OR "Formol" OR "Ivalon" OR "Karsan" OR "Lysoform" OR "Methaldehyde" OR "Methan 21" OR

"Methanal" OR "Methanediol" OR "Methyl aldehyde" OR "Methylene glycol" OR "Methylene oxide" OR "Morbicid" OR "NCI-C02799" OR "NSC 298885" OR "Oplossingen" OR "Optilyse" OR "Oxomethane" OR "Oxymethylene" OR "Paracide-F" OR "Superlysoform" OR "Tetraoxy methylene") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)

N = 33,035

PROQUEST Dissertations and Theses @ CIC Institutions:
ProQuest Dissertations and Theses may be accessed through the Kathryn A. Martin Library at the University of Minnesota at Duluth (https://libguides.d.umn.edu/az.php) by clicking the Dissertations and Theses link or by copying and pasting (https://search.proquest.com/pqdtlocal1005857/advanced?accountid=8111)

Date Searched: 04/26/19
Date Range of Search: 1900 to Present
N = 397

ALL("Caswell No. 465" OR "Chlodithan" OR "Chlodithane" OR "Fannoform" OR "F-gen" OR "Floguard 1015" OR "FM 282" OR "Fordor" OR "Formacide-B" OR "Formalaz" OR "formaldehido" OR "Formaldehyd" OR "Formaldehyde" OR "Formalin" OR "Formalin 40" OR "Formalin LM" OR "Formalin Taisei" OR "Formalina" OR "Formaline" OR "Formalith" OR "Formic aldehyde" OR "Formol" OR "Ivalon" OR "Karsan" OR "Lysoform" OR "Methaldehyde" OR "Methan 21" OR "Methanal" OR "Methanediol" OR "Methyl aldehyde" OR "Methylene glycol" OR "Methylene oxide" OR "Morbicid" OR "NCI-C02799" OR "NSC 298885" OR "Oplossingen" OR "Optilyse" OR "Oxomethane" OR "Oxymethylene" OR "Paracide-F" OR "Superlysoform" OR "Tetraoxy methylene") AND LA(ENG)

N = 397

SCIENCE DIRECT:
Science Direct may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking Science Direct or by copying and pasting (https://www.sciencedirect.com/).
(Maximum of 500 References per Download).

Date Searched: 05/13/19
Date Range of Search: 1823 to Present
N = 87,731

Science Direct 01:
"Caswell No. 465" OR "Chlodithan" OR "Chlodithane" OR "Fannoform" OR "F-gen" OR "Floguard 1015" OR "FM 282" OR "Fordor" OR "Formacide-B"

N = 1,826

Science Direct 02:

"Formalaz" OR "formaldehido" OR "Formaldehyd" OR "Formaldehyde" OR "Formalin" OR "Formalin 40" OR "Formalin LM" OR "Formalin Taisei" OR "Formalina"

N = 29,376

Science Direct 03:
"Formaline" OR "Formalith" OR "Formic aldehyde" OR "Formol" OR "Ivalon" OR "Karsan" OR "Lysoform" OR "Methaldehyde" OR "Methan 21"

N = 647

Science Direct 04:
"Methanal" OR "Methanediol" OR "Methyl aldehyde" OR "Methylene glycol" OR "Methylene oxide" OR "Morbicid" OR "NCI-C02799" OR "NSC 298885" OR "Oplossingen"

N = 55,222

Science Direct 05:
"Optilyse" OR "Oxomethane" OR "Oxymethylene" OR "Paracide-F" OR "Superlysoform" OR "Tetraoxy methylene"

N = 660

AGRICOLA:
Agricola may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking Agricola or by copying and pasting (https://agricola.nal.usda.gov/) or Agricola may be accessed from within the EndNote environment.

Date Searched: 05/16/19
Date Range of Search: 15th century to the Present
N = 7,048

Agricola 01:
Caswell No. 465
Chlodithan
Chlodithane
Fannoform
F-gen
Floguard 1015
FM 282
Fordor
Formacide-B
Formalaz

N = 1

Agricola 02:

formaldehido
Formaldehyd
Formaldehyde
Formalin
Formalin 40
Formalin LM
Formalin Taisei
Formalina
Formaline
Formalith

N = 6,837

Agricola 03:
Formic aldehyde
Formol
Ivalon
Karsan
Lysoform
Methaldehyde
Methan 21
Methanal
Methanediol
Methyl aldehyde

N = 151

Agricola 04:
Methylene glycol
Methylene oxide
Morbicid
NCI-C02799
NSC 298885
Oplossingen
Optilyse
Oxomethane
Oxymethylene
Paracide-F

N = 59

Agricola 05:
Superlysoform
Tetraoxy methylene

N = 0

TOXNET/(Toxline):
TOXNET(Toxline) may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking the TOXNET link or by copying and pasting (https://toxnet.nlm.nih.gov/newtoxnet/toxline.htm).

Date Searched: 05/04/19
Date Range of Search: All Available Years

N = 16,899

TOXNET 01:
50-00-0 OR 1053659-79-2 OR 1156543-56-4 OR 1158237-02-5 OR 1227476-28-9

Through 1990
N = 4,012

Search	Database	Query	Time	Result
# 1	toxline	((formaldehyde OR formalin OR methanal OR "formaldehyde usp " OR superlysoform OR oxymethylene OR oxomethane OR morbicid OR "methylene oxide" OR "methyl aldehyde" OR lysoform OR fyde OR formol OR "formic aldehyde" OR formalith OR fannoform OR 50-00-0 [rn]) OR 1053659 79 2 OR 1156543 56 4 OR 1158237 02 5 OR 1227476 28 9) AND 1900:1990 [yr] AND (eng [la]) AND (BIOSIS [org] OR NTIS [org] OR PESTAB [org] OR PubMed [org] OR TSCATS [org])	14:01:51	4,012

Through 2000
N = 4,443

Search	Database	Query	Time	Result
# 1	toxline	((formaldehyde OR formalin OR methanal OR "formaldehyde usp " OR superlysoform OR oxymethylene OR oxomethane OR morbicid OR "methylene oxide" OR "methyl aldehyde" OR lysoform OR fyde OR formol OR "formic aldehyde" OR formalith OR fannoform OR 50-00-0 [rn]) OR 1053659 79 2 OR 1156543 56 4 OR 1158237 02 5 OR 1227476 28 9) AND 1991:2000 [yr] AND (eng [la]) AND (BIOSIS [org] OR NTIS [org] OR PESTAB [org] OR PubMed [org] OR TSCATS [org])	18:34:41	4,443

Through 2010
N = 3,960

Search	Database	Query	Time	Result
# 1	toxline	((formaldehyde OR formalin OR methanal OR "formaldehyde usp " OR superlysoform OR oxymethylene OR oxomethane OR morbicid OR "methylene oxide" OR "methyl aldehyde" OR lysoform OR fyde OR formol OR "formic aldehyde" OR formalith OR fannoform OR 50-00-0 [rn]) OR 1053659 79 2 OR 1156543 56 4 OR 1158237 02 5 OR 1227476 28 9) AND 2001:2010 [yr] AND (eng [la]) AND (BIOSIS [org] OR NTIS [org] OR PESTAB [org] OR PubMed [org] OR TSCATS [org])	17:15:39	3,960

Through 2019
N = 4,482

Search	Database	Query	Time	Result
# 3	toxline	((formaldehyde OR formalin OR methanal OR "formaldehyde usp " OR superlysoform OR oxymethylene OR oxomethane OR morbicid OR "methylene oxide" OR "methyl aldehyde" OR lysoform OR fyde OR formol OR "formic aldehyde" OR formalith OR fannoform OR 50-00-0 [rn]) OR 1053659 79 2 OR 1156543 56 4 OR 1158237 02 5 OR 1227476 28 9) AND 2011:2019 [yr] AND (eng [la]) AND (BIOSIS [org] OR NTIS [org] OR PESTAB [org] OR PubMed [org] OR TSCATS [org])	17:45:10	4,482

TOXNET 02:
8005-38-7 OR 2230356 OR 8013-13-6 OR 112068-71-0 OR 1417997-02-4
Through 1990
N = 0

Through 2000
N = 1

Through 2010
N = 0

Through 2019
N = 1

PUBMED:
PubMed may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking the PubMed link or by copying and pasting (https://www.ncbi.nlm.nih.gov/pubmed/).

Date Searched: 10/30/19
Date Range of Search: 1809 to the Present
N = 58,805

"Caswell No. 465" OR "Chlodithan" OR "Chlodithane" OR "Fannoform" OR "F-gen" OR "Floguard 1015" OR "FM 282" OR "Fordor" OR "Formacide-B" OR "Formalaz" OR "formaldehido" OR "Formaldehyd" OR "Formaldehyde" OR "Formalin" OR "Formalin 40" OR "Formalin LM" OR "Formalin Taisei" OR "Formalina" OR "Formaline" OR "Formalith" OR "Formic aldehyde" OR "Formol" OR "Ivalon" OR "Karsan" OR "Lysoform" OR "Methaldehyde" OR "Methan 21" OR "Methanal" OR "Methanediol" OR "Methyl aldehyde" OR "Methylene glycol" OR "Methylene oxide" OR "Morbicid" OR "NCI-C02799" OR "NSC 298885" OR "Oplossingen" OR "Optilyse" OR "Oxomethane" OR "Oxymethylene" OR "Paracide-F" OR "Superlysoform" OR "Tetraoxy methylene"

N = 58,805

ECOTOX UNIFY:
This is an internal EPA database that is not accessible to the public. Results from the ECOTOX Unify search strategy.

Date Searched: 10/29/19
Date Range of Search: All years
N = 591

Chemical(s) of Concern:
FML
N = 591

UNIFY Title Search String:
Caswell No. 465|Chlodithan|Chlodithane|Fannoform|F-gen|Floguard 1015|FM 282|Fordor|Formacide-B|Formalaz|formaldehido|Formaldehyd|Formaldehyde|Formalin|
Formalin 40|Formalin LM|Formalin Taisei|Formalina|Formaline|Formalith|Formic aldehyde|Formol|Ivalon|Karsan|Lysoform|Methaldehyde|Methan 21|Methanal|Methanediol|Methyl aldehyde|Methylene glycol|Methylene oxide|Morbicid|NCI-C02799|NSC 298885|Oplossingen|Optilyse|Oxomethane|
Oxymethylene|Paracide-F|Superlysoform|Tetraoxy methylene

A.1.2.2 Data Prioritization for Environmental Hazard, Human Health Hazard, Fate and Physical Chemistry

In brief, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content from those that likely do not (*e.g.*, analytical methods). The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or medical subject headings (MeSH*)* fields content. The applied SWIFT Review filters focused on lines of evidence: human, animal models for human health, ecological taxa (which includes ecotoxicological animal models, plants, and other taxa), and *in vitro* studies. The details of the search strategies that underlie the filters are available online. Studies not retrieved using these filters were not considered further. Studies that included one or more of the search terms in the title, abstract, keyword, or MeSH fields were exported as a RIS file for screening in Swift-ActiveScreener or DistillerSR[16].

[16] DistillerSR is a web-based systematic review software used to screen studies available at https://www.evidencepartners.com/products/distillersr-systematic-review-software

A.1.2.3 Data Prioritization for Occupational Exposures and Environmental Releases and General Population, Consumer and Environmental Exposures

To prioritize references related to occupational exposure, environmental release, general population exposure, consumer exposure, and environmental exposure, EPA used positive and negative seed studies to build a classification model in SWIFT Review. The positive seeds were identified using relevant literature pool for the first ten TSCA risk evaluations, while the negative seeds were identified from a subset of literature for the current high-priority substances. The model was then applied to the unclassified literature to generate a classification score for each reference. Scores above a certain threshold value were then prioritized for further review in SWIFT-ActiveScreener.

A.2 Peer-Reviewed Screening Process

The studies identified from publicly available database searches and SWIFT-Review filtering/ prioritization were housed in HERO system and imported into SWIFT-ActiveScreener or DistillerSR for title/abstract and full-text screening. Both title/abstract and full-text screening were conducted by two independent reviewers. Screening is initiated with a pilot phase of screening (between 10 and 50) studies to identify areas where clarification in screening criteria might be needed or chemical-specific supplemental material tags might be identified. Records that met PECO (or equivalent criteria (Appendix A.2.1) during title and abstract screening were considered for full-text screening. At both the title/abstract and full-text review levels, screening conflicts were resolved by topic-specific experts and/or discussion among the primary screeners. For citations with no abstract, the articles are initially screened based on all or some of the following: title relevance (titles that suggest a record is not relevant can be excluded rather than marked as unclear), and page numbers (articles two pages in length or less were assumed to be conference reports, editorials, or letters). During title/abstract or full-text level screening in DistillerSR, studies that did not meet the PECO criteria, but which could provide supporting information were categorized (or "tagged") as supplemental information.

It is important to emphasize that being tagged as supplemental material does not mean the study would necessarily be excluded from consideration in an assessment. The initial screening level distinctions between a study meeting the PECO criteria and a supplemental study are often made for practical reasons and the tagging structures (as seen in the literature inventory trees and heat maps in Section 2.1 of this document) are designed to ensure the supplemental studies are categorized for easy retrieval if needed while conducting the assessment. The impact on the assessment conclusions of individual studies tagged as supporting material is often difficult to assess during the screening phase of the assessment. These studies may emerge as being critically important to the assessment and need to be evaluated and summarized at the individual study level (*e.g.*, cancer MOA mechanistic or non-English-language studies), or be helpful to provide context (*e.g.*, summarize current levels of exposure, provide hazard evidence from routes or durations of exposure not pertinent to the PECO), or not be cited at all in the assessment (*e.g.*, individual studies that contribute to a well-established scientific conclusion). Studies maybe be tagged as supplemental material during either title and abstract or full-text screening. When tagged as supplemental material during title and abstract screening, it may not be completely clear whether the chemical of interest is reported in the study (*i.e.*, abstracts may not describe all chemicals investigated). In these cases, studies are still tagged with the expectation that if full-text retrieval is pursued, then additional screening would be needed to clarify if the study is pertinent.

A.2.1 Inclusion/Exclusion Criteria

A PECO statement is typically used to focus the research question(s), search terms, and inclusion/exclusion criteria in a systematic review. PECO criteria were developed *a priori* to screening

and modified to fit the various discipline areas supporting the TSCA risk evaluations. Variations include the RESO (receptor, exposure, scenario/setting, and outcome) used for the occupational exposure and environmental releases discipline, and PESO (pathways/ processes, exposures, setting/scenario, and outcomes) used by the fate and transport discipline. All PECOs and PECO-equivalent criteria can be found in the following sections.

A.2.1.1 PECO for Environmental and Human Health Hazards

The PECO used in this evidence map to identify literature pertinent to formaldehyde effects on human health and environmental hazard is presented in Table_Apx A-3. In addition to the PECO criteria, studies containing potentially relevant supplemental material were tracked and categorized during the literature screening process as outlined in Table_Apx A-4.

Table_Apx A-3. Hazards Title and Abstract and Full-text PECO Criteria for Formaldehyde

PECO Element	Evidence
P	• **Human:** Any population and life stage (occupational or general population, including children and other sensitive populations). • **Animal:** Aquatic and terrestrial species (live, whole organism) of any life stage (including preconception, in utero, lactation, peripubertal, and adult stages). Animal models will be further inventoried according to the categorization below: – Human health models: rat, mouse, rabbit, dog, hamster, guinea pig, cat, non-human primate, pig, hen (neurotoxicology only). – Environmental models: invertebrates (*e.g.*, insects, spiders, crustaceans, mollusks and worms) and vertebrates (*e.g.*, mammals and all amphibians, birds, fish, and reptiles). All hen studies (including neurotoxicity studies) will be included for ecotoxicological models. • **Plants:** Aquatic and terrestrial species (live), all plants including algal, moss, lichen and fungi species.
E	**Relevant forms:** • Formaldehyde (CASRN 50-00-0). Relevant isomer: o Paraformaldehyde (CAS No. 30525-89-4) Synonyms include formalin and other validated synonyms. For synonyms see Appendix A and a list of validated synonyms on the EPA Chemistry Dashboard. • **Human:** Any exposure to formaldehyde or paraformaldehyde singularly or in mixture, including exposure as measured by internal concentrations of these chemicals or metabolites of these chemicals in a biological matrix (*i.e.*, urine, blood, semen, etc.). Studies on occupations known to use or produce formaldehyde (*e.g.*, pathologists, funeral directors, embalmers) should be considered a relevant proxy for formaldehyde exposure. • **Animal:** Any exposure to formaldehyde or paraformaldehyde including via water (including environmental aquatic exposures), soil or sediment, diet, gavage, injection, dermal, and inhalation. • **Plants:** Any exposure to formaldehyde or paraformaldehyde including via water, soil, sediment.
C	• **Human:** A comparison or referent population exposed to lower levels (or no exposure/exposure below detection limits) of formaldehyde or paraformaldehyde, or exposure to formaldehyde or paraformaldehyde for shorter periods of time. • **Animal and Plants:** A concurrent control group exposed to vehicle-only treatment and/or untreated control (control could be a baseline measurement).

PECO Element	Evidence
O	• **Human**: All health outcomes (cancer and noncancer) at the organ level or higher. • **Animal and Plants**: All apical biological effects (effects measured at the organ level or higher) and bioaccumulation from laboratory studies with concurrently measured media and/or tissue concentrations. Apical endpoints include but are not limited to reproduction, survival, and growth.

Table_Apx A-4. Major Categories of "Potentially Relevant" Supplemental Materials for Formaldehyde

Category	Evidence
Mechanistic studies or studies with below organ-level effects	All studies that report results at the cellular level and lower in both mammalian and non-mammalian model systems, including *in vitro*, *in vivo*, *ex vivo*, and *in silico* studies. These studies include assays for genotoxicity or mutagenicity using bacteria or yeast.
ADME, PBPK, and toxicokinetic	Studies designed to capture information regarding absorption, distribution, metabolism, and excretion (ADME), toxicokinetic studies, or physiologically based pharmacokinetic (PBPK) models.
Case reports or case series	Case reports ($n \leq 3$ cases) and case series (non-occupational) will be tracked as potentially relevant supplemental information.
Susceptible populations (no health outcome)	Studies that identify potentially susceptible subgroups; for example, studies that focus on a specific demographic, life stage, or genotype. This tag applies primarily during full text screening.
Mixture studies	Experimental mixture studies that are not considered PECO-relevant because they do not contain an exposure or treatment group assessing only the chemical of interest. Human health animal model and eco animal model/plant will be tagged separately for mixture studies.
Non-English records	Non-English records will be tracked as potentially relevant supplemental information.
Records with no original data	Records that do not contain original data, such as other agency assessments, informative scientific literature reviews, editorials or commentaries.
Conference abstracts	Records that do not contain sufficient documentation to support study evaluation and data extraction.
Field Studies	Field studies with media concentrations (*e.g.*, surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants if biological effects reported
Isomer	PECO-relevant studies with an exposure to one of the identified isomers, if any.
Use of formaldehyde as a reference compound to induce a sensitization response	Formaldehyde is a known sensitizer and can be used as a reference compound to induce sensitization responses in experimental studies (*e.g.*, formalin tests, dermatitis, airway sensitization, or other allergenic response). Such studies were tagged s supplements. However, studies that focused on characterizing a sensitization response that included an apical outcome were considered PECO relevant.

A.2.1.2 PECO for Consumer, Environmental, and General Population Exposures.

Table_Apx A-5. Generic Inclusion Criteria for the Data Sources Reporting Exposure Data on General Population, Consumers and Environmental Receptors

PECO Element	Evidence
Population	**Human:** General population; consumers; bystanders in the home; near-facility populations (includes industrial and commercial facilities manufacturing, processing, or using the chemical substance); children; susceptible populations (life stages, preexisting conditions, genetic factors), pregnant women; lactating women, women of child bearing age. Many human population groups may be exposed. No chemical-specific exclusions are suggested at this time.
	Environmental: aquatic species, terrestrial species, terrestrial plants, aquatic plants (field studies only)
Exposure	**Expected Primary Exposure Sources, Pathways, Routes:** Pathways: indoor air/vapor/mist; indoor dust; particles; outdoor/ambient air; surface water; biosolids; sediment; breastmilk; food items containing formaldehyde including fish; consumer product uses in the home (including consumer product containing chemical); Routes of Exposure: Inhalation, Oral, Dermal
Comparator (Scenario)	**Human:** Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
	Environmental Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
Outcomes for Exposure Concentration or Dose	**Human:** Acute, sub-chronic, and/or indoor air and water concentration estimates (mg/m^3 or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered. Characteristics of consumer products or articles (weight fraction, emission rates, etc.) containing formaldehyde.
	Environmental: A wide range of ecological receptors will be considered (range depending on available ecotoxicity data) using surface water concentrations, sediment concentrations.

Table_Apx A-6. Pathways Identified as Supplemental for Formaldehyde[a]

Chemical	Drinking Water	Ambient Air	Air Disposal	Land Disposal	Underground Disposal	Ground Water
Formaldehyde	X	X	X	X	X	--

[a] "Supplemental pathways" refer to pathways addressed by other EPA administered statutes (see Section 2.6.3.1). Studies tagged under these pathways provide media information that is not prioritized in the screening process.

A.2.1.3 RESO for Occupational Exposure and Environmental Releases

EPA developed a generic RESO statement to guide the screening of engineering and occupational exposure data or information sources for the TSCA risk evaluations. Data or information sources that comply with the inclusion criteria specified in the RESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental release and occupational exposure

assessments. On the other hand, data or information sources that fail to meet the criteria in the RESO statement are excluded from further consideration.

Assessors seek information on various chemical-specific engineering and occupational exposure data needs as part of the process of developing the exposure assessment for each risk evaluation. EPA uses the RESO statement (Table_Apx A-7) along with the information in Table_Apx A-8. when screening the engineering and occupational exposure data and information.

Table_Apx A-7. Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data

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

* Metrics (*e.g.*, mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering, Release and Occupational Exposure Data Needs (Table_Apx A-8.) provides a list of related and relevant general information.

Table_Apx A-8. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments

Objective Determined during Scoping	Type of Data [a]
General Engineering Assessment (may apply to Occupational Exposures and / or Environmental Releases)	Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (*e.g.*, each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. Description of processes, equipment, and unit operations during each industrial/ commercial life cycle step. Material flows, use rates, and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations. Concentration of the chemical of interest
Occupational Exposures	Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. Potential routes of exposure (*e.g.*, inhalation, and dermal). Physical form of the chemical(s) of interest for each exposure route (*e.g.*, liquid, vapor, and mist) and activity. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). For solids, bulk and dust particle size characterization data. Dermal exposure data. Exposure duration (hr/day). Exposure frequency (days/yr). Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. PPE types employed by the industries within scope. EC employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions.
Environmental Releases (to relevant environmental media)	Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (water) and treatment and disposal methods (POTW), including releases per site and aggregated over all sites (annual release rates, daily release rates) Release or emission factors. Number of release days per year.

Objective Determined during Scoping	Type of Data [a]
	Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions.

[a] These are the tags included in the full-text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.
In addition to the data types listed above, EPA may identify additional data needs for mathematical modeling. These data needs will be determined on a case-by-case basis.

Abbreviations:
hr=Hour
kg=Kilogram(s)
lb=Pound(s)
yr=Year
PV=Particle volume
POTW=Publicly owned treatment works
PPE=Personal protection equipment
PSD=Particle size distribution
TWA=Time-weighted average

A.2.1.4 PESO for Fate and Transport

EPA developed a generic PESO statement to guide the screening of environmental fate data or information sources for the TSCA risk evaluations. Data or information sources that comply with the inclusion criteria in the PESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental fate assessment. On the other hand, data or information sources that fail to meet the criteria in the PESO statement are excluded from further consideration.

Assessors seek information on various chemical-specific fate endpoints and associated fate processes, environmental media and exposure pathways as part of the process of developing the environmental fate assessment for each risk evaluation. EPA uses the PESO statement (Table_Apx A-9) along with the information in Table_Apx A-10 when screening the fate data or information sources to ensure complete coverage of the processes, pathways and data or information relevant to the environmental fate and transport of the chemical substance undergoing risk evaluation.

Table_Apx A-9. Inclusion Criteria for Data or Information Sources Reporting Environmental Fate and Transport Data

PESO Element	Evidence
Pathways and **P**rocesses	Environmental fate, transport, partitioning and degradation behavior across environmental media to inform exposure pathways of the chemical substance of interest Exposure pathways included in the conceptual models: air, surface water, groundwater, wastewater, soil, sediment and biosolids. Processes associated with the target exposure pathways Bioconcentration and bioaccumulation Destruction and removal by incineration Please refer to the conceptual models for more information about the exposure pathways included in each TSCA risk evaluation.

PESO Element	Evidence
Exposure	Environmental exposure of environmental receptors (*i.e.*, aquatic and terrestrial organisms) to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Environmental exposure of human receptors, including any PESS, to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Please refer to the conceptual models for more information about the environmental and human receptors included in each TSCA risk evaluation.
Setting or **S**cenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (*e.g.*, buildings including homes or workplaces, or wastewater treatment facilities) that would expose environmental (*i.e.*, aquatic and terrestrial organisms) or human receptors (*i.e.*, general population, and PESS)
Outcomes	Fate properties which allow assessments of exposure pathways: Abiotic and biotic degradation rates, mechanisms, pathways, and products Bioaccumulation magnitude and metabolism rates Partitioning within and between environmental media (see Pathways and Processes)

Table_Apx A-10. Fate Endpoints and Associated Processes, Media and Exposure Pathways Considered in the Development of the Environmental Fate Assessment

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways			
		Surface Water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
Required Environmental Fate Data					
Abiotic reduction rates or half-lives	Abiotic reduction, Abiotic dehalogenation	X			
Aerobic biodegradation rates or half-lives	Aerobic biodegradation	X	X		
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	X	X	X	
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	X			
Atmospheric photolysis (direct and indirect) rates or half-lives	Atmospheric photolysis (direct and indirect)				X
Bioconcentration factor (BCF), Bioaccumulation factor (BAF)	Bioconcentration, Bioaccumulation	X	X		X
Biomagnification and related information	Trophic magnification	X			
Desorption information	Sorption, Mobility	X	X	X	
Destruction and removal by incineration	Incineration				X
Hydrolysis rates or half-lives	Hydrolysis	X	X	X	

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways			
		Surface Water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
K_{OC} and other sorption information	Sorption, Mobility	X	X	X	
Wastewater treatment removal information	Wastewater treatment	X	X		
Supplemental (or Optional) Environmental Fate Data					
Abiotic transformation products	Hydrolysis, Photolysis, Incineration	X			X
Aerobic biotransformation products	Aerobic biodegradation	X	X		
Anaerobic biotransformation products	Anaerobic biodegradation	X	X	X	
Atmospheric deposition information	Atmospheric deposition				X
Coagulation information	Coagulation, Mobility	X		X	
Incineration removal information	Incineration				X

A.2.1.5 Generation of Hazard Heat Maps

As stated in Appendix A.1.2.2, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content. The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or MeSH fields content.

After the completion of full-text screening for hazard data, all references tagged as included (or "PECO-relevant) were uploaded to the SWIFT Review tool for further filtering. The SWIFT Review filters applied at this phase focused on types of health outcomes included: "ADME", "PBPK", "cancer", "cardiovascular", "developmental", "endocrine", "gastrointestinal", "hematological and immune", "hepatic", "mortality", "musculoskeletal", "neurological", "nutritional and metabolic", "ocular and sensory", "renal", "reproductive", "respiratory", and "skin and connective tissue". The details of these health outcome search strategies that underlie the filters are available online. Studies that included one or more of the search terms in the title, abstract, keyword, or MeSH fields were exported and used to populate the Hazard Heat Map (Figure 2-9). Studies that were not retrieved using these filters were tagged as "No Tag". The evidence type listed in the heat map (*e.g.*, human, animal-human health model, animal- environmental model, and plant) was manually assigned to each reference by screeners during the full-text screening.

The health outcome tags were originally designed for vertebrate systems, and as such, did not conform well to plant evidence. Therefore, any plant studies tagged for: "cancer", "cardiovascular", "gastrointestinal", "hematological and immune", "hepatic", "musculoskeletal", "neurological", "ocular

and sensory" and "renal and respiratory" were manually reviewed and re-tagged to more appropriate health outcomes.

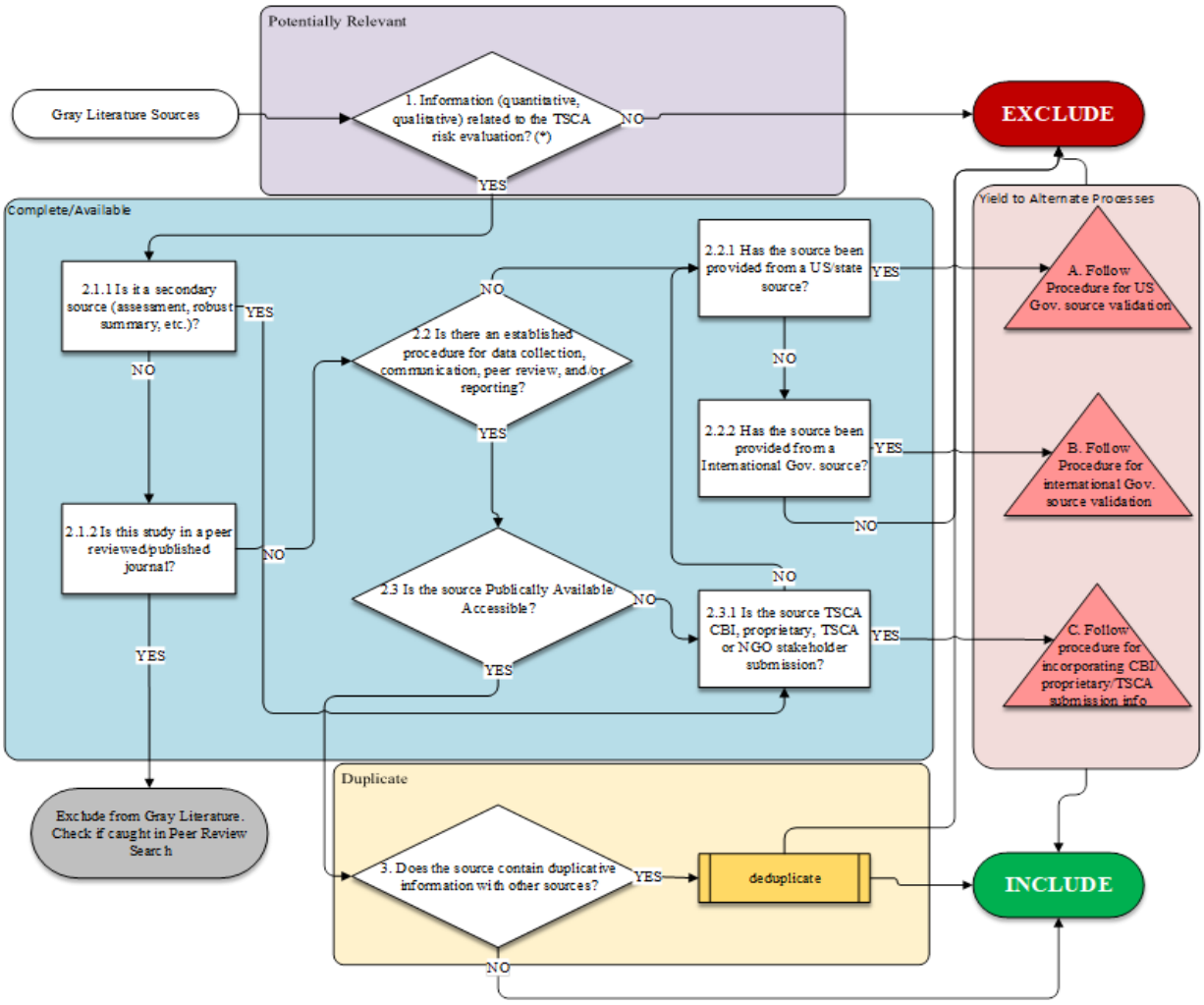
A.3 Gray Literature Search and Screening Strategies

EPA conducted a gray literature search for available information to support the TSCA risk evaluations for the next twenty TSCA risk evaluations. Gray literature is defined as the broad category of data/information sources not found in standard, peer-reviewed literature 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. Given the nature of how gray literature is searched and collected, results may not come with a bibliographic citation or abstract and were therefore processed using a decision tree logic described in Appendix A.3.1 for potential relevance prior to entering full text screening where a discipline-specific PECO is applied.

Search terms were variable dependent on source and based on knowledge of a given source to provide discipline-specific information. A summary of sources is provided in Appendix A.3.4. The criteria for determining the potential relevance of documents identified from gray literature sources is described in the following sections for each discipline.

A.3.1 Screening of Gray Literature

To reduce the overall burden of processing gray literature results, EPA developed a screening process to determine the potential relevance of gray literature. This step was introduced prior to collecting the resulting documents. Figure_Apx A-1 describes the decision logic used to screen gray literature results.



Figure_Apx A-1. Decision Logic Tree Used to Screen Gray Literature Results

A.3.2 Initial Screening of Sources using Decision Logic Tree

The purpose of the inclusion/exclusion decision logic tree in Figure_Apx A-1 is to provide a broad, general screening technique to determine whether each gray literature source should be included and further screened or excluded with no additional screening necessary. The diamonds in the decision tree require analysis by the screener, whereas the rectangular boxes are used to classify the type of source. All the questions used in the decision process are provided in Table_Apx A-11.

Table_Apx A-11. Decision Logic Tree Overview

Step	Metric	Questions to consider
1	Potential Relevance	Does the result have information (qualitative or quantitative) related to TSCA risk evaluations? *Apply Discipline relevancy metric
2.1.1	Complete / Available	Is it a secondary data source (assessment, robust summary, TSCA submission databases, etc.)?
2.1.2		Is the document from a peer reviewed/published journal?

Step	Metric	Questions to consider
2.2		Is there an established procedure for data collection, communication, peer review, and/or reporting?
2.2.1		Has the data been provided by a US governmental/state source?
2.2.2		Has the data been provided by an international governmental source?
2.3		Are these data publicly available/accessible?
2.3.1		Is the source TSCA CBI, proprietary, TSCA or NGO stakeholder submission?
3	Duplicate	Does the result contain any duplicative information found in other sources?

Results of the gray literature search and decision tree process are included in Section A.3.4.

A.3.3 TSCA Submission Searching and Title Screening

EPA screens information submitted under TSCA Sections 4, 5, 8(e), and 8(d), as well as for your information (FYI) submissions. In the gray literature process defined in Appendix A.3.2, EPA considers the databases that contain TSCA submissions to be secondary sources (Step 1.1) because the metadata in the databases are secondary. These databases then advance to Step 2.3.1 and then to Process C. The Process C steps are described here.

EPA first screens the titles using two screeners per title. EPA conducts this step primarily to reduce the number of full studies to be obtained because some studies are available only on microfiche or in long-term storage. Screening is done using the inclusion and exclusion criteria within the relevant PECOs, PESOs or RESOs for each topic area (Appendix A.2.1). EPA excludes interim reports (*e.g.*, interim sacrifices for toxicity studies) and only final reports are further considered. If the title is not clear regarding the document's contents, EPA obtains the full text and advances to the next steps.

After full texts were obtained, EPA reviewed some sources (prior to full-text screening) based on whether they have several factors; primary data, an established procedure for peer review, data collection, communication and/or reporting and are publicly available. Sources that have these factors will move on to full text screening. Other sources will go straight to full text screening using PECO-type criteria without going through this extra step.

EPA may decide to initiate a backwards search on sources that are deemed to have secondary data. In situations where parameters such as procedures for peer review and data collection are unclear, EPA may reach out to the authors to retrieve information to gauge whether the source should be included or excluded. Studies that are not publicly available (such as proprietary or CBI sources) may undergo additional screening steps.

During the full-text screening step, two individuals screen each source according to the PECOs, PESOs and RESOs (Appendix A.2.1).

Results of the TSCA submission search and decision tree process are included in Appendix A.3.4.

A.3.4 Gray Literature Search Results for Formaldehyde

Table_Apx A-12 provides a list of gray literature sources that yielded results for formaldehyde.

Table_Apx A-12. Gray Literature Sources that Yielded Results for Formaldehyde

Source Agency	Source Name	Source Type	Source Category	Source Website
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/profilesaddenda.asp
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/index.asp
Australian Government, Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document	https://www.industrialchemicals.gov.au/chemical-information/search-assessments
CAL EPA	Technical Support Documents for regulations: Cancer Potency Information	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Reference Exposure Levels (RELs)	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
ECHA	Annex XV Restriction Report	International Resources	Assessment or Related Document	https://echa.europa.eu/current-activities-on-restrictions
ECHA	ECHA Documents	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals
Env Canada	Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment	International Resources	Assessment or Related Document	https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list/priority-list.html
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document	https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/chemicals-glance.html
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document	https://www.canada.ca/en.html

Source Agency	Source Name	Source Type	Source Category	Source Website
EPA	OPPT: TSCATS database maintained at SRC (TSCA submissions)	US EPA Resources	Database	
EPA	OPPT: Chemview (TSCA submissions - chemical test rule data and substantial risk reports)	US EPA Resources	Database	https://chemview.epa.gov/chemview
EPA	OPPT: 8e database (CBI) (TSCA submissions)	US EPA Resources	Database	
EPA	OPPT: CIS (CBI LAN) (TSCA submissions)	US EPA Resources	Database	
EPA	Included in 2011 NATA	US EPA Resources	Assessment or Related Document	https://www.epa.gov/aegl/access-acute-exposure-guideline-levels-aegls-values#chemicals
EPA	Office of Air: AQS, Annual	US EPA Resources	Database	https://aqs.epa.gov/aqsweb/airdata/download_files.html#Annual
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database	https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data
EPA	Office of Air: National Emissions Inventory (NEI) - Additional Documents	US EPA Resources	Assessment or Related Document	https://www.epa.gov/air-emissions-inventories/national-emissions-inventory-nei
EPA	Office of Water: STORET and WQX	US EPA Resources	Database	https://www.waterqualitydata.us/portal/
EPA	Support document for AEGLS	US EPA Resources	Assessment or Related Document	https://www.epa.gov/aegl/access-acute-exposure-guideline-levels-aegls-values
EPA	EPA Pesticide Chemical Search (assessment)	US EPA Resources	Assessment or Related Document	https://iaspub.epa.gov/apex/pesticides/
EPA	Office of Air: Air Emission Factors	US EPA Resources	Regulatory Document or List	https://www.epa.gov/air-emissions-factors-and-quantification#:~:text=An%20emissions%20factor%20is%20a,emitted%20with%20an%20industrial%20activity. /
EPA	IRIS Summary	US EPA Resources	Assessment or Related Document	https://cfpub.epa.gov/ncea/iris_drafts/atoz.cfm?list_type=alpha
EPA	Office of Air: TRI	US EPA Resources	Database	https://www.epa.gov/toxics-release-inventory-tri-program/tri-data-and-tools

Source Agency	Source Name	Source Type	Source Category	Source Website
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List	https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors
EPA	EPA Ambient Monitoring Technology Information Center – Air Toxics Data	US EPA Resources	Database	https://www3.epa.gov/ttnamti1/toxdat.html
EPA	Other EPA: Misc. sources	US EPA Resources	General Search	https://www.epa.gov/
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List	https://www.epa.gov/eg
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List	https://www.epa.gov/stationary-sources-air-pollution
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document	https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios
IARC	IARC Monograph	International Resources	Assessment or Related Document	http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php
ILO	International Chemical Safety Cards (ICSCs)	International Resources	Database	https://www.ilo.org/safework/info/publications/WCMS_113134/lang--en/index.htm
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List	https://www.env.go.jp/en/chemi/prtr/substances/
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia	https://onlinelibrary.wiley.com/doi/book/10.1002/0471238961
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document	https://www.cdc.gov/niosh/docs/81-123/default.html
NIOSH	CDC NIOSH - Pocket Guide	Other US Agency Resources	Database	https://www.cdc.gov/niosh/npg/default.html

Source Agency	Source Name	Source Type	Source Category	Source Website
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/hhe/search.asp
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/nioshtic-2/
NTP	Additional NTP Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/publications/index.html
NTP	RoC Monographs	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/pubhealth/roc/listings/index.html
OECD	OECD SIDS	International Resources	Assessment or Related Document	https://hpvchemicals.oecd.org/ui/Publications.aspx
OECD	OECD Substitution and Alternatives Assessment	International Resources	Assessment or Related Document	http://www.oecdsaatoolbox.org/
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document	http://www.oecd.org/document/46/0,2340,en_2649_201185_2412462_1_1_1_1,00.html
OECD	OECD: General Site	International Resources	General Search	https://www.oecd.org/
OSHA	OSHA Chemical Exposure Health Data	Other US Agency Resources	Database	https://www.osha.gov/opengov/healthsamples.html
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document	https://www.rivm.nl/en
RIVM	Probit Function Technical Support Document	International Resources	Assessment or Related Document	https://www.rivm.nl/en/probit-functions/probit-function-status-overview
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document	https://tera.org/index.html

Appendix B PHYSICAL AND CHEMICAL PROPERTIES

Appendix B summarizes statistics for the physical and chemical property values identified through systematic review as of June 2020. The "N" column indicates the number of unique primary sources of data for that endpoint. That is, if multiple sources presented equivalent values and cited the same primary source, only one of those was included in these statistics and included in the statistical calculations. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0438).

Table_Apx B-1. Summary Statistics for Reviewed Physical Properties

Property or Endpoint	N	Unit	Mean	Standard Deviation	Min	Max
Molecular formula	-	-	NA	NA	NA	NA
Molecular weight	-	g/mol	NA	NA	NA	NA
Physical state	5	-	NA	NA	NA	NA
Physical properties	3	-	NA	NA	NA	NA
Melting point	7	ºC	-99.5	12.7	-118.3	-92.0
Boiling point	14	ºC	-41	26	-88	-19
Density	5	g/cm^3	0.919	0.143	0.815	1.083
Vapor pressure	3	mm Hg	1803	1807	760	3890
Vapor density	1		1.067		1.067	1.067
Water solubility	2	mg/L	475000	106066	400000	550000
Octanol/water partition coefficient (log Kow)	3		0.35	0	0.35	0.35
Henry's Law constant	1	$atm \cdot m^3/mol$	3.37×10^{-7}	0	3.37×10^{-7}	3.37×10^{-7}
Flash point	4	ºC	62	6.45	56	71
Auto flammability	1	ºC	300		300	300
Viscosity	1	cP	0.1421		0.1421	0.1421
Refractive index	2		1.3756	0.0013	1.3746	1.3765
Dielectric constant	0					

NA = Not applicable

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

Table_Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for formaldehyde. This information was presented in the *Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and may be updated as EPA collects additional information through systematic review methods.

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 et al. (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)	NLM (2019); 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); NLM (2019); ATSDR (1999)
Biodegradation (Aerobic)	Water: 100%/30 hours (die-away test) in stagnant lake water	NLM (2019); ATSDR (1999) citing U.S. EPA (1976)
	Sediment: 90%/28 days (OECD 301D) with non- acclimated inoculum	OECD (2002) citing Gerike and Gode (1990); NLM (2019)
Biodegradation (Anaerobic)	Water: 100%/48 hours (die-away test) in stagnant lake water	NLM (2019); 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)

Property or Endpoint	Value[a]	Reference
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)
Soil organic Carbon:Water Partition Coefficient (Log K_{OC})	Absorbs to clay minerals; used as a soil fumigant	NLM (2019); 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 Statutes/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(a)	The TSCA Section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	Formaldehyde manufacturing (including importing), processing and use information is reported under the CDR rule (85 FR 20122, April 9, 2020).
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	23 risk reports received for formaldehyde, or containing information related to

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	formaldehyde were received between 1989 and 2011. (U.S. EPA, ChemView, Accessed April 3, 2019). Link to the 8(e) submission crosswalk HERE:
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 (40 CFR 770).
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	Formaldehyde was registered as an antimicrobial, conventional chemical on January 25, 1967. In June 2008 EPA published a reregistration eligibility

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either (1) the pesticide, labeling, or other material does not comply with FIFRA; or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	decision for formaldehyde and paraformaldehyde (Case 0556; EPA Document 739-R-08-004). Formaldehyde is currently under registration 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	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).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	
Clean Air Act (CAA) – Section 112(b)	Defines the original list of 189 hazardous air pollutants (HAPs). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAPs 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 HAPs by adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	Formaldehyde is listed as a HAP (42 U.S.C 7412).
Clean Air Act (CAA) – Section 112(d) and 112(f)	Risk and technology review (RTR) of section 112(d) national emission standards for hazardous air pollutants (NESHAP). Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to section 112(d) NESHAP that require maximum achievable control technology (MACT), and to determine if additional standards are needed to reduce remaining risks. Section 112(d)(6) requires EPA to review and revise the emission standards, as necessary, taking into account developments in practices, processes and control technologies.	A has promulgated a number of RTR NESHAP and will do so, as required, for the remaining source categories with NESHAP. 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 63 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 O_3/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).
Clean Water Act (CWA) Section 311(b)	Requires EPA to develop, promulgate, and revise as may be appropriate, regulations designating as hazardous substances, other than oil, which, when discharged present an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches.	Formaldehyde is designated as hazardous substances in accordance with Section 311(b)(2)(A) of the CWA
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-

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		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. 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

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		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. 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

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		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 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

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		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 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

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		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.
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 as number 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 Statutes/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 an indirect food additive under its food additive and GRAS regulations (21 CFR 175.105, 175.210, 175.300, 176.170, 176.180, 176.200, 176.210, 177.1460, 177.1900, and 177.2480).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		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 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.	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),

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
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 (updated in 2016) ACGIH TLVs if they are more protective than the OSHA PEL.
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	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

State Actions	Description of Action
Standards and Guidelines	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).
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).

State Actions	Description of Action
	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 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).

Country/ Organization	Requirements and Restrictions
	Formaldehyde was evaluated under the 2013 Community rolling action plan (CoRAP) under regulation (EC) No1907/2006 - REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals, (European Chemical Agency (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) • 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.

Country/ Organization	Requirements and Restrictions
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 New Zealand, People's Republic of China, Poland, Romania, Singapore, South Korea, Spain, Sweden, Switzerland, the Netherlands, U.S.A, and the United Kingdom	Occupational exposure limits for formaldehyde (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. (Accessed April 18, 2019).

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, 2019a).

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 and Seaman, 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 and Seaman, 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 and Seaman, 2013).

New production processes are in development, including the partial oxidation of methane and the dehydrogenation of methanol, but no units are commercial (Gerberich and Seaman, 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 and Seaman, 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, 2019a).

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 and Seaman, 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 and Kane, 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, 2019a).

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 Section 2.2.1, formaldehyde is used as a reactant or intermediate in the production of the following products:

- 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).

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 and Seaman, 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 (Binder et al., 2005; Williams, 2002).

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. This polycondensation step is the prevalent resin synthesis pathway based on this feedback from industry (EPA-OPPT-0438-0041). 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 (Binder et al., 2005; Williams, 2002).

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; U.S. 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; U.S. 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 and Seaman, 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. Some of these uses may correspond to uses of resins that contain residual formaldehyde used for their thermosetting properties, which could be described using CDR functional codes as adhesives, finishing agents and additives in Section 2.2. Some specific processes are noted below:

- Formaldehyde-based resins used as wood product adhesives (wood product manufacturing);
- Formaldehyde-based polymers used in coatings that are applied to transportation equipment;
- Formaldehyde-based resins used in fiberglass mats (construction);
- Formaldehyde-based resins used in paper treating and coating (paper manufacturing);
- Formaldehyde-based resins used in pre-impregnated fiber composites(construction);
- Formaldehyde-based resins used in textile finishing (textile, leather manufacturing); and
- Formaldehyde-based resins used in plastic and resin manufacturing (*e.g.*, foam, laminates, molds)

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%, these can be used various insulation and other roofing products (EPA-HQ-OPPT-2018-0438-0008; EPA-HQ-OPPT-2018-0438-0005). The aerospace industry uses epoxy and phenolic resins in pre-impregnated fiber composites (EPA-HQ-OPPT-2018-0438-0006). Tire manufacturing uses formaldehyde-based resins and textiles pretreated with resorcinol-formaldehyde latex dip (EPA-HQ-OPPT-2018-0438-0054).

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, 2015). For leather manufacturing, formalin has been reported to be used as a tanning agent in leather tanning (Dionisio et al., 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 (NICNAS, 2006; U.S. EPA, 1994).

In general, for plastic manufacturing, the final plastic article is produced in a conversion process that forms the compounded plastic into the finished products (OECD, 2009a; U.S. EPA, 2004a). The converting process is different depending on whether the plastic is a thermoplastic or a thermosetting material (U.S. EPA, 2004b). Thermoplastics converting involves the melting of the plastic material, forming it into a new shape and then cooling it (OECD, 2004; U.S. EPA, 2004b). The converting of

thermoplastics may involve extrusion, injection molding, blow molding, rotational molding or thermoforming (OECD, 2004; U.S. EPA, 2004b). Formaldehyde may be used in the reinforcing and tackifying resins used in tire manufacturing (EPA-HQ-OPPT-2018-0438-0054).

Conversion of thermosetting materials involves using heat and pressure to promote curing, typically through cross-linking (OECD, 2004). 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, 2004). 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, 2004b).

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, 2009b); (U.S. EPA, 2014). Adhesive formulations involve mixing together volatile and non-volatile chemical components in sealed, unsealed or heated processes (OECD, 2009b). Sealed processes are most common for adhesive formulation because many adhesives are designed to set or react when exposed to ambient conditions (OECD, 2009b). Lubricant formulation typically involves the blending of two or more components, including liquid and solid additives, together in a blending vessel (OECD, 2004). The formulation step can involve compounding with additives and other raw materials to form a masterbatch in either open or closed blending processes (OECD, 2009b; U.S. EPA, 2004a).

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 for 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). IPC provided public comments describing formaldehyde used as a reducing agent in the electroless copper plating process. The process covers the inside of the through-holes in printed circuit boards with copper to create electrical continuity and contact between multiple layers of boards. At the end of the plating process there is no formaldehyde

remaining in the deposited copper or in the end product (EPA-HQ-OPPT-2018-0438-0050; EPA-HQ-OPPT-2018-0438-0025).

The 2016 CDR reports a processing aid use of formaldehyde in oil and gas drilling, extraction, and support activities (U.S. EPA, 2019a). Preliminary literature reported the use of formaldehyde as a corrosion inhibitor and hydrogen sulfide scavenger in oil production operations (Gerberich and Seaman, 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, 2016).

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 (Calgon Corporation, 1990; Chemetrics, 1989; Mansfield Sanitary Inc., 1985). 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 (Dionisio et al., 2015). EPA plans to evaluate this condition of use during risk evaluation.

A commenter (EPA-HQ-OPPT-2018-0438-0057) provided descriptions of their use of formaldehyde as a component of common off the shelf adhesives and caulks, further informing EPA's understanding of this condition of use.

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 automotive coatings, coil and metal coatings, wood coatings, packaging coatings and specialty coatings (EPA-HQ-OPPT-2018-0438-0055; EPA-HQ-OPPT-2018-0438-0023). 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. 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 (see use in paints and coatings). In semiconductor manufacturing, formaldehyde may be contained in leveling additives during electrolytic copper plating, chemical mechanical planarization slurry formulations, lithography formulations, mold compounds used for plastic packages (EPA-HQ-OPPT-2018-0438-0053). 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 (EPA-HQ-OPPT-2018-0438-0006). 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. Formaldehyde-based materials are used in tires (EPA-HQ-OPPT-2018-0438-0054).

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 is 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% (Elmer's, 2012; Day-Glo Color Corporation, 1993). 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.

A commenter (EPA-HQ-OPPT-2018-0438-0057) provided descriptions of their use of formaldehyde in laboratory use including such applications as analytical standards, research, equipment calibration, sample preparation, including calibration of formaldehyde sensors for airborne and satellite-based measurements and analysis of extraterrestrial material samples, which the commenter also indicated was a critical use, further informing EPA's understanding of this condition of use.

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 or disposal may include wastewater and solid waste. 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 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). The conceptual model depicted in Figure 2-15 presents the exposure pathways, exposure routes and hazards to general population and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of formaldehyde that EPA plans to evaluate.

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).

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.

HHEs can be found at https://www.cdc.gov/niosh/hhe/

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
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

NAICS	NAICS Description	Number of Data Points
322299	All Other Converted Paper Product Manufacturing	2
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

NAICS	NAICS Description	Number of Data Points
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	3
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

NAICS	NAICS Description	Number of Data Points
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing	4
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 Children's 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

NAICS	NAICS Description	Number of Data Points
424120	Stationery and Office Supplies Merchant Wholesalers	4
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

NAICS	NAICS Description	Number of Data Points
611511	Cosmetology and Barber Schools	9
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

Source: https://www.osha.gov/opengov/healthsamples.html

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.
				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.

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 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 - 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	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.
				Vapor	Inhalation	Workers, ONU	Yes	Formaldehyde is volatile (3890 mm Hg at room temperature). EPA plans to evaluate inhalation exposures.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		- 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		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	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.

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	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.
				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	Additive in rubber product manufacturing	Use of additives in 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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Mist	Inhalation	Workers, ONU	Yes	Includes release agents, which could be spray applied. Mist generation can occur 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 –Paper Manufacturing	Use of binding agent for wood product, and general construction material manufacturing (fiberglass, composite materials, wood products) Plastic Product Manufacturing Paper 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 off gassing of the resin and from the final article will be evaluated.
				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		Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing.		Liquid Contact	Dermal	Workers	Yes	Formaldehyde may be handled in an aqueous solution form; therefore, EPA plans to evaluate for potential dermal exposure.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	Incorporation into a formulation, mixture, or reaction product	- 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 - 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	Processing of formaldehyde into formulations, mixtures, or reaction products	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
		- 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 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						

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		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.
				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.
				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.
Processing	Recycling	Recycling	Recycling	Liquid Contact	Dermal	Workers	Yes	Formaldehyde may be handled in an aqueous solution; therefore, dermal exposure is expected for workers.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	Yes	Due to its high volatility, inhalation exposures will be analyzed.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during recycling.
				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.

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.
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	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.
Industrial Use	Non-incorporative activities	Oxidizing/reducing agent; processing aids, not otherwise listed (*e.g.*, electroless copper plating)	Reducing Agent in electroless Metal Plating	Liquid Contact	Dermal	Workers	Yes	Dermal exposures to formulations containing formaldehyde are expected for workers.

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 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 *i.e.*, no formaldehyde remains in printed circuit boards.
Industrial/Commercial Use	Chemical substances in industrial products	Paints and coatings; adhesives and sealants; lubricants	Uses of paints, coatings, adhesives, sealants, Use of lubricants Foundry binder (mist not expected for this scenario)	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.
				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 furnishing treatment/care products Chemical substances in construction, paint, electrical, and metal products	-Floor coverings -Foam seating and bedding products -Furniture and furnishings not covered elsewhere -Building/ construction materials (wood and engineered wood products) -Building/ construction materials not covered elsewhere	Installation and demolition of formaldehyde-based furnishings and building/construction materials in residential, public and commercial buildings, and other structures	Liquid Contact	Dermal	Workers	Yes	Depending on products covered for this exposure scenario, dermal contact with liquid for workers may occur.
				Vapor	Inhalation	Workers, ONU	Yes	Off-gassing of formaldehyde from these products 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 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.

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 Furnishing, cleaning, and treatment/care products	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.
				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.

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 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 electrical products	Electrical and electronic products (including semiconductors)	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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	Chemical substances in metal products	Metal products not covered elsewhere		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.
				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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
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.
				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.

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 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.
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.

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 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.
				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.

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	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.
				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.
			Long-term emission/mass-transfer					

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
	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.
			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.

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					
	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.
			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					

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
	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					
	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.

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			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.
			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					

Life Cycle Stage	Category	Subcategory	Release from Source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
	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					
	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	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 Receptors	Yes	Release of formaldehyde into surface water and indirect partitioning to sediment exposure pathways to the general population, and aquatic receptors will be analyzed.

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
			Direct release into surface water and partitioning to sediment	Oral Dermal and Inhalation	General Population	Yes	
			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 NPDWR.
			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 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	