

Conditions of Use of the Risk Evaluation for Formaldehyde

CASRN 50-00-0

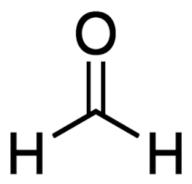


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1 INTRODUCTION

This document provides an overview of the conditions of use (COUs) considered for the formaldehyde risk evaluation, pursuant to the TSCA section 3(4) definition of "conditions of use" and TSCA section 3(2) definition of "chemical substance." EPA did not directly assess risk from any formaldehyde exposures occurring from non-TSCA uses (*e.g.*, exposures from biogenic production of formaldehyde or uses excluded from the TSCA section 3(2) definition of chemical substance, such as pesticides used for embalming and taxidermy as well as any food, food additive, drug, cosmetic, or device). However, EPA did consider potential exposures from non-TSCA uses, as appropriate, to help inform the Agency's risk determination for formaldehyde under the TSCA conditions of use. This document also presents an explanation of the scope of certain conditions of use of formaldehyde and explains EPA's rationale for any changes to the scope of the risk evaluation after publication of the *Final Scope for the Risk Evaluation for Formaldehyde*; 50-00-0 (U.S. EPA, 2020c).

2 RISK EVALUATION SCOPE

The formaldehyde risk evaluation comprises a series of assessments spread across may documents. A basic diagram showing the layout and relationships of these assessments is provided in Figure 2-1. In some cases, individual assessments were completed jointly under TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

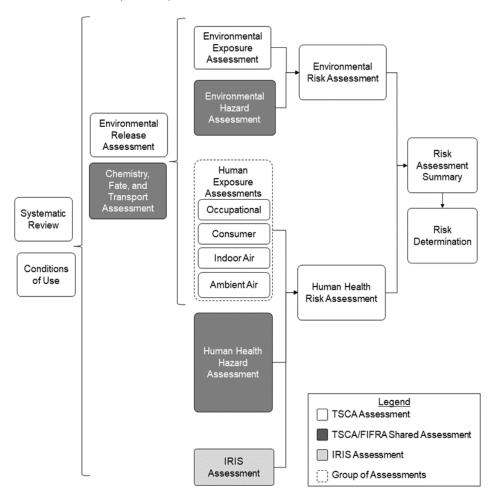


Figure 2-1. Risk Evaluation Document Summary Map

2.1 Conditions of Use Included in the Risk Evaluation

The *Final Scope for the Risk Evaluation for Formaldehyde; CASRN 50-00-0* (U.S. EPA, 2020c) (2020 Final Scope) identified and described the categories and subcategories of COUs that EPA planned to consider in the formaldehyde risk evaluation. TSCA § 3(4) defines "conditions of use" (COUs) as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." Table 2-1 presents all COUs for formaldehyde.

In the *Draft Risk Evaluation for Formaldehyde*, EPA edited the formaldehyde COUs listed in the 2020 Final Scope. Those edits reflected EPA's improved understanding of formaldehyde's COUs based on further outreach, public comments received, and updated processing, industrial, consumer, and commercial product category names for reporting under the Chemical Data Reporting (CDR) for 2020. Those edits included: (1) updated additions based on new reporting in CDR for 2020; (2) updated product category name changes based on new codes used in CDR for 2020; and (3) changes based on

EPA's further understanding of non-TSCA uses for formaldehyde that were initially included as TSCA COUs for formaldehyde in the 2020 Final Scope. EPA further examined some COU subcategories included in the 2020 Final Scope and determined that the subcategories were not formaldehyde COUs, either because EPA determined that the uses are excluded from the TSCA section (2) definition of "chemical substance" or that the uses are not actually circumstances under which formaldehyde is intended, known, or reasonably foreseen to manufactured, processed, distributed in commerce, used, or disposed of. These subcategories are further discussed in Section 2.2 and were removed from the draft risk evaluation. In addition, certain exposure pathways that are administered by other EPA statutes, such as TSCA Title VI, were included in the final risk evaluation and are further discussed in Section 2.4.

In this final risk evaluation, as described in Section 2.1.2, EPA added one COU in the final risk evaluation based on public comment received on the *Draft Risk Evaluation for Formaldehyde*. EPA has also further clarified certain COU uses and activities in Section 2.2 determined not to be chemical substances based on public comment and new information received between the *Final Scope for the Risk Evaluation for Formaldehyde*; *CASRN 50-00-0* and this final risk evaluation.

Table 2-1 presents the COUs that were included and evaluated in this risk evaluation for formaldehyde. Appendix A provides a description of the COUs included in this risk evaluation.

Table 2-1. Conditions of Use Included in the Risk Evaluation for Formaldehyde

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019a)
Manufacturing	Importing	Importing	U.S. EPA (2019a)
Processing	Reactant	Adhesives and sealant chemicals in: plastic and resin manufacturing; wood product manufacturing; paint and coating manufacturing; basic organic chemical manufacturing	U.S. EPA (2019a)
Processing	Reactant	Intermediate in: pesticide, fertilizer, and other agricultural chemical manufacturing; petrochemical manufacturing; soap, cleaning compound, and toilet preparation manufacturing; basic organic chemical manufacturing; plastic materials and resin manufacturing; adhesive manufacturing; chemical product and preparation manufacturing; paper manufacturing; paint and coating manufacturing; plastic products manufacturing; synthetic rubber manufacturing; wood product manufacturing; construction; agriculture, forestry, fishing, and hunting	<u>U.S. EPA (2019a)</u>
Processing	Reactant	Functional fluid in: oil and gas drilling, extraction, and support activities	U.S. EPA (2019a)

Life Cycle Stage ^a			Reference(s)
Processing	Reactant	Processing aids, specific to petroleum production in basic chemical manufacturing	U.S. EPA (2019a)
Processing	Reactant	Bleaching agent in wood product manufacturing	U.S. EPA (2019a)
Processing	Reactant	Agricultural chemicals in agriculture, forestry, fishing, and hunting	<u>U.S. EPA (2019a)</u>
Processing	Incorporation into an article	Finishing agents in textiles, apparel, and leather manufacturing	<u>U.S. EPA (2019a);</u> USTMA (<u>EPA-HQ-OPPT-</u> <u>2018-0438-0054)</u>
Processing	Incorporation into an article	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)
Processing	Incorporation into an article	Additive in rubber product manufacturing	USTMA (EPA-HQ-OPPT- 2018-0438-0026); USTMA (EPA-HQ-OPPT-2018- 0438-0054)
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 (including roofing materials); paper manufacturing	U.S. EPA (2019a); AIA (EPA-HQ-OPPT-2018- 0438-0006); ARMA (EPA- HQ-OPPT2018-0438- 0005); ARMA (EPA-HQ- OPPT-2018-0438-0051); USTMA (EPA-HQOPPT- 2018-0438-0054)
Processing	Incorporation into a formulation, mixture, or reaction product	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; basic organic chemical manufacturing; and petroleum and coal products manufacturing	U.S. EPA (2019a); AIA (EPA-HQ-OPPT-2018- 0438-0006); Everlube (EPA-HQ-OPPT2018- 0438-0024)
Processing	Incorporation into a formulation, mixture, or reaction product	Asphalt, paving, roofing, and coating materials manufacturing	U.S. EPA (2019a); ARMA (EPA-HQ-OPPT-2018- 0438- 0005)
Processing	Incorporation into a formulation, mixture, or reaction product	Solvents (which become part of a product formulation or mixture) in paint and coating manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Processing aids, specific to petroleum production in: oil and gas drilling, extraction, and support activities; chemical product and preparation manufacturing; and basic inorganic chemical manufacturing	U.S. EPA (2019a); AIA (EPAHQ-OPPT-2018- 0438-0006); EDF (EPA- HQ-OPPT-2018- 0438- 0017)

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Processing	Incorporation into a formulation, mixture, or reaction product	Paint additives and coating additives not described by other categories in: paint and coating manufacturing; plastic material and resin manufacturing	<u>U.S. EPA (2019a)</u>
Processing	Incorporation into a formulation, mixture, or reaction product	Intermediate in: basic chemical manufacturing; 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)
Processing	Incorporation into a formulation, mixture, or reaction product	Solid separation agents in miscellaneous manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Agricultural chemicals (nonpesticidal) in: Agriculture, forestry, fishing, and hunting; pesticide, fertilizer, and agricultural chemical manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Surface active agents in plastic material and resin manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Ion exchange agents in adhesive manufacturing and paint and coating manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Lubricant and lubricant additive in adhesive manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Plating agents and surface treating agents in chemical product and preparation manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Soap, cleaning compound, and toilet preparation manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Laboratory chemicals	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Adhesive and sealant chemical in adhesive manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Bleaching agents in textile, apparel, and leather manufacturing	U.S. EPA (2019a)
Processing	Repackaging	Sales to distributors for laboratory chemicals	U.S. EPA (2019a)

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Processing	Recycling	Recycling	<u>U.S. EPA (2019a)</u>
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 (EPAHQ-OPPT-2018- 0438-0017)
Industrial Use	Non-incorporative activities	Used in: construction	U.S. EPA (2019a)
Industrial Use	Non-incorporative activities	Oxidizing/reducing agent; processing aids, not otherwise listed	IPC (EPA-HQ-OPPT- 2018- 0438-0025); IPC (EPA-HQ-OPPT0438- 0050); SAI (EPA-HQ- OPPT-0438-0053)
Industrial Use	Chemical substances in industrial products	Paints and coatings; adhesives and sealants; lubricants	AFS (EPA-HQ-OPPT- 2023-0613-0234); AIA (EPA-HQ-OPPT-2018- 0438-0006);
Industrial Use	Chemical substances in industrial products	Aerospace use in: paints and coating; adhesives and sealants; lubricants; and foam insulation	AIA (EPA-HQ-OPPT- 2018- 0438-0006); AIA (EPA-HQ-OPPT-2023- 0613-0199)
Commercial Uses	Chemical substances in furnishing treatment/care products	Floor coverings; foam seating and bedding products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; cleaning and furniture care products; leather conditioner; leather tanning, dye, finishing impregnation and care products; textile (fabric) dyes; textile finishing and impregnating/ surface treatment products.	U.S. EPA (2020a); U.S. EPA (2019a);
Commercial Uses	Chemical substances in treatment products	Water treatment products	U.S. EPA (2019a)
Commercial Uses	Chemical substances in treatment/care products	Laundry and dishwashing products	U.S. EPA (2019a)
Commercial Uses	Chemical substances in construction, paint, electrical, and metal products	Adhesives and sealants; paint and coatings	U.S. EPA (2019a)
Commercial Uses	Chemical substances in furnishing treatment/care products	Construction and building materials covering large surface areas, including wood articles; construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	U.S. EPA (2019a); U.S. EPA (2020a)

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Commercial Uses	Chemical substances in electrical products	Machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/electronic articles	<u>U.S. EPA (2019a)</u>
Commercial Uses	Chemical substances in metal products	Construction and building materials covering large surface areas, including metal articles	U.S. EPA (2019a):
Commercial uses	Chemical substances in automotive and fuel products	Automotive articles and automotive care products; lubricants and greases; fuels and related products	U.S. EPA (2019a); USTMA (EPA-HQ-OPPT- 2018-0438-0026); Everlube (EPA-HQ-OPPT- 2018-0438-0024)
Commercial uses	Chemical substances in agriculture use products	Lawn and garden products	U.S. EPA (2019a)
Commercial Uses	Chemical substances in outdoor use products	Explosive materials	U.S. EPA (2019a)
Commercial Uses	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)
Commercial uses	Chemical substances in packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	U.S. EPA (2019a)
Commercial Uses	Chemical substances in packaging, paper, plastic, hobby products	Ink, toner, and colorant products; photographic supplies	U.S. EPA (2019a);
Commercial Uses	Chemical substances in products not described by other codes	Laboratory Chemicals	U.S. EPA (2019a)
Consumer Uses	Chemical substances in furnishing treatment/care products	Floor coverings; foam seating and bedding products; cleaning and furniture care products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles	U.S. EPA (2019a); U.S. EPA (2020a)
Consumer Uses	Chemical substances in furnishing treatment/care products	Fabric, textile, and leather products not covered elsewhere (clothing)	U.S. EPA (2019a); U.S. EPA (2020a)
Consumer Uses	Chemical substances in treatment products	Water treatment products	<u>U.S. EPA (2019a)</u>

Life Cycle Stage ^a	$Category^b$	Subcategory ^c	Reference(s)
Consumer Uses	Chemical substances in treatment/care products	Laundry and dishwashing products	<u>U.S. EPA (2019a)</u>
Consumer Uses	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; paint and coatings	U.S. EPA (2019a)
Consumer Uses	Chemical substances in construction, paint, electrical, and metal products	Construction and building materials covering large surface areas, including wood articles; construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	U.S. EPA (2019a); U.S. EPA (2020a)
Consumer Uses	Chemical substances in electrical products	Machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/electronic articles	<u>U.S. EPA (2019a)</u>
Consumer Uses	Chemical substances in automotive and fuel products	Automotive articles and automotive care products; lubricants and greases; fuels and related products	U.S. EPA (2019a); USTMA (EPA-HQ-OPPT- 2018-0438- 0026); Everlube (EPA-HQ-OPPT- 2018-0438-0024)
Consumer Uses	Chemical substances in agriculture use products	Lawn and garden products	U.S. EPA (2019a)
Consumer Uses	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)
Consumer Uses	Chemical substances in hobby products	Arts, crafts, and hobby materials	U.S. EPA (2019a)
Consumer Uses	Chemical substances in packaging, paper, and plastic	Ink, toner, and colorant products; Photographic supplies	U.S. EPA (2019a)
Disposal	Disposal	Disposal	U.S. EPA (2019a)

Life Cycle Stage ^a Category ^b	Subcategory ^c	Reference(s)
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^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.

2.1.1 Additions and Name Changes to Conditions of Use Based on Updated 2020 CDR Reported Data

After the 2020 Final Scope, EPA received updated submissions under the 2020 CDR reported data. In addition to new submissions received under the 2020 CDR, the reporting name codes changed for the 2020 CDR reporting cycle. Therefore, EPA amended the description of certain formaldehyde COUs based on those new submissions and new reporting name codes. Table 2-2 summarizes the changes to the COUs based on the new reporting codes in the 2020 CDR. Those changes are included in Table 2-1.

Table 2-2. Additions and Name Changes to Categories and Subcategories of Conditions of Use Based on Updated Reporting in the 2020 CDR

Life Cycle Stage and Category	Original Subcategory in the 2020 Scope Document	Occurred Change	Revised Subcategory in the 2024 Risk Evaluation
Processing – Reactant	Adhesives and sealant chemicals in: plastic and resin manufacturing; wood product manufacturing; all other basic organic chemical manufacturing	Added – 'paint and coating manufacturing'	Adhesives and sealant chemicals in: plastic and resin manufacturing; wood product manufacturing; paint and coating manufacturing; basic organic chemical manufacturing
Processing – Reactant	Intermediate in: pesticide, fertilizer, and other agricultural chemical manufacturing; petrochemical manufacturing; soap, cleaning compound, and toilet preparation manufacturing; all other basic organic chemical manufacturing; plastic materials and resin manufacturing; adhesive manufacturing; all other chemical product and preparation manufacturing; paper manufacturing; plastic products manufacturing; wood product manufacturing; construction; agriculture, forestry, fishing, and hunting	Added – 'paint and coating manufacturing' Added – 'synthetic rubber manufacturing'	Intermediate in: pesticide, fertilizer, and other agricultural chemical manufacturing; petrochemical manufacturing; soap, cleaning compound, and toilet preparation manufacturing; basic organic chemical manufacturing; plastic materials and resin manufacturing; adhesive manufacturing; chemical product and preparation manufacturing; paper manufacturing; paint and coating manufacturing; plastic products manufacturing; synthetic rubber manufacturing; wood product manufacturing; construction;

^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 and for consumer uses.

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

Life Cycle Stage and Category	Original Subcategory in the 2020 Scope Document	Occurred Change	Revised Subcategory in the 2024 Risk Evaluation
			agriculture, forestry, fishing, and hunting
Processing – Incorporation into a formulation, mixture, or reaction product	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; and all other basic organic chemical manufacturing	Added – 'petroleum and coal products manufacturing'	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; basic organic chemical manufacturing; and petroleum and coal products manufacturing
Processing – Incorporation into a formulation, mixture, or reaction product	Processing aids, specific to petroleum production in: oil and gas drilling, extraction, and support activities; and all other basic inorganic chemical manufacturing	Added – 'chemical product and preparation manufacturing'	Processing aids, specific to petroleum production in: oil and gas drilling, extraction, and support activities; chemical product and preparation manufacturing; and basic inorganic chemical manufacturing
Processing — Incorporation into a formulation, mixture, or reaction product	Functional fluids (closed system) in soap, cleaning compound, and toilet preparation manufacturing	Name change based on new industry code	Soap, cleaning compound, and toilet preparation manufacturing
Commercial Use – 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	Name change based on new industry code	Floor coverings; foam seating and bedding products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; cleaning and furniture care products; leather conditioner; leather tanning, dye, finishing impregnation and care products; textile (fabric) dyes; textile finishing and impregnating/ surface treatment products.
Commercial Use – chemical substances in furnishing treatment/care products	Building/construction materials – wood and engineered wood products; building/ construction materials not covered elsewhere	Name change based on new industry code	Construction and building materials covering large surface areas, including wood articles; construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
Commercial Use – chemical substances in electrical products	Electrical and electronic products	Name change based on new industry code	Machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/electronic articles

Life Cycle Stage and Category	Original Subcategory in the 2020 Scope Document	Occurred Change	Revised Subcategory in the 2024 Risk Evaluation
Commercial Use - chemical substances in metal products	Metal products not covered elsewhere	Name change based on new industry code	Construction and building materials covering large surface areas, including metal articles
Consumer Use - 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	Name change based on new industry code	Floor coverings; foam seating and bedding products; cleaning and furniture care products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles
Consumer Use – chemical substances in furnishing treatment/care products	Building/construction materials — wood and engineered wood products; building/ construction materials not covered elsewhere	Name change based on new industry code	Construction and building materials covering large surface areas, including wood articles; construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
Consumer Use – chemical substances in electrical products	Electrical and electronic products	Name change based on new industry code	Machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/electronic articles

2.1.2 Additions and Name Changes to Conditions of Use Based on Public Comments Received on the Draft Risk Evaluation

After the *Draft Risk Evaluation for Formaldehyde* was published in March 2024, EPA received public comments from certain industry and government agencies that supported an addition to the list of COU subcategories under evaluation. Therefore, EPA amended the COU Table to include an additional COU subcategory based on those comments. Table 2-3 summarizes the changes to the COUs based on submitted public comments. Those changes are included in Table 2-1.

Table 2-3. Additions and Name Changes to Categories and Subcategories of Conditions of Use Based on Public Comments Received

Life Cycle Stage and Category	Original Subcategory in the 2020 Scope Document	Occurred Change	Revised Subcategory in the 2024 Risk Evaluation
Industrial use – chemical substances in industrial products	N/A	Added new COU based on public comments for aerospace use	Aerospace use in: paints and coating; adhesives and sealants; lubricants; and foam insulation

This COU, Aerospace use in: paints and coating; adhesives and sealants; lubricants; and foam insulation, was added to the Formaldehyde Risk Evaluation based on detailed comments provided by the Aerospace

Industries Association (AIA) (EPA-HQ-OPPT-2023-0613-0199). This commentor provided evidence that certain uses of formaldehyde in aerospace products merited a separate, dedicated COU subcategory based on these specialty uses ranging from anti-friction coating applications on airplanes to foam sealants for rockets. This COU was evaluated for the final risk evaluation.

2.2 Activities Determined Not to Be Conditions of Use

Section 2.2.2 of the 2020 Final Scope explained that EPA determined that several uses of formaldehyde were outside the scope of TSCA. When developing the draft risk evaluation, EPA concluded that some subcategories of the conditions of use listed in the final scope are either excluded from the TSCA § 3(2) definition of "chemical substance" or not actually circumstances under which formaldehyde is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. Therefore, EPA removed those subcategories from the risk evaluation. Table 2-4 summarizes the changes to the COU subcategory descriptions between publication of the 2020 Final Scope and publication of the 2024 draft risk evaluation. No further changes were made in this regard between the draft and final risk evaluation

Table 2-4. Subcategories Removed from the Risk Evaluation

Life Cycle	Original Subcategory in the 2020	Occurred Change	Revised Subcategory in
Stage and Category	Scope Document		the 2024 Risk Evaluation
Processing; Incorporation into a formulation, mixture, or reaction product	Other: preservative in all other chemical product and preparation manufacturing	Removed	N/A
Industrial Use; non- incorporative activities	Used in: construction and agriculture, forestry, fishing, and hunting	Removed "and agriculture, forestry, fishing, and hunting"	Used in: construction
Commercial Use – chemical substances in treatment/care products	Laundry and dishwashing products; personal care products (covered by TSCA)	Removed "personal care products (covered by TSCA)"	Laundry and dishwashing products
Commercial Use – chemical substances in packaging, paper, plastic, hobby products	Food packaging; paper products; plastic and rubber products; toys, playground, and sporting equipment	Removed "food packaging"	Paper products; plastic and rubber products; toys, playground, and sporting equipment
Commercial Use – chemical substances in products not described by other codes	Laboratory chemicals (<i>e.g.</i> , specimen preservation, medical samples, mortuary science)	Removed "(e.g., specimen preservation, medical samples, mortuary science)"	Laboratory chemicals
Consumer Use – chemical substances in treatment/care products	Laundry and dishwashing products; personal care products (covered by TSCA)	Removed "personal care products (covered by TSCA)"	Laundry and dishwashing products

These activities were removed from the scope of the risk evaluation because they did not meet the definition of "chemical substance" and instead, aligned with the Federal Insecticide, Fungicide, and Rodenticide Act or the Federal Food, Drug, and Cosmetic Act, or because they were determined not to

be circumstances under which formaldehyde is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. Each activity is listed below under each respective jurisdiction for clarity.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

TSCA section 3(2)(B)(ii) excludes from the "chemical substance" definition "any pesticide (as defined in [FIFRA]) when manufactured, processed, or distributed in commerce for use as a pesticide." Activities determined to be pesticidal uses under FIFRA include:

- Processing incorporation into a formulation, mixture, or reaction product "other: preservative in all other chemical product and preparation manufacturing" was removed after EPA determined that this is a pesticidal use under FIFRA. These preservative products meet the definition of "pesticide" under FIFRA (7 U.S.C. § 136(u)) and are therefore excluded from the TSCA § 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for these uses. (Related: see Commercial Use laboratory chemicals "specimen preservation, medical samples, mortuary science" below).
- Commercial Use laboratory chemicals "specimen preservation, medical samples, mortuary science" were removed as listed examples because these terms encompass pesticidal uses under FIFRA. Specifically, EPA has identified the following types of products as pesticides that are exempt from the requirements of FIFRA: embalming fluids; products used to preserve animal or animal organ specimens, in mortuaries, laboratories, hospitals, museums and institutions of learning; and products used to preserve the integrity of milk, urine, blood, or other body fluids for laboratory analysis (see 40 CFR 152.25(c); 53 FR 15952, 15977 (May 4, 1988)). These products meet the definition of "pesticide" under FIFRA (7 U.S.C. § 136(u)) and are therefore excluded from the TSCA § 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for these uses. Other uses of formaldehyde as a laboratory chemical remain within the scope of the TSCA risk evaluation, such as fixative use for slide preparation. Formaldehyde can be used in commercial laboratories for microscope slide preparation and is used to bind proteins in order to make cells or tissues more structurally solid in the short term. For example, an animal cell may be mobile on a glass slide so a fixative that contains formaldehyde could be applied to that slide so the cell is no longer mobile. EPA has determined that these fixative purposes are in scope because this use is considered nonpesticidal. Use for slide preparation could potentially have a short-term fixative (nonpreservation) purpose if there is not also an intent to preserve the tissue for later analysis.

Federal Food, Drug, and Cosmetic Act (FFDCA)

TSCA section 3(2)(B)(vi) excludes from the "chemical substance" definition "any food, food additive, drug, cosmetic, or device (as such terms are defined in . . . 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." Activities determined to be uses under FFDCA or not to be intended, known, or reasonably foreseen beyond the scope of the FFDCA exclusion include:

• Industrial Use - non-incorporative activities - "agriculture, forestry, fishing, and hunting" was removed after EPA determined that this is not a circumstance under which formaldehyde is intended, known, or reasonably foreseen to be used. Based on additional information provided by the submitter of the 2016 CDR submission identifying this subcategory, EPA believes that the correct interpretation of the submission is of an incorporative activity involving the use of formaldehyde in the manufacture of animal feeds for agriculture and aquaculture/hatchery usage

(Bakelite EPA-HQ-OPPT-2018-0438-0134). Use of formaldehyde in animal feed meets the definition of a food, food additive, or drug under the FFDCA (21 U.S.C. § 321) and is therefore excluded from the TSCA § 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for that use. For example, FDA currently regulates the use of formaldehyde as a food additive in the manufacture of certain animal feeds under 21 CFR § 573.460 and as an animal drug (Formalin) to control external parasites on hatchery fish and their eggs under 21 CFR § 529.1004.

- Commercial and Consumer Uses "personal care products (covered by TSCA)" under the "laundry and dishwashing products; personal care products (covered by TSCA)" was removed because, upon further investigation, EPA did not identify any formaldehyde-containing personal care products covered by TSCA. Many personal care products meet the definition of cosmetic, drug, or device under the FFDCA (21 U.S.C. § 321) and are therefore excluded from the TSCA § 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for those uses. As noted in the final scope document for formaldehyde, such products subject to FDA's jurisdiction were excluded from the final scope, and could include eyelash adhesives, hair treatments, moisturizers, mouthwashes, hand cleaning creams, shampoos, conditioners, deodorants, certain nail treatments, perfumes and fragrances, shaving creams, and certain body cleansers containing synthetic detergents.
- Commercial Use "food packaging" under the "food packaging; paper products; plastic and rubber products; toys, playground, and sporting equipment" was removed because EPA determined that the "food packaging" meets the definition of food additive under the FFDCA (21 U.S.C. § 321(s)) and is therefore excluded from the TSCA definition of "chemical substance" when manufactured, processed, or distributed in commerce for that use.

2.2.1 Industries Affected by Activities Determined Not to Be Conditions of Use

Section 2.2.2 of the 2020 Final Scope explained that EPA determined that several uses of formaldehyde were outside the scope of TSCA or were not considered. Consistent with the draft risk evaluation, this unit provides clarifications and details for certain uses outside the scope of TSCA based on public request to explicitly state which uses will not be covered under the formaldehyde risk evaluation.

Aquaculture, Hatchery, and Animal Feeds

In the 2020 Final Scope, EPA explained TSCA Section 3(2) 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." EPA is clarifying that the use of formaldehyde in animal feed or as an animal drug meets the definition of a "food, food additive, [or] drug," respectively, under the FFDCA (21 U.S.C. § 321), and is therefore excluded from the TSCA § 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for that use. For example, FDA regulates the use of formaldehyde as a food additive in the manufacture of certain animal feeds under 21 CFR § 573.460, and as an animal drug (formalin) to control external parasites on hatchery fish and their eggs under 21 CFR § 529.1004.

Embalming and Taxidermy

In the 2020 Final Scope EPA explained TSCA Section 3(2) also excludes from the definition of "chemical substance" "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." Products intended for use as a preservative for biological specimens in embalming and

taxidermy are considered pesticides under FIFRA. EPA has identified the following types of products as pesticides that are exempt from the requirements of FIFRA: embalming fluids; products used to preserve animal or animal organ specimens, in mortuaries, laboratories, hospitals, museums and institutions of learning; and products used to preserve the integrity of milk, urine, blood, or other body fluids for laboratory analysis (see 40 CFR 152.25(c); 53 FR 15952, 15977, (May 4, 1988)). Because these products meet the definition of "pesticide" under FIFRA (7 U.S.C. § 136(u)), such formaldehydecontaining products are therefore excluded from the TSCA § 3(2) definition of "chemical substance" when manufactured, processed, or distributed in commerce for these uses.

Because embalming and taxidermy products intended for preservation of biological specimens are considered pesticides under FIFRA and because FIFRA has a specific exemption for pesticides used for biological preservation under the circumstances described in 40 CFR 152.25(c), uses that fall within the 40 CFR 152.25(c) exemption from regulation under FIFRA are not covered by either the Office of Pesticide Programs formaldehyde registration review under FIFRA or by OPPT in this TSCA risk evaluation.

2.2.2 Biogenic Sources of Formaldehyde Not Considered as Conditions of Use

EPA does not consider biogenic formation of formaldehyde, such as emissions from trees, plants, and soil microbes, to be conditions of use under TSCA section 3(4). The biogenic formation can significantly contribute to total formaldehyde concentration in ambient air. For purposes of this TSCA risk evaluation for formaldehyde, some of the data used in the ambient air exposure assessment includes the biogenic formation and other sources of formaldehyde.

2.3 Secondary Formation of Formaldehyde and Certain Combustion Sources

Formaldehyde can be emitted from many types of combustion. In indoor settings these can include burning candles, tobacco smoke, fireplaces and household appliances. These sources can also include tailpipe emissions (including cars, trucks and boats), emissions from outdoor fires (including wildfires, prescribed fires and agricultural burning), and emissions from industrial sources. Some combustion activities that produce formaldehyde could occur during the manufacture, processing, use or disposal of another chemical substance(s) or mixture(s).

Significant concentrations of formaldehyde are also found in the environment due to secondary formation of the chemical after degradation of other compounds, for example when a different chemical undergoes chemical reactions in the air and forms formaldehyde.

Combustion sources and secondary formation of formaldehyde are so abundant and likely result in cooccurring exposures. For purposes of this TSCA risk evaluation for formaldehyde, EPA considered ambient (outdoor) and indoor air monitoring data that is expected to represent formaldehyde concentrations attributable to a variety of sources, which may include secondary formation and/or combustion, including, data related to short term and long-term exposures to people living or working near facilities releasing formaldehyde (fenceline populations).

2.4 Additions to the Scope Pertaining to Exposure Pathways and Risks Addressed by Other EPA-Administered Statutes

Section 2.6.3.1 of the 2020 Final Scope explained that EPA would not consider certain exposure pathways and risks addressed by other EPA-administered statutes. As first announced on June 30, 2021, and codified by regulation at 40 CFR 702.39(d)(9) in 2024, EPA is no longer excluding exposure

pathways that are addressed under other EPA-administered statutes or regulatory programs from the scope of TSCA risk evaluations. As explained in the preamble to the final rule, *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act* (89 FR 37028, May 3, 2024), EPA reconsidered the text of the relevant statutory provisions, overarching statutory structure and context, and legislative history, and no longer interprets the law to authorize exclusion of exposure pathways from the scope of TSCA risk evaluations because other EPA offices have already or could in the future regulate those chemicals. Accordingly, consistent with the draft risk evaluation, EPA has included in the final formaldehyde risk evaluation the exposure pathways described below and in Section 2.6.3.1 of the 2020 Final Scope.

Composite Wood Products Under TSCA Title VI

EPA stated in the 2020 Final Scope that the Agency had 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 (40 CFR part 770, promulgated under TSCA Title VI), would not be included in the scope of the risk evaluation. Since the 2020 Final Scope's publication, EPA has now included exposure pathways that are addressed under other EPA-administered statutes or regulatory programs in the scope of TSCA risk evaluations. Therefore, all composite wood products, including those regulated under TSCA Title VI, are included in the formaldehyde risk evaluation.

EPA determined that excluding TSCA Title VI regulated composite wood products from the formaldehyde risk evaluation would reduce the comprehensiveness of the risk evaluation and introduce complexities and uncertainties due to the regulated vs. non-regulated materials that may be present in a finished good in indoor environments.

Regulated composite wood products under TSCA Title VI include hardwood plywood, medium density fiberboard, and particle board. These products and articles are included in the following COUs:

- Commercial use in floor coverings; foam seating and bedding products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; cleaning and furniture care products; leather conditioner; leather tanning, dye, finishing, impregnation and care products; textile (fabric) dyes; textile finishing and impregnating/surface treatment products;
- Commercial use in construction and building materials covering large surface areas, including wood articles; construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles;
- Consumer use in floor coverings; foam seating and bedding products; cleaning and furniture care products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles;
- Consumer use in construction and building materials covering large surface areas, including wood articles; construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles.

Exposure Pathways from Ambient Air, Drinking Water, Onsite Releases to Land, Disposal and Soil The formaldehyde risk evaluation includes exposure pathways from ambient air, drinking water, onsite releases to land, disposal and soil that were described in Section 2.6.3.1 of the 2020 Final Scope document. The conceptual model depicted in Figure 2-15 of the 2020 Final Scope document has been updated in Figure 1-7 of the Human Health Risk Assessment for Formaldehyde to reflect the exposure

pathways, exposure routes and hazards to human receptors from releases and wastes from industrial, commercial, and consumer uses of formaldehyde that EPA considered in the risk evaluation.

2.5 Clarification Regarding Consideration of Formalin and Paraformaldehyde in the Risk Evaluation

Formalin

Formaldehyde is a gas that is distributed in solution as formalin. Formalin is a formulation of formaldehyde in aqueous solution and is composed of three components – formaldehyde, methanol, and water. It occurs as a colorless liquid at room temperature. Therefore, formalin was assessed as a part of the formaldehyde risk evaluation under the TSCA conditions of use as listed in Table 2-1. It should be noted that certain uses of formalin, such as the use as an animal drug as defined in the FFDCA to control external parasites on hatchery fish and their eggs, are excluded from the TSCA § 3(2) definition of "chemical substance" and therefore not included in the risk evaluation.

Paraformaldehyde

Paraformaldehyde was not assessed since it is considered a different chemical substance, with a different CAS number (30525-89-4), and not prioritized or included in the *Final Scope of the Risk Evaluation for Formaldehyde (HCHO); CASRN 50-0-0.*

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Appendix A DESCRIPTION OF CONDITIONS OF USE

The following descriptions are intended to include examples of uses, so as not to exclude other activities that may also be included in the COUs of the chemical substance. To better describe the COU, EPA considered CDR submissions from the last two CDR cycles for formaldehyde (CASRN 50-00-0), public comments submitted on the draft scope and draft risk evaluation, and stakeholder meetings. The COU descriptions reflect what EPA identified as the best fit for each type of submission and information. Examples of articles, products, or activities are included in the following descriptions to help describe the COU but are not exhaustive. EPA uses the terms "articles" and "products" or product mixtures in the following descriptions and is generally referring to articles and products as defined by 40 CFR 751.5. There may be instances where the terms are used interchangeably by a company or commenters, or by EPA in reference to a code from the CDR reports which are referenced, *e.g.* "plastic products manufacturing," or "fabric, textile, and leather products." EPA will clarify as needed when these references are included throughout the COU descriptions below.

A.1 Manufacturing – Domestic Manufacturing

Domestic manufacturing means to manufacture or produce formaldehyde within the United States. For purposes of the formaldehyde risk evaluation, this includes the extraction of formaldehyde from a previously existing chemical substance or complex combination of chemical substances and loading and repackaging (but not transport) associated with the manufacturing, production of formaldehyde. This condition of use includes the two commonly used manufacturing processes described below. 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 (Kralj, 2015; Gerberich and Seaman, 2013; NICNAS, 2006; U.S. EPA, 1991; ICFI, 1984; IARC, 1982; NIOSH, 1981a). Both processes mix preheated air with vaporized methanol, feed the gaseous mixture into a reactor, cool the reactor products, and then separate the products through absorption towers and distillation columns to recover an aqueous formaldehyde solution (Gerberich and Seaman, 2013; NICNAS, 2006; ICFI, 1984). 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 percent of newly installed formaldehyde production capacity uses the metal oxide process (Gerberich and Seaman, 2013). Methanol arrives at the facility in tank trucks or railroad tank cars and is transferred to a large bulk storage tank, where it is then pumped to a methanol vaporizer (NICNAS, 2006; Dunn et al., 1983b; Dunn et al., 1983a; Monsanto Research Corp, 1981). The manufacture of formaldehyde is typically an enclosed continuous process.

A.2 Manufacturing – Importing

Import refers to the import of formaldehyde into the customs territory of the United States. This condition of use includes loading/unloading and repackaging (but not transport) associated with the import of formaldehyde. Commodity chemicals such as formaldehyde may be imported into the United States in bulk via water, air, land, and intermodal shipments. These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and intermodal tank containers. Common formaldehyde grades include formulations of 37, 44, 50, and 56 by wt% (Kralj, 2015; Gerberich and Seaman, 2013; NIOSH, 1986; Dunn et al., 1983b; Monsanto Research Corp, 1983; IARC, 1982; NIOSH, 1981a).

A.3 Processing – Reactant – Adhesives and Sealant Chemicals in: Plastic and Resin Manufacturing; Wood Product Manufacturing; Paint and Coating Manufacturing; Basic Organic Chemical Manufacturing

This COU refers to the use of a chemical substance in chemical reactions for the manufacturing of another chemical substance or product. In this case, formaldehyde is used as a feedstock in the production of another chemical substance in which formaldehyde is consumed during the chemical reaction. This COU includes the use of formaldehyde in several sectors, including as an adhesive and sealant chemical in plastic and resin manufacturing, wood product manufacturing, paint and coating manufacturing, and basic organic chemical manufacturing.

The most common use of formaldehyde in processing as a reactant is in resin manufacturing. In the manufacturing of resins using formaldehyde, formaldehyde arrives at the site in the form of formalin, a solution that typically consists of 37 to 40 percent formaldehyde (NIOSH, 1981d). However, EPA expects that the concentration of formaldehyde for each process where formaldehyde is processed under processing as a reactant will vary depending on the desired final product. The processing typically begins with the input components being charged into the reactor at concentrations and temperatures necessary to meet customer specifications. The raw materials used in the reaction will vary depending on the desired resin. As an example, raw materials for phenol formaldehyde resins may include formalin, phenol, sodium hydroxide, concentrated sulfuric acid, hexamethylenetetramine (HMT), ethanol, methanol, and xylene (NIOSH, 1981c). Some examples of products produced in which formaldehyde is consumed during the reaction include: urea-formaldehyde resins; hexamethylenetetramine; phenol-formaldehyde resins; pentaerythritol; acetal resins; 1,4-butanediol; melamine-formaldehyde resins; other acetylenic chemicals; chelating agents; urea-formaldehyde concentrates; trimethylol propane; 4,4-methylenedianiline; acrylic esters; pyridine compounds, and nitroparaffins.

A.4 Processing – Reactant – Intermediate in: Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing; Petrochemical Manufacturing; Soap, Cleaning Compound, and Toilet Preparation Manufacturing; Basic Organic Chemical Manufacturing; Plastic Materials and Resin Manufacturing; Adhesive Manufacturing; Chemical Product and Preparation Manufacturing; Paper Manufacturing; Paint and Coating Manufacturing; Plastic Products Manufacturing; Synthetic Rubber Manufacturing; Wood Product Manufacturing; Construction; Agriculture, Forestry, Fishing, and Hunting

This COU refers to the use of a chemical substance in chemical reactions for the manufacturing of another chemical substance or product. In this case, formaldehyde is used as a feedstock or intermediate in the production of another chemical product via a chemical reaction in which formaldehyde is consumed to form the product, and that final product does not have any traces of formaldehyde. This condition of use encompasses the use of formaldehyde as an intermediate in the following industrial sectors: pesticide, fertilizer, and other agricultural chemical manufacturing; petrochemical manufacturing; soap, cleaning compound, and toilet preparation manufacturing; basic organic chemical manufacturing; plastic materials and resin manufacturing; adhesive manufacturing; chemical product and preparation manufacturing; paper manufacturing; paint and coating manufacturing; plastic products manufacturing; synthetic rubber manufacturing; wood product manufacturing; construction; agriculture, forestry, fishing, and hunting.

A public comment from The Fertilizer Institute states that the most common formaldehyde-based reactant (FBR) used to produce urea is urea-formaldehyde concentrate (CAS No. 9011-05-6). The typical concentration for this FBR is 60% formaldehyde, 25% urea, and 15% water. For the manufacturing of formaldehyde-based fertilizers, FBRs are received onsite in stabilized water solutions via tank trucks which are pumped into storage. The FBRs are often stored in bulk warehouses containing up to 100,000 tons of urea. Slow-release urea solid fertilizer products are packaged in 25-1,000 kg bags, and triazone fertilizer products are packaged in 275-gallon totes.

A.5 Processing – Reactant – Functional Fluid in: Oil and Gas Drilling, Extraction, and Support Activities

This COU refers to the use of a chemical substance in chemical reactions for the manufacturing of another chemical substance or product. In this case, formaldehyde is used as a feedstock in the production of another chemical substance.

This COU is referring to the use of formaldehyde in the production of functional fluids for oil and gas drilling activities. A functional fluid is a fluid which can be used for both open and closed systems. After the reaction, it is expected that formaldehyde remains as a component of certain functional fluids in hydraulic fluids used for oil and gas drilling activities.

A.6 Processing – Reactant – Processing Aids, Specific to Petroleum Production in Basic Chemical Manufacturing

This COU refers to the use of a chemical substance in chemical reactions for the manufacturing of another chemical substance or product. In this case, formaldehyde is used as a feedstock in the production of another chemical product in which formaldehyde is consumed during the chemical reaction.

This COU is referring to the use of formaldehyde in the production of products that are then used as a processing aid during petroleum production for the manufacturing of other chemicals.

A.7 Processing – Reactant – Bleaching Agent in Wood Product Manufacturing

This COU refers to the use of a chemical substance in chemical reactions for the manufacturing of another chemical substance or product. In this case, formaldehyde as a feedstock in the production of another chemical product via a chemical reaction in which formaldehyde is consumed to form the product.

This COU is referring to the use of formaldehyde in the production of bleaching aids for wood product manufacturing. Wood bleaching is the process of treating wood and woody pulps with chemical agents that contain formaldehyde to increase the brightness of the pulp by removing lignin. This COU was not reported in the 2020 CDR.

A.8 Processing – Reactant – Agricultural Chemicals in Agriculture, Forestry, Fishing, and Hunting

This COU refers to the use of a chemical substance in chemical reactions for the manufacturing of another chemical substance or product. In this case, formaldehyde is used as a feedstock in the production of another chemical product in which formaldehyde is consumed during the chemical reaction. Use of formaldehyde in agricultural products accounts for approximately 2-5% percent of total formaldehyde production volume.

This COU is referring to the use of formaldehyde as an intermediate in the production of agricultural chemicals and includes the use of formaldehyde during the manufacturing of urea. Urea is primarily an

agricultural product used in fertilizer mixtures and animal feed supplements. Formaldehyde is injected into the urea product during the coating process and reacts to form methylenediurea, which is a conditioning agent. Urea-formaldehyde is used in the manufacture of controlled-release fertilizers, which release nutrients at a constant rate over time. End users of controlled-release fertilizers include agricultural, horticultural, landscaping, and consumer markets. Urea-formaldehyde concentrates comprise approximately 80% of the slow-release fertilizer market.

A.9 Processing – Incorporation into an Article – Finishing Agents in Textiles, Apparel, and Leather Manufacturing

This COU refers to the preparation of an article, meaning formaldehyde becomes an integral component of the article after its manufacture for distribution in commerce. In this case, formaldehyde is used as a finishing agent in textile processing. Formaldehyde can be either used alone, together with other reagents such as softeners or wetting agents, or in the form of simple formaldehyde derivatives (NIOSH, 1981b; Hovding, 1959). Resins containing formaldehyde are used as cross-linking agents and can impart beneficial characteristics upon fabric such as wear and crease resistance, water repellency, increased fabric resistance, and aiding in dye fixation (NICNAS, 2006; Cornwell, 1988; NIOSH, 1984a, 1981b). Textile finishing can be divided into three main steps: fabric pretreatment (e.g., washing, bleaching, desizing); coloring; and functional finishing (OECD, 2004; Bendix Corp, 1979). Formaldehyde is only included in the functional finishing. During the finishing process, resins containing formaldehyde are combined with catalysts and cured in ovens at high temperatures to form the "permanent-press" treatment of fabrics. Formaldehyde has been identified as a preservative, finishing agent, and fixing agent in leather tanning (U.S. EPA, 2020b; Cuadros et al., 2016; NICNAS, 2006; U.S. EPA, 2001). Tanning is a general term for the processing steps involved in converting animal hides or skins to leather (OECD, 2004). In the case of white sheepskin tanning, commercial grade formaldehyde (11%) is added to the depickled skins in a drum and allowed to sit overnight (Hernon, 1981).

A.10 Processing – Incorporation into an Article – Paint Additives and Coating Additives Not Described by Other Categories in Transportation Equipment Manufacturing (Including Aerospace)

This COU refers to the preparation of an article meaning formaldehyde becomes an integral component of the article after its manufacture for distribution in commerce. In this case, the use of formaldehyde in paints and coatings for transportation equipment manufacturing, including formaldehyde present in trace amounts in raw materials used for adhesives and sealants in the aerospace industry (NASA, 2020; ACA, 2019; AIA, 2019). Formaldehyde is also in synthetic latex resins and is found in fluorescent pigments. The concentration of formaldehyde in the final product may range from 0.1 to 1 percent, although formulators expect the actual concentration of formaldehyde to be lower (ACA, 2019). However, submitters in the 2020 CDR indicated 1 to 30 percent maximum concentration for two-component glues (U.S. EPA, 2020a). A typical process begins with liquid formulations being manually poured from transport containers directly into a coating reservoir (OECD, 2015b). Solid formulations received are loaded directly into dispensing equipment. The application procedure depends on the type of adhesive or sealant formulation and the type of substrate. Typically, the formulation is loaded into the application reservoir or dispensing equipment and applied to the substrate via spray, roll, curtain, syringe, or bead application.

According to a public comment, formaldehyde may also be present in trace amounts in most raw materials used in paints and coatings with a range from 0.1 to 1 percent (EPA-HQ-OPPT-2018-0438-0004) (ACA, 2019). A public comment indicates the use of formaldehyde in a wide range of coatings, such as primers, topcoats, varnishes, lacquers, and specialty coatings (EPA-HQ-OPPT-2018-0438-0006)

(AIA, 2019).

Spray application of paints and coatings containing formaldehyde are utilized in the automotive refinishing industry (OECD, 2011a). Various coating products such as hardeners, reducers, activators, atomizing agents, or colorants may be blended into their final formulations according to the paint manufacturer's specifications before application.

A.11 Processing – Incorporation into an Article – Additive in Rubber Product Manufacturing

This COU refers to the preparation of an article meaning formaldehyde becomes an integral component of the article after its manufacture for distribution in commerce. In this case, formaldehyde and formaldehyde resins have several uses in the rubber and elastomer manufacturing industry including as a vulcanizing agent which is a cross-linking of rubber with sulfur to make a product stronger, as a preservative and coagulant for rubber latex, as an anti-oxidizer and curing agent for synthetic rubber, as a tackifier which makes the rubber more sticky to help with the binding process, and as a reinforcing resin for other rubber-based materials (U.S. EPA, 2023; USTMA, 2020, 2019; Gunter, 1977; NIOSH, 1973). In tire manufacturing, formaldehyde-based resins are used as crosslinking agents or to build adhesion between different tire components. Formaldehyde may also be in coatings on fabric belts (USTMA, 2019).

During tire manufacturing, low levels of formaldehyde are present in reinforcing and tackifying resins (<u>USTMA</u>, <u>2020</u>, <u>2019</u>). The formaldehyde resins are incorporated into the tire compound during mixing, which may occur at tire manufacturing facilities or separate mixing facilities. According to a public comment any formaldehyde present in the resins is expected to be fully consumed during curing (<u>USTMA</u>, <u>2020</u>, <u>2019</u>; <u>U.S. EPA</u>, <u>1995</u>).

Formaldehyde is also used during high-pressure hose manufacturing, which is used by the automotive, oil, and farming industries (<u>Gunter, 1977</u>; <u>NIOSH, 1973</u>). During rubber hose manufacturing, rayon or polyester cords are treated by a rewinder. The rewinding process involves dipping the cord into a solution containing formaldehyde. After the cord is treated with formaldehyde, a rubber hose is fed into a braiding machine. The braiding machine reinforces the rubber hose by braiding the treated cord around the rubber hose (<u>Gunter, 1977</u>; <u>NIOSH, 1973</u>).

A.12 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 (Including Roofing Materials); Paper Manufacturing

This COU refers to the preparation of an article meaning formaldehyde becomes an integral component of the article after its manufacture for distribution in commerce. In this case, formaldehyde resins are incorporated into adhesives used to manufacture composite wood products (NICNAS, 2006; Van der Wal, 1982). These products include but are not limited to particleboard, fiberboard, oriented strand board, and plywood (Solenis, 2020; NICNAS, 2006; Van der Wal, 1982). Concentrations of formaldehyde in the resins used to manufacture these products range from less than 0.2 to 0.5 percent.

The process of incorporating formaldehyde resins into wood products involves injecting the resins with refined wood fiber, mixing, then rolling and pressing the wood product (NICNAS, 2006; Saary et al.,

2001; NZ DOH, 1981; Breysse, 1980). Types of formaldehyde resins used include urea, phenol, melamine, or a combination of these resins (NICNAS, 2006). In the case of plywood, the formaldehyde resins are pumped into glue spreaders and applied to the veneer using rollers, which are then pressed (NICNAS, 2006; Breysse, 1980). The manufacture of compressed wood products is an automated process (Sussell, 1995). Compressed wood products can be used in several construction applications, such as residential buildings, commercial and industrial structures, furniture, and material handling such as pallets (NICNAS, 2006; Sussell, 1995).

Formaldehyde is a constituent in pre-impregnated materials used to manufacture composite materials such as fibrous insulation, asphalt roofing, and composite panels (ARMA, 2019; NAIMA, 2019; NICNAS, 2006). Pre-impregnated materials include reinforcement fibers loaded with a partially cured resin (AIA, 2024). Fiber glass and mineral wool building insulation products typically contain 3 to 6 percent by weight cured formaldehyde binder (NAIMA, 2019). During fiberglass or mineral wool insulation manufacturing, aqueous solutions of formaldehyde resin are sprayed onto fibers. The fibers are then sent to a curing oven, in which the binder is thermally set. According to public comment, virtually all free formaldehyde content is eliminated during the curing process (EPA-HQ-OPPT-2018-0438-0008).

Urea-formaldehyde resins are incorporated into fiberglass mats used for asphalt roofing (ARMA, 2019). During the manufacture of fiberglass mats, a binder solution containing formaldehyde resin is uniformly applied to the surface of fiberglass mats. A vacuum removes excess binder solution for re-use. The mat is then passed through drying and curing ovens to remove moisture and set the binder (ARMA, 2019). Asphalt roofing manufacturing typically involves the following processes: coating, mineral surfacing, cooling, drying, product finishing, and packaging (ARMA, 2019; Apol and Okawa, 1977).

Finished fiberglass mats may be further incorporated into gypsum wallboard. During gypsum wallboard production, a gypsum slurry is fed between continuous layers of fiberglass mats to create reinforced boards. The gypsum slurry recrystallizes as the reinforced boards move down a conveyor belt. The boards are then cut to length and sent through dryers.

Formaldehyde resins are incorporated into adhesives and sizing agents used in the manufacturing and finishing of paper products (Robinson et al., 1986). Paper manufacturing often takes place in the same plant where pulp is produced (Robinson et al., 1986). The pulp product is mixed with water and additives such as sizing agents which can include formaldehyde compounds. The pulp slurry is then formed into sheets, then dried and coated. Formaldehyde can also be present in the final coating applied to the paper product (Apol and Thoburn, 1986).

Formaldehyde is also a raw material in the manufacturing of polyoxymethylene (POM). POM is a specialized, engineered polymer in which formaldehyde is used as an upstream ingredient and can be found in a wide range of automobile products including interiors such as seatbelts, buckles, door trims, and dashboards. In general, for the manufacturing of plastic articles, polymer resin is typically received at the compounding sites from the resin manufacturer in the form of pellets. The plastic resins are then typically heated and formed into products through extrusion, thermoforming, compression molding, calendaring, and encapsulation. After the heating and forming processes, the plastic may be further processed and molded into the finished product. These molding processes can include injection molding, transfer molding, compression molding, blow molding, and rotational molding. The final plastic product manufacturing operations are usually finishing and trimming. Solid waste from this process is typically sent to landfill or incineration (U.S. EPA, 2004a).

A.13 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Petrochemical Manufacturing, Petroleum, Lubricating Oil and Grease Manufacturing; Fuel and Fuel Additives; Lubricant and Lubricant Additives; Basic Organic Chemical Manufacturing; and Petroleum and Coal Products Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is used in the manufacturing of various petrochemicals, petroleum, and coal products, lubricating oils and greases, and organic chemicals.

A.14 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Asphalt, Paving, Roofing, and Coating Materials Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is incorporated into asphalt, paving, roofing, and coating material products. In addition, this COU includes the incorporation of formaldehyde into a urea-formaldehyde resin that is used in the manufacturing of glass fiber roofing mats in order to bind the fiberglass fibers. Formaldehyde is also incorporated into hot asphalt products used for paving and as a base structure for roofing mats (EPA-HQ-OPPT-2023-0613-0241).

A.15 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Solvents (Which Become Part of a Product Formulation or Mixture) in Paint and Coating Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is incorporated into a variety of paints and coatings, including lacquers, stains, varnishes, primers, topcoats, and specialty coatings. Functional uses of formaldehyde in the manufacture of paints and coatings include as an ion exchange agent and solvent (which become part of the final product).

A.16 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Processing Aids, Specific to Petroleum Production in: Oil and Gas Drilling, Extraction, and Support Activities; Chemical Product and Preparation Manufacturing; and Basic Inorganic Chemical Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is incorporated into products that then are used as processing aids specific to petroleum production such as oil and gas drilling, extraction, and support activities, chemical product and preparation manufacturing, and basic inorganic chemical manufacturing. Processing aid means any chemical substance used to aid in the manufacture or synthesis of another chemical substance such that it comes into contact with the product during manufacture but is not intended to remain with or become part of the final product or mixture. Formaldehyde is also

incorporated into corrosion inhibitors and anti-scaling agents for oil and gas drilling, extraction, and other related support activities.

A.17 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Paint Additives and Coating Additives Not Described by Other Categories in: Paint and Coating Manufacturing; Plastic Material and Resin Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is incorporated into a variety of paints and coatings, including lacquers, stains, varnishes, primers, topcoats, and specialty coatings. Functional uses of formaldehyde in the manufacture of paints and coatings include: as a paint additive and coating additive, as a hardener, as a corrosion inhibitor, and as a diluent.

A.18 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Intermediate in: Basic Chemical Manufacturing; Chemical Product and Preparation Manufacturing; Plastic Material and Resin Manufacturing; Oil and Gas Drilling, Extraction, and Support Activities; Wholesale and Retail Trade

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. An intermediate means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions. In this case, formaldehyde is incorporated into an intermediate product that then is used in the manufacturing of other chemical substances, plastic and resin manufacturing, and for use in oil and gas drilling activities.

A.19 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Solid Separation Agents in Miscellaneous Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is incorporated into a solid separation agent product. The formaldehyde-containing product then is added to a chemical mixture in which solid materials are then separated from that mixture in order to recover certain substances or reduce waste. This COU was not reported in the 2016 or 2020 CDR.

A.20 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Agricultural Chemicals (nonpesticidal) in: Agriculture, Forestry, Fishing, and Hunting; Pesticide, Fertilizer, and Agricultural Chemical Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is incorporated into nonpesticidal

agricultural chemicals for uses in agriculture, forestry, fishing, and hunting, and pesticide, fertilizer, and agricultural chemical manufacturing.

Formaldehyde is used in agricultural products which accounts for approximately 2-5% percent of total formaldehyde consumption. In this case, formaldehyde is incorporated into formulation, mixture, or reaction product, that then is used in the manufacturing of fertilizers.

A.21 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Surface Active Agents in Plastic Material and Resin Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is incorporated into a surface-active agent for plastic and resin manufacturing. The surface-active agent containing formaldehyde is added during the manufacturing process to decreases the surface tension.

A.22 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Ion Exchange Agents in Adhesive Manufacturing and Paint and Coating Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is incorporated into an ion exchange agent for adhesive, paint, and coating manufacturing. Formaldehyde is used in liquid solutions in order to absorb positively or negatively charged ions from an aqueous electrolyte solution and, simultaneously, release other ions of equivalent amount into the aqueous solution.

A.23 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Lubricant and Lubricant Additive in Adhesive Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is used as a lubricant in adhesive manufacturing.

A.24 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Plating Agents and Surface Treating Agents in Chemical Product and Preparation Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is used as a plating agent and surface treating agent in chemical product and preparation manufacturing. Formaldehyde is the most widely employed reducing agent in electroless copper plating applications. Formaldehyde is also used as a surface coating and treatment of metals, such as chromatisizing agents, and as a cooling agent for metal processing.

A.25 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Soap, Cleaning Compound, and Toilet Preparation Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is used as a deodorizer for soap and cleaning chemicals used for toilet bowl cleaners and drain cleaners.

A.26 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Laboratory Chemicals

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is added to other substances to produce a laboratory chemical in the medical diagnostic/pathology profession in which formaldehyde acts as a form of fixative. Formaldehyde for laboratory use is typically used at a concentration of at least 1 but less than 30% by weight. Formaldehyde can be used in downstream uses in commercial laboratories for microscope slide preparation and is used to bind proteins in order to make cells or tissues more structurally solid in the short term. For example, an animal cell may be mobile on a glass slide so a fixative that contains formaldehyde could be applied to that slide, so the cell is no longer mobile. Use for slide preparation could potentially have a short-term fixative (non-preservation) purpose if there is not also an intent to preserve the tissue for later analysis.

A.27 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Adhesive and Sealant Chemical in Adhesive Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde's functional use in adhesive and sealant chemical can be as a hardener, as a binding agent, as an ion exchange agent, a lubricant and lubricant additive.

A.28 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Bleaching Agents in Textile, Apparel, and Leather Manufacturing

This COU refers to the preparation of a product in which formaldehyde is added into a formulation, mixture, or a reaction product after its manufacture, but prior to further distribution in commerce of the product containing formaldehyde. In this case, formaldehyde is used as a part of another chemical substance to whiten and brighten cloth fibers. Various concentrations of these chemicals containing formaldehyde may be used to obtain the desired brightness of the final cloth.

A.29 Processing – Repackaging – Sales to Distributors for Laboratory Chemicals

Repackaging refers to the preparation of formaldehyde for distribution in commerce in a different form, state, or quantity than originally received or stored for use as laboratory chemical. This COU can be undertaken by various industrial sectors, including chemical product and preparation manufacturing, wholesale and retail trade, and laboratory chemicals manufacturing.

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, such as repackaging bulk packaging into drums or bottles. The type and size of the container will vary depending on customer requirements. In some cases, quality control 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. This COU includes the transferring of formaldehyde from a bulk container into smaller containers for distribution to professional laboratories. Most repackaging of formalin or product containing formaldehyde are from 200 L drums to smaller containers, such as 5 L and 20 L containers. They are decanted into smaller containers either through a pump (enclosed process) or fed via gravity.

This COU would not apply to the relabeling or redistribution of a chemical substance without removing the chemical substance from the original container it was supplied in.

A.30 Processing – Recycling

This COU refers to the process of treating generated waste streams (*i.e.*, which would otherwise be disposed of as waste), containing formaldehyde, that are collected, either on-site or transported to a third-party site, for commercial purpose.

Formaldehyde may be present during the process of recycling electronic waste (e-waste) as the polymer phenol formaldehyde (PF) is used in electronic applications. The recycling process of e-waste typically begins with the recovery of waste from different storage facilities. The waste then usually undergoes a pretreatment technology consisting of washing, size reduction, sorting, and melt filtration. The sorting of plastics is the typical next step in the process and may use separation techniques such as density-based sorting, electrostatic sorting, and others. The formal recycling process can consist of either a mechanical, chemical or thermal recycling process (Flaris et al., 2009).

A.31 Distribution in Commerce

For purposes of assessment in this risk evaluation, distribution in commerce consists of the transportation associated with the moving of formaldehyde-containing products between sites manufacturing, processing or recycling formaldehyde-containing products, or to final use sites, or for final disposal of formaldehyde-containing products. In this risk evaluation, EPA has assessed the exposure from temporary storage and warehousing of formaldehyde during distribution for commerce. More broadly under TSCA, "distribution in commerce" and "distribute in commerce" are defined under TSCA section 3(5). EPA anticipates that formaldehyde and its products are distributed throughout commerce for the COUs evaluated throughout other lifecycle stages assessed in this evaluation. The physical form of formaldehyde in transit can vary amongst the different COUs. Domestically manufactured commodity chemicals, such as formaldehyde, may be shipped within the United States in liquid cargo barges, railcars, tank trucks, tank containers, intermediate bulk containers (IBCs)/totes, and drums.

A.32 Industrial Use – Non-Incorporative Activities – Process Aid in: Oil and Gas Drilling, Extraction, and Support Activities; Process Aid Specific to Petroleum Production, Hydraulic Fracturing

This COU refers to formaldehyde use in non-incorporative activities, such as a chemical processing aid or manufacturing aid, in various industrial sectors oil and gas drilling and related support activities as well as petroleum production and hydraulic fracturing. 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.

Traditional oil extraction is comprised of four main steps: (1) exploration, (2) well development, (3) petroleum production, and (4) site abandonment. The main activities typically involved in petroleum production are bringing the fluid to the surface and separating each component in the extracted fluid. The extracted mixture is typically first processed to remove the gaseous components, followed by the removal of solids from the resulting emulsion. The remaining oil-water emulsion is then further treated to separate the oil. Petroleum production is typically divided into three stages: primary production, secondary recovery, and tertiary recovery. Primary production is the first stage of production where natural well pressure is used to recover oil. This segment of the production process usually only utilizes maintenance chemicals, such as corrosion inhibitors which contain formaldehyde, to protect metallic components of the piping and well structure. After primary production is no longer feasible, secondary recovery is then employed. This process typically involves the injection of water into the well to repressurize the reservoir. The only chemicals in this stage of the process are those which remain from primary production. Tertiary recovery is the final stage of petroleum production which is typically used only when the other methods have been exhausted. The chemicals involved in this process may include surfactants, friction reducers, gases, acids, and proppants. The goal of this stage is to modify the physical characteristics of the crude oil to make it more conducive to flow (OECD, 2012). Formaldehyde is present in hydraulic fracturing fluid additives as an inhibitor aid, corrosion inhibitor, friction reducer, surfactant, acid, breaker, gelling agent, and crosslinker. (GWPC and IOGCC, 2022). Hydraulic fracturing stimulates an existing oil or gas well by injecting a pressurized fluid containing chemical additives into the well(U.S. EPA, 2022). Hydraulic fracturing fluids typically arrive as a liquid in totes, drums, or bulk containers these formulations are usually charged to a temporary storage tank, or fracturing fluid additives are charged to a mixing tank with other additives to formulate the final fracturing fluid that is injected into the well. Once fracturing fluid is formulated to the desired specification, the injection process may begin(U.S. EPA, 2022). The hydraulic fracturing fluid is pumped into a wellbore where it cracks and permeates the rock below. A portion of the fracturing fluid, including any chemical additives such as formaldehyde, may remain in the underground shale formation. The remaining fluid will return to the surface in water that flows back to the surface from the well. This is known as flow-back water. Initially, this flow-back water is mostly fracturing fluid, which includes chemical additives, but as time goes on, it becomes water produced from the rock formation. Wastewater containing chemical additives such as formaldehyde is usually stored and accumulated at the surface for eventual reuse or disposal. Typical storage facilities include open-air impoundments and closed containers. This wastewater is collected and may be taken to disposal wells, recyclers, wastewater treatment plants (on- or off-site), or in some cases the water may be left in pits to evaporate or infiltrate (U.S. EPA, 2022).

A.33 Industrial Use – Non-Incorporative Activities – Used in: Construction

This COU refers to formaldehyde use in non-incorporative activities, such as a chemical processing aid or manufacturing aid, in construction. A processing or manufacturing aid is a chemical added to a chemical mixture that is used to improve the processing of the chemical mixture or a manufacturing process but does not become part of the reaction product and not intended to affect the function of a substance or article created.

In construction, formaldehyde is used to manufacture an end product or article which does not contain formaldehyde. These industrial uses can include building insulation, concrete and cement, glass products, laminates, furniture, and other miscellaneous construction materials including tiles, wall coverings, bricklaying, plumbing components, and plastic materials.

A.34 Industrial Use – Non-Incorporative Activities – Oxidizing/ Reducing Agent; Processing Aids, Not Otherwise Listed

This COU refers to formaldehyde use in non-incorporative activities, such as a chemical processing aid or manufacturing aid, in various industrial operations not covered by other COUs. 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.

This COU includes the use of formaldehyde as a reducing agent in the electroless copper plating process to reduce copper ions (IPC International, 2019). The electroless copper plating process includes hole formation, hole wall prep, electroless copper hole wall plating, and electrolytic hole wall plating (IPC International, 2019). Formaldehyde is used in the semiconductor manufacturing industry as a processing aid for metal plating formulations (SIA, 2020). Formaldehyde may be present in semiconductor products as a byproduct in concentrations less than 10 ppm. Semiconductor device fabrication creates integrated circuits present in electronic devices. The fabrication process starts with a semiconductor material wafer. During the photolithography step, the wafer is coated with photoresist material and covered with a mask that defines patterns to be retained or removed in the following processing steps. Formaldehyde may be present in the photoresist material utilized in this step of the process (SIA, 2020).

A.35 Industrial Use – Industrial Products – Paints and Coatings; Adhesives and Sealants; Lubricants

This COU refers to formaldehyde used as a component of industrial paints and coatings, adhesives and sealants, and lubricants. Meaning the use of formaldehyde after it has already been incorporated into a paint or coating product or mixture, as opposed to when it is used upstream (*e.g.*, when formaldehyde is processed into the paint or coating, adhesive and sealant formulations).

This COU includes the use of formaldehyde-based phenol resins as liquid binding agents to coat sand that is then used in the core making in the foundry industry (Löfstedt et al., 2011b; NTP, 2010; Oliva-Teles et al., 2009; NICNAS, 2006; RTI, 1980; Kominsky and Stroman, 1977). Castings produced by foundries are used in a wide range of manufactured products. These include vehicles, industrial production equipment, water and wastewater systems, various piping and valves, railcars and locomotives, military equipment and vehicles, and household appliances. The resins generally contain <0.1 to 1 percent free formaldehyde (EPA-HQ-OPPT-2023-0613-0234). The formaldehyde resin arrives at sand coating sites in large drums. The resin is pumped into a mixer and typically mixed with silica sand for 5 minutes. Some sites may decant the resin manually from drums into a measuring cup, then pour it into the mixer. After mixing, the coated sands are decanted into bags for core-making at foundry sites. The sand coating is a batch operation, and the frequency may vary depending on the site. At foundry sites, iron castings are produced for the manufacture of metal products (Löfstedt et al., 2011b; NICNAS, 2006). The coated sand arrives in bags from the sand coating sites and is used to make solid shape "cores," via a binding system. The cores determine the internal cavities of the casting. Cores are primarily produced by hot or warm box technology using urea formaldehyde resin. The sand coated with resin is blown into a hot mold, where the formaldehyde resin melts and acts as a binding agent to form the core. At larger operations, sand coating and core making may take place in an enclosed system, where a set dosage of formaldehyde resin is automatically supplied to core-making machines (Löfstedt et al., 2011b; Löfstedt et al., 2011a; Löfstedt et al., 2009; NICNAS, 2006; NIOSH, 1993).

The urethane cold box process is another widely used process in foundries in the automotive, transportation, mining, agricultural, and military sectors. This process utilizes liquid phenol-

formaldehyde resins. Formaldehyde-containing resins are also used in the following foundry processes: urethane no bake, shell resins, phenolic ester no bake, furan no bake, warm box/hot box, and inorganic cold box, and alkyd no bake. These resins typically contain < 0.1 to 1 percent free formaldehyde (EPA-HQ-OPPT-2023-0613-0234).

This COU also includes activities identified by the U.S. Department of Defense.

This condition of use was not reported in the 2016 or 2020 CDR.

A.36 Industrial Use – Aerospace Use in: Paints and Coatings; Adhesives and Sealants; Lubricants; and Foam Insulation

This COU refers to formaldehyde used as a component of industrial paints and coatings, adhesives and sealants, lubricants, and foam insulation used in aerospace applications. Meaning the use of formaldehyde after it has already been incorporated into a paint or coating product or mixture, as opposed to when it is used upstream (*e.g.*, when formaldehyde is processed into the paint or coating, adhesive and sealant formulations).

This COU includes the use of formaldehyde in the manufacture, operations, and maintenance of aerospace products, specifically in adhesives and sealants for the purpose of sealing specialized fuel tanks. Other activities include formaldehyde in graphite paste, electrical insulators, marking inks, and epoxy and phenolic resins used for the assembly of pre-impregnated fiber composites. Formaldehyde is also in broad uses of coatings such as primers, polyurethane topcoats, adhesive bound primers, wash primers, and other specialty coatings applied to aerospace products such as anti-friction coatings and varnish, cleaners, sheet molding compounds, a brazing alloy protective coating, phenolic fillers, landing gear shock strut fluid, chemical processing agents (including a bath stabilizer, reducing agent, photo resist, calibration/indicator standards), and potting compounds for electronic assemblies. Formaldehyde is also used in the manufacture, operations, and maintenance of aerospace products in lubricants which can include dry film lubricants and lubricating oil (EPA-HQ-OPPT-2023-0613-0199).

Finally, formaldehyde is present in foam insulation to protect and completely cover specific, critical components of a rocket. Referred to as a 'close out' foam because it completely seals these components from the extreme temperatures before, during, and after a launch into space, this foam insulation is manually applied via a spray application.

A.37 Commercial Use – Chemical Substances in Furnishings Treatment/Care Products – Floor Coverings; Foam Seating and Bedding Products; Furniture and Furnishings Including Stone, Plaster, Cement, Glass and Ceramic Articles; Metal Articles; or Rubber Articles; Cleaning and Furniture Care Products; Leather Conditioner; Leather Tanning, Dye, Finishing Impregnation and Care Products; Textile (Fabric) Dyes; Textile Finishing and Impregnating/Surface Treatment Products

This COU is referring to the commercial use of formaldehyde in furnishings treatment and care products. Meaning the use of formaldehyde-containing furnishings treatment and care products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of the treatment products) or use in an industrial setting.

This COU includes several uses of formaldehyde in furniture and furnishings, included the production of wood-based and composite panels. Formaldehyde-based resins are used as adhesives in the production

of wood-based and composite panels including particleboards, medium-density fiberboard (MDF), oriented strand board (OSB), plywood, and blockboards (<u>FWIC</u>, <u>2020</u>; <u>Solenis</u>, <u>2020</u>; <u>Offermann</u>, <u>2017</u>; <u>Kim</u>, <u>2010</u>; <u>NICNAS</u>, <u>2006</u>). Wood panel products may be used for shelving, furniture, doors, cabinets, and flooring. Wood panel products are then used for shelving, furniture, doors, cabinets, and flooring.

A.38 Commercial Use – Chemical Substances in Treatment Products – Water Treatment Products

This COU is referring to the commercial use of formaldehyde in water treatment products. Meaning the use of formaldehyde-containing water treatment products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of the treatment products) or use in an industrial setting.

Formaldehyde is used in water testing kits and as a waste treatment liquid chemical used in wastewater treatment facilities.

Examples of CDR Submissions

In the 2016 CDR cycle, two reporters indicated the commercial use of formaldehyde as a liquid in water treatment products. One facility reported 6 percent of its PV towards this use with a formaldehyde concentration of less than 1 percent by weight. The other facility reported 28 percent of its PV with a concentration of 1 to less than 30 percent by weight (<u>U.S. EPA, 2016</u>).

This COU was not reported in the 2020 CDR cycle.

A.39 Commercial Use – Chemical Substances in Treatment/Care Products – Laundry and Dishwashing Products

This COU is referring to the commercial use of formaldehyde in laundry and dishwashing products. Meaning the use of formaldehyde-containing laundry and dishwashing products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of the treatment products) or use in an industrial setting.

Formaldehyde is used in liquid laundry detergent and fabric softener for laundry facilities in industrial and institutional settings (OECD, 2011b). Industrial laundries wash soiled laundry received from hospitals, repair shops, doctor's offices, and other customers. Institutional laundries are located within a hospital, nursing home, hotel, or other institutional facilities (OECD, 2011b). Industrial laundry detergents typically arrive as a liquid or powder in drums, totes, or bulk tanker trucks.

This COU was not reported in the 2016 or 2020 CDR cycles.

A.40 Commercial Use – Chemical Substances in Construction, Paint, Electrical, and Metal Products – Adhesives and Sealants; Paint and Coatings

This COU is referring to the commercial use of formaldehyde in adhesives, sealants, paint and coatings products. Meaning the use of formaldehyde-containing adhesives, sealants, paint and coatings products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (e.g., when formaldehyde containing products are used in the manufacturing of the construction products) or use in an industrial setting.

Formaldehyde is used in commercial adhesive and sealant products, including craft glues, wood glues, caulking and putty, tile grout and sealer, spackle, and other construction adhesives. Formaldehyde is also used in a variety of paints and coatings, including lacquers, stains, varnishes, primers, topcoats, and specialty coatings.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.41 Commercial Use – Chemical Substances in Construction, Paint, Electrical, and Metal Products – Construction and Building Materials Covering Large Surface Areas, Including Wood Articles; Construction and Building Materials Covering Large Surface Areas, Including Paper Articles; Metal Articles; Stone, Plaster, Cement, Glass and Ceramic Articles

This COU is referring to the commercial use of formaldehyde in furnishing treatment and care products. Meaning the use of formaldehyde-containing furnishing treatment and care products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of the treatment products) or use in an industrial setting.

Formaldehyde-based resins are used as adhesives in the production of wood-based and composite panels including particleboards, medium-density fiberboard (MDF), oriented strand board (OSB), plywood, and blockboards. Plywood is used in several commercial applications, such as the construction of residential, commercial, or industrial structures, building components for homes or other structures, and material handling such as pallets. Wooden boards are cut to size on-site using a circular saw, then fitted and sanded before installation. The lifespan of plywood, veneers, and wood paneling typically ranges from 20-100 years before demolition is required.

Formaldehyde resins may also be present in fiberglass insulation and urea-formaldehyde foam insulation (NAIMA, 2019; Rossiter and Mathey, 1985; Enviro Control Inc., 1983; NIOSH, 1982c, 1980). Final concentrations of formaldehyde in fiberglass insulation may be negligible.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.42 Commercial Use – Chemical Substances in Electrical Products – Machinery, Mechanical Appliances, Electrical/Electronic Articles; Other Machinery, Mechanical Appliances, Electronic/Electronic articles

This COU is referring to the commercial use of formaldehyde in electrical products. Meaning the use of formaldehyde-containing electrical products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of the electrical products) or use in an industrial setting.

Formaldehyde is found in numerous electrical and electronic products, including in printed circuit board materials and in appliances, electric controls, telephones, electrical switches, circuit breakers, and virtually all electronic products (<u>Schripp and Wensing, 2009</u>; <u>LaDou, 2006</u>). Electrical and electronic products may be used in a variety of occupational settings, such as repair shops, office buildings, copy centers, and electronic waste recycling centers (Vicente et al., 2017; Schripp and Wensing, 2009;

<u>Klincewicz and Reh, 1989</u>). The concentration of formaldehyde in electronic products is unknown; although, public comments report a negligible amount of formaldehyde in electronics (<u>IPC International, 2020</u>; SIA, 2020).

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.43 Commercial Use – Chemical Substances in Metal Products – Construction and Building Materials Covering Large Surface Areas, Including Metal Articles

This COU is referring to the commercial use of formaldehyde in metal products. Meaning the use of formaldehyde-containing metal products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of the metal products) or use in an industrial setting.

Formaldehyde and formaldehyde resins are found in metal products and fabricated metal products, including metal finishings such as metal hardware like screws, nails, and bolts. Formaldehyde is also used in the surface coating of certain metal products.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.44 Commercial Use – Chemical Substances in Automotive and Fuel Products – Automotive Articles and Automotive Care Products; Lubricants and Greases; Fuels and Related Products

This COU is referring to the commercial use of formaldehyde in automotive and fuel products. Meaning the use of formaldehyde-containing automotive and fuel products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of the automotive products) or use in an industrial setting.

Formaldehyde and formaldehyde resins are found in a range of automotive products such as interior molded components, under-the-hood components, exterior primers and paints, tire-cord adhesives, brake pads and linings, clutch facings, automatic transmission components, and fuel system components. For automotive care products such as waxes and polishes, they may be applied directly onto the car or application equipment (*e.g.*, cloths, buffer pads), or they may be diluted with water in a bucket before use. For the interior of the vehicle detailers may apply a protective coating to vinyl or leather surfaces by wiping the coating onto surfaces and removing excess coating with cloths. Carpet and upholstery are cleaned by pre-treating stains, then using portable carpet cleaning machines.

Formaldehyde is present in lubricants that may be used in the automotive industry (NICNAS, 2006). A lubricant is defined as a material used to reduce friction between surfaces in relative motion with each other (OECD, 2020). In the automotive industry, lubricants are used in gasoline and diesel engines.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.45 Commercial Use – Chemical Substances in Agriculture Use Products – Lawn and Garden Products

This COU is referring to the commercial use of formaldehyde in agricultural use products. Meaning the use of formaldehyde-containing agricultural products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of the agricultural products) or use in an industrial setting. Formaldehyde is used in the production of three type of fertilizers: solid urea, slow-release urea solid fertilizer, or slow-release urea liquid fertilizers. In both products, formaldehyde is used as a reactant/intermediate in the process with only impurity levels of formaldehyde in fertilizer products. Urea-formaldehyde is found in controlled-release fertilizers used in agricultural, horticultural, landscaping, and consumer markets (ECHA, 2019). The application depends on a variety of factors including crop type, soil type, and climate. Common application techniques include surface broadcasting, incorporation into the soil using attachments to plow, and injection of liquid/gaseous formulations by pumping through cultivator knives (Taylor, 2004). Dry granulated formaldehyde fertilizers are either broadcast or suspended in water and root-zone injected or spray-applied (Koch Turf, 2016).

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.46 Commercial Use – Chemical Substances in Outdoor Use Products – Explosive Material

This COU is referring to the commercial use of formaldehyde in explosive material products. Meaning the use of formaldehyde-containing explosive material products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of the explosive materials) or use in an industrial setting.

Formaldehyde is found in explosive materials such as ground-level pyrotechnics (<u>Croteau et al., 2010</u>). Explosive materials are intended to be used when a worker conducts outdoor pyrotechnic performances. The explosive material is ignited, undergoes a reaction, and explodes (<u>Croteau et al., 2010</u>).

This COU also includes activities identified by the U.S. Department of Defense.

This use was not reported in the 2020 CDR.

A.47 Commercial Use – Chemical Substances in Packaging, Paper, Plastic, Hobby Products – Paper Products; Plastic and Rubber Products; Toys, Playground, and Sporting Equipment

This COU is referring to the commercial use of formaldehyde in packaging, paper, plastic, hobby products, toys, playground equipment, and sporting equipment. Meaning the use of these formaldehyde-containing products and articles in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of these materials) or use in an industrial setting.

Formaldehyde and formaldehyde resins are found in pulp and paper products such as paper, cardboard, wallpaper, and abrasive paper, such as sandpaper, including certain coatings in paper and cardboard (ACC, 2019). Formaldehyde has been identified in carbonless copy paper which may be used in office settings, educational supply stores, and printing shops (NIOSH, 2000; Zimmer and Hadwen, 1993;

NIOSH, 1984b). Formaldehyde can be found in certain plastics used to manufacture toys, playground equipment, and sporting equipment.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.48 Commercial Use – Chemical Substances in Packaging, Paper, Plastic, Hobby Products – Arts, Crafts, and Hobby Materials

This COU is referring to the commercial use of formaldehyde in arts, crafts, and hobby products. Meaning the use of formaldehyde-containing arts, crafts, and hobby products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of these materials) or use in an industrial setting. Formaldehyde can be found in colorants, pigments, and dyes in children's arts and craft supplies and needlework supplies. Paints, coatings, and adhesives are applied manually by brush, roller, or spray onto the substrate. Following application, the substrate is cured or dried before use. Formaldehyde can also be found in other hobby materials such as colored paper, cardboard, small woodworking crafts, hobby glues, and common arts and craft store items. EPA expects that these products would be used by commercial hobbyists who are using these products to create saleable goods.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.49 Commercial Use – Chemical Substances in Packaging, Paper, Plastic, Hobby Products – Ink, Toner, and Colorant Products; Photographic Supplies

This COU is referring to the commercial use of formaldehyde in ink, toner, and colorant products as well as photographic supplies. Meaning the use of formaldehyde-containing ink, toner, colorant, and photographic products in a commercial setting, such as a business or at a job site, as opposed to upstream use of formaldehyde (*e.g.*, when formaldehyde containing products are used in the manufacturing of these materials) or use in an industrial setting.

Phenol-formaldehyde based resins are found in printing ink, toner, and colorants. Formaldehyde can also be used as a photochemical agent, a reprographic agent, a stopping material, a developer, a sensitizer (photo conductor), a hardener, and a component of printing and writing inks. Formaldehyde is a component of printing inks, which may include letterpress, offset, lithographic, inkjet, and flexographic inks (U.S. EPA, 2020b, 2010; Tuomi et al., 2000). The inks may be used for newspapers, books, labeling, and packaging. Printing activities may be categorized by the following processes: lithography, gravure, flexography, letterpress, digital, and screen-printing, with lithography being the most used (U.S. EPA, 2010).

Formaldehyde has been identified as a component in photographic film processing (<u>Eastman Kodak</u>, 2009; <u>NICNAS</u>, 2006; <u>NIOSH</u>, 1982a, 1974). Formaldehyde is used as a preservative, stabilizer, replenisher, and hardener in final baths to prevent deterioration of image quality and damage to film coatings (<u>NICNAS</u>, 2006).

Commercial film processing sites typically use enclosed machines with a final bath tank specifically for formaldehyde solutions (NICNAS, 2006). Film development is typically done via a batch process (NICNAS, 2006). The final product is transferred to containers and dispatched to customers. The concentration of formaldehyde in the end product is typically 10.4 percent (NICNAS, 2006).

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.50 Commercial Use – Chemical Substances in Products Not Described by Other Codes – Laboratory Chemicals

This COU is referring to the commercial use of formaldehyde in laboratory chemicals. Meaning the use of formaldehyde in a commercial or industrial laboratory setting.

Formaldehyde may be used as a fixative in forensic, pathology laboratories, other medical-related laboratories, and aerospace-related laboratories (<u>Bruno et al., 2018</u>; <u>NICNAS, 2006</u>). Formaldehyde used in laboratories is often a neutral buffered formalin which can contain up to a range of 2.5 to 50 percent formaldehyde, with a mode of < 20 percent. (<u>Bruno et al., 2018</u>; <u>Xu and Stewart, 2016</u>; <u>Sancini et al., 2014</u>; <u>Viegas and Prista, 2010</u>; <u>NICNAS, 2006</u>; <u>Roy, 1999</u>).

Gross dissection and examination of the tissue typically take place in pathology or other medical laboratories after the specimen has been in full contact with a formalin solution containing 3.7 percent formaldehyde for several hours or longer (Xu and Stewart, 2016; NIOSH, 1983). The tissue is placed into plastic cassettes and the cassettes are immersed in trays of formalin during grossing (Xu and Stewart, 2016). The cassettes are processed into paraffin blocks, sliced extremely thin, and mounted on a slide (Xu and Stewart, 2016; Kilburn et al., 1985; NIOSH, 1982b). The slide goes through a series of solutions where stains are applied, and the slides are fixed (NIOSH, 1982b). A pathologist examines the slide via microscopic analysis (Xu and Stewart, 2016; NIOSH, 1982b). One source indicates that specimens no longer needed are disposed of once a week. The specimen is rinsed with water and the formaldehyde is washed down the sink (NIOSH, 1982b). Loading tissue cassettes and tissue processing typically takes 1.5 hours and may occur up to several times a week (NIOSH, 2013).

Formaldehyde can be used in commercial laboratories for microscope slide preparation and is used to bind proteins in order to make cells or tissues more structurally solid in the short term. For example, an animal cell may be mobile on a glass slide so a fixative that contains formaldehyde could be applied to that slide, so the cell is no longer mobile. EPA has determined that these fixative purposes are in scope because this use is considered non-pesticidal. Use for slide preparation could potentially have a short-term fixative (non-preservation) purpose if there is not also an intent to preserve the tissue for later analysis.

In the aerospace industry, formaldehyde is used in laboratories for tissue fixing, freeze drying aerosol droplets, and lab reagent purposes. This COU also includes activities identified by the U.S. Department of Defense.

Formaldehyde may also have uses in laboratories as an analytical standard for various applications. The users of products under this category would be expected to apply these products through general laboratory use applications.

A.51 Consumer Use – Chemical Substances in Furnishings Treatment/Care Products – Floor Coverings (Including Stone, Plaster, Cement, Glass and Ceramic Articles); Foam Seating and Bedding Products; Cleaning and Furniture Care Products; Furniture and Furnishings; Metal Articles; or Rubber Articles

This COU is referring to the consumer use of formaldehyde as a chemical substance in furnishings, such as floor coverings, foam seating and bedding products, as well as furniture and furnishings including

stone, plaster, cement, glass, ceramic, metal, or rubber articles.

This COU includes several uses of formaldehyde in furniture and furnishings. For example, formaldehyde-based resins are also found in wood-based articles such as composite wood articles. Wood panel articles may be used for shelving, furniture, doors, cabinets, and flooring. Formaldehyde based resins are also present in other wood products such as bamboo and cork flooring.

Formaldehyde resins may also be present in fiberglass insulation and urea-formaldehyde foam insulation products which are found at local home improvement stores.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.52 Consumer Use – Chemical Substances in Furnishings Treatment/Care Products – Fabric, Textile, and Leather Products (Clothing)

This COU is referring to the consumer use of formaldehyde as a chemical substance in fabric, textile, and leather products such as clothing.

Formaldehyde is found in wrinkle-resistant clothing and may also be present in certain clothing fabrics and synthetic fibers to preserve the color.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.53 Consumer Use – Chemical Substances in Treatment Products – Water Treatment Products

This COU is referring to the consumer use of formaldehyde as a chemical substance in water treatment products.

This use was not reported in 2016 or 2020 CDR.

A.54 Consumer Use – Chemical Substances in Treatment/Care Products – Laundry and Dishwashing Products

This COU is referring to the consumer use of formaldehyde as a chemical substance in laundry and dishwashing products.

Safety data sheets have, in the past, identified the use of formaldehyde in liquid laundry detergent and fabric softener, as well as dishwashing liquid. Such products have historically included laundry detergents, fabric conditioners, and rug and upholstery cleaners that contain formaldehyde. EPA has not found any current safety data sheets indicating that formaldehyde is still present in consumer uses for laundry and dishwashing products.

EPA expects that these products are likely to be used in both commercial and consumer applications.

This COU was not reported in the 2016 or 2020 CDR.

A.55 Consumer Use – Chemical Substances in Construction, Paint, Electrical, and Metal Products – Adhesives and Sealants; Paint and Coatings

This COU is referring to the consumer use of formaldehyde as a chemical substance in adhesives, sealants, paints, and coatings.

Formaldehyde is found in certain consumer adhesive and sealant products, including craft glues, wood glues, caulking and putty, tile grout and sealer, spackle, and other construction adhesives. Formaldehyde is also used in a variety of household paints and coatings, including lacquers, stains, varnishes, primers, topcoats, and specialty coatings. Such products can be found at local home improvement stores, hardware stores, and department stores.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.56 Consumer Use – Chemical Substances in Construction, Paint, Electrical, and Metal Products – Construction and Building Materials Covering Large Surface Areas, Including Wood Articles; Construction and Building Materials Covering Large Surface Areas, Including Paper Articles; Metal Articles; Stone, Plaster, Cement, Glass and Ceramic Articles

This COU is referring to the consumer use of formaldehyde as a chemical substance in construction and building materials including wood articles, paper articles, metal articles, and stone, plaster, cement, glass, and ceramic articles.

Formaldehyde is in construction-based materials found at local home improvement stores including building insulation, concrete and cement, glass products, laminates, and other miscellaneous construction materials such as ceiling tiles, wall coverings, bricklaying, plumbing components, glass fiber roofing mats, and plastic construction materials.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.57 Consumer Use – Chemical Substances in Electrical Products – Machinery, Mechanical Appliances, Electrical/Electronic Articles; Other Machinery, Mechanical Appliances, Electronic/Electronic articles

This COU is referring to the consumer use of formaldehyde as a chemical substance in electrical, mechanical, and appliance products and articles.

Formaldehyde is found in numerous electrical and electronic products and articles, including in printed circuit board materials and in appliances, electric controls, telephones, electrical switches, circuit breakers, and virtually all electronic products such as cell phones, video game consoles, laptop computers, and calculators. The expected users of products under this category would be consumers who are living in indoor environments with various electrical and electronic products or articles containing components made with formaldehyde as part of their construction.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.58 Consumer Use – Chemical Substances in Automotive and Fuel Products – Automotive Articles and Automotive Care Products; Lubricants and Greases; Fuels and Related Products

This COU is referring to the consumer use of formaldehyde as a chemical substance in automotive articles and automotive care products, lubricants and greases, and fuel related products.

Formaldehyde and formaldehyde resins are found in a range of automotive products and articles such as, under-the-hood components, exterior primers and paints, tire-cord adhesives, brake pads and linings, clutch facings, automatic transmission components, and fuel system components. Formaldehyde is also found in certain lubricants and greases used for maintenance of a vehicle which are available at local autobody and mechanical stores.

Formaldehyde is also found in a variety of automotive care products such as waxes, polishes, auto soaps. Such products may be applied directly onto the car or application equipment (e.g., cloths, buffer pads), or they may be diluted with water in a bucket before use. For the interior of the vehicle, certain cleaning materials may be used for vinyl or leather surfaces by wiping the coating onto surfaces and removing excess coating with cloths.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.59 Consumer Use – Chemical Substances in Agriculture Use Products – Lawn and Garden Products

This COU is referring to the consumer use of formaldehyde as a chemical substance in non-pesticidal lawn and garden products.

Urea-formaldehyde is found in controlled-release fertilizers, which release nutrients at a constant rate over time. End users of controlled-release fertilizers include agricultural, horticultural, landscaping, and consumer markets. The application depends on a variety of factors including crop type, soil type, and climate. Common application techniques include surface broadcasting, incorporation into the soil using attachments to plow, and injection of liquid/gaseous formulations by pumping through cultivator knives. Dry granulated formaldehyde fertilizers are either broadcast or suspended in water and root-zone injected or spray-applied.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.60 Consumer Use – Chemical Substances in Packaging, Paper, Plastic, Hobby Products – Paper Products; Plastic and Rubber Products; Toys, Playground, and Sporting Equipment

This COU is referring to the consumer use of formaldehyde as a chemical substance in paper products, plastic and rubber products, toys, and playground and sporting equipment.

Formaldehyde and formaldehyde resins are found in pulp and paper products such as paper, cardboard, wallpaper, and abrasive paper, such as sandpaper, including certain coatings in paper and cardboard. Formaldehyde has been identified in carbonless copy paper which may be used in office settings, educational supply stores, and printing shops.

Formaldehyde can be found in certain plastics and foams used to manufacture toys, playground equipment, and sporting equipment.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.61 Consumer Use – Chemical Substances in Packaging, Paper, Plastic, Hobby Products – Arts, Crafts, and Hobby Materials

This COU is referring to the consumer use of formaldehyde as a chemical substance in arts, crafts, and hobby products.

Formaldehyde can be found in colorants, pigments, and dyes in children's arts and craft supplies and needlework supplies. Paints, coatings, and adhesives are applied manually by brush, roller, or spray onto the substrate. Following application, the substrate is cured or dried before use.

Formaldehyde can also be found in other hobby materials such as colored paper, cardboard, small woodworking crafts, hobby glues, and common arts and craft store items.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.62 Consumer Use – Chemical Substances in Packaging, Paper, Plastic, Hobby Products – Ink, Toner, and Colorant Products; Photographic Supplies

This COU is referring to the consumer use of formaldehyde as a chemical substance in ink, toner, colorant products, and photographic supplies.

Phenol-formaldehyde based resins are found in printing ink, toner, and colorants which are commonly purchased at office supply stores and department stores. Formaldehyde has been identified as a component in photographic film processing. Formaldehyde is used as a preservative, stabilizer, replenisher, and hardener in final baths to prevent deterioration of image quality and damage to film coatings. EPA would expect hobbyists to utilize specialized photographic supplies. Formaldehyde is also found in printing inks used for newspapers, books, labeling, and packaging.

EPA expects that these products are likely to be used in both commercial and consumer applications.

A.63 Disposal – Disposal

This condition of use refers to the process of disposing generated wasted streams from each of the conditions of use of formaldehyde that are collected from facilities and households and are unloaded at and treated or otherwise disposed (e.g., landfilling, waste incineration, underground injection) at third-party sites. Point source discharges of formaldehyde to surface water are assessed in each discharging condition of use. Wastes of formaldehyde that are generated during a condition of use and sent to a third-party site for treatment or final disposition may include wastewater and solid waste. Formaldehyde may be contained in wastewater discharged to publicly owned treatment works (POTW) or other, non-public treatment works for treatment. Industrial wastewater containing formaldehyde discharged to a POTW may be subject to EPA or authorized National Pollution Discharge Elimination System (NPDES) state pretreatment programs.

Wastes of formaldehyde that are generated during a condition of use and sent to a third-party site for disposal, including treatment or final disposition (e.g., landfilling, incineration, underground injection) may include the following:

Wastewater

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

Solid Wastes

Solid wastes are defined under RCRA as any material that is discarded by being: abandoned; inherently waste-like; a discarded military munition; or recycled in certain ways (certain instances of the generation and legitimate reclamation of secondary materials are exempted as solid wastes under RCRA).

Wastes Exempted as Solid Wastes under RCRA

Certain COUs of formaldehyde may generate wastes of formaldehyde that are exempted as solid wastes under 40 CFR 261.4(a). For example, the generation and legitimate reclamation of hazardous secondary materials of formaldehyde may be exempt as solid waste.

Appendix B REGULATORY HISTORY

The chemical substance, formaldehyde, is subject to federal and state laws and regulations in the United States (Table_Apx B-1 and Table_Apx B-2). Regulatory actions by other governments, tribes, and international agreements applicable to formaldehyde are listed in Table_Apx B-3. EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to formaldehyde. Appendix B contains the compiled information from available federal, state, international and other government sources.

B.1 Federal Laws and Regulations

Table_Apx B-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	EPA regulations	
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Formaldehyde is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of formaldehyde as high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) – Section 8(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(d)	Provides EPA with authority to issue rules requiring manufacturers (including importers), processors, and distributors of a chemical substance or mixture to submit lists and/or copies of ongoing and completed, unpublished health and safety studies. EPA's Health and Safety Data Reporting Rule at 40 CFR part 716 generally requires such submissions for manufacturers (including importers) and (if specified) processors of substances covered by part 716.	29 health and safety studies received for Formaldehyde (2021) (U.S. EPA, ChemView. Accessed February 5, 2024).
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical	23 risk reports received for formaldehyde, or containing information related to formaldehyde were received between 1989 and 2011. (U.S. EPA, <u>ChemView</u> , Accessed February 5, 2024). Link to the 8(e) submission crosswalk <u>HERE</u> .

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	substance or mixture presents a substantial risk of injury to health or the environment.	
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, thin-medium density fiberboard, and particleboard) 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) – sections 311- 312	The Community Right-to-Know Requirements of EPCRA sections 311-312 require facilities to submit Safety Data Sheets (SDS) to certain authorities for hazardous chemicals present above certain thresholds if the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS) requires the facility to prepare or have the SDS. (The SDS were formerly known as material safety data sheets (MSDS).) Facilities must submit the SDS or a list of hazardous chemicals to their State or Tribal Emergency Response Commission (SERC or TERC), Local or Tribal Emergency Planning Committee (LEPC or TEPC), and local fire department. Facilities must also submit an annual inventory of these chemicals by March 1 of each year to their State or Tribal Emergency Response Commission (SERC or TERC), Local or Tribal Emergency Planning Committee (LEPC or TEPC), and local fire department. The information submitted by facilities must be made available to the public.	Formaldehyde is categorized as an Extremely Hazardous Substance for purposes of the Community Right-to-Know Reporting Requirements under 40 CFR part 370. As an Extremely Hazardous Substance under 40 CFR part 355, Formaldehyde has a threshold planning quantity (TPQ) of 500 pounds.
EPCRA – Section 313	EPCRA Section 313 established the Toxic Release Inventory (TRI) and requires annual reporting from facilities in specific industry sectors that employ 10 or	Formaldehyde is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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).	
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. EPA assesses the whole formulation of pesticide products including active ingredients which have pesticidal effects and inert ingredients that do not. EPA keeps lists of inert ingredients that have been approved for use in pesticide products distinguishing between those that have been approved for use on food and those that have not. Pesticide products may only be registered if, among other things, they do not cause "unreasonable adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either (1) the pesticide, labeling, or other material does not comply with FIFRA; or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	Formaldehyde was registered as an antimicrobial, conventional chemical on January 25, 1967. In June 2008 EPA published a reregistration eligibility decision for formaldehyde and paraformaldehyde (Case 0556; EPA Document 739-R-08-004). Formaldehyde is currently under registration review, and the final work plan has been published (EPAHQ-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 establish 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	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).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	determine that the tolerance or exemption is "safe." Section 408(b) of the FFDCA defines "safe" to mean a reasonable certainty that no harm will result from aggregate exposures (which includes dietary exposures from food and drinking water as well as 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, or where pesticide residues in food exceed an existing tolerance limit, a food containing that pesticide residue is considered adulterated and may not be distributed in interstate commerce.	
Clean Air Act (CAA) – Section 111(b)	Requires EPA to establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution, which may reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction (BSER) which (taking into account the cost of achieving reductions and environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	EPA has established NSPS for a number of source categories that regulate emissions of Formaldehyde to air. (See https://www.epa.gov/stationary-sources-air-pollution/new-source-performance-standards).
Clean Air Act (CAA) – Section 112(b)	Contains the original list of 189 hazardous air pollutants (HAPs) that Congress added in 1990. Under 112(c) of the CAA, EPA must identify and list source categories that emit listed 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 HAP by adding or deleting a substance. Since 1990, EPA has both removed HAPs from and added HAPs to the original list.	
Clean Air Act (CAA) – Section 112(d)	Directs EPA to establish, by rule, National Emission Standards for Hazardous Air Pollutants (NESHAPs) for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)).	EPA has established NESHAPs for a number of source categories that emit Formaldehyde to air. (See https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-8)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	For major sources, the standards must require the maximum degree of emission reduction that EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For areas sources, the standards must require generally achievable control technology (GACT) though may require MACT. Section 112(d)(6) requires EPA to review, and revise, as necessary, (taking into account developments in practices, processes and control technologies) the emission standards every 8 years.	
Clean Air Act (CAA) – Section 112(f)	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; this is required within 8 years of promulgating the NESHAP.	EPA has promulgated a number of Risk and Technology Review (RTR) NESHAP and will do so, as required, for the remaining source categories with NESHAP.
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 volatile organic compound (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.
Clean Water Act (CWA) – Section 311(b) (2)(A) and 501(a) of the Federal Water Pollution Control Act.	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 a designated hazardous substance in accordance with Section 311(b) (2)(A) of the Federal Water Pollution Control Act (40 CFR Section 116.4, see 43 FR 10474 (March 13, 1978)).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Safe Drinking Water Act (SDWA) – Section 1412(b)	Every 5 years, EPA must publish a list of contaminants that: (1) are currently unregulated, (2) are known or anticipated to occur in public water systems (PWSs) and (3) may require regulations under SDWA. EPA must also determine whether to regulate at least five contaminants from the list every 5 years.	Formaldehyde was identified on both the Third (2009) and Fourth (2016) Contaminant Candidate Lists (CCL) (74 FR 51850, October 8, 2009) and (81 FR 81099, November 17, 2016).
Resource Conservation and Recovery Act (RCRA) – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Formaldehyde is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U122 (40 CFR 261.33). Formaldehyde is also listed as part of various groups of chemicals in Appendix VII to Part 261 – Basis for Listing Hazardous Waste as K009, K010, K038, K040, K156, and K157 (40 CFR Appendix VII to Part 261). Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the AutoAlliance International, Inc. of Flat Rock Michigan and DamlierChrysler Corporation, Jefferson North Assembly Plant, Detroit Michigan entries which permit a TCLP extraction sample not-to-exceed limit of 84.2 mg/L of formaldehyde in their leachate extract, and a total concentration of formaldehyde not to exceed 689 mg/kg, and a maximum allowable groundwater concentration (µg/L) of 1,380. 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 700 mg/kg, and a total concentration of formaldehyde not to exceed 700 mg/kg, and a total concentration of formaldehyde not to exceed 88 mg/kg, and a

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		maximum allowable groundwater concentration (µg/L) of 1,400.
		Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company, Kansas City Assembly Plant which permits a TCLP extraction sample not to exceed 343 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 6880 mg/kg.
		Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company, Michigan Truck Plant and Wayne Integrated Stamping and Assembly Plant which permits a TCLP extraction sample not to exceed 84.2 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 689 mg/kg, and a maximum allowable groundwater concentration (µg/L) of 1,380.
		Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company, Wixom Assembly Plant which permits a TCLP extraction sample not to exceed 84.2 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 689 mg/kg.
		Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation Assembly Plant which permits a TCLP extraction sample not to exceed 84 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 700 mg/kg, and a maximum 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

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		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 Janesville Truck Assembly Plant which permits a TCLP extraction sample not to exceed 43 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 540 mg/kg, and a maximum 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 <u>Appendix IX to Part 261</u> – Wastes Excluded from Non-Specific Sources under the Trigen/Cinergy-USFOS of Lansing LLC at General Motors Corporation, Lansing Grand River which permits a TCLP extraction sample not to exceed 84.2 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 689 mg/kg.
Comprehensive Environmental	Authorizes EPA to promulgate regulations designating as hazardous substances, in addition to those referred to in section 101(14) of CERCLA, those elements,	Formaldehyde is a hazardous substance under CERCLA. Releases of formaldehyde in excess of 100 pounds must be reported (40 CFR 302.4).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	compounds, mixtures, solutions, and 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. CERCLA Hazardous substances listed under 40 CFR Table 302.4 are subject to EPCRA Section 304 notification requirements.	
Superfund Amendments and Reauthorization Act (SARA)	Amendments made several important changes to CERCLA, for example: 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 regulations	
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics, except residues of pesticides in food are regulated by EPA under FFDCA section 408 (discussed above where applicable).	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). Formaldehyde is also listed as an adhesive used in food packaging at 21 CFR 175.105. Formaldehyde is regulated by FDA as a food additive used
		in the manufacture of animal feeds in accordance with 21 CFR 573.460. Formalin (an aqueous solution containing approximately 37% by weight of formaldehyde gas, U.S.P.) is regulated by

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		FDA as a new animal drug when used to control external parasites on hatchery fish and their eggs. 21 CFR 529.1004. Formaldehyde is also listed as an "Inactive Ingredient for approved Drug Products" by FDA with an established limit of 0.2% Weight/Weight (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 (OSH Act)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C 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 as an 8-hour TWA, a 15-minute STEL of 2 ppm, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1048). OSHA has separate sections of the CFR for formaldehyde standards for shipyard (29 CFR 1915.1048) and construction (29 CFR 1926.1148) employment; however, those sections reference the general formaldehyde requirements at 29 CFR 1910.1048. 10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2016 American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (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.	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)).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	• Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	

B.2 State Laws and Regulations

Table_Apx B-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 (μ g/m³) for a 24-hour AAL, 0.88 (μ g/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 (μ g/m³) for a 1-hour AAL, 40 (μ g/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 (<u>Air Pollution Regulation No. 22.4.2(c)</u>).	
State Drinking Water Standards and Guidelines	Formaldehyde is listed in the groundwater: residential and nonresidential part 201 generic cleanup criteria and screening levels in Michigan with the following levels: residential drinking water criteria of 1,300 ppm, nonresidential drinking water criteria of 3,800 ppm, groundwater surface water interface criteria of 120 ppm, residential groundwater volatilization to indoor air inhalation criteria of 63,000 ppm, nonresidential groundwater volatilization to indoor air inhalation criteria of 360,000 ppm, and a water solubility of 550,000,000 ppm (Mich. Admin. Code r.299.44 and r.299.49, 2017).	
State PELs	California (PEL of 0.75 ppm and a STEL of 2 (<u>Cal Code Regs. Title 8, § 5155 and Cal Code Regs. Title 8, § 5217</u>) Hawaii PEL: 0.75 ppm and a STEL of 2 for 15 minutes (<u>Hawaii Administrative Rules Section 12-60-50 which refer to 29 CFR § 1910.1048 as a proxy for formaldehyde</u>).	
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 aerosol coating products and antiperspirant and deodorant (among other products). 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	

State Actions	Description of Action
	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.
Airborne Toxic Control Measure (ATCM)	California regulates Formaldehyde emissions for Composite Wood Products (<u>Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 7.5, Section 93120</u>)
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 (<u>Hazard Evaluation System and Information Service</u> , 2016).
	Massachusetts designated formaldehyde as a Higher Hazard Substance requiring reporting starting in 2012 (301 CMR 41.00).

B.3 International Laws and Regulations

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

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 (Environment Canada Database, Accessed February 23, 2024.) Other regulations include: • Canada's National Pollutant Release Inventory (NPRI). • Off Road Compression-Ignition Engine Emission Regulations (SOR/2005-32).

Country/ Organization	Requirements and Restrictions
	 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). Formaldehyde Emissions from Composite Wood Products Regulations (SOR/2021-148)
European Union	Formaldehyde is listed on the European Chemicals Agency (ECHA) Inventory (EC Number 200-001-8) and the European Union (EU): Classification, Labelling and Packaging (CLP) Harmonized Classification (index number 605-001-00-5). Formaldehyde was evaluated under the 2013 Community rolling action plan (CoRAP) under regulation (EC) No1907/2006 - REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals (European Chemicals Agency (ECHA) database, Accessed February 5, 2024).
	On July 2023, the European Union revised the restrictions under REACH with respect to formaldehyde and formaldehyde releasers, and established limits for formaldehyde releases of 0.062 mg/m³ for furniture and wood-based articles and of 0.080 mg/m³ for articles other than furniture and wood-based articles. In addition, the regulations established a maximum concentration of formaldehyde in the interior of in road vehicles of 0.062 mg/m³. (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1464&qid=1690878840638)
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 February 5, 2024).
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 (Pollutant Release and Transfer Registers & Safety Data Sheet Law (PRTR-SDS Law))

Country/ Organization	Requirements and Restrictions
	 Industrial Safety and Health Act (ISHA) Air Pollution Control Law Water Pollution Control Law Soil Contamination Countermeasures Act Poisonous and Deleterious Substances Control Act Act on the Control of Household Products Containing Harmful Substances Food Sanitation Act Fire Service Act (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP]. Accessed February 5, 2024).
Basel Convention	B3010 (urea, phenol, and melamine formaldehyde resins) are listed as a category of waste under the <u>Basel Convention</u> . Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters.
OECD Control of Transboundary Movements of Wastes Destined for Recovery Operations	B3010 (urea, phenol, and melamine formaldehyde resins) are listed as a category of waste subject to The Amber Control Procedure under Council Decision C (2001) 107/Final.
World Health Organization (WHO)	WHO has not established a tolerable daily intake for formaldehyde; however, did note that the average daily intake of formaldehyde is 0.02 mg/day for outdoor air; 0.05–2 mg/day for indoor conventional buildings, <1–10 mg/day for buildings without sources of formaldehyde, 0.2–0.8 mg/day for workplaces without occupational use of formaldehyde, 4 mg/day for work places using formaldehyde, and 0-1 mg/day for environmental tobacco smoke (smoking 20 cigarettes a day corresponds with an intake of 1 mg/day of formaldehyde). The average daily intake of formaldehyde in drinking water is generally 0.2 mg/day and the quantity of formaldehyde generally ingested in food (contingent on the meal composition) may range from 1.5 to 14 mg/day. (Environmental Health Criteria (EHC) Monograph 89, 1989).
Australia, Austria, Belgium, Canada, Denmark, European Union, Finland, France, Germany,	Occupational exposure limits for Formaldehyde (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed February 5, 2024).

Hungary, Ireland,	
Israel, Italy, Japan,	
Latvia, New	
Zealand, Norway,	
People's Republic	
of China, Poland,	
Romania,	
Singapore, South	
Africa, South	
Korea, Spain,	
Sweden,	
Switzerland, The	
Netherlands,	
United Kingdom	