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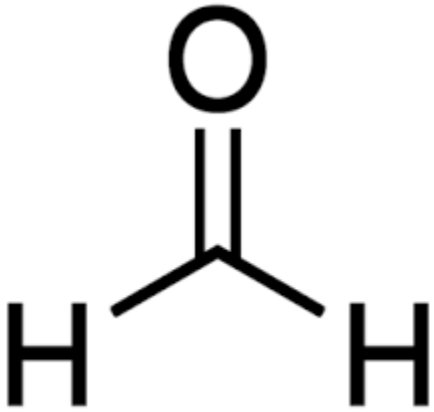
Draft Consumer Exposure Assessment for Formaldehyde

CASRN 50-00-0



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Key Points: Consumer Exposure Assessment for Formaldehyde

Formaldehyde is found in consumer products (*e.g.*, car wax) and articles (*e.g.*, clothing) that are readily available for public purchase at common retailers and through online shopping venues. Although predominantly a volatile gas, formaldehyde may be found as a solid or liquid depending on the consumer product (*e.g.*, solvent-based paint) or article (*e.g.*, seat cover). EPA quantitatively assessed consumer exposure to formaldehyde for both users and bystanders. The following bullets summarize the key points of this draft consumer exposure assessment:

- Users of consumer products (*e.g.*, spray leather cleaner) and articles (*e.g.*, wood furniture) generally were estimated to be exposed to higher 15-minute peak and long-term formaldehyde concentrations, in comparison with bystanders.
- Across all relevant age groups and scenarios, the highest estimated 15-minute peak formaldehyde air concentration was for consumer users of floor coverings; foam seating and bedding products; etc., while the lowest 15-minute peak formaldehyde concentration was for individuals using or wearing textiles or clothing that emit formaldehyde.
- Consumer users of adhesives and sealants, paint and coatings were estimated to be exposed to the highest average daily air concentration of formaldehyde, while consumer users of automotive care products were estimated to be exposed to the lowest estimated average daily air concentration.
- The highest acute dermal loading for consumer users resulted from use of automotive care products, while the lowest acute dermal loading resulted from use of art, craft, and hobby (crafting paint).

EXECUTIVE SUMMARY

This assessment considers human exposure to formaldehyde in consumer products resulting from Toxic Substances Control Act (TSCA) conditions of use (COUs). The major routes of exposure considered were via inhalation and dermal exposure. Although oral exposures were also considered low bioavailability, lack of monitoring data, and chemical properties significantly reduced the plausibility of these exposure scenarios. Chemical weight fractions were gathered from safety data sheets (SDSs) and used to tailor COU-specific consumer exposure scenarios for products and articles identified in the consumer market.

For inhalation, EPA's Consumer Exposure Model (CEM) was used to estimate acute and chronic inhalation exposures to consumer users and bystanders. Confidence in these estimates was high. Direct users of consumer products and articles had the highest estimated 15-minute peak exposures. The highest 15-minute peaks were for users of floor coverings; foam seating and bedding products; etc (2,520 µg/m^3). The lowest acute exposures were for individuals using or wearing textiles or clothing that emit formaldehyde (560 µg/m^3). The highest estimated average daily air exposure was for users of adhesives and sealants; paint and coatings (36.6 µg/m^3). The lowest chronic exposures were estimated to be for users of automotive care products (0.04 µg/m^3), although many COUs had no estimated chronic exposure. A full and detailed list of all exposure concentrations is described in Section 2.1.2.1 and may be found in Appendix B.

For dermal, the Thin-Film Model was used to estimate dermal exposures to users of consumer products that contain formaldehyde. Confidence in these estimates is medium. Users of automotive care products had the highest exposure (3,090 µg/cm^2), while users of arts, crafts and hobby materials had the lowest

123 estimated dermal exposures (10.3 µg/cm^2). Detailed dermal results are described in Section 2.1.1.2 and
124 provided in Appendix B.

1 INTRODUCTION

This draft document provides and assessment of formaldehyde consumer exposures resulting from Toxic Substances Control Act (TSCA) conditions of use (COUs) only, as defined by the TSCA section 3(2) definition of chemical substance. For instance, embalming & taxidermy, and personal care products, were not included in the consumer analysis. It was determined that all circumstances under which formaldehyde is intended, known, or reasonably foreseen to be used in personal care products and embalming & taxidermy products are excluded from the chemical substance definition under TSCA section 3(2)(B)(vi) (pertaining to cosmetics as defined under the Federal Food, Drug, and Cosmetic Act) and (ii) (pertaining to pesticides as defined under the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA]), respectively. Generally, potential exposures and risks from non-TSCA uses are evaluated and addressed by other relevant agencies or EPA offices.

1.1 Risk Evaluation Scope

The TSCA risk evaluation of formaldehyde comprises several human health hazard and environmental assessment modules and two risk assessment documents—the environmental risk assessment and the human health risk assessment. A basic diagram showing the layout of these modular assessments and their relationships is provided in Figure 1-1. This draft consumer exposure assessment is shaded blue. In some cases, modular assessments were completed jointly under TSCA and FIFRA. These modules are shown in dark gray.

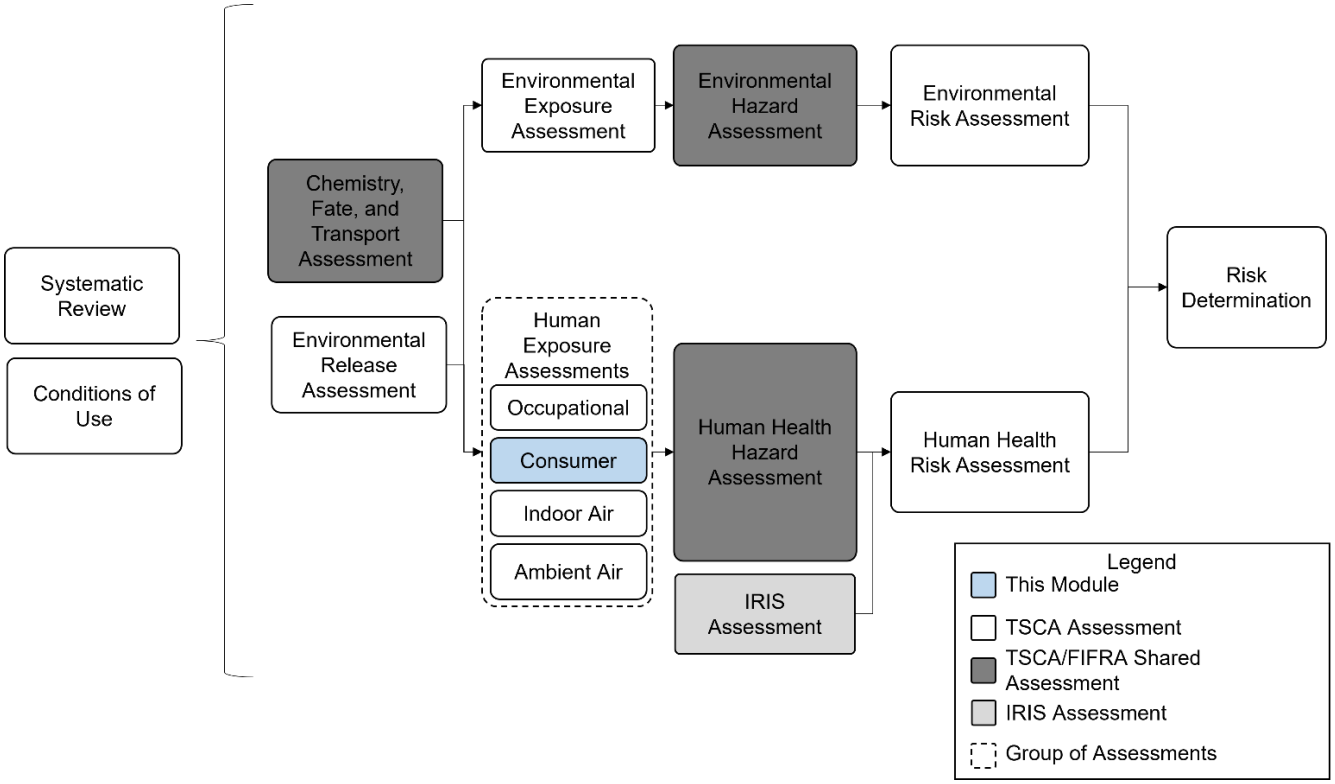


Figure 1-1. Risk Evaluation Document Map

1.1.1 Scope of the Consumer Exposure Assessment

Formaldehyde is found in consumer products and articles that are readily available for purchase at common retailers and through online shopping venues. Consumer products include textiles, foam bedding/seating, semiconductors, resins, glues, composite wood products, paints, coatings, plastics,

rubber, resins, construction materials (including roofing), furniture, toys, and various adhesives and sealants. Section 1.3 presents a conceptual model of all consumer COUs that are in scope for the consumer exposure assessment. EPA identified these COUs from information reported to the Agency through Chemical Data Reporting (CDR) and Toxics Release Inventory (TRI) reporting, published literature, and consultation with stakeholders for products currently in production or not discontinued. EPA revised the COUs in the *Final Scope of the Risk Evaluation for Formaldehyde CASRN 50-00-0* (EPA, 2020b) based on additional information and public comments (Docket ID EPA-HQ-OPPT-2018-0438) on the draft scope document. Figure 1-2 lists the COUs within the scope of this draft consumer exposure assessment.

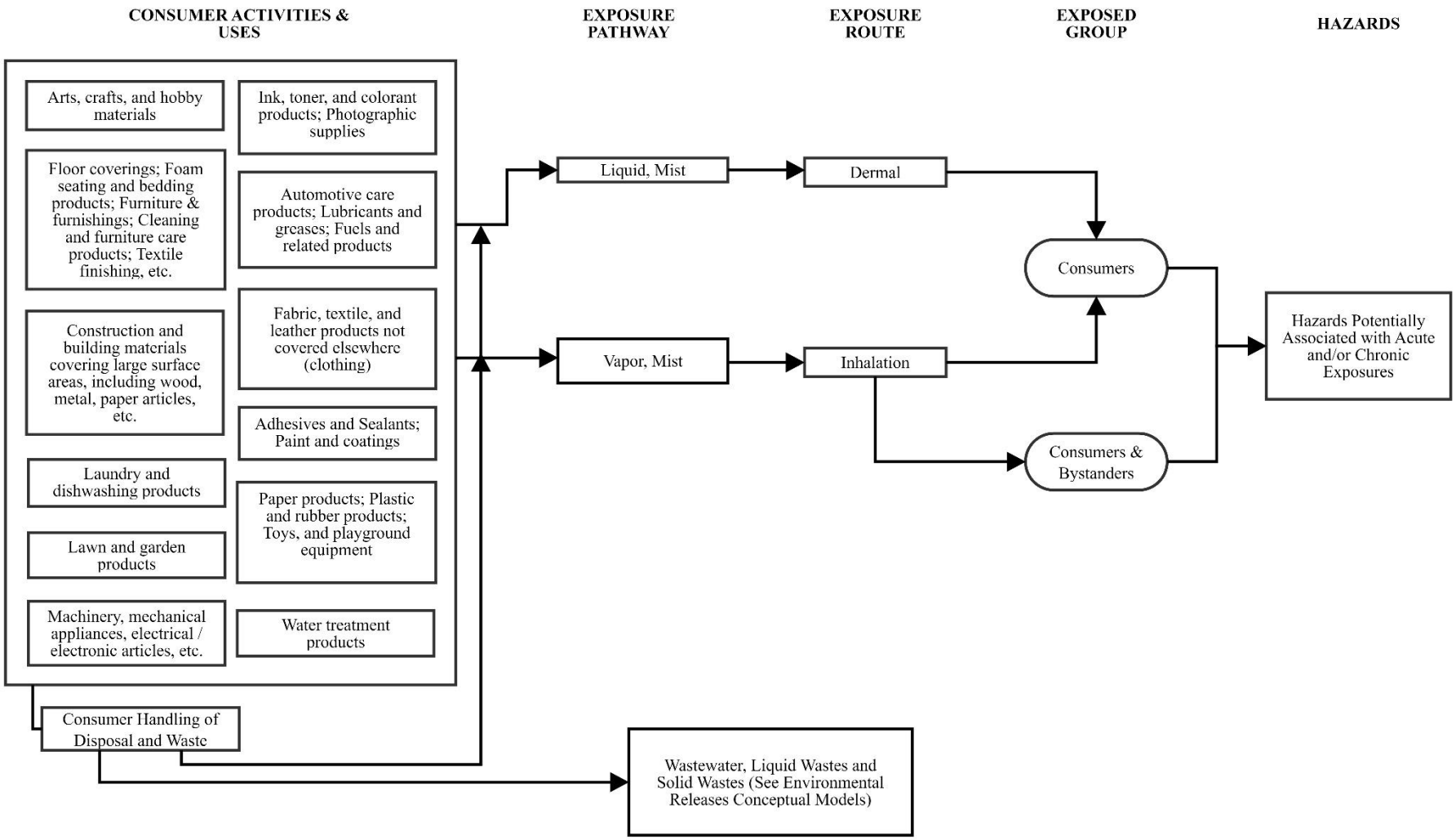
EPA estimated consumer exposures from products containing formaldehyde for TSCA COUs identified in the final scope document that could be either a chemical ingredient in a consumer product or a component in material(s) utilized in the manufacturing of consumer products or articles (adhesives, resins, glues, etc.) or both. As an ingredient or component in material within a consumer product, use of such product is expected to result in exposures to both consumers who use a product (consumer user) and bystanders (individuals that are not directly using a product but are exposed while the product is being used by someone else).

It should be noted that this consumer assessment is separate from the indoor air assessment of formaldehyde (EPA, 2024c) because the latter air assessment is focused on the potential exposures that occur from long-term emissions of formaldehyde from articles. Specifically, the indoor air assessment highlights potential exposures from articles that have been reported as being significant contributors to the indoor air concentrations of formaldehyde.

In addition, EPA did *not* quantify exposures for COUs in which EPA had a low exposure assessment confidence. The Agency qualitatively assessed the following COUs:

- Water treatment products, because no supporting products could be identified other than a fish tank cleaning solution, and because formaldehyde is highly reactive in water.
- Laundry and dish washing products, because formaldehyde is highly reactive in water. EPA believes these preliminary CEM modeling results are implausible.
- Lawn and garden products, because (1) the non-pesticidal exposure scenario for this TSCA COU is unclear; (2) when mixed in water formaldehyde is highly reactive; and (3) although formaldehyde is volatile, EPA's Consumer Exposure Model (CEM) assumes no inhalation exposure from such products—likely due the default assumption that such activities typically occur outdoors where the chemical would be diluted in the ambient air during and after use.

EPA also had a low confidence in the assessment of potential exposures from furniture foam insulation scenarios because formaldehyde exposures from such products are expected to be minimal. During the public comment period for the draft high priority designation of formaldehyde, the North American Insulation Manufacturers Association stated "for those insulation products in which formaldehyde is a component of the binder, the products are cured at high temperatures during the manufacturing process after the binder has been applied, virtually eliminating the free formaldehyde content. Any free formaldehyde released from the binder during cure is destroyed either during the cure process or by emissions control equipment required by the MACT standard. Therefore, formaldehyde off-gassing from the majority of finished products is highly unlikely" (Docket ID EPA-HQ-OPPT-2019-0131).



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195 **Figure 1-2. Formaldehyde Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards**

1.1.1.1 Scope of Exposure Routes

Per the *Final Scope of the Risk Evaluation for Formaldehyde CASRN 50-00-0* (EPA, 2020b), consumer exposures to formaldehyde are primarily expected to occur via inhalation and dermal routes during and after use of consumer products containing formaldehyde within a residence or vehicle.

1.1.1.1.1 Inhalation

Consumer exposure to formaldehyde is expected to occur via inhalation due to off-gassing from various products used or installed within a residence or vehicle. Consumer and bystander inhalation exposure to formaldehyde is expected to be the most significant route of exposure through the direct inhalation of sprays and vapors and mists (EPA, 2020b). The magnitude of inhalation exposure depends upon the concentration of formaldehyde in products, use patterns (including frequency, duration, amount of product used, room of use), and product application methods (EPA, 2011). EPA assumed mists containing formaldehyde sprayed from consumer products are absorbed via inhalation, rather than the oral route.

1.1.1.1.2 Oral

Consumer exposure to formaldehyde from TSCA COUs via the oral (ingestion) route is not expected, per the final scope document (EPA, 2020b). Formaldehyde is highly volatile and not expected to adsorb to dust or other particles within a residence that could subsequently be ingested. Through a systematic review of the formaldehyde exposure literature, no studies were identified that support the potential for formaldehyde oral exposures from the TSCA COUs of interest. Furthermore, no studies were identified to address the migration of formaldehyde from a product to saliva resulting from mouthing a plastic or rubber product. A supplemental, qualitative assessment of formaldehyde oral exposures was conducted according to potentially relevant TSCA COUs subject to this draft consumer assessment and is presented in Appendix C. Due to uncertainties surrounding the bioavailability of formaldehyde in the manufactured consumer products that may result in intentional mouthing, EPA has a low confidence in an assessment of oral exposures to formaldehyde and did not further assess this route of exposure.

The Agency acknowledges that some oral exposures to formaldehyde may occur through incidental contact (*i.e.*, not expected during reasonable product or article use). For instance, oral exposures to lawn and garden products (fertilizers) were also qualitatively assessed due to potential incidental exposures during fertilizer application where the individual may accidentally touch their mouth prior to washing their hands. In addition, an individual who has finished painting and not thoroughly washed their hands may have some paint residues left on fingers that may accidentally be ingested while eating. Nevertheless, such residual exposures to formaldehyde are beyond the scope of this draft risk evaluation. In addition, although intentional ingestion of formalin has been reported and resulted in deaths (ATSDR, 1999), such cases do not constitute an intended use of products and articles.

1.1.1.1.3 Dermal

Dermal exposure to formaldehyde may occur via contact with mist deposition on the skin during use of spray products or via direct liquid contact during use. Generally, the magnitude of dermal exposure depends on factors like skin surface area, product volume, chemical loading, weight fraction, and exposure duration (EPA, 2011). Because the identified dermal point of departure (POD) already incorporates absorption, as a measurement of dermal exposures, an estimate of dermal loading onto the skin was estimated using the Thin Film Model instead of a calculation of internal dermal doses of formaldehyde resulting from dermal contact with liquid consumer products; see the *Draft Human Health Assessment for Formaldehyde* (EPA, 2024b) for detailed information regarding the dermal POD.

Although formaldehyde that may deposit on the skin is primarily expected to evaporate rapidly based on physical chemical properties (*e.g.*, vapor pressure) limiting exposure, some may remain on the skin long enough to be absorbed dermally. When evaporation of formaldehyde is reduced or impeded (*e.g.*, continued contact with a formalin-soaked rag), dermal exposure is expected to be higher. Dermal exposures are not expected to contribute significantly to overall bystander exposure.

Owing to volatility and expected use patterns, dermal loading of formaldehyde from solid products is unlikely, except for certain textiles including clothing that are treated with formaldehyde in the dyeing and wrinkle prevention step in the textile manufacturing process (Herrero et al., 2022). EPA could not identify supporting evidence for dermal loading exposures from the handling or wear of fabrics. EPA also could not identify a diffusion coefficient of formaldehyde for clothing. Therefore, EPA had a low level of confidence in the estimation of dermal loading from textiles including clothing. Hence, a qualitative assessment is reported for this product type in Appendix D.

1.2 Summary of the Chemistry, Fate, and Transport Assessment

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

In air, the half-life of the formaldehyde depends greatly on the intensity and duration of sunlight and ambient conditions such as temperature and humidity. Under direct sunlight, formaldehyde will undergo photolysis with a half-life up to 4 hours yielding mainly hydroperoxyl radical (HO_2), carbon monoxide (CO), and hydrogen (H_2). In the absence of sunlight, studies indicate that formaldehyde can persist with a half-life value up to 114 days. In addition, formaldehyde may hydrate in moist air to form methylene glycol and later formic acid.

Formaldehyde is not subject to the various transformation and degradation processes in the indoor air environment that are expected in the outdoor environment (Salthammer et al., 2010). Thus, its persistence is driven by dissipation and adsorption. The major route of dissipation of formaldehyde in the indoor environments is by mechanical removal via ventilation systems. Adsorption of formaldehyde to surfaces may occur based on the surface composition; however, it may re-emit at warmer temperatures (Plaisance et al., 2013; Cousins, 2012; Traynor et al., 1982). Based on this information, while formaldehyde is expected to readily transform in outdoor air, it may be persistent in indoor air.

In a solution, formaldehyde is often distributed in water and methanol as formalin, in which methanol is used as a stabilizer to stop polymerization. It is miscible in water and highly reactive with most nucleophiles. Formaldehyde may also be distributed as paraformaldehyde in a white crystalline solid form.

Formaldehyde is not expected to bind to soil. Based on an empirical Henry's Law constant of 3.37×10^{-7} atm-m^3/mol at 25 °C (Nlm, 2019), formaldehyde can volatilize slowly from moist soil. In dry soil, formaldehyde is expected to volatilize more rapidly.

1.3 Conceptual Exposure Model

EPA considered reasonably available information including physical chemical properties of formaldehyde based on its specific forms in relevant products, as well as public comments received on

the draft scope document for formaldehyde in finalizing the exposure pathways, exposure routes, and hazards subject to this assessment. Figure 1-2 is a graphical depiction of the actual or predicted relationships of TSCA COUs, exposure pathways (media), exposure routes (*e.g.*, inhalation), hazards, and exposed groups throughout the consumer life cycle of formaldehyde. For example, a passenger may be exposed to formaldehyde through inhalation for the duration of a taxi ride due to formaldehyde offgassing to air from seat covers within the vehicle.

The conceptual model in Figure 1-2 presents the exposure pathways, exposure routes, and hazards to exposed groups from formaldehyde based on TSCA COUs. It should be noted that aside from consumers and bystanders, exposed groups include potentially exposed susceptible subpopulations (PESS). As defined by TSCA section 3(12) to be a group of individuals within the general population identified by EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, the elderly, or overburdened communities. As such, EPA acknowledges that PESS exposure to formaldehyde in indoor air may be more significant exposures relative to others within the general population.

Table 1-1 provides a summary of the formaldehyde consumer exposure scenarios and routes that were evaluated by EPA. The table includes 30 established exposure scenarios, form of the products identified in chemical safety data sheets (SDSs) and the relevant routes of exposure for consumers and bystanders. Greyed-out boxes in Table 1-1 and succeeding tables represent a parameter that could either not be found or was irrelevant to the assessment of the exposure scenario based on the product type and expected use patterns. For a list of the COU relevant to each consumer exposure scenario, see Table_Apx B-1.

311 **Table 1-1. Summary of Consumer Conditions of Use, Exposure Scenarios, and Exposure Routes**

Consumer Exposure Scenario[a]	Form	Routes Evaluated[b]			
		Consumer User		Bystander	
		Inhalation	Dermal	Inhalation	Dermal
Fertilizers (garage/outside)	Solid/Liquid[c]				
Craft paint – generic	Liquid	✓	✓		
Glues and adhesives, small scale	Liquid	✓	✓		
Building/construction materials – wood articles: hardwood floors	Solid	✓			
Glues and adhesives, small scale	Liquid		✓		
Caulk (sealants)	Liquid	✓	✓	✓	
Liquid concrete – glues and adhesives, small scale	Liquid		✓		
Drain and toilet cleaners	Liquid	✓	✓	✓	
Textile and leather finishing products	Liquid	✓	✓	✓	
Electronic appliances	Solid[d]	✓			
Fabrics: furniture covers, car seat covers, tablecloth (automobiles)	Solid	✓			
Fabrics: furniture covers, car seat covers, tablecloth (living room)	Solid	✓			
Fabrics: clothing	Solid	✓			
Varnishes and floor finishes	Liquid	✓	✓	✓	
Plastic articles: foam insulation (automobile)	Solid				
Plastic articles: foam insulation (living room)	Solid				
Liquid fuels/motor oil	Liquid		✓		
Furniture and furnishings – wood articles: furniture	Solid	✓			
Inks applied to skin	Liquid		✓		
Laundry detergent (liquid)	Liquid				
Hand dishwashing soap/ liquid detergent	Liquid				
Lubricants (non-spray)	Liquid	✓	✓	✓	
Water-based wall paint	Liquid		✓		
Solvent-based wall paint	Liquid		✓		
Paper articles: with potential for routine contact (diapers, wipes, newspaper, magazine, paper towels)	Solid	✓			
Liquid photographic processing solutions	Liquid	✓	✓	✓	
Rubber articles: flooring, rubber mats	Solid	✓		✓	
Rubber articles: with potential for routine contact	Solid	✓		✓	
Exterior car wax and polish	Liquid		✓		
Plastic articles: other objects with potential for routine contact	Solid	✓		✓	
Drinking water treatment	Liquid				

[a] The CEM allows for the user to input a potential consumer exposure scenario according to room of use. For this analysis, a product modeled in multiple rooms (*i.e.,* seat covers in cars and living rooms) is listed as having multiple exposure scenarios.
[b] In this table, a checkmark indicates the exposure route to the population evaluated for each COU; whereas greyed-out boxes represent exposure routes deemed not appropriate and, therefore, not quantitatively assessed for the relevant COU.
[c] A quantitative dermal assessment was performed using a liquid form of formaldehyde in lawn and garden products (fertilizers) while a qualitative oral assessment was performed using a solid form of formaldehyde in such products.
[d] While where may be potential inhalation exposures from components of electronic products, consumer exposures for the appropriate durations (*e.g.,* 15-minute peak and chronic daily average) could not be quantified using CEM.

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2 APPROACH AND METHODOLOGY

2.1 Consumer

Consumer products containing formaldehyde were identified through review and searches of a variety of sources, including the *Final Scope of the Risk Evaluation for Formaldehyde CASRN 50-00-0* (EPA, 2020b), 2016 and 2020 Chemical Data Reporting (EPA, 2020a, 2016), in addition to chemical SDSs identified through product-specific internet searches. Identified consumer products containing formaldehyde were categorized into 12 COUs. EPA developed a total of 30 exposure scenarios to assess consumer exposures under the associated COUs. The exposure scenarios developed by EPA considered (1) consumer use patterns, (2) consumer activity patterns, (3) information reported in SDSs, (4) product availability to the public, and (5) likely exposure routes under the associated COUs. EPA evaluated relevant routes of exposure according to the 30 identified consumer exposure scenarios.

Exposure scenarios were developed by identifying the product or article that is available for purchase and use on the consumer market for each COU. Based on the product type, EPA identified the type of consumer and bystander that may be exposed while a product is being used. For instance, for small scale glues under the arts, crafts, and hobby materials COU, EPA assumes the following:

1. Exposure to formaldehyde may occur while the relevant products are in use that may range from a few minutes to a few hours and possibly occur a few times per year.
2. Exposure occurs only to the consumer users in the immediate vicinity of the product as these individuals are the ones directly interacting with the small product; therefore, bystander exposure is not expected.
3. Gluing activities typically involve applying a viscous liquid to various materials by hand and due to the sticky nature of these products, dermal exposures are expected.
4. Inhalation exposures are also expected as formaldehyde is highly volatile and expected to evaporate into the immediate breathing space of the consumer, who may be a child, teenager, or adult.

EPA utilized the *Exposure Factors Handbook* and the Westat Survey to parametrize consumer modeling according to consumer use and activity patterns. The activity pattern selected for consumer modeling was stay-at-home for all consumer scenarios. The start time for product use was 9:00 a.m. and the product users were adult (>21 years of age), youth (16 through 20 years), and youth (11 through 15 years) for most scenarios; all other individuals were considered as non-users (*i.e.*, treated as bystanders). For some scenarios, the adult was considered the only product user (Floor coverings; Fuels and related products; Lubricants and greases; Paints and coatings; Photographic supplies). Other scenarios evaluated exposure for all exposed population categories (adults, youths, and children); these scenarios included Arts, crafts, and hobby; Building and construction materials (wood & engineering wood products); Electrical & electronic products; Fabric, textile, & leather products; Foam seating & bedding products; Furniture & furnishings; Ink, toner, and colorant products; Paper products; Plastic and rubber products; Polish and wax; and Toys, playground, and sporting.

This COU-specific exposure scenario identification exercise is important in fine-tuning the formaldehyde consumer exposure assessment to best exemplify real-world circumstances and was applied for each of the 12 TSCA COUs. Section 2.1.1 further describes route-specific considerations with respect to the relevant formaldehyde consumer exposure scenarios.

Inhalation exposures were assessed for all age groups as listed in Appendix A. Because there might be multiple scenarios per COU, once results were generated, EPA selected a representative scenario

according to the highest estimated concentration per duration (*e.g.*, 15-minute peak) and route of exposure, across all age groups. EPA assumes this approach is protective of most consumers within a given COU and allows the Agency to regulate according to the overall COU as mandated under TSCA. Although a few associated uncertainties with this approach include (1) the identified representative scenario according to highest estimated concentration may not necessarily be the most common, and (2) one individual may be exposed to formaldehyde through multiple scenarios within a single COU.

In addition, it should be noted that EPA only quantified exposures for plausible exposure pathways, routes, and timespans of exposure. This means that for some COUs (*i.e.*, solid products) a dermal loading was not generated because it was not deemed appropriate (*e.g.*, dermal loading from machinery, mechanical appliances, electrical/electronic articles) given the best available tools and data. This also means that the total number of COUs assessed for acute and chronic exposure scenarios (*e.g.*, 15-minute peak compared to yearly average daily concentration estimations) varied according to their relevance for the exposure assessment being performed. However, as presented in Table 1-1, EPA quantified exposures for all relevant TSCA COUs for at least one route of exposure.

2.1.1 Consumer Routes of Exposure

Based on the established 30 exposure scenarios, all routes of exposures were evaluated. The sections that follow provide route-specific considerations and examples of formaldehyde exposure scenarios relevant to this draft TSCA risk evaluation.

2.1.1.1 Inhalation

Because formaldehyde is a volatile gas, inhalation is expected to be the most common and most significant route of exposure during product use for consumers and bystanders at home (EPA, 2020b). Even when certain products or articles are not in use, formaldehyde emissions continue to occur, although they are expected to decrease over time in indoor residential environments. Consumer and bystander inhalation exposures are expected to occur during direct use of a product or article with formaldehyde vapors emitted, mists or aerosols sprayed from the product (*e.g.*, consumer inhalation of formaldehyde during use of aerosolized toilet bowl cleaners), and inhalation from indirect use after product application (*e.g.*, bystanders walking into a room that has been recently painted with a paint that emits formaldehyde after application). Generally, EPA assumes mists are absorbed via deposition of vapors and mists in the upper respiratory tract.

2.1.1.2 Dermal

Consumer exposure to formaldehyde via the dermal route from consumer products use primarily occurs via direct contact with liquids or mists sprayed during product use (*e.g.*, getting some liquid product on hands while cleaning a toilet or while using a rag to wax a car with a liquid or sprayable wax). Due to the high volatility of formaldehyde, formaldehyde vapor already dispersed in air is not expected to deposit and adhere onto skin long enough to lead to exposure. Similarly, bystander exposure to formaldehyde via the dermal route is not expected to occur because bystanders do not have direct contact with liquids or mists sprayed during product uses.

Formaldehyde is a highly volatile and reactive solvent expected to rapidly evaporate from skin (EPA, 2024a). However, there are certain consumer use scenarios where such rapid evaporation may be inhibited. For example, immersing hands into a reservoir of cleaning products without appropriate use of personal protective equipment (PPE) or using a product-soaked rag, thus leading to a higher dermal exposure than otherwise expected.

2.1.2 Consumer Modeling: Use of CEM for Inhalation and Thin Film Dermal Analysis

EPA's CEM V3.0 was used to model inhalation exposures to formaldehyde resulting from consumer product use and bystander exposure to formaldehyde via the inhalation route. EPA's Thin Film Model was used to model dermal exposures to formaldehyde resulting from consumer product use.

2.1.2.1 Inhalation Exposure Assessment

EPA estimated consumer exposures from products containing formaldehyde for COUs and exposure scenarios identified in the final scope document for formaldehyde (EPA, 2020b). Several hundred sources were reviewed during the systematic review process (EPA, 2023a) to identify information and data pertinent to TSCA relevant COUs—products which contain formaldehyde, are currently available for consumer purchase/use, and are within the scope of this draft risk evaluation. Product and/or specific information and data identified in these sources were used to support this consumer exposure assessment of formaldehyde (Maddalena et al., 2009; Kelly et al., 1999; Yu and Crump, 1998; Matthews et al., 1984; Pickrell et al., 1984; Pickrell et al., 1983). No formaldehyde-specific personal monitoring data was identified during the systematic review of relevant exposure studies. Therefore, EPA applied a modeling approach to assess consumer exposures for the TSCA COUs relevant to this risk evaluation, using the supporting information and data identified through systematic review (EPA, 2023c).

EPA's CEM version 3.0 was used to assess consumer exposure. CEM is a deterministic model that utilizes user-provided input parameters and various assumptions (or defaults) to generate exposure estimates for consumer product users and bystanders. CEM version 3.0 includes both pre-defined exposure scenarios, as well as broader generic scenarios where users are able to modify certain default values when chemical and scenario specific inputs are available. CEM is peer reviewed, provides flexibility to the user allowing modification of certain default parameters when chemical-specific information is available, and does not require chemical-specific emissions data (although in some generic scenarios emissions data may be manually input). Readers are referred to CEM's user guide and associated user guide appendices for details on the model, as well as information related to equations used within the model, default values, and the basis for default values (EPA, 2019).

Numerous input parameters are required to generate exposure estimates within CEM. When modeling to assess consumer exposures, EPA relied upon certain input parameters identified in literature during systematic review and in safety data sheets. Where input parameters were not identified in literature or SDS, or where CEM version 3.0 does not allow manual entry of a specific input, EPA relied upon default values within CEM for those inputs. Default values within CEM are a combination of high end and mean or central tendency values derived from EPA's *Exposure Factors Handbook* (EPA, 2011), literature, and other studies. Where input parameters were neither identified during systematic review or in SDS sheets nor included as a default parameter in CEM, EPA relied upon values calculated by CEM based on physical chemical properties of formaldehyde. Table 2-1 lists the consumer product scenarios modeled in CEM, in addition to supporting input parameters. The percentage of formaldehyde in formulation identified through a review of current product SDSs, CEM default product densities, and models were used to model COUs, based upon the most appropriate CEM 3.0 modeling scenario. A summary of CEM input parameters can be found in Appendix A.

444 **Table 2-1. Consumer Product CEM Modeling Scenarios and Key Product Parameters**

Consumer Product Type	Form	No. of Products Identified [a]	Range of % Formaldehyde Identified [b]	% Formaldehyde Selected for Modeling			Selected Product Density (g/cm^3) [c]	CEM 3.0 Modeling Scenario [d]	Emission Model Applied [e]
				Min	Mean	Max			
Non Pesticidal Fertilizers	Solid	2	0.10–10	0.1	2.58	10	1.00	Qualitative assessment only	N/A
	Liquid	1	0.1		0.1		1.00	Qualitative assessment only	N/A
Craft Paint	Liquid	1	0.1		0.1		1.00	Generic	E5
Building / Construction Materials – Wood Articles: Hardwood Floors	Solid	5	0.002–10	0.002	1.67	10	0.1	Wood articles: hardwood floors, furniture	E6
Glue and Adhesives	Liquid	5	0.1–10	0.1	2.96	10	1.19	Glues and adhesives, small scale	E1
Caulk	Liquid	2	0.01–0.1	0.01	0.05	0.1	1.29	Caulk (sealant)	E1
Liquid concrete	Liquid	3	0.01–0.5	0.01	0.20	0.50	1.59	Glues and adhesives, small scale	E1
Drain and Toilet Cleaners	Liquid	1	10		10		N/A	Drain and toilet cleaners	E4
Textile and Leather Finishing Products	Liquid	1	0.01–1	0.01	0.51	1.00	1.001	Textile and leather finishing products	E3
Electronic Appliances [f]	Solid	1	0.1		0.1		1.00	Electronic appliances	E6
Furniture/Seat Covers	Solid	2	1–30	1.0	8.25	30	1.00	Fabrics: furniture covers, car seat covers, tablecloths	E6
Clothing	Solid	1	0.38		0.38		0.1	Fabrics: clothing	E6
Varnishes and Floor Finishes	Liquid	1	0.10		0.10		0.88	Varnishes and floor finishes	E2
Foam Insulation	Solid	1	5–20	5	12.5	20	0.1	Not assessed as formaldehyde content in finished good insulation is expected to me minimal	N/A
Liquid Fuels/Motor Oil	Liquid	1	10–15	10	12.5	15	0.88	Liquid fuels/motor oil	N/A
Furniture & Furnishings –Wood Articles: Furniture	Solid	3	0.1–10	0.10	2.90	10	0.7	Wood articles: hardwood floors, furniture	E6
Ink, Toner, and Colorant Products	Liquid	1	0.5–0.75	0.5	0.63	0.75	1.06	Inks applied to skin	N/A
Laundry Detergent	Liquid	1	0.01		0.01		N/A	Qualitative assessment only	N/A
Hand Dishwashing Soap/Liquid Detergent	Liquid	1	0.1–0.5	0.1	0.3	0.5	1.03	Qualitative assessment only	E4
Lubricants and Greases	Liquid	2	1.00		1.00		0.9	Lubricants (non-spray)	E1
Water-Based Wall Paint	Liquid	2	0.10		0.1		1.25	Water-based wall paint	E2

Consumer Product Type	Form	No. of Products Identified [a]	Range of % Formaldehyde Identified [b]	% Formaldehyde Selected for Modeling			Selected Product Density (g/cm^3) [c]	CEM 3.0 Modeling Scenario [d]	Emission Model Applied [e]
				Min	Mean	Max			
Solvent-based Wall Paint	Liquid	3	0.1–1	0.1	0.62	1	1.2	Solvent-based wall paint	E2
Paper Products	Solid	1	1.00		1.00		0.1	Paper articles: with potential for routine contact	E6
Photographic Supplies	Liquid	1	5–15	5.00	10.0	15	1.07	Liquid photographic processing solutions	E2
Flooring/Rubber Mats	Solid	3	0.10–0.60	0.10	0.28	0.60	0.1	Rubber articles: flooring, rubber mats	E6
Plastic and Rubber Products	Solid	1	1.00–30	1.00	15.50	30	0.1	Rubber articles: with potential for routine contact	E6
Polish and Wax	Liquid	3	0.02–30	0.02	5.51	30	1.077	Exterior car wax and polish	
Toys, Playground and Sporting Equipment	Solid	2	1–30	1.00	9.25	30	0.1	Plastic articles: other objects with potential for routine contact	E6
Water Treatment (fish tank cleaning)	Liquid	3	1–30	1.00	10.83	30	N/A	Qualitative assessment only	N/A

[a] The number of products identified is based on a review of the *Formaldehyde and Paraformaldehyde Use Report* (EPA, 2020c), CDR, and a supplemental internet search of relevant products currently on the market and are not discontinued (as of final search date of May 22, 2023), during the scoping phase of the risk evaluation.
[b] The range in weight fractions is reflective of the identified products containing formaldehyde; weight fractions were sourced from product SDSs or Material Safety Data Sheets (MSDSs). See Appendix A for a detailed explanation pertaining to the estimation of low, med, and high weight fractions.
[c] Product densities were identified from product SDSs or MSDSs. When density was not reported in product MSDS or SDSs, the product density used was based on default values provided in EPA's CEM Version 3.0 (EPA, 2019).
[d] The listed CEM 3.0 modeling scenario reflects the default product options within the model, which are prepopulated with certain default parameters. However, due to EPA choosing to select and vary many key inputs, the specific model scenario matters less than the associated emission and dermal exposure models (*e.g.*, E1, E3, P_DER2a). There is some uncertainty associated with scenarios for which a CEM default product could not be identified for modeling. In such cases a generic scenario was used (*e.g.*, Arts, Crafts, and Hobby Materials).
[e] Emission models used for formaldehyde include E1 – Emission from Product Applied to a Surface Indoors Incremental Source Model, E2 – Emission from Product Applied to a Surface Indoors Double Exponential Model, E3 – Emission from Product Sprayed, E5 – Emission from Product Placed in Environment, and E6 – Emission from Article Placed in Environment.
[f] For electronic appliances weight fractions from a circuit board SDS were used, alhough it is unclear how a consumer exposure during normal use of an electronic product, solely based on a circuit board component within an electronic product.

The physical and chemical properties utilized were taken from the fate assessment for formaldehyde (EPA, 2024a). Key input parameters used to assess consumer exposure are included in Table 2-1 for each of the 30 consumer exposure scenarios evaluated with CEM and discussed in Section 3.1 and Appendix A. Additional information on key input parameters selected and the basis for that selection is provided as part of the weight of scientific evidence in Section 3.2.1 3.2.2 and the Formaldehyde Consumer CEM Exposure Planning supplemental file.

2.1.2.1.1 Inhalation Exposure Estimation

Inhalation exposure to formaldehyde-containing products was estimated using CEM, which predicts indoor air concentrations (mg/m^3) by implementing a deterministic, mass-balance calculation derived from emission calculation profiles within the model. There are six emission calculation profiles within CEM (E1–E6), which are summarized in the CEM users guide and associated appendices. If selected, CEM provides a time series air concentration profile for each run. These are intermediate values produced prior to applying pre-defined activity patterns. This approach was used to generate 15-minute peak time-weighted average (TWA) concentrations for relevant COUs per assumed location or product or article exposure. This location of exposure is colloquially referred to as a *zone* or *field* of exposure, which is further explained below. Additionally, the aforementioned reported peak concentration is defined as the highest instantaneous air concentration that is calculated by the model during any 30-second timestep and should not be interpreted as a daily maximum concentration. In addition, this 15-minute peak concentration may occur several hours after the consumer product has been used.

CEM uses a two-zone representation of the building of use when predicting indoor air concentrations. Zone 1 represents the room where the consumer product is used; zone 2 represents the remainder of the building. Each zone is considered well-mixed. CEM allows further division of zone 1 into a near-field and far-field to accommodate situations where a higher concentration of product is expected very near the product user when the product is used. Zone 1-near-field represents the breathing zone of the user at the location of the product use while zone 1-far-field represents the remainder of the zone 1 room.

Inhalation exposure is estimated in CEM based on zones and pre-defined activity patterns. The simulation run by CEM places the product user within zone 1 for the duration of product use while the bystander is placed in zone 2 for the duration of product use. Following the duration of product use, the user and bystander follow one of three predefined activity patterns established within CEM, based on modeler selection. The selected activity pattern takes the user and bystander in and out of zone 1 and zone 2 for the period of the simulation. The user and bystander inhale airborne concentrations within those zones, which will vary over time, resulting in the overall estimated exposure to the user and bystander.

Where applicable, formaldehyde consumer scenarios were quantitatively assessed using the near-field/far-field model option to capture the potentially higher concentration in the breathing zone of a product user during use.

2.1.2.2 Dermal Exposure Assessment

For formaldehyde-containing products, EPA estimated dermal exposure using CEM's Thin Film Model outside of CEM, using Microsoft Excel. The Thin Film Model (see Equation 2-1) was identified as the most appropriate tool to assess dermal exposures to formaldehyde from use of various consumer products including paints and coatings, wax and polish, and cleaning and furnishing care products. This is because the dermal POD that has been identified for formaldehyde, as discussed in the *Draft Human Health Hazard Characterization Assessment* (EPA, 2024b), already incorporates absorption. This also means that the CEM versions of this calculation (*e.g.*, P_DER2a sub-model) were not applicable

because since they assume an internal dose resulting from dermal exposures based on age-group specific body weights. For this formaldehyde dermal exposure assessment, EPA assumed the product used may involve immersion into a liquid and that a pool of a liquid product was formed on the skin, or that a rag was used that reduced the evaporation of formaldehyde during use.

Dermal exposures were calculated by estimating the dermal loading (μg/cm^2) of formaldehyde onto skin during product use whereby:

Equation 2-1.

$$\boldsymbol{Dermal\ Loading} = [\boldsymbol{Weight\ Fraction}\ (\boldsymbol{ppm})\ /\boldsymbol{1,000,000\ ppm}] \times \boldsymbol{Qu} \times \boldsymbol{1,000\ ug/mg}$$

Dermal calculations were based the weight fractions (or application rate) of the product in ppm, assuming no usage of PPE. The *Qu* is the constant for assuming quantity of the material on the skin. A *Qu* of 10.3 mg/cm^2 was used to approximate hand immersion and wiping experiments, using oil-based products expected to have longer residence times on the skin relative to water-based products, as reported in (EPA, 1992). Although this is the most protective value for consumer usage of oil-based products, it may overestimate exposures in some cases including when using water-based liquid products. Dermal exposures are only reasonably foreseen for consumers but not bystanders. In addition, only acute exposures were quantitatively assessed given the identified dermal skin sensitization POD is likely only relevant to acute exposures (EPA, 2024b).

3 RESULTS

3.1 Consumer Exposure Results

The results are presented according to the exposure scenario with the highest estimated concentration (or representative exposure scenarios) relative to other exposure scenarios per COU, as noted in Section 2.1. For instance, for the laundry and dishwashing products COU, the estimated 15 minute peak concentrations presented in Figure 3-1 and Figure 3-2 are based upon estimated concentrations from use of dishwashing products instead of laundry detergents because the estimated concentrations of formaldehyde were at least 1 and 2 orders of magnitude higher for dishwashing products in zones 1 and 2, respectively.

3.1.1 Inhalation Exposure Assessment

Figure 3-1 and Figure 3-2 present the estimated inhalation exposures for consumer users and bystanders for acute and chronic scenarios, respectively. Figure 3-1 presents inhalation exposure results according to zone or field of exposure. As noted in Section 2.1.2.1.1, estimated exposures in zone 1 or near-field are associated with consumer users of products and articles, while estimated exposures in zone 2 or far-field of exposure are associated with bystanders when consumer products or articles being used by another individual. Detailed modeling results for all exposure scenarios are provided in Table_Apx B-2 and Table_Apx B-3. For 15-minute peak inhalation concentrations, high-end scenarios are presented; that is, the maximum weight fractions of formaldehyde across products identified, 95th percentile duration of use, amount used, and frequency of use. On the other hand, for yearly average daily inhalation concentrations, central tendency scenarios are presented; that is, the arithmetic average weight fractions of formaldehyde across products identified, 50th percentile duration of use, amount used, and frequency of use.

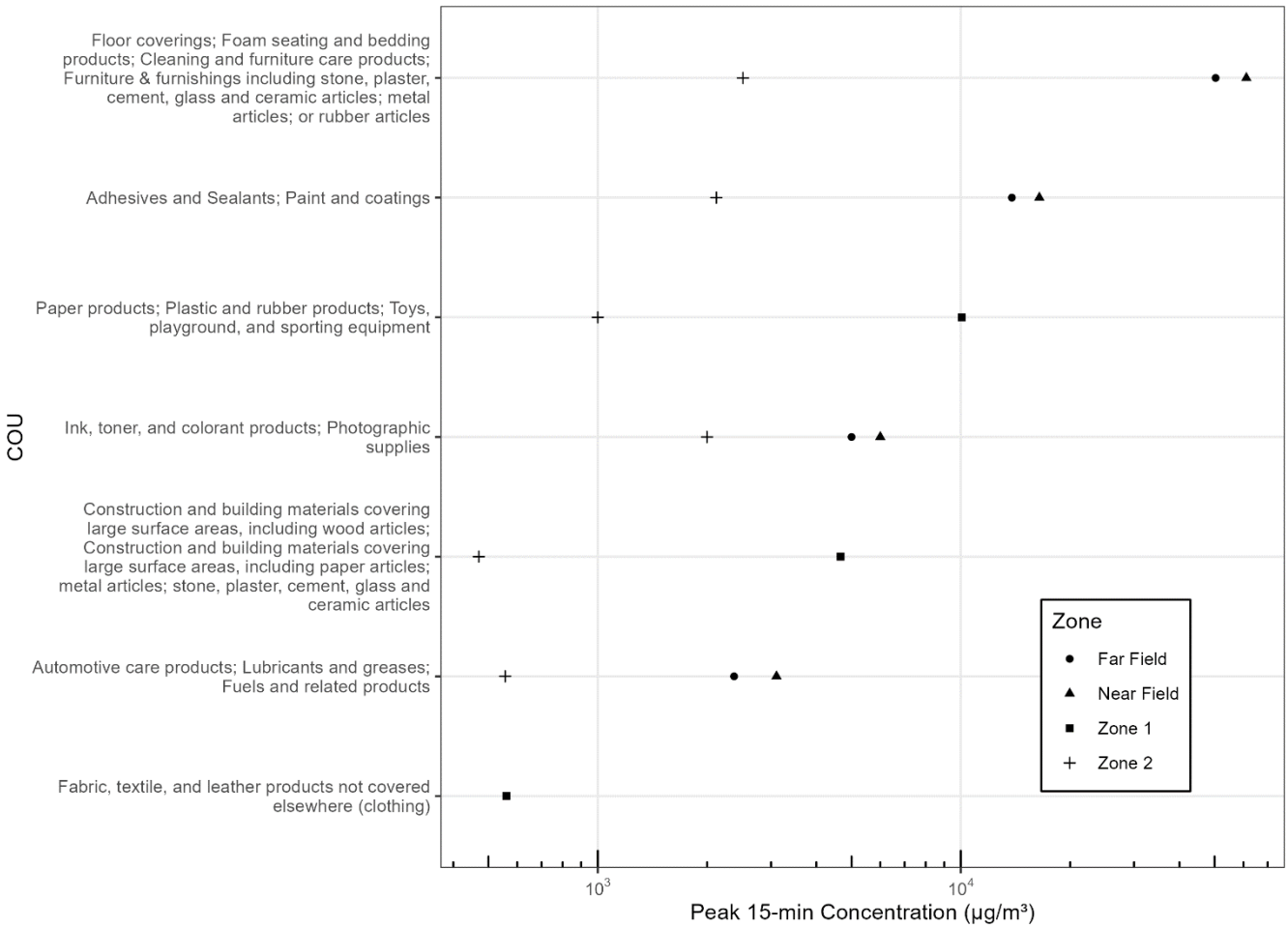

Figure 3-1. Summary of Acute Consumer Inhalation Exposures (Based on CEM)
For some products, air concentrations were modeled for near-field and far-field (generally describing differences in exposure within the same room), while for other products, concentrations were modeled for zones 1 and 2 (generally describing different rooms). Risks from near-field and zone 1 exposures generally represent risks from direct exposures to consumer users while far-field and zone 2 tend to represent risks to consumer bystanders. The x-axis presents the 15-minute peak inhalation non-cancer concentration, and the y-axis presents the modeled TSCA COU.

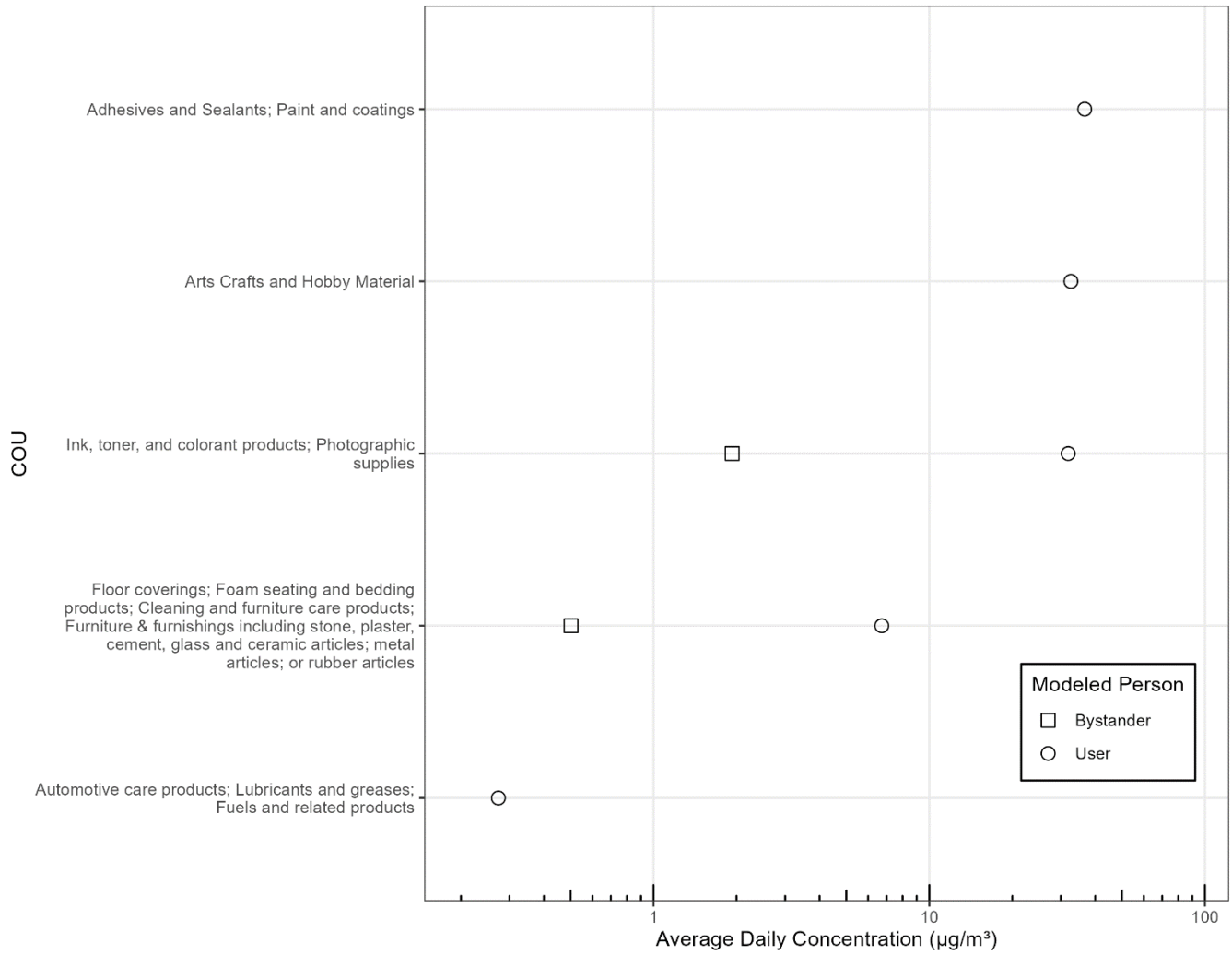

Figure 3-2. Summary of Chronic Consumer Inhalation Exposures (Based on CEM)
The x-axis presents the chronic inhalation average daily concentration per year and the y-axis presents the modeled exposure TSCA COU.

3.1.2 Dermal Exposure Assessment

Figure 3-3 presents the estimated acute dermal exposures, expressed as dermal loading in µg/cm^2 for consumer users. Detailed modeling results for all exposure scenarios are provided in Table_Apx B-4 products. For dermal loading concentrations, high-end scenarios are presented; that is, the maximum weight fractions of formaldehyde across products identified. The duration of use, amount used, and frequency of use were not relevant for this assessment.

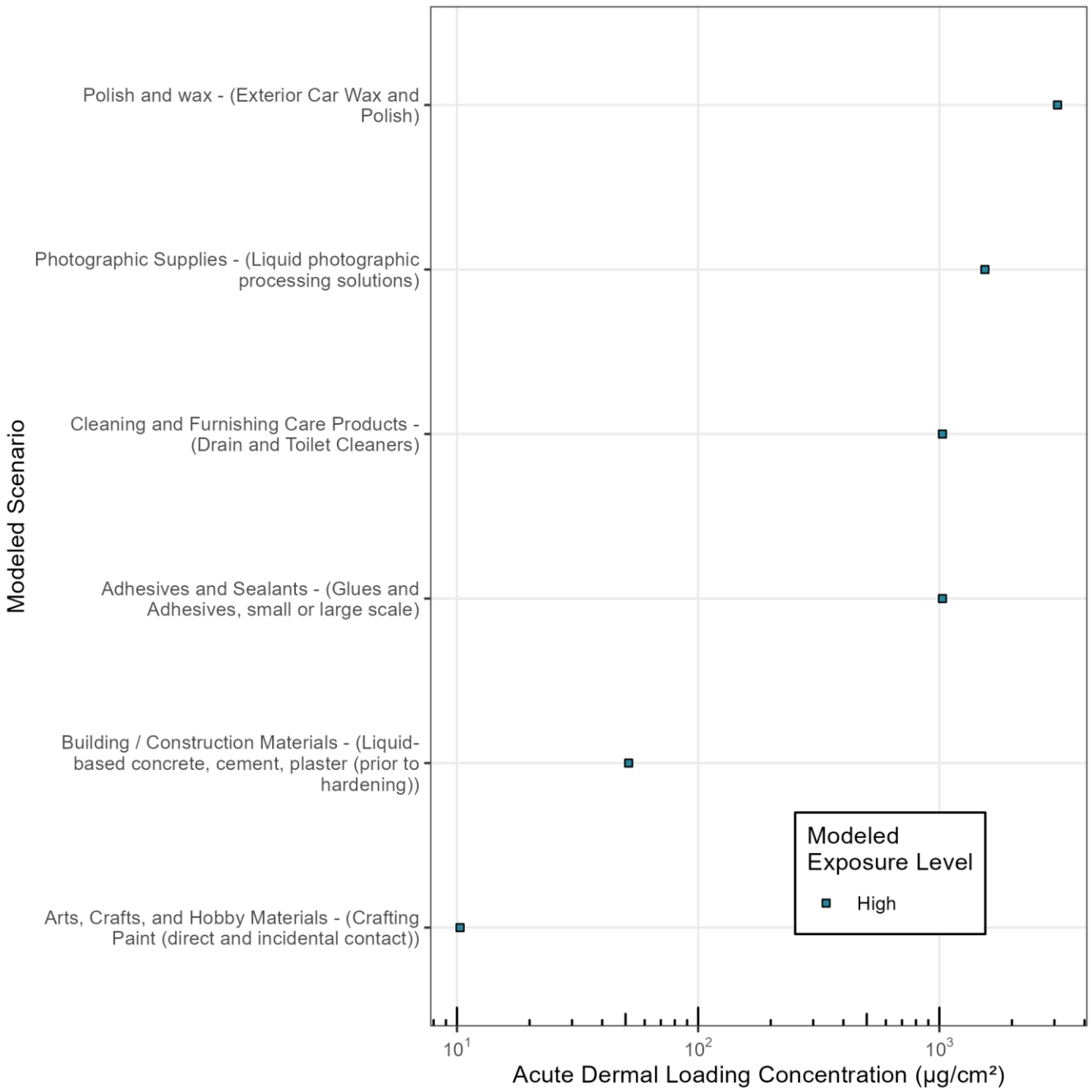

Figure 3-3. Summary of Acute Consumer Dermal Exposures (Based on Thin Film Model)
The x-axis presents dermal loading concentration and the y-axis presents the modeled TSCA COUs. The term *High* in the figure refers to high-end scenarios as described above.

3.2 Integration and Exposure Conclusions

3.2.1 Weight of Scientific Evidence

As noted in Section 1.1.1, EPA only quantitatively assessed exposures for COUs in which it had sufficient supporting evidence and at least a medium level of confidence in the relevant assessment. To summarize, EPA had a low confidence in the potential exposures of water treatment products, lawn and garden products, laundry and hand dish washing products. EPA also had a low confidence in the

assessment of oral exposures to formaldehyde and the dermal exposures from textiles treated with formaldehyde. Hence, the reported overall consumer exposure assessment confidence below do not reflect the low confidence in the aforementioned qualitative consumer assessments.

3.2.1.1 Consumer Exposure

EPA evaluated over 1,200 exposure studies with potential relevance to the draft risk evaluation for formaldehyde. Out of this total, 290 studies were of most relevance to the air pathway and contained COU-specific data for the formaldehyde exposure assessment. Out of this 290, 41 studies were rated high per systematic review exposure evaluation metrics (EPA, 2021b). Data from these 41 studies were extracted and summarized in the *Draft Risk Evaluation for Formaldehyde (HCHO) – Systematic Review Supplemental File: Data Extraction Information for General Population, Consumer, and Environmental Exposure* (EPA, 2023b) to inform the contextualization of the inhalation exposure scenarios identified for formaldehyde. See Appendix E for a detailed description of a fit-for-purpose approach implemented to identify TSCA product- and article-specific formaldehyde data from literature. In addition, CEM modeling was parameterized based on weight fractions from safety data sheets, activity and product use pattern data from EPA's *Exposure Factors Handbook* (EPA, 2011) and the 1987 Westat survey (Westat, 1987). This is the best available data we have to define the exposure scenario/consumer activities. Altogether, modeling input data (EPA, 2011; Westat, 1987) and, where appropriate, contextual information from such sources in addition to the data and information presented in the chemistry, fate, and transport assessment (EPA, 2024a), and the CEM version 3.0 modeling methodology (EPA, 2019) provide a high overall confidence in the consumer and bystander inhalation exposure assessment of formaldehyde (Table 3-1).

See Appendix E for a detailed description of a fit-for-purpose approach implemented to identify TSCA product- and article-specific formaldehyde data from literature. In addition, CEM modeling was parameterized based on weight fractions from safety data sheets, activity, and product use pattern data from the EPA's *Exposure Factors Handbook* (EPA, 2011) and the 1987 Westat survey (Westat, 1987). This is the best available data to define the exposure scenario/consumer activities. Altogether, data and information from such sources in addition to the data and information presented in the chemistry, fate, and transport assessment (EPA, 2024a) and CEM version 3.0 modeling methodology (EPA, 2019) provide a high overall confidence in the consumer and bystander inhalation exposure assessment of formaldehyde (Table 3-1).

With regard to a hazard effect of skin sensitization, only one applicable exposure study was identified for the formaldehyde risk evaluation (EPA, 1992). That study, published by OPPT, has been used extensively in previous dermal exposure assessments by OPPT and the Office of Pesticide Programs (OPP). It was used to run the Thin Film Model to estimate potential formaldehyde dermal loading following the use of a relevant consumer product. A Q_u of 10.3 mg/cm2 was used to approximate hand immersion and wiping experiments, using oil-based products expected to have longer residence times on the skin relative to water-based products, as reported in (EPA, 1992). While this is the most protective value for consumer usage of oil-based products, it may overestimate exposures for water-based products. Dermal exposures are only reasonably foreseen for consumers but not bystanders. It is possible that the expected occlusion scenarios may not occur in certain circumstances (*i.e.*, if gloves are used with a rag during cleaning). However, EPA believes the quantitatively assessed scenarios are representative of most expected dermal exposures to formaldehyde. In general, based upon the applicability of the Thin Film Model and supporting evidence, the overall confidence in the dermal exposure assessment is medium.

Table 3-1. Weight of Scientific Evidence Conclusions for the Consumer Exposure Assessments

Consumer Route (Assessment)	Confidence in Model Used[a]	Confidence in Model Default Values[b]	Confidence in User-Selected Varied Inputs[c]				Number of Monitoring Data (Confidence Rating)	Weight of Scientific Evidence Conclusion[h]
			Mass Used[d]	Use Duration[e]	Weight Fraction[f]	Room of Use[g]		
Inhalation (Consumer)	High	High	High	High	High	High	41 (rated High)	High
Dermal (Consumer)	Medium	Medium	High	High	High	High	None	Medium

[a] Confidence in "Model Used" considers whether model has been peer reviewed as well as whether it is being applied in a manner appropriate to its design and objective. CEM has been peer reviewed, is publicly available, and has been applied in a manner intended—to exposures associated with uses of household products. The Thin Film Model has been used in several OPP chemical dermal risk assessments.

[b] Confidence in "Model Default Values" considers default value data source(s) such as building and room volumes, interzonal ventilation rates, and air exchange rates in CEM. These CEM default values are all central tendency values (*i.e.*, mean or median values) sourced from EPA's *Exposure Factors Handbook* (EPA, 2011). The one CEM default value with a high-end input is the overspray fraction, which is used in the aerosol or spray scenarios. It assumes a certain percentage is immediately available for inhalation. For the Thin Film Model, a standard value (*Qu*) was used based on hand immersion and wiping experiments reported in (EPA, 1992).

[c] Confidence in "User-Selected Varied Inputs" considers the quality of their data sources, as well as relevance of the inputs for the selected consumer COU.

[d] "Mass Used" is primarily sourced from high quality studies used to develop CEM's COU-specific default mass of products used {U.S. EPA, 2019, 5205098}, which have been applied in previous agency assessments.

[e] "Use Duration" is primarily sourced from high quality studies used to develop CEM's COU-specific default mass of products used {U.S. EPA, 2019, 5205098}, which have been applied in previous agency assessments.

[f] "Weight Fraction" of formaldehyde in products is sourced from product SDSs, which were not reviewed as part of systematic review but were taken as authoritative sources on a product's ingredients.

[g] "Room of Use" (zone 1 in modeling) is informed by responses in the Westat survey {Westat, 1987, 1005969}, which received a high-quality rating during data evaluation, although professional judgment is also applied for some scenarios. The reasonableness of these judgements is considered in the reported confidence ratings.

[h] See the chemical-specific systematic review protocol for a detailed description of weight of scientific evidence ratings (EPA, 2023a).

3.2.2 Consumer Exposure Conclusions

As with other TSCA chemical risk evaluations, the formaldehyde consumer exposure assessment depends primarily on the use of CEM. As a result of the various forms of formaldehyde found in consumer products, EPA tailored its consumer exposure assessment according to the most relevant physical chemical properties (*e.g.*, molecular weight) identified in the literature and presented in the formaldehyde chemistry, fate, and transport assessment (EPA, 2024a). Weight fractions were gathered from SDSs identified and were used to tailor COU-specific consumer exposure modeling based upon products and articles identified in the consumer market. Otherwise, default parameters (Appendix A) were utilized and are also based on the literature with regards to typical consumer product and article use (EPA, 2011; Westat, 1987). The sections that follow discuss route-specific conclusions for the formaldehyde consumer exposure assessment.

Of note, while EPA attempted to assess potential exposures to the machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/ electronic articles TSCA COU. CEM did not yield any expected inhalation exposures via estimates of 15 min peak and average daily concentration per year, although modeled estimates for adhesives and sealants may be used as surrogates for the exposures to electronic products since adhesives and sealants are used in the binding of internal components and especially at the seams of electronic products. EPA does not expect dermal (skin loading) or oral exposures from use of such products.

3.2.2.1 Inhalation Exposure Assessment

As presented in Section 3.1.1, direct users of consumer products and articles (in zone 1 or near-field) generally had higher 15-minute peak TWA inhalation exposures, in comparison to bystanders (in zone 2 or far-field) as expected for all COUs. Across all relevant age groups and exposure scenarios, the highest estimated 15-minute peak TWA formaldehyde air exposure was for consumer users of floor coverings; foam seating and bedding products; etc., while the lowest acute exposure was for individuals using or wearing textile or clothing that emit formaldehyde (Figure 3-1). Consumer users of adhesives and Sealants; paint and coatings had the highest estimated yearly average daily air exposure to formaldehyde (Figure 3-2), while users of automotive care products had the lowest estimated yearly average daily air exposures.

3.2.2.2 Dermal Exposure Assessment

As presented in Figure 3-3 of Section 3.1.2, acute dermal loading for consumer users ranged from 10.3 ug/cm^2, based on the lowest identified weight fraction across all products for arts, crafts, and hobby material (crafting paint), and up to 3,090 ug/cm^2 based on the highest identified consumer product weight fractions for automotive care products. Therefore, it is reasonable to assume that dermal loading is likely driven by the identified weight fraction in the literature and SDSs. A low-, medium-, high-end estimated dermal loading corresponded with the respective low-, medium-, and high-end weight fractions identified. If only one weight fraction was identified, only one dermal loading was estimated (*e.g.*, Cleaning and furnishing care products – [drain and toilet cleaners]). This dermal assessment was only relevant to consumer users using liquid products. However, a similar supplemental dermal assessment was conducted for textile articles and is presented Appendix C.

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APPENDICES

Appendix A CEM INPUT PARAMETERS

Consumer Exposure Scenario: This represents the COU under which this product and pathway fall within the lifecycle diagram provided in the final formaldehyde scope document (EPA, 2020b).

Formaldehyde Form: This represents the form of the consumer product containing formaldehyde; extracted from the product-specific MSDS and SDS sheets identified via internet searches, etc.

Number of Products: This represents the number of products within that COU (or consumer exposure scenario); extracted from the formaldehyde scope document (EPA, 2020b).

Weight Fraction and Density: Formaldehyde weight fractions and product densities of formaldehyde containing products were compiled from publicly available product MSDS or SDS documents. If product densities were not reported, the product density used was based on default values provided in EPA's CEM version 3.0.

Weight Fraction Selected for Modeling: Weight fractions (wt%) were extracted from formaldehyde product SDSs and the formaldehyde use report (EPA, 2020c). If only one wt% was identified for a COU, EPA used this single value across low, mid, high wt%, for that given condition of use. In instances, where the true wt% was less than a given value (say a reported value of <0.1%) and no other weight fractions are reported, EPA used that value (*i.e.*, 0.1%) as the weight fraction. If there was a reported weight fraction of less than 0.1 percent and another at 5 percent, then the low and high wt% would be 0.1 and 5 percent, respectively. To report a central tendency or mid, an arithmetic average of all reported weight fractions was used across products within a COU category. If a range of weight fractions was reported, the midpoint of that range was used as the central tendency input value. Some variability in the identified weight fractions for various products, oftentimes with an undefined range (*i.e.*, <0.01%) may lead to uncertainty.

Vapor Pressure Selected for Modeling: A vapor pressure of 3,890 mm Hg (formaldehyde as a gas) was used to assess solid products such as building materials and plastics. A value of 3.3 mm Hg (formaldehyde as a polymer) was used to assess certain solid articles such as clothing and furniture covers, whereas a value of 1.3 mm Hg (formaldehyde in formalin) was used to assess liquid products such as glues, cleaners, and paints.

Selected CEM Modeling Scenario: CEM modeling scenarios were generated based on the types of products that were identified in SDSs, the scope document, and use report (EPA, 2020c) during the scoping phase of the risk evaluation for formaldehyde. Each exposure scenario was mapped according to the relevant COU.

Emission Model Applied: Five emission models were used to assess inhalation exposure for consumers and bystanders depending on the type of product or article used: E1 to E5.

- E1 is an incremental source model used to estimate emissions from products applied to surfaces and assumes a constant application rate over a specified duration of use where each instantaneously applied segment has an emission rate that declines exponentially over time at a rate that depends on the chemical's vapor pressure and molecular weight.

- E2 is a double exponential model with an initial rapid release of the chemical governed by its evaporation. This is followed by a slower release driven by diffusion. Latex paint is an example of a product for which E2 is applicable.
- E3 is the emission model for product sprayed (*e.g.*, spray cleaners) that assumes that upon a product's use a small percent of the product is aerosolized and therefore immediately available for uptake by inhalation. The remainder is assumed to contact the target surface and to later volatilize at a rate that depends on the chemical's molecular weight and vapor pressure.
- E4 is the emission from products applied to water model that assumes a constant rate of emission over time depending on its vapor pressure and molecular weight.
- E5 is model used to estimate emissions from products placed in an environment and assumes emission at a constant rate over a duration that depends on its vapor pressure and molecular weight.
- E6 (similar to E5) is a model for estimating emissions from articles placed in an environment and provides time-varying estimates of indoor gas-phase, suspended particulates, and settled particulate concentrations based on chemical emissions from an article located in an indoor environment (EPA, 2019).

Physical and Chemical Properties: Consumer products containing formaldehyde are available in several different forms (although typically liquids or solids), depending on the product. Due to the high reactivity and variability of physical chemical properties of formaldehyde in different forms and temperatures (EPA, 2024a), when assessing consumer exposures using models, EPA selected the relevant physical chemical property inputs associated with the form of the consumer product (*e.g.*, formaldehyde, paraformaldehyde, formalin). Thus, if a consumer product is a solid, then EPA utilized physical chemical properties associated with the solid form of formaldehyde from the chemistry, fate, and transport assessment (*e.g.*, vapor pressure of solid formaldehyde at room temperature). Although temperature can affect the physical chemical properties, the inputs selected for modeling assumes the product (and thus formaldehyde in the product) remains in the respective form at room temperature.

Emission Rate and Saturation Concentration: Emission rate and saturation concentration in air were estimated using default equations within CEM based on physical and chemical properties and other input parameters for those scenarios requiring such values. A background concentration of 0 mg/m^3 of formaldehyde was assumed for all scenarios.

Frequency of Use: Frequency of product use for acute exposure calculations was held constant at one event per day, and for chronic exposure calculations was assumed to be one or more events per year.

Aerosol Fraction: The aerosol fraction (*i.e.*, amount of overspray immediately available for uptake via inhalation) selected within CEM for all consumer product uses evaluated was 6 percent.

Building Volume: Building volume used for all consumer uses was the default value for a residence within CEM (492 m^3).

Near-Field Volume (Zone 1): Generally, EPA assumes that when a consumer product is used, only the user is in the room of use (zone 1) while the bystander is assumed to be outside of the room of use (zone 2). It is possible that a bystander may be in the room of use or located next to the product user. The near-field volume selected for all consumer product uses was 1 m^3.

Averaging Time: Averaging time for acute exposure was estimated according to 15 minute peak time-weighted averages during 1 day of use, and for chronic exposure was assumed to an entire lifetime (up to 78 years).

Room of Use: Room of use was selected based on either CEM scenario default room of use or professional judgment informed by Westat survey results (Westat, 1987). For some consumer use scenarios, exposures were evaluated using two different rooms of use; for the agricultural products (non-pesticidal) scenario, the analysis was conducted for both the garage and outside; for the fabric, textile, and leather products (not covered elsewhere) scenario, the rooms of use were the living room and automobile.

Acute and Chronic Scenarios: While inhalation exposure can be acute or chronic in nature, EPA does not expect consumer exposure to be chronic in nature because product use patterns tend to be infrequent with relatively short durations of use. However, the Agency presents the acute and chronic consumer results to estimate potential chronic risks. Acute exposures were defined as those occurring within a single day, whereas chronic exposures were defined as exposures comprising 10 percent or more of a lifetime, according to EPA's *Exposure Factors Handbook* (EPA, 2011). Air concentrations were estimated and reported as the 15-minute peak TWA. For acute scenarios, as customary, EPA used an upper-bound estimate of duration, amount used, and weight fraction for its CEM modeling of TSCA COUs. For chronic exposures, EPA used a central tendency estimate of duration, amount used, and weight fraction for its CEM modeling of TSCA COUs.

Activity Pattern: The activity pattern selected within CEM was stay-at-home for all consumer scenarios. The start time for product use was 9:00 a.m. and the product users were adult (>21 years of age), youth (16 through 20 years), and youth (11 through 15 years) for most scenarios; all other individuals were considered as non-users (*i.e.*, treated as bystanders). For some scenarios, the adult was considered the only product user (Floor coverings; Fuels and related products; Lubricants and greases; Paints and coatings; Photographic supplies). Other scenarios evaluated exposure for all exposed population categories (adults, youths, and children); these scenarios included Arts, crafts, and hobby; Building and construction materials (wood & engineering wood products); Electrical & electronic products; Fabric, textile, & leather products; Foam seating & bedding products; Furniture & furnishings; Ink, toner, and colorant products; Paper products; Plastic and rubber products; Polish and wax; and Toys, playground, and sporting.

Exposed Populations (Age Categories): As indicated above, consumer use scenarios were quantitatively assessed for adults (age 21+) and two youth age-groups (16 through 20 years and 11 through 15 years) as product users for most scenarios. All other individuals were considered as non-users (treated as bystanders). CEM was parameterized based on characteristics of exposed populations and default factors for those exposed populations, such as age-specific body weight, skin surface area, inhalation rates, etc., and all based on EPA's *Exposure Factors Handbook* (EPA, 2021a)—including user and bystander activity patterns.

Appendix B CONSUMER EXPOSURE DETAILS

Table_Apx B-1. Consumer Exposure COU Crosswalk

Condition of Use (COU)			Consumer Exposure Scenario (CES) Mapped to COU
Life Cycle Stage	**Category**	**Subcategories**	
Consumer Use	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	Varnishes and floor finishes
			Plastic articles: foam insulation (Living room)
			Plastic articles: foam insulation (Automobile)
			Drain and toilet cleaners
			Textile and leather finishing products
			Furniture & furnishings – wood articles: furniture
		Fabric, textile, and leather products not covered elsewhere	Fabrics: furniture covers, car seat covers, tablecloth (automobiles)
			Fabrics: furniture covers, car seat covers, tablecloth (living room)
			Fabrics: clothing
	Chemical substances in treatment products	Water treatment products	Drinking water treatment
	Chemical substances in treatment/care products	Laundry and dishwashing products	Laundry detergent (liquid)
			Hand dishwashing soap/liquid detergent
	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; Paint and coatings	Water-based wall paint
			Solvent-based wall paint
			Glues and adhesives, small scale
			Caulk (sealants)
	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	Building/construction materials – wood articles: hardwood floors
			Liquid concrete
	Chemical substances in electrical products	Machinery, mechanical appliances, electrical/electronic articles; Other machinery, mechanical appliances, electronic/electronic articles	Electronic appliances
			Lubricants (Non-spray)

Condition of Use (COU)			Consumer Exposure Scenario (CES) Mapped to COU
Life Cycle Stage	**Category**	**Subcategories**	
Consumer Use	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products	Exterior car wax and polish
			Liquid Fuels/Motor Oil
	Chemical substances in agriculture use products	Lawn and garden products	Fertilizers (garage/outside)
	Chemical substances in packaging, paper, plastic, hobby products	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	Paper articles: with potential for routine contact (diapers, wipes, newspaper, magazine, paper towels)
			Rubber articles: flooring, rubber mats
			Rubber articles: with potential for routine contact
			Plastic articles: other objects with potential for routine contact
	Chemical substances in packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Craft paint – generic
	Chemical substances in packaging, paper, plastic, hobby products	Ink, toner, and colorant products; Photographic supplies	Inks applied to skin
			Liquid photographic processing solutions

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883 **Table_Apx B-2. Acute Inhalation Exposure Summary (Based on CEM Version 3.0)**

Condition	Condition(s) of Use	Exposure Scenario[a]	Zone of Exposure[b]	15-Minute Peak Concentration (ppm)
High-End	Adhesives and sealants; Paint and coatings	**Glues and adhesives**	Near-Field	**1.34E01**
High-End		**Glues and adhesives**	Far-Field	**1.13E01**
High-End		**Glues and adhesives**	Zone 2	**1.73E00**
High-End		Caulk (sealant)	Near-Field	9.70E−01
High-End		Caulk (sealant)	Far-Field	8.00E−01
High-End		Caulk (sealant)	Zone 2	2.10E−01
High-End	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	**Building/construction materials – wood articles: hardwood floors**	Zone 1	**3.80E00**
High-End		**Building/construction materials – wood articles: hardwood floors**	Zone 2	**3.80E−01**
High-End	Fabric, textile, and leather products not covered elsewhere (clothing)	Furniture seat covers (residential)	Zone 1	1.00E−01
High-End		Furniture seat covers (residential)	Zone 2	1.00E−02
High-End		**Seat covers (automobile)**	Zone 1	**4.60E−01**
High-End		Textile – clothing (residential)	Zone 1	1.00E−02
High-End		Textile – clothing (residential)	Zone 2	5.62E−04
High-End	Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; Metal articles; Rubber articles	Furniture & furnishings – wood articles: furniture	Zone 1	2.04E00
High-End		Furniture & furnishings – wood articles: furniture	Zone 2	2.00E−01
High-End		**Drain and toilet cleaners**	Near-Field	**4.98E01**
High-End		**Drain and toilet cleaners**	Far-Field	**4.10E01**
High-End		**Drain and toilet cleaners**	Zone 2	**2.05E00**
High-End		Textile and leather finishing products	Near-Field	5.90E−01
High-End		Textile and leather finishing products	Far-Field	4.60E−01
High-End		Textile and leather finishing products	Zone 2	1.10E−01
High-End		Varnishes and floor finishes	Near-Field	5.00E−02
High-End		Varnishes and floor finishes	Far-Field	4.00E−02
High-End		Varnishes and floor finishes	Zone 2	1.00E−02

Condition	Condition(s) of Use	Exposure Scenario[a]	Zone of Exposure[b]	15-Minute Peak Concentration (ppm)
High-End	Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; Metal articles; Rubber articles	Foam seating (automobile)	Zone 1	6.80E−01
High-End		Foam seating (residential)	Zone 1	4.91E00
High-End		Foam seating (residential)	Zone 2	4.90E−01
High-End	Automotive care products; Lubricants and greases; Fuels and related products	**Lubricants non-spray**	Near-Field	**2.53E00**
High-End		**Lubricants non-spray**	Far-Field	**1.93E00**
High-End		**Lubricants non-spray**	Zone 2	**4.50E−01**
High-End	Ink, toner, and colorant products; Photographic supplies	**Liquid photographic processing solutions**	Near-Field	**4.89E00**
High-End		**Liquid photographic processing solutions**	Far-Field	**4.07E00**
High-End		**Liquid photographic processing solutions**	Zone 2	**1.63E00**
High-End	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	**Rubber articles (residential)**	Zone 1	**8.19E00**
High-End		**Rubber Articles (residential)**	Zone 2	**8.10E−01**

[a] Representative exposure scenarios, as noted in Section 2.1, are bold as these scenarios had the highest estimated concentrations per COU.
[b] Consumer user exposures are expected to occur in zone 1 and near-field, whereas bystander exposures are expected to occur in zone 2 and far-field of the residence in which the TSCA product is being used.

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886 **Table_Apx B-3. Chronic Inhalation Exposure Summary (Based on CEM Version 3.0)**

Condition	Condition(s) of Use	Exposure Scenario[a]	Receptor	Average Daily Concentration (ppm)[b]
Central Tendency	Arts, crafts, and hobby materials	**Crafting paint**	User	**2.66E−02**
Central Tendency	Adhesives and Sealants; Paint and coatings	**Glues and adhesives**	User	**2.98**E−**02**
		Caulk (sealant)	User	1.75E−04
Central Tendency			Bystander	2.20E−07
Central Tendency	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	Drain and toilet cleaners	User	5.47E−03
Central Tendency			Bystander	4.09E−04
Central Tendency		**Textile and leather finishing products**	User	**2.56**E−**03**
Central Tendency			Bystander	**1.71**E−**03**
Central Tendency		Varnishes and floor finishes	User	2.19E−04
Central Tendency			Bystander	7.93E−04
Central Tendency	Automotive care products; Lubricants and greases; Fuels and related products	**Lubricants non-spray**	User	**2.23**E−**04**
Central Tendency	Ink, toner, and colorant products; Photographic supplies	**Liquid photographic processing solutions**	User	**2.60**E−**02**
Central Tendency			Bystander	**1.57**E−**03**

[a] Representative exposure scenarios, as noted in Section 2.1, are bold as these scenarios had the highest estimated concentrations per COU.
[b] Modeling estimates are based on exposures occuring over 1-year period.

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888 **Table_Apx B-4. Detailed Estimation of Dermal Exposure for Formaldehyde (Based on Thin Film Model)**

Condition of Use	Consumer Exposure Scenario [a]	Form	Application Rate [b] in Weight% (decimal)			Application Rate in Weight% (ppm)			*Qu* [c] (mg/cm^2)	Dermal Loading[d] (µg/cm^2)		
			Low	Med	High	Low	Med	High		Low	Med	High
Arts, crafts, and hobby materials	**Crafting paint (direct and incidental contact)**	Liquid	0.001			1000.000			10.3	**10.3**		
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	Building/ construction materials – wood articles: hardwood floors	Solid										
	Liquid-based concrete, cement, plaster (prior to hardening)	Liquid	0.0001	0.002	0.005	100.000	2033.000	5000.000	10.3	**1.03**	**20.9399**	**51.5**
Machinery, mechanical appliances, electrical/electronic articles; Other machinery, mechanical appliances, electronic/ electronic articles	Electronic appliances	Solid										

Condition of Use	Consumer Exposure Scenario [a]	Form	Application Rate [b] in Weight% (decimal)			Application Rate in Weight% (ppm)			*Qu* [c] (mg/cm^2)	Dermal Loading[d] (µg/cm^2)		
			Low	Med	High	Low	Med	High		Low	Med	High
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	**Drain and toilet cleaners**	Liquid	0.100			100000.000			10.3	**1030**		
	Textile and Leather Finishing Products (stain remover, waterproofing agent, leather tanning)	Spray	0.0001	0.005	0.010	100.000	5050.000	10000.000	10.3	1.03	52.015	103
	Furniture & furnishings – wood articles: furniture	Solid										
	Varnishes and floor finishes	Liquid	0.001			1000.000			10.3	10.3		
Fabric, textile, and leather products not covered elsewhere (clothing)	Furniture covers, car seat covers, tablecloths (residential-living room or automobile)	Solid										
	Fabrics: clothing	Solid										
Automotive care products; Lubricants and greases; Fuels and related products	Lubricants (non-spray)	Liquid	0.010			10000.000			10.3	103		
	Exterior car wax and polish	Liquid	0.0002	0.055	0.300	200.000	55066.000	300000.000	10.3	**2.06**	**567.1798**	**3090**
	Liquid fuels/motor oil	Liquid	0.100	0.125	0.150	100000.000	125000.000	150000.000	10.3	1030	1287.5	1545
Ink, toner, and colorant products; Photographic supplies	Inks applied to skin	Liquid	0.005	0.006	0.008	5000.000	6250.000	7500.000	10.3	51.5	64.375	77.25
	Liquid photographic processing solutions	Liquid	0.050	0.100	0.150	50000.000	100000.000	150000.000	10.3	**515**	**1030**	**1545**

Condition of Use	Consumer Exposure Scenario [a]	Form	Application Rate [b] in Weight% (decimal)			Application Rate in Weight% (ppm)			*Qu* [c] (mg/cm^2)	Dermal Loading[d] (µg/cm^2)		
			Low	Med	High	Low	Med	High		Low	Med	High
Adhesives and Sealants; Paint and coatings	**Glues and Adhesives, small or large scale**	Liquid	0.001	0.030	0.100	1000.000	29600.000	100000.000	10.3	**10.3**	**304.88**	**1030**
	Caulk (sealant)	Liquid	0.00009	0.001	0.001	90.000	545.000	1000.000	10.3	0.927	5.6135	10.3
	Water-based wall paint	Liquid	0.001			1000.000			10.3	10.3		
	Solvent-based wall paint	Liquid	0.001	0.006	0.010	1000.000	6166.000	10000.000	10.3	10.3	63.5098	103
Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	Paper products – paper articles: with potential for routine contact (diapers, wipes, newspaper, magazine, paper towels)	Solid										
	Rubber articles: flooring, rubber mats	Solid										
	Rubber articles: with potential for routine contact (baby bottle nipples, pacifiers, toys)	Solid										
	Plastic articles: other objects with potential for routine contact (toys, foam blocks, tents)	Solid										

[a] Representative exposure scenarios, as noted in Section 2.1, are bolded as these scenarios had the highest estimated concentrations per COU.
[b] Based on the product weight fraction (application rate), assuming no usage of personal protective equipment.
[c.] Standard value used based on hand immersion and wiping experiments reported in (EPA, 1992).
[d.] Dermal Loading = [Weight Fraction (ppm) /1,000,000 ppm] × Q_u × 1,000 ug/mg.

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Appendix C SUPPLEMENTAL CONSUMER ANALYSIS: ESTIMATING ORAL EXPOSURES FROM PRODUCTS/ARTICLES

C.1 Scope of the Oral Exposure Assessment

A small amount of consumer exposure to formaldehyde via the oral/ingestion route from consumer products use may occur primarily via direct transfer of the chemical from hand to mouth (*e.g.*, getting some liquid product on fingers and then placing fingers in or near the mouth for possible ingestion of that liquid) or mouthing of formaldehyde-containing consumer products (*e.g.*, plastic toys). However, due to the high volatility of formaldehyde and rapid evaporation rate, and due to a lack of supporting evidence for the bioavailabiliity of formaldehyde via the oral pathway from products and articles, this exposure pathway is not expected to significantly contribute to exposure when compared to inhalation and dermal routes.

C.1.1 Weight of Scientific Evidence

No oral exposure studies on formaldehyde in consumer products were identified. Thus, it is unclear whether oral exposures to formaldehyde is reasonably foreseen from any TSCA COU. In addition, while CEM is traditionally an excellent for assessing oral exposures for many non-volatile chemicals, due to formaldehyde's volatility, the default values from CEM (in the absence of better data) may not be ideal to model potential leaching of formaldehyde into saliva during mouthing of products or other potential sources of oral formaldehyde exposures. The overall confidence in a quantitative assessment of oral exposures to formaldehyde from uses of products and articles, based on the available modeling tools and supporting modeling data, is low due to a lack of supporting evidence for this pathway.

Appendix D SUPPLEMENTAL CONSUMER ANALYSIS: ESTIMATING DERMAL LOADING FROM SOLID PRODUCTS/ARTICLES – CLOTHING

In addition to the estimated dermal loading analysis performed for liquid products, especially where immersion or occlusion is anticipated, EPA also performed a supplemental analysis of dermal loading to certain types of solid materials like clothing. Although EPA does not anticipate direct formaldehyde exposure from any solid articles qualitatively assessed, due to a lack of supporting evidence, the Agency investigated this potential exposure scenario. Out of all the formaldehyde consumer COUs, Fabrics: clothing was identified as the most sensible COU to assess direct formaldehyde exposure from a solid material. This is because formaldehyde and paraformaldehyde are known to be added to clothing as a fixative during the dyeing, for wrinkle reduction and other reasons through the clothing manufacturing process (IPCS, 2002). Wearing newly purchased clothing that has been treated with formaldehyde might lead to direct full body and skin loading of this chemical especially as the clothing item is worn throughout the day. Other solid consumer articles qualitatively assessed are not expected to lead to this extended acute level of exposure. Once the clothing item is washed, it is assumed that the formaldehyde used to treat the clothing will be significantly depleted (ATSDR, 1999), especially due to formaldehyde's rapid transformation in water.

According to the CEM user guide (bottom of page 70) (EPA, 2019), dermal loading from a solid article to the skin by estimating the average diffusion distance of a molecule within a solid matrix to the surface of the skin. When the diffusion distance is multiplied by the chemical concentration of the article, a daily dermal load in units of mass/area/time (mg/cm^2/day) can be calculated. CEM references (Delmaar et al., 2013) for chemical diffusion rates across articles, where Table 2 in that study provides values for solid phase diffusion coefficient for several compounds and materials. Because the diffusion coefficient of formaldehyde was not listed specifically, it was estimated using the listed chemical molecular weights and their estimated diffusion coefficient; assuming the chemical molecular weights presented in Table 2 of that study are proportional to their chemical diffusion rates from fabrics (carpet).

The reported values for carpeting fabrics were used as a surrogate, due to a lack of diffusion rate data for clothing fabrics. As such, formaldehyde's diffusion clothing-specific diffusion rate per Table 2 in (Delmaar et al., 2013) was estimated using a proportion equation whereby, if the average molecular weight per material = X diffusion rate (cm/day) then formaldehyde molecular weight of 30.031 g/mol = Y. EPA cross-multiplied this equation resulting in the average reported molecular weight (g/mol) × Y formaldehyde diffusion rate (m^2/s) = formaldehyde of 30.031 g/mol × average diffusion rate (m^2/s). Solving for Y in this equation, EPA generated an estimated formaldehyde diffusion rate (m^2/s).

The chemical concentration, due to formaldehyde applied to clothing for non-pesticidal purposes, was also estimated given that formaldehyde in most products in commerce is reported in weight fraction. From a systematic review of the literature, the reported concentrations of formaldehyde in various fabrics were extracted. Such concentrations were reported in varying units from the literature, with varying levels of accuracy (*i.e.*, concentrations reported in mg/g vs mg/sample). Only formaldehyde concentrations from clothing items were utilized for this analysis. All concentration estimates were converted to the equivalent units, in concentrations of mass per mass (*e.g.*, mg/g). The geometric mean, instead of other measures of mean, concentration of formaldehyde was estimated for clothing due to the varying units reported in the literature.

However, since mass per volume (mg/cm^3) was required to calculate dermal loading, concentrations were further converted to mass per volume (mg/cm^3) using the following equation: volume = mass / density. Density of clothing fabric was extracted from CEM (Isaacs et al., 2014). The estimated diffusion rate for formaldehyde from clothing was 46.5 cm/day. This was multiplied by the estimated formaldehyde concentration 0.0798 mg/cm^3 in fabrics to generate and estimated dermal loading of approximately 3,712 µg/cm^2/day. This is much higher than the estimated dermal loading 3,090 µg/cm^2 per use for Polish and wax – (exterior car wax and polish). It is unclear how realistic this exposure may be. It is possible that the assumptions led to an overestimate of dermal exposures through fabrics. Therefore, there is a low confidence in this assessment.

965 **Table_Apx D-1. Estimating Diffusion Coefficients of Formaldehyde for Clothing Based on Chemical Molecular Weights and**
966 **Diffusion Rates from Literature**

Substance	Matrix	Diffusion Rate (m^2/s)	Diffusion Rate (cm^2/s)	Diffusion Rate (cm/s)	Diffusion Rate (cm/day)	Mol. Weight (g/mol)	Reference
Ethyl acetate	Carpet	1.03E−8	1.03E−4	1.01E−2	8.77E2	88.11	Zhang and Niu (2004)
n-Octane	Carpet	1.69E−11	1.69E−7	4.11E−4	3.55E1	114.23	
Styrene	Carpet	4.00E−12	4.00E−8	2.00E−4	1.73E1	104.15	Little et al. (1994)
Styrene	Carpet	3.10E−12	3.10E−8	1.76E−4	1.52E1	104.15	
4-Ethenylcyclohexane	Carpet	5.20E−12	5.20E−8	2.28E−4	1.97E1	110.2	
4-Ethenylcyclohexane	Carpet	2.11E−12	2.11E−8	1.45E−4	1.26E1	110.2	
				Averages:	1.63E2	105.1733333	
	Clothing			Estimating formaldehyde diffusion rate:	4.65E1	30.031	

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969 **Table_Apx D-2. Estimating Formaldehyde Concentrations from Fabrics**

Source: HERO ID	Concentrations	Units in Mass/Nass	Concentrations in Mass/Mass (mg/g)	Density (g/cm^3)	Concentrations in Mass/ Volume (mg/cm^3)	Notes
4635	89	µg/g	0.089	0.1	0.89	Fleece (gray) 89 ug/g
4635	47	µg/g	0.047	0.1	0.47	Jersey (gray) 47 ug/g
27010	1	mg/kg	0.001	0.1	0.01	Concentrations in 112 fabric samples ranged from 1–3,517 ppm (mg/kg); 18 samples had a free formaldehyde content >750 ppm
3001257	39.8	mg/kg	0.0398	0.1	0.398	Printed cotton, underside, 39.8 mg/kg; printed shirt formaldehyde emissions in childrens' clothes with the median about 20 mg/kg and max about 59 mg/kg; mens' clothing max of 75 mg/kg
3001257	58.5	mg/kg	0.0585	0.1	0.585	Phosphorescent 58.5 mg/kg
3001257	106	mg/kg	0.106	0.1	1.06	Shirt with an "non-iron" treatment had 106 mg/kg formaldehyde
5944049	0.02	µg/mL		0.1	0.00002	0.02 µg/mL free formaldehyde in treated textiles
						Average concentrations in mass/volume: 0.0798 mg/cm^3

970 **Table_Apx D-3. Estimating Formaldehyde Dermal Loading for Clothing Articles**

Condition of Use	CEM Consumer Exposure Scenario	Average Diffusion Rate from Product or Article (*l*, in cm/day)	Chemical Concentration in Product or Article (*Cart*, in mg/cm^3)	Dermal Loading (mg/cm^2/day)	Dermal Loading (µg/cm^2/day)
Fabric, textile, and leather products not covered elsewhere (clothing)	Fabrics: clothing	46.50	0.0798	3.712	3,712

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Appendix E SYSTEMATIC REVIEW PRIORITIZATION FOR FORMALDEHYDE DATA

Summary of the Proposed Change to Systematic Review (SR) Approach for Exposure Discipline

OPPT plans to publish a draft TSCA RE for formaldehyde by December 2023. This change allows for the prioritization of high-quality, fit-for-purpose data that is critical for the formaldehyde exposure analyses and meets the current schedule for the development of exposure assessments in the draft TSCA risk evaluation.

To support this aspiration, a targeted approach was implemented to the systematic review of exposure studies for formaldehyde to address key data needs for the formaldehyde exposure assessment. This document is intended to memorialize the process agreed upon.

As of March 17, 2023, there were a total of 1,137 exposure studies; of which, 1,029 studies had completed initial reviews (*i.e.,* primary evaluations performed by the contractor) and 388 studies with QC checks completed by EPA staff. A total of 135 had data evaluation issues pending resolution. Generally, after exposure studies undergo initial review QC, data relevant to the draft TSCA risk evaluation are extracted. Of all exposure studies, only about 30 percent were available for extraction with an internal due date of June 30, 2023. To meet aforementioned deadlines and improve the quality and relevance of formaldehyde data incorporated into the relevant exposure assessments, the formaldehyde systematic review approach had to be improved to be more efficient and fit-for-purpose.

Prioritization Methodology

The data needs highlighted in Appendix E.1, according to exposure study type, emphasize the formaldehyde risk evaluation team's focus on the inhalation pathway. This is because through a review and discussion of the physical and chemical properties and exposure literature, the Formaldehyde Team determined that the inhalation pathway, especially in the indoor air environment, is likely a key risk driver for the formaldehyde risk evaluation. Thus, the formaldehyde team has taken a fit-for-purpose approach not only with the exposure assessment of formaldehyde but with the systematic review data approach that supports it. Through this fit-for-purpose systematic review, the Formaldehyde Team wanted to identify studies that contained indoor air concentration and emission rate data that were product-, article-, and COU-specific. The extracted data would be from studies that have received an overall high study rating from the exposure systematic review process (EPA, 2023a), assuming that such studies would be distinctly supportive to the formaldehyde exposure assessment, and despite the presence of studies rated medium or low that might also provide some supporting data. Those medium or low rated studies could always be extracted as needed.

To identify the most relevant studies to the formaldehyde exposure assessment, the Formaldehyde Team performed a title and abstract screening using over 130 key words (Appendix E.2) determined to be associated with formaldehyde COUs and indoor air parameters of interest, using a list of all existing formaldehyde exposure studies from Distiller that are population, exposure, comparator, and outcome (PECO) supplemental or PECO relevant-and have primary data. A Boolean search criteria was applied, generally separating keywords by COU/product or article synonym using an *or* followed by an *and* with the air/emission criteria. For example, "paint" OR "vinyl wallpaper" OR "fiber glass" OR "fiberglass" OR "latex paint" OR "glue" OR "adhesive" AND "air" OR "indoor air" OR "ambient air" OR "air pollution" OR "air release" OR "emission*" OR "emission rate*" OR "emission flux" OR "flux" OR "inhalation" OR "atmosphere" OR "fume*" OR "fugitive" OR "gas*" OR "release*" OR "air release*". Effectively, this creates a scenario where EPA was able to identify a paper with a product term such as "adhesive" in its title or abstract, but only when they appeared with an air/emission term.

Of 1,137 studies, approximately 290 were relevant to the exposure assessment of formaldehyde based on the aforementioned prioritization criteria. Of the 290 relevant studies, 185 had outstanding QCs that have now been completed. In addition, 41 articles out of the 290 prioritized studies were rated high according to the exposure discipline data evaluation metrics and proceeded through data extraction for incorporation into the exposure assessment as needed. A visual representation of the formaldehyde exposure systematic review prioritization scheme has been attached in Appendix E.3.

Impacts

The expected extracted data provides a high-level of confidence in the supporting data that is available for formaldehyde's exposure analysis, while improving the efficiency of the systematic review of formaldehyde exposure studies and data. This required the reassignment of EPA and contractors to the formaldehyde systematic review project as necessary. This proposal has facilitated the ability to meet the necessary deadlines to complete the draft formaldehyde exposure assessments.

Actions

EPA with contractor support assigned appropriate staff to support the proposed approach to review and extract formaldehyde data of interest. As directed, for the review of formaldehyde data, EPA and the contractor prioritized the evaluation and extraction of COU-specific air concentration and emission rate (and other supporting exposure modeling parameters) data.

E.1 Formaldehyde Data Needs

Within the Exposure study pool are 6 key study types: monitoring, experimental, modeling, completed assessment, database, and survey.

- ***Monitoring:*** The Formaldehyde Team determined that measured indoor and ambient air data associated with formaldehyde COUs from the monitoring study type are most relevant to the formaldehyde exposure assessment. This is because the primary media of exposure for formaldehyde is air. Some monitoring studies contain air concentration data which may be used to compare with formaldehyde exposure modeling results. In addition, modeling parameters such as room ventilation rates, may also be useful for the refinement of models such as CEM or the execution of higher-tier models like the Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) Model. This monitoring data has been identified as the top priority for formaldehyde. This data has been identified as important to extract.
- ***Completed Assessment:*** Completed assessments may contain completed risk evaluations of formaldehyde, this study type can be informational and may be referred to for contextual information (*e.g.*, methodologies, conclusions, and other information). Some completed assessment studies contain modeling parameters which may be used for the formaldehyde exposure analysis—namely, product-specific formaldehyde emission rates (and room ventilation rates, if available) useful in CEM modeling refinements or higher tier models like the IECCU. Under the current systematic review protocol for exposure, completed assessments are extracted as monitoring or modeling studies. Completed assessments typically utilize secondary data that are not extracted for any study type. However, if completed assessments have been deemed to use primary monitoring data that are COU-specific, these data are extracted. However, do not extract any other data for this study type as it is not a critical need for the formaldehyde exposure assessment.
- ***Databases:*** Databases may provide quantitative or supplementary information often useful for exposure analyses. These may include datasets that contain air or water concentration data (*e.g.*, monitoring data) such as the Water Quality Portal (WQP). Data from such source streams may

be referenced or potentially used for comparison to EPA modeled concentrations in its evaluation of formaldehyde exposures. Key datasets of need including the TRI, Discharge Monitoring Report (DMR, which contain data from the WQP), and National Emissions Inventory (NEI) and other datasets that provide direct inputs to EPA modeling efforts for formaldehyde have already been extracted and provided by ECRAD engineers according to the chemical-specific systematic review protocol (EPA, 2023a). Thus, there is currently no need for any other datasets for the formaldehyde exposure assessment. Relevant data evaluation, QC, and extraction for databases that may contain monitoring data relevant to the ambient air, indoor air, and water pathways relevant to formaldehyde COUs have been completed.

- ***Experimental:*** Modeling parameters typically found in experimental studiesm, such as permeability coefficients, and absorption fractions, have already been identified through other disciplines' systematic reviews for formaldehyde. However, COU-specific emission rates, room ventilation rates and others, and via chamber studies, for instance, are typically found in experimental study types. Such modeling parameters are useful in CEM modeling refinements or higher-tier models like the IECCU model. This experimental data has been identified as the top priority for formaldehyde and such data has been extracted as needed to support the formaldehyde exposure assessment.
- ***Modeling:*** Similar to experimental studies, modeling studies are needed for the draft formaldehyde risk evaluation. Because such COU-specific modeling parameters (*e.g.*, emission rates) have been identified as essential to the refinement of CEM modeling of consumer products or the execution of the IECCU model for the formaldehyde exposure assessment, these types of modeling data have been identified as a top priority for formaldehyde. Furthermore, such data have been extracted as appropriate to support the formaldehyde exposure assessment.
- ***Survey:*** No survey data specific to formaldehyde were identified.

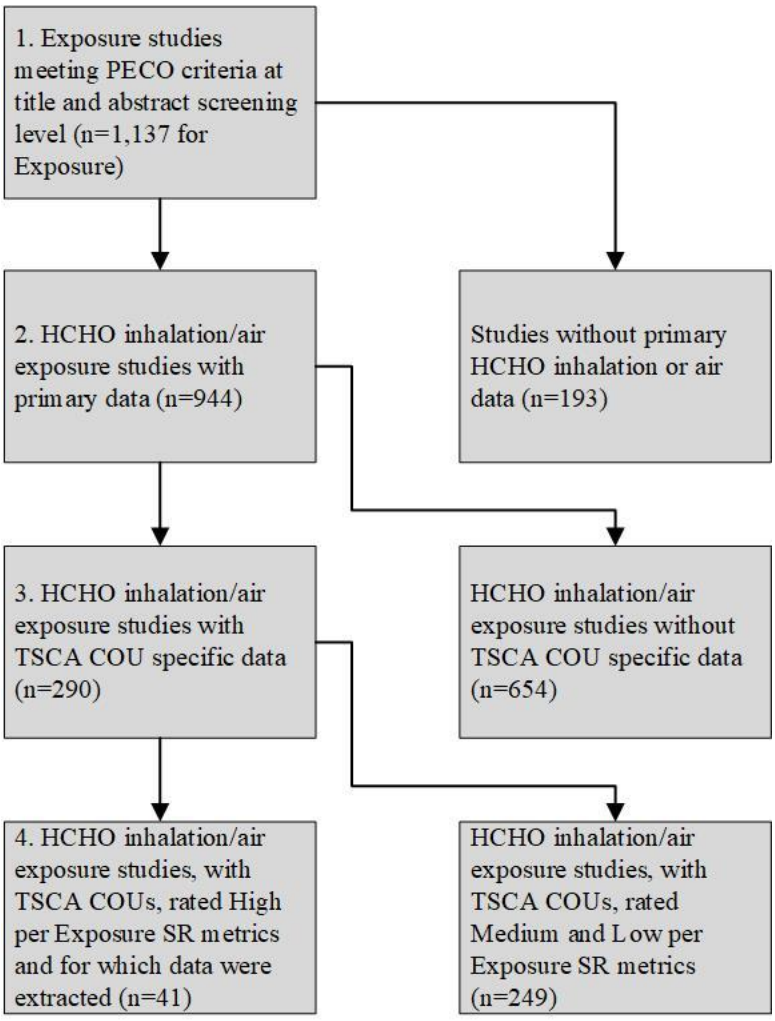
E.2 Boolean Search Terms

The following is a list of search terms derived from the formaldehyde TSCA COUs presented in the final scope of the risk evaluation for formaldehyde (U.S. EPA, 2020):

Fertilizer, paint, vinyl wallpaper, fiber glass wallpaper, fiberglass, latex paint, glue, building, wood, hardwood floor, furniture, pressed wood products, particle board, plywood, bare urea-formaldehyde wood product, coated urea-formaldehyde wood product, bare phenol-formaldehyde wood product, adhesive, caulk, sealant, vinyl covering, concrete, cement, plaster, pvc foam wallpaper, pvc wall covering, vapor barriers (bituminous tar), drain cleaner, toilet cleaner, multi-purpose cleaner, cleaner, stain remover, waterproofing agent, leather tanning, electronic, electronic appliance, furniture cover, car seat cover, tablecloth, textile wall, acoustic partitions, office chair, chair, textile, clothing, new clothing, fabric, permanent press fabric, varnish, floor finishes, floor coverings, decorative laminates, commercially applied urea-formaldehyde floor finish, foam insulation, insulation products, insulation, mineral wool insulation batt, glass wool fibrous insulation, insulant, PVC, liquid fuel, motor oil, oil, hardwood floor, furniture, chair, sofa, ink, toner, laundry detergent, dishwashing soap, soap, hand soap, liquid soap, liquid hand soap, lubricant, grease, paper, diaper, wipe, newspaper, magazine, paper towel, paper plates, paper cups, paper grocery bag, glues/adhesives (already noted above), fingernail hardener, photographic supplies, liquid photographic processing solutions, photographic processing solutions, photographic solutions, plastic, rubber, flooring, carpet, rubber mats, vinyl tiles, soft plastic flooring, cork floor tiles, plastic laminated board, black rubber trim, jointing, baby bottle nipple, pacifier, toy, car wax, polish, foam block, foam, tent, fish tank, water treatment product, drinking water treatment

product, embalming, taxidermy [and] air, indoor air, ambient air, air pollution, air release, emission, emission rate, emission flux, flux, inhalation, atmosphere, fume, fugitive, gas, release, release rate.

E.3 Formaldehyde Data Prioritization Schematic



Figure_Apx E-1. Schematic of the Approach Used to Identify and Extract TSCA COU-Specific Data Pertinent to the Formaldehyde Exposure Assessment

Appendix F ABBREVIATIONS AND ACRONYMS

µg	Microgram(s)
AC	Acute Concentration
ADC	Average Daily Concentrations
ATSDR	Agency for Toxic Substances and Disease Registries
Avg	Average
BW	Body weight
CASRN	Chemical Abstracts Service Registry Number
CDC	Centers for Disease Control
CDR	Chemical Data Reporting
CEM	Consumer Exposure Model
CFR	Code of Federal Regulations
CI	Confidence interval
COU	Condition of use
cP	Centipoise
CPCat	Chemical and Product Categories
CPSC	Consumer Product Safety Commission
CT	Central Tendency
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FR	Federal Register
GM	Geometric mean
GS	Generic Scenario
GSD	Geometric standard deviation
HERO	Health and Environmental Research Online (database)
IRIS	Integrated Risk Information System
LADC	Lifetime Average Daily Concentration
LOD	Limit of detection
Max.	Maximum
MCCEM	Multi-chamber Concentration Exposure Model
Min.	Minimum
mmHg	Millimeter(s) of Mercury
MSDS	Material Safety Data Sheet
ND	Non-detect
NR	Not reported
NRC	National Research Council (now National Academies of Sciences, Engineering, and Medicine)
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEHHA	Office of Environmental Health Hazard Assessment

OPPT	Office of Pollution Prevention and Toxics
PBZ	Personal breathing zone
PECO	Populations, exposures, comparators and outcomes
PESS	Potentially Exposed Susceptible Subpopulation
pH	Potential for Hydrogen (also Power of Hydrogen)
PPE	Personal protective equipment
RESO	Receptors, exposure, setting (or scenario), outcome
SD	Standard Deviation
SDS	Safety Data Sheet
t1/2	Half-life
TCCR	Transparent, clear, consistent, and reasonable
TCE	Trichloroethylene
TSCA	Toxic Substances Control Act
TWA	Time-weighted average
U.S.	United States
UFs	Uncertainty factors
VOC	Volatile organic compound
WHO	World Health Organization
WOSE	Weight of scientific evidence

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