

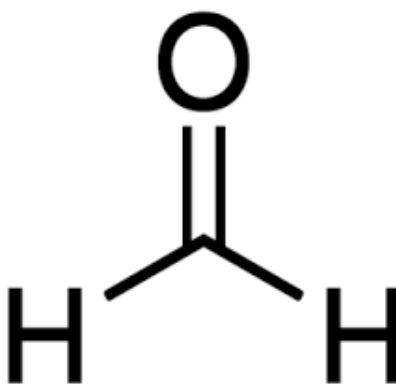


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Unreasonable Risk Determination of the Risk Evaluation for Formaldehyde

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1 RISK EVALUATION SCOPE

The TSCA risk evaluation of formaldehyde comprises a series of assessments spread across several documents. A basic diagram showing the layout and relationships of these assessments is provided below in Figure 1-1. In some cases, these assessments were completed jointly under TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These assessments are shown in dark gray. Additionally, EPA specifically recommends reviewing the *Conditions of Use of Formaldehyde* technical support document in order to provide additional clarity and context for those conditions of use (COUs) which significantly contribute to the unreasonable risk of formaldehyde.

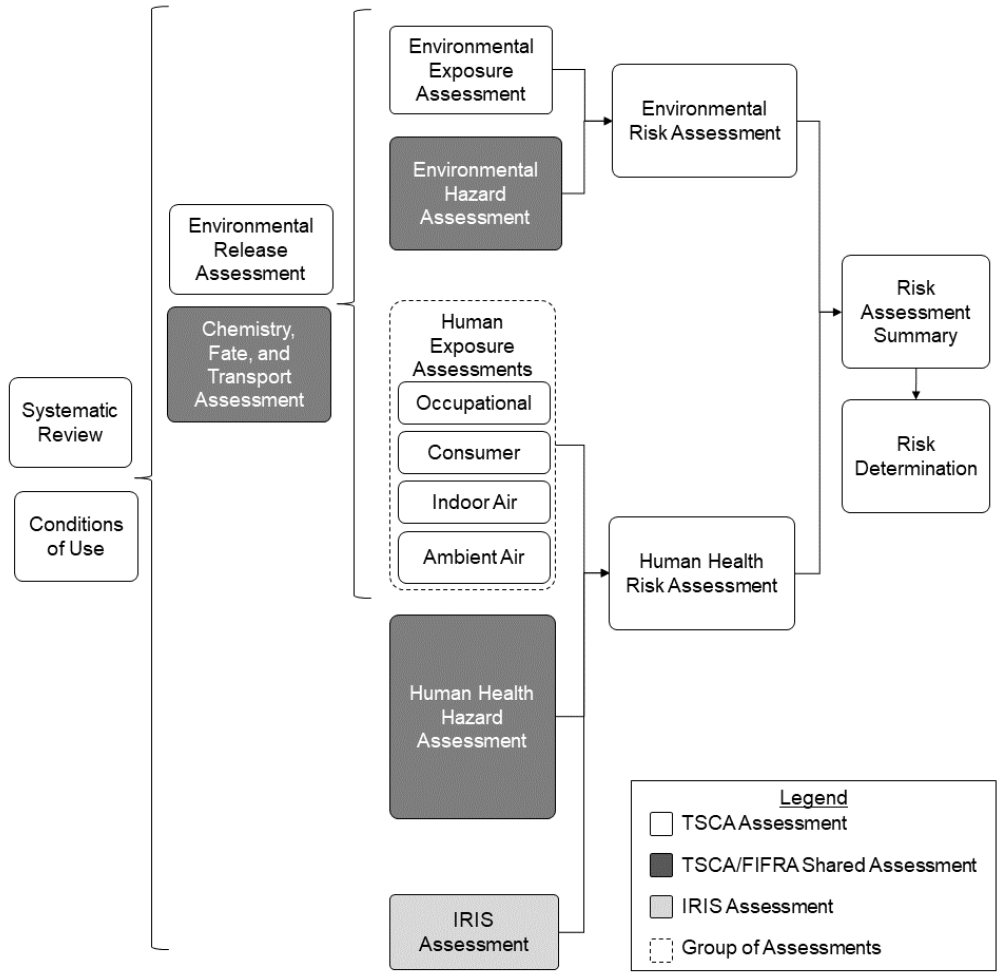


Figure 1-1. Risk Evaluation Document Summary Map

2 UNREASONABLE RISK DETERMINATION

TSCA section 6(b)(4) requires EPA to conduct a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation (PESS) identified by EPA as relevant to this risk evaluation, under the conditions of use (COUs; also called TSCA COUs).

EPA has determined that formaldehyde presents an unreasonable risk of injury to human health under the COUs because of acute inhalation and dermal exposures. The Agency also identified cancer and other chronic risk due to long-term inhalation of formaldehyde. EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk determination for formaldehyde. This unreasonable risk determination is based on the information in the *Human Health Risk Assessment for Formaldehyde*, the *Environmental Risk Assessment for Formaldehyde*, appendices contained within those documents, and TSDs (also called modules) that comprise this completed risk evaluation in accordance with TSCA section 6(b). It is also based on TSCA's best available science (TSCA section 26(h)) and weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702 including the amendments to the procedures for chemical risk evaluation (89 FR 37028; May 3, 2024).

EPA will initiate risk management for formaldehyde by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents an unreasonable risk. The risk management requirements will likely focus on those COUs that significantly contribute to the unreasonable risk. However, under TSCA section 6(a), EPA is not limited to regulating the specific COUs found to significantly contribute to unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal to address the unreasonable risk. For instance, the Agency may regulate upstream COUs (*e.g.*, Processing, Distribution in commerce) to address downstream COUs that significantly contribute to unreasonable risk (*e.g.*, consumer use)—even if the upstream COUs are not significant contributors to the unreasonable risk. The Agency would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another Federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate.

TSCA COUs represent a subset of exposures to formaldehyde. Formaldehyde is found nearly everywhere. Living things—plants, animals, and people—produce and release formaldehyde just through natural life (biogenic) processes. It is also formed when other chemicals breakdown in the environment, and is released into the air when things burn, such as when automobiles emit exhaust, when furnaces and stoves operate, and through forest fires. Formaldehyde sources in this risk evaluation involve the manufacturing, processing, distribution in commerce, use, and disposal of formaldehyde and formaldehyde-containing products and articles that are subject to TSCA. The highest releases of formaldehyde from articles occur when articles are new. In addition, other articles and products containing formaldehyde may not be subject to TSCA (*i.e.*, comprise non-TSCA COUs), including pesticides, food additives, drugs, cosmetics, and may be on the market. This results in a complex exposure profile for formaldehyde.

Overall, the unreasonable risk presented by formaldehyde is based on the significant contribution from 58 out of 63 COUs (50 out of 51 occupational COUs and 8 out of 12 consumer COUs). Specifically, EPA has determined that the unreasonable risk presented by formaldehyde is due to the following:

- Non-cancer effects in workers from acute dermal (skin sensitization) exposure, meaning that skin contact can result in an allergic response, for 48 out of 51 occupational COUs.
- Non-cancer effects in workers, including occupational non-users (ONUs), from acute inhalation (sensory irritation) exposure, meaning that formaldehyde in air can result in irritation of eyes and upper airways, for 46 out of 51 occupational COUs.
- Cancer effects in workers, including ONUs, from long-term inhalation exposure for 43 out of 51 occupational COUs.
- Non-cancer effects in consumers from acute dermal (skin sensitization) exposure for 6 out of 12 consumer COUs.
- Non-cancer effects in consumers, including bystanders, from acute inhalation (sensory irritation) exposure for 8 out of 12 consumer COUs.

The COUs evaluated for formaldehyde are listed in Table 2-1 and Table 2-2. The *Conditions of Use of the Risk Evaluation for Formaldehyde* technical support document provides additional context regarding the COUs evaluated. The following COUs are determined to significantly contribute to the unreasonable risk:

- Manufacturing (domestic manufacture)
- Manufacturing (import)
- Processing – as a reactant in:
 - adhesives and sealant chemicals in plastic and resin manufacturing; wood product manufacturing; paint and coating manufacturing; and basic organic chemical manufacturing
 - an intermediate in pesticide, fertilizer, and other agricultural chemical manufacturing; petrochemical manufacturing; soap, cleaning compound, and toilet preparation manufacturing; basic organic chemical manufacturing; plastic materials and resin manufacturing; adhesive manufacturing; chemical product and preparation manufacturing; paper manufacturing; paint and coating manufacturing; plastic products manufacturing; synthetic rubber manufacturing; wood product manufacturing; construction; and agriculture, forestry, fishing, and hunting
 - a functional fluid in oil and gas drilling, extraction, and support activities
 - processing aids specific to petroleum production in all other basic chemical manufacturing
 - bleaching agent in wood product manufacturing
 - agricultural chemicals in agriculture, forestry, fishing, and hunting
- Processing – incorporation into an article, in:
 - finishing agents in textiles, apparel, and leather manufacturing
 - paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace)
 - additive in rubber product manufacturing
 - adhesives and sealant chemicals in wood product manufacturing; plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction (including roofing materials); and paper manufacturing
- Processing – incorporation into a formulation, mixture, or reaction product, in:
 - petrochemical manufacturing; petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; petroleum and coal products manufacturing; and basic organic chemical manufacturing
 - asphalt, paving, roofing, and coating materials manufacturing

- solvents (which become part of a product formulation or mixture) in paint and coating manufacturing
- processing aids, specific to petroleum production oil and gas drilling, extraction, and support activities; chemical product and preparation manufacturing; and basic inorganic chemical manufacturing
- paint additives and coating additives not described by other categories in paint and coating manufacturing and plastic material and resin manufacturing
- an intermediate in basic chemical manufacturing; chemical product and preparation manufacturing; plastic material and resin manufacturing; oil and gas drilling, extraction, and support activities; and wholesale and retail trade
- solid separation agents in miscellaneous manufacturing
- agricultural chemicals (nonpesticidal) in agriculture, forestry, fishing, and hunting; pesticide, fertilizer, and agricultural chemical manufacturing
- surface active agents in plastic material and resin manufacturing
- ion exchange agents in adhesive manufacturing and paint and coating manufacturing
- lubricant and lubricant additive in adhesive manufacturing
- plating agents and surface treating agents in chemical product and preparation manufacturing
- soap, cleaning compound, and toilet preparation manufacturing
- laboratory chemicals
- adhesive and sealant chemical in adhesive manufacturing
- bleaching agents in textile, apparel, and leather manufacturing
- Processing – repackaging – sales to distributors for laboratory chemicals
- Processing – recycling
- Distribution – distribution in commerce
- Industrial use (non-incorporative activities)
 - as a process aid in oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing
 - used in: construction
 - oxidizing/ reducing agent; processing aids, not otherwise listed
- Industrial use – chemical substances in industrial products
 - paints and coatings; adhesives and sealants; lubricants
 - aerospace use in: paints and coatings; adhesives and sealants; lubricant; and foam insulation
- Commercial use in:
 - floor coverings; foam seating and bedding products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles ; cleaning and furniture care products; leather conditioner; leather tanning, dye, finishing, impregnation and care products; textile (fabric) dyes; textile finishing and impregnating/surface treatment products
 - water treatment products
 - laundry and dishwashing products
 - adhesives and sealants; paint and coatings
 - 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
 - machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/electronic articles
 - construction and building materials covering large surface areas, including metal articles;

- automotive care products; lubricants and greases; fuels and related products
- lawn and garden products
- explosive materials
- arts, crafts, and hobby materials
- ink, toner, and colorant products; photographic supplies
- laboratory chemicals
- Consumer use in:
 - floor coverings; foam seating and bedding products; cleaning and furniture care products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles
 - fabric, textile, and leather products (clothing)
 - adhesives and sealant; paint and coatings
 - 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
 - automotive care products; lubricants and greases; fuels and related products
 - paper products; plastic and rubber products; toys, playground, and sporting equipment
 - arts, crafts, and hobby materials
 - ink, toner, and colorant products; photographic supplies
- Disposal.

The following COUs do *not* significantly contribute to the unreasonable risk:

- Commercial use in paper products; plastic and rubber products; toys, playground, and sporting equipment
- Consumer use in water treatment products
- Consumer use in laundry and dishwashing products
- Consumer use in machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/electronic articles
- Consumer use in lawn and garden products.

Whether EPA makes a determination of unreasonable risk for a particular chemical substance under TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of the effect, exposure-related considerations (*e.g.*, duration, magnitude, frequency of exposure, population exposed), and the confidence in the information used to inform the hazard and exposure values. EPA also considered, where relevant, the Agency's analyses on aggregate exposures. This unreasonable risk determination explains how the Agency considered these risk related factors in the determination.

In the risk evaluation, the Agency describes the strength of the scientific evidence supporting the human health and environmental assessments as robust, moderate, or slight. Robust confidence suggests thorough understanding of the scientific evidence and uncertainties, and the supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that the uncertainties could have a significant effect on the risk estimates. Moderate confidence suggests some understanding of the scientific evidence and uncertainties, and the supporting scientific evidence weighed against the uncertainties is reasonably adequate to characterize risk. Slight confidence is assigned when the weight of scientific evidence may not be adequate to characterize the risk, and when the Agency is making the best scientific assessment possible in the absence of complete information.

This risk evaluation discusses important assumptions and key sources of uncertainty in the risk characterization, and these are described in more detail in the weight of the scientific evidence and overall confidence in exposure assessment (Section 2.5), as well as the weight of scientific evidence and overall confidence in hazard assessment (Section 3.2) in the *Human Health Risk Assessment for Formaldehyde*. In the *Environmental Risk Assessment for Formaldehyde* (Section 2.3.3), the Agency describes weighing the scientific evidence to determine confidence in the environmental risk assessment. The strengths, limitations, assumptions, and key sources of uncertainty in the fate and transport of formaldehyde are discussed in Section 3.8 of the *Chemistry, Fate, and Transport Assessment for Formaldehyde*.

In the formaldehyde unreasonable risk determination, EPA reviewed risk estimates with an overall confidence rating of slight, moderate, or robust and the Agency considered COUs with indeterminate exposures and COUs with limited reasonably available information. In general, EPA makes an unreasonable risk determination based on risk estimates that have an overall confidence rating of moderate or robust—because those confidence ratings indicate the scientific evidence is adequate to characterize risk estimates despite uncertainties or is such that it is unlikely the uncertainties could have a significant effect on the risk estimates.

2.1 Human Health

Calculated risk estimates (margin of exposures [MOEs] or cancer risk estimates) can provide a risk profile of formaldehyde by presenting a range of estimates for different health effects for different COUs. When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk from a baseline scenario that does not assume use of respiratory protection or other personal protective equipment (PPE)¹. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread noncompliance with existing regulations that may be applicable to formaldehyde. Rather, it reflects the Agency’s recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by Occupational Safety and Health Administration (OSHA) standards, such as self-employed individuals and public sector workers who are not covered by a state plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements. In general, the risk estimates are based on exposure scenarios with monitoring data that reflect existing requirements, such as those established by EPA (*e.g.*, National Emission Standards for Hazardous Air Pollutants [NESHAP] under the Clean Air Act), OSHA (*i.e.*, formaldehyde standard), or industry or sector best practices. However, in the case of formaldehyde, the monitoring data might not fully reflect some recent regulatory actions under TSCA Title VI, as described below.

A calculated MOE that is less than the benchmark MOE is a starting point for informing a determination of unreasonable risk of injury to health, based on non-cancer effects. Similarly, a calculated cancer risk estimate that is greater than the cancer benchmark is a starting point for informing a determination of unreasonable risk of injury to health from cancer. It is important to emphasize that these calculated risk estimates alone are not “bright-line” indicators of unreasonable risk.

¹ It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

2.1.1 Populations and Exposures EPA Assessed for Human Health

EPA evaluated risk to workers, including occupational non-users (ONUs), consumer users and bystanders, and the general population using reasonably available monitoring and modeling data for inhalation and dermal exposures, as applicable.

EPA evaluated risk from two exposure routes—inhalation and dermal—and to different population groups:

- Workers: evaluated risk from inhalation and dermal exposures;
- ONUs: evaluated risk from inhalation exposures;
- Consumers: evaluated risk from inhalation and dermal exposures;
- Bystanders (consumer): evaluated risk from inhalation exposures; and
- General population: evaluated risk from inhalation exposures.

Oral exposures were not assessed quantitatively for occupational, consumer, and the general population as there is no supporting evidence indicating that the oral route is a route of exposure (*Human Health Risk Assessment for Formaldehyde*, Section 3.2.5). EPA qualitatively assessed some oral exposures for relevant consumer COUs, but EPA is determining that this route is not likely to contribute to risk to consumers or bystanders due to the high volatility of formaldehyde, rapid evaporation rate, and due to a lack of supporting evidence via the oral pathway from products and articles (*Consumer Exposure Assessment for Formaldehyde*, Section 1.1.1.1.2.; Appendix C). Descriptions of the data used for human health exposure and human health hazards are provided in the *Human Health Risk Assessment for Formaldehyde*, Section 2.1, 2.2, 2.3, 2.4, and Section 3.1. Uncertainties for overall exposures and hazards are presented in the *Human Health Risk Assessment for Formaldehyde* Section 2.5 and Section 3.2, are described in the *Occupational Exposure Assessment for Formaldehyde*, *Consumer Exposure Assessment for Formaldehyde*, *Indoor Air Exposure Assessment for Formaldehyde*, and *Ambient Air Exposure Assessment for Formaldehyde*, and are considered in the unreasonable risk determination.

2.1.2 Summary of Unreasonable Risks to Human Health

EPA has determined that the unreasonable risk presented by formaldehyde is due to

- non-cancer effects in workers from acute inhalation (sensory irritation) and acute dermal (skin sensitization) exposures;
- non-cancer effects in ONUs from acute inhalation (sensory irritation) exposures;
- cancer effects in workers and ONUs from long-term inhalation exposures; and
- non-cancer effects in consumers and bystanders from acute inhalation (sensory irritation) and acute dermal (skin sensitization) exposures.

Table 2-1 and Table 2-2 provide further detail regarding the conditions of use that EPA has determined significantly contribute to the unreasonable risk of formaldehyde.

Sensory irritation consists of irritation of eyes and upper airways and is commonly used as a parameter for setting occupational exposure limits. Although sensory irritation may be reversible and less serious than cancer, sensory irritation is still a serious effect that can lead to other undesirable outcomes such as reduced visibility or falls in the workplace. As such, risk estimates based on sensory irritation in workers, including ONUs, are a starting point for informing a determination of unreasonable risk. In addition, sensory irritation may have similar effects in consumers and bystanders, so EPA considers the effect from these acute exposures to inform a determination of unreasonable risk.

Similarly, skin sensitization or irritation of the skin, including allergic reaction, is a known occupational illness. Due to its prevalence, persistence, and impact on quality of life, skin sensitization is recognized

as an important occupational and general health issue. The risk estimates based on skin sensitization are a starting point for informing a determination of unreasonable risk.

EPA's exposure and overall risk characterization confidence levels are summarized in the *Human Health Risk Assessment for Formaldehyde*, Sections 2.5 and 3.2. The health risk estimates for workers, including ONUs—as well as the general population, consumers, and bystanders—are presented in Section 4.2 of the *Human Health Risk Assessment for Formaldehyde*.

2.1.3 Basis for Unreasonable Risk to Human Health

In developing the exposure and hazard assessments for formaldehyde, EPA analyzed reasonably available information to ascertain whether some human populations may have greater exposure and/or susceptibility than the general population to the hazard posed by formaldehyde. The Agency identified as Potentially Exposed or Susceptible Subpopulations (PESS) people who are expected to have greater exposure to formaldehyde, such as people exposed to formaldehyde at work, those who frequently use consumer products containing high concentrations of formaldehyde, people living or working near facilities that emit formaldehyde, and people living in mobile homes and other indoor environments with high formaldehyde concentrations (see *Human Health Risk Assessment for Formaldehyde*, Section 4.2.6 and Table 4-4). Additionally, EPA identified as PESS people who may have greater susceptibility to the health effects of formaldehyde, including, infants and children, developing embryos and fetuses, people of reproductive age, and people who have pre-existing health conditions, such as asthma, allergies, or nasal damage. A full PESS analysis is in Appendix C.1. and Appendix C.2 of the *Human Health Risk Assessment for Formaldehyde*.

Risk estimates based on high-end exposure levels (*e.g.*, 95th percentile) are generally intended to cover individuals with sentinel exposure, whereas risk estimates for the central tendency exposure are intended to cover average or typical exposure. In terms of aggregate exposures, cancer risk is only quantified for inhalation exposures and therefore cannot be quantitatively aggregated across multiple routes. Similarly, the non-cancer risks are highly route-specific with the effect occurring near the portal of entry. EPA concluded that the non-cancer risks are not additive across routes (*i.e.*, inhalation and dermal). EPA considered the combined exposures that may result from multiple sources releasing formaldehyde to air in a particular indoor or outdoor environment. More information on how EPA characterized sentinel and aggregate risks is provided in Section 4.3 of the *Human Health Risk Assessment for Formaldehyde*.

2.1.4 Workers

Based on the occupational risk estimates and related risk factors, EPA has determined that formaldehyde presents unreasonable risk due to:

- non-cancer risks from acute inhalation exposure to workers, including ONUs;
- non-cancer risks from acute dermal exposure to workers; and
- cancer risk from long term inhalation exposure to workers, including ONUs.

With respect to the non-cancer chronic effects, the point of departure (POD) used is based on pulmonary function response in children, however, several SACC Committee members had concerns with determining risk to workers based on health effects observed in children. See page 56 of the *Meeting Minutes and Final Report for the Science Advisory Committee on Chemicals Public Virtual Meeting "Peer Review of the 2024 Draft Risk Evaluation for Formaldehyde."*

For each occupational COU, EPA provided a high-end and a central tendency risk estimate. The high-end risk estimates are based on the 95th percentile of the exposure data and the central tendency risk estimates are based on the 50th percentile of the exposure data. The distributions may show large

variability for each exposure scenario due to variations in work tasks, different processes, and engineering controls across the different sites represented in the data. The 95th percentile represents those worker exposure groups that may have high exposure or sentinel exposure at the workplace.

For acute effects, the use of the high-end risk estimate was used to make a risk determination as the hazard effect can occur after experiencing the exposure only once and no additional assumptions on frequency are needed. For long-term exposures leading to cancer risks, in general, EPA considered the high-end risk estimates for workers and central tendency for ONUs, since EPA generally used monitoring data (*i.e.*, workplace measured concentrations) that represents a range of exposure scenarios across workers and, in most cases, cannot be tied to specific worker tasks.

For acute exposures, EPA calculated risk estimates based on samples that were measured for 15 minutes and up to 60 minutes. In addition, EPA considered exposure samples that fell between 15 minutes and 330 minutes, the cut-off EPA used for full-shift estimates. In addition, EPA analyzed and considered risk estimates for the occupational scenarios using a time-weighted average (TWA) for a typical 8-hour shift as well as a 12-hour shift. EPA assumes that the worker is exposed for 250 days (8 hrs/day, 5 days per week for 50 weeks) unless additional information suggests otherwise. Cancer risk estimates were calculated and included an exposure time frame over a 40-year work tenure for the high-end exposure and a 31-year work tenure for the central tendency exposure. Worker cancer risk estimates across occupational TSCA COUs for inhalation exposure range from 6.7×10^{-9} to 1.3×10^{-2} for both high-end and central tendency exposures. More detail regarding the assumptions is described in Section 4.2.1.1.2. of the *Human Health Risk Assessment for Formaldehyde*.

For many COUs assessed, ONUs were evaluated using the central tendency estimates for workers since the risk to ONUs are assumed to be equal to or less than risk to workers who handle materials containing formaldehyde as a part of their job. Additionally, EPA evaluated dermal exposures only for workers since ONUs are not expected to directly handle formaldehyde.

For two commercial COUs that contain wood articles and composite wood products regulated under TSCA Title VI—floor coverings; foam seating and bedding products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; cleaning and furniture care products; leather conditioner; leather tanning, dye, finishing impregnation and care products; textile (fabric) dyes; textile finishing and impregnating/ surface treatment products; and 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—the exposure scenario is based on monitoring data of installation and demolition of building and construction materials, and EPA does not expect that the monitoring data reflects exposures from articles covered under TSCA Title VI. Although EPA found risks to workers from these COUs, the Agency has determined that composite wood products regulated under Title VI do not significantly contribute to the unreasonable risk of formaldehyde included in this two commercial COUs.

More information on EPA's confidence in these risk estimates and the uncertainties associated with them can be found in Section 2.5.1 of the *Human Health Risk Assessment for Formaldehyde*.

2.1.5 Consumers

Based on the consumer risk estimates and related risk factors, EPA has determined that formaldehyde presents unreasonable risk due to

- non-cancer risks from acute inhalation and dermal exposure to consumers; and

- non-cancer risk from acute inhalation exposure to bystanders.

Dermal exposures were assessed for acute non-cancer risks for consumers only since bystanders would not be expected to physically interact with any of the consumer COUs. EPA does not expect most consumer exposures to be chronic in nature because product use patterns generally tend to be infrequent with relatively short durations of use, such as glue, craft paint, lawn fertilizers, and automotive polishes. Therefore, EPA did not consider risks for consumers due to long-term exposures, but EPA considered chronic exposures to the general population from many sources of formaldehyde within homes and vehicles.

Consumers and bystander risks were evaluated for consumer COUs that represent applicable age groups. Typically, consumers are adults since most COUs/products purchased are for adult use or application, while bystanders would include other adults in the home as well as children.

For some consumer COUs, EPA determined that certain exposure routes were not likely and, therefore, were not assessed for the relevant COU. For example, for one consumer COU—Machinery, mechanical appliances, electrical/ electronic articles; other machinery, mechanical appliances, electronic/ electronic articles—no assessment was made for any exposure route as EPA determined there were no viable exposure pathways via inhalation or dermal routes for products within this COU. This is because normal consumer use of an electronic product, such as a circuit board component located within an electronic product, will not entail handling them in a way that would result in exposure to the consumer. Circuit boards may include formaldehyde-based adhesives in small amounts to glue the intricate parts, such as wiring separate components together before encasing them in a larger body. Many of these products might include appliances, electric controls, telephones, electrical switches, and circuit breakers (Section 2.2. of the *Human Health Risk Assessment for Formaldehyde*).

For the remaining consumer COUs, EPA evaluated the risk to consumers and bystanders using the 15-minute peak and 1-year average daily concentrations for inhalation exposures and the dermal loading during relevant product and article use with the Consumer Exposure Model (CEM). For the unreasonable risk determination, EPA considered the high-end exposures, because it is reasonable that a consumer may experience high-end exposure from use of a single product (e.g., one that contains a high amount of formaldehyde) and that exposure can result in a hazard effect.

For two consumer COUs that contain wood 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 and 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, EPA found acute inhalation risks. Both COUs contain wood articles and composite wood products regulated under TSCA Title VI. However, consistent with EPA's findings as part of the *Indoor Air Exposure Assessment for Formaldehyde* and as explained in Section 2.1.6. of this Unreasonable Risk Determination, the Agency has determined that composite wood products regulated under Title VI do not significantly contribute to the unreasonable risk of formaldehyde due to acute inhalation effects for consumers.

EPA has medium confidence in the inhalation exposure assessment for consumers and medium confidence in the dermal exposure assessment for consumers. More information on EPA's confidence in these risk estimates and the uncertainties associated with them can be found in the *Human Health Risk Assessment for Formaldehyde*, Section 2.5.2.

EPA did not quantify exposures for some COUs in which EPA had a slight confidence in the exposure assessment. For this reason, the Agency has determined that the following consumer COUs do not significantly contribute to the unreasonable risk: (1) Water treatment products, (2) Laundry and dishwashing products, and (3) Lawn and garden products.

2.1.6 General Population

The risk estimates calculated using releases from manufacturing, processing, and industrial uses of formaldehyde indicates risk for general population due to formaldehyde concentration in ambient air. In addition, EPA considered residential and nonresidential exposures for its evaluation of formaldehyde indoor air concentrations. Although the risk evaluation indicates risk, EPA did not identify risk from the following exposure routes that would contribute to the unreasonable risk of formaldehyde:

- non-cancer risk from acute inhalation exposure to ambient and indoor air to the general population;
- non-cancer risk from long-term inhalation exposure to ambient and indoor air to the general population; and
- cancer risk from long-term inhalation exposure to ambient and indoor air to the general population.

For members of the general population exposed due to releases from the manufacturing, processing, and industrial COUs, EPA considers a cancer risk benchmark of 1×10^{-6} ; however, the benchmark is not considered a bright-line and other risk related factors were considered such as the endpoint under consideration, the reversibility of the effect, exposure-related considerations (*e.g.*, duration, magnitude, frequency of exposure, population exposed), and the confidence in the information used to inform the hazard and exposure values.

Formaldehyde is not expected to persist in water or land based on the chemical, fate, and transport properties of formaldehyde. As such, EPA does not expect general population exposure to formaldehyde to occur via either the water or land pathway and therefore did not quantitatively assess exposures via these routes.

Section 4.2.4 of the *Human Health Risk Assessment for Formaldehyde* provides detailed information regarding the risk estimates for ambient air, and Section 4.2.3 of the *Human Health Risk Assessment for Formaldehyde* provides detailed information regarding the risk estimates for indoor air.

Inhalation – Ambient Air

EPA's assessment relied on a combination of monitoring data for formaldehyde from the Ambient Monitoring Technology Information Center (AMTIC) Ambient Monitoring Archive from 2015 through 2020, and modeled data using tools like the AirTox Screening Tool and the Integrated-Outdoor Air Calculator (IIOAC). The AMTIC data reflects aggregate exposures from all sources of formaldehyde (including TSCA and other sources of formaldehyde). The IIOAC modeled concentrations are specific to TSCA sources, based on industry sector release data from 2016 to 2021 under the Toxics Release Inventory (TRI) program, and are linked to relevant TSCA COUs for the formaldehyde risk evaluation. EPA also used the Human Exposure Model (HEM) to help understand how modeled air concentrations (and associated risks) at the national level intersected with populated areas. The HEM results also represent an aggregation of exposures from multiple nearby facilities (*e.g.*, facilities in proximity to others releasing formaldehyde to the ambient air).

Short-term risk estimates for ambient air in this assessment are based on the maximum release scenario and the 95th percentile modeled daily average exposure concentrations at 100 meters (m) from a

releasing facility as described in Section 2.4.2.1.1 of the *Ambient Air Exposure Assessment for Formaldehyde*.

Acute Risk: None of the risk estimates were below the acute benchmark MOE of 3 for exposures primarily attributable to the manufacturing, processing, and industrial COUs, indicating that acute risk to the general population is not expected.

Chronic Risk: Long-term risk estimates for ambient air are based on the 95th percentile release scenario and the 95th percentile modeled annual average exposure concentrations within the area distance of 100 to 1,000 meters from a releasing facility as described in Section 2.4.2.1.2 and the *Ambient Air Exposure Assessment for Formaldehyde*. The population living or working within 100 to 1,000 m of the facilities (or fence-line population) are considered PESS and would represent the highest exposure group of the general population exposed to formaldehyde.

Non-Cancer Chronic Risk: None of the non-cancer risk estimates were below the benchmark MOE of 3 for exposures primarily attributable to the TSCA COUs, indicating that non-cancer chronic risk to the general population is not expected.

Cancer Risk: The risk evaluation calculated cancer risk to the general population for 23 of the 44 COUs assessed due to formaldehyde concentrations in ambient air; however, formaldehyde concentrations are highly variable based on location, releases, weather conditions, and other sources of formaldehyde, and there is uncertainty in the geographic and temporal nature of the cancer risk estimates. EPA has medium confidence in the ambient air risk assessment, due to uncertainties related to input parameters, and spatial and temporal differences across the multiple lines of evidence considered.

The highest risk is above the 1×10^{-6} cancer benchmark for some communities—particularly those near releasing facilities and especially some facilities with releases attributed to combustion. There remain uncertainties with regard to cancer hazard assessment as described in the *Human Health Risk Assessment for Formaldehyde*. Additional conservative assumptions that reduce EPA's confidence in the realism of its risk calculations include:

- that individuals within 100 to 1000 m are exposed to high-end modeled formaldehyde concentrations in ambient air for the entire duration of their life (*i.e.*, 78 years); and
- that no atmospheric degradation of formaldehyde occurs, which may reduce ambient air concentrations.

Furthermore, additional regulatory measures already promulgated but not yet implemented under the Clean Air Act (*e.g.*, regulations expected to reduce emissions from combustion sources such as vehicles, oil and gas and other facilities), as well as regulatory steps EPA expects to promulgate under TSCA to address the unreasonable risk to workers and consumers would be expected to also reduce ambient exposures to the general population. As such, all of these considerations lead the Agency to find that general population exposures from ambient air emissions under the conditions of use of formaldehyde do not significantly contribute to the unreasonable risk of formaldehyde. More information on EPA's confidence in exposures, risk estimates, and risk characterization for ambient air can be found in Section 4.2.4.7 of the *Human Health Risk Assessment for Formaldehyde*.

Inhalation – Indoor Air

There are many sources of formaldehyde within homes and vehicles. These include sources from articles such as building materials, wood flooring, paint, and fabrics as well as combustion sources like candles, fireplaces, or stoves. Additionally, consumer products containing formaldehyde may also add to indoor

concentrations of formaldehyde. EPA considered monitoring data as an indication of aggregate exposure and risks from all sources contributing to formaldehyde in indoor air, but the monitoring data do not provide information about the relative contributions of each source. EPA also used models to estimate formaldehyde concentrations from TSCA conditions of use that cannot otherwise be distinguished from other sources of formaldehyde reflected in measured indoor concentration data. EPA used the Consumer Exposure Model (CEM) to estimate long-term indoor air exposures and refined the results with IECCU modeling to estimate acute and long-term risks for exposure to formaldehyde in residential indoor air associated with specific TSCA COUs.

Using the AHHS II, EPA estimated a median aggregate cancer risk of 2×10^{-4} and a maximum risk value of 1.3×10^{-3} . However, this risk estimate is expected to represent long-term aggregate exposures that include TSCA COUs as well as other sources. Furthermore, the survey was conducted from March 2018 through June 2019, and therefore does not fully reflect implementation of the Formaldehyde Standards for Composite Wood Products (40 CFR Part 770), which required (1) compliance with emissions standards for certain composite wood panels by June 2018, and (2) compliance for laminated products by March 2024. It is expected that this aggregate cancer risk will decrease considerably as a result of implementation of the composite wood products rule. EPA further refined the indoor air assessment by using two different models.

EPA estimated risks for four COUs expected to be significant and persistent emitters of formaldehyde in the indoor air environment. These types of products can include furniture, cabinetry, drywall, plaster, tile, wallpaper, flooring, foam seating, mattresses, clothing, household cleaning supplies, cardboard boxes, plastic home articles, toys, and sporting equipment. The four consumer COUs assessed included

- 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;
- Fabric, textile, and leather products not covered elsewhere (clothing);
- 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; and
- Paper products; plastic and rubber products; toys, playground, and sporting equipment.

The risk estimates in the indoor air scenario for the residential COUs included two COUs with wood products: (1) 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; and (2) 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. These COUs contain composite wood products, many of which are regulated as finished goods under TSCA Title VI. Finished goods include furniture and cabinetry while other regulated composite wood products include flooring. TSCA Title VI reduces exposure to formaldehyde emissions from certain composite wood products such as hardwood plywood, medium density fiberboard, and particleboard.

The CEM is commonly used by EPA to estimate exposure to chemicals in consumer products and articles for TSCA conditions of use; however, the model tends to over-estimate formaldehyde indoor air concentrations since it has a constant rate of formaldehyde emissions. Previous studies have demonstrated that articles generally exhibit an initial period of high emissions, followed by a rapid, non-linear decline in the emission rate. To address the uncertainties for the CEM, EPA modeled indoor air concentrations using the IECCU Model. However, based on studies conducted in residential homes, it is

possible that air concentrations resulting from formaldehyde emissions from articles may remain elevated longer than the IECCU models indicate. In general, articles with large surface areas may contribute significantly to formaldehyde concentrations measured in homes. The extent of this contribution is variable, depending on the article, consumer preferences, room of use, home size and configuration, ventilation rates, and relevant meteorological parameters (*i.e.*, temperature and humidity). Peak exposures to formaldehyde from these articles are expected to occur within 1 year of manufacture or use and formaldehyde concentrations substantially diminish within the first few months and years of the article life. Using both models provides the potential range of formaldehyde concentrations in indoor air given the uncertainties of both models. The lowest long-term, non-cancer risk estimate calculated with CEM is 0.59 (for construction materials) and with IECCU all the risk estimates are greater than the benchmark MOE of 3. The highest cancer risk estimates calculated with CEM was 3.6×10^{-4} (for construction materials), and with IECCU was 7.03×10^{-5} (for construction materials). Beyond the scope of the models were other variables involved during the production of composite wood products subject to TSCA Title VI, such as resin chemistry, core type, and curing process. Based on emissions associated with the four COUs assessed, as described in the *Human Health Risk Assessment for Formaldehyde*, Section 4.2.3, EPA did not identify risk from the general population long-term inhalation exposure to indoor air from wood articles that would contribute to the unreasonable risk of formaldehyde. This includes wood articles and composite wood products that are regulated pursuant to TSCA Title VI.

The largest contributors to the average daily concentration of formaldehyde in a typical home are the wood articles, and the lowest contributions are from the Fabrics and paper, included in the paper products; plastic and rubber products; toys, playground, and sporting equipment and fabric, textile, and leather products not covered elsewhere (clothing) COUs. Therefore, EPA did not identify risk based on acute inhalation exposures to the general population in indoor air that would significantly contribute to the unreasonable risk determination for formaldehyde.

Finally, EPA assessed the risk to the general population in automobiles using CEM only, because IECCU modeling (*i.e.*, Simulation Program for Estimating Chemical Emissions from Sources and Related Changes to Indoor Environmental Concentrations in Buildings with Conditions and Unconditioned Zones) cannot account for the indoor environment in automobiles. Polyoxymethylene or POM, is a specialized, engineered polymer in which formaldehyde is used as an upstream ingredient and can be found in a wide range of automobile products—including interiors such as seatbelts, buckles, door trims, and dashboards. Formaldehyde emissions are expected to be very low since most of the formaldehyde in POM materials are expected to be mostly reacted by the time of installation in a vehicle. Therefore, based on the CEM results, EPA did not identify risk from exposures to the general population in automobiles indoor air that would contribute to the unreasonable risk of formaldehyde.

In summary, EPA did not identify risk from general population exposure to the indoor air in homes and automobiles for common household products and automobile interiors that would contribute to the unreasonable risk of formaldehyde. This includes composite wood products manufactured under TSCA Title VI and automobile products made from POM. EPA's overall confidence in the indoor air consumer analysis was medium. More information on the Agency's confidence in these risk estimates and the uncertainties associated with them can be found in the *Human Health Risk Assessment for Formaldehyde*, Section 2.5.3. and in the model discussions in Section 3.2.2. and Section 3.3.2 of the *Indoor Air Exposure Assessment for Formaldehyde*.

2.2 Environment

In general, the Agency determines a risk profile by comparing a range of environmental toxicity endpoints with ambient concentrations associated with the COUs of formaldehyde. When the ambient

concentrations are less than the concentrations associated with the toxicity endpoint, this generally means that risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance is not indicated. When the ambient concentration is greater than the concentration associated with the toxicity endpoint, this generally means that risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance is indicated.

2.2.1 Populations and Exposures EPA Assessed for the Environment

For terrestrial organisms, EPA evaluated exposures via air. The Agency expects the air pathway (inhalation, ambient air exposure) is the dominant pathway and route of exposure to formaldehyde for terrestrial organisms based on the continuous release of formaldehyde from various sources.

EPA did not quantitatively evaluate exposures to aquatic organisms via water or land pathways. Although formaldehyde is directly released to water, land, and air, formaldehyde concentrations were not modeled for the water and land pathways because formaldehyde is not expected to persist in soil and water based on physical-chemical, fate, and transport characteristics. Formaldehyde does not absorb or bind to soil or sediment and does not persist on land (due to volatility and reactivity of formaldehyde). Because formaldehyde is not expected to persist in water or soils, EPA determined that an in-depth analysis of releases to water or land was not justified and targeted its review of releases to air.

In general, EPA has medium to robust confidence in environmental releases for industrial COUs² and slight to medium confidence in commercial COUs. Environmental fate and transport data indicate formaldehyde does not bioaccumulate. The Agency concluded that risk to terrestrial organisms via the dietary pathway is not indicated. EPA has high confidence in this assessment conclusion.

2.2.2 Summary of Environmental Effects

EPA quantitatively assessed risk via the ambient air pathway for the COUs evaluated and has determined that

- no indication of risk to terrestrial mammals through air exposure because air concentrations are much lower than the concentration needed to produce an adverse effect; and
- no indication of risk to plants from formaldehyde exposures in ambient air because air concentrations are approximately 7 times below concentrations that would result in adverse effects to plants.

EPA qualitatively assessed risk via the surface water, dietary, and land pathways and concluded that these were not relevant pathways of exposure and has determined that

- no indication of risk to terrestrial organisms through soil exposure because exposure is not expected since formaldehyde does not absorb or bind to soil and does not persist on land;
- no indication of risk to aquatic organisms because exposure is not expected since formaldehyde rapidly transforms in water and is not expected to persist; and
- no indication of risk to terrestrial organisms through a dietary pathway because formaldehyde does not bioaccumulate.

Although terrestrial organisms may be exposed to formaldehyde in air, EPA did not identify risk to any environmental taxa due to formaldehyde under its COUs. The Agency has high confidence in its environmental assessment conclusion.

² COUs that are included under the life cycle stage of manufacturing, processing, and industrial use.

2.2.3 Basis for Unreasonable Risk of Injury to the Environment

Based on the risk evaluation for formaldehyde, including the risk estimates, the environmental effects of formaldehyde, the exposures, physical and chemical properties of formaldehyde, and consideration of uncertainties, EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk determination for formaldehyde. Ambient air was determined to be the driver of exposure, but the Agency does not expect this pathway to contribute to unreasonable risk to the environment. EPA does not expect exposure to formaldehyde via water, land, or dietary pathways to contribute to unreasonable risk to the environment. The Agency's overall environmental risk characterization confidence levels were varied and are summarized in Section 2.4 of the *Environmental Exposure Assessment for Formaldehyde*.

2.3 Additional Information Regarding the Basis for the Unreasonable Risk

Table 2-1 and Table 2-2 summarize the basis for this unreasonable risk determination of injury to human health and the environment presented in this formaldehyde risk evaluation. In these tables, a checkmark (✓) indicates how the COU significantly contributes to the unreasonable risk by identifying the type of effect (*e.g.*, non-cancer and cancer for human health) and the exposure route to the population or receptor that results in such contribution. As explained in Section 2, for this unreasonable risk determination, EPA considered the effects of formaldehyde to human health at the central tendency and high-end—as well as effects of formaldehyde to human health from the exposures associated from the condition of use, risk estimates, and uncertainties in the analysis. See Section 4.2 of the *Human Health Risk Assessment for Formaldehyde* for a summary of risk estimates. In addition, certain exposure routes for some COUs were not assessed because it was determined that there was no viable exposure pathway. These COUs and their respective exposure routes are grayed-out in Table 2-1 and Table 2-2.

Table 2-1. Supporting Basis for the Unreasonable Risk Determination for Human Health^b (Occupational Conditions of Use)

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Acute Non-cancer	Cancer
Manufacturing	Domestic Manufacturing	Domestic Manufacturing	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation	✓	✓
			General Population	Inhalation – Ambient Air		
	Import	Import	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
Processing	Processing – reactant	Adhesives and sealant chemicals in: Plastic and resin manufacturing; Wood product manufacturing; Paint and coating manufacturing; Basic organic chemical manufacturing	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
			Worker	Dermal	✓	
				Inhalation	✓	✓
		ONU	Inhalation			
		General Population	Inhalation – Ambient Air			
		Functional fluid in: Oil and gas drilling, extraction, and support activities	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
	Worker		Dermal	✓		
			Inhalation	✓	✓	
	ONU	Inhalation				

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Acute Non-cancer	Cancer
Processing	Processing – reactant		General Population	Inhalation – Ambient Air		
			Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		
		General Population	Inhalation – Ambient Air			
		Agricultural chemicals in agriculture, forestry, fishing, and hunting	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		
	General Population		Inhalation – Ambient Air			
	Processing – incorporation into an article	Finishing agents in textiles, apparel, and leather manufacturing	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		
		Paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace)	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		✓
		Additive in rubber product manufacturing	Worker	Dermal		
				Inhalation	✓	✓
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
		Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation	✓	✓
			General Population	Inhalation – Ambient Air		
				Worker	Dermal	✓

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Acute Non-cancer	Cancer	
Processing	Processing – incorporation into formulation, mixture, or reaction product	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; basic organic chemical manufacturing; and petroleum and coal products manufacturing		Inhalation	✓	✓	
			ONU	Inhalation			
			General Population	Inhalation – Ambient Air			
		Asphalt, paving, roofing, and coating materials manufacturing	Worker	Dermal	✓		
				Inhalation	✓	✓	
			ONU	Inhalation			
		General Population	Inhalation – Ambient Air				
			Worker	Dermal	✓		
				Inhalation	✓	✓	
		ONU	Inhalation				
			General Population	Inhalation – Ambient Air			
				Worker	Dermal	✓	
		Inhalation	✓		✓		
			ONU	Inhalation			
		General Population		Inhalation – Ambient Air			
				Worker	Dermal	✓	
		Inhalation	✓		✓		
			ONU	Inhalation			
		General Population		Inhalation – Ambient Air			
				Worker	Dermal	✓	
		Inhalation	✓		✓		
			ONU	Inhalation			
		General Population		Inhalation – Ambient Air			
				Worker	Dermal	✓	
Inhalation	✓	✓					
	ONU	Inhalation					
General Population		Inhalation – Ambient Air					
		Worker	Dermal	✓			
Inhalation	✓		✓				
	ONU	Inhalation					
General Population		Inhalation – Ambient Air					

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Acute Non-cancer	Cancer
Processing	Processing – incorporation into formulation, mixture, or reaction product	Agricultural chemicals (nonpesticidal) in: Agriculture, forestry, fishing, and hunting; pesticide, fertilizer, and agricultural chemical manufacturing	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		
		General Population	Inhalation – Ambient Air			
			Worker	Dermal	✓	
				Inhalation	✓	✓
		ONU	Inhalation			
			General Population	Inhalation – Ambient Air		
				Worker	Dermal	✓
		Inhalation			✓	✓
		ONU	Inhalation			
			General Population	Inhalation – Ambient Air		
				Worker	Dermal	✓
		Inhalation			✓	✓
		ONU	Inhalation			
			General Population	Inhalation – Ambient Air		
				Worker	Dermal	✓
		Inhalation			✓	✓
		ONU	Inhalation			
			General Population	Inhalation – Ambient Air		
				Worker	Dermal	✓
		Inhalation			✓	✓
		ONU	Inhalation			
			General Population	Inhalation – Ambient Air		
Worker	Dermal			✓		
	Inhalation	✓		✓		
ONU	Inhalation					
	General Population	Inhalation – Ambient Air				
		Worker	Dermal	✓		
Inhalation			✓	✓		
ONU	Inhalation					

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Acute Non-cancer	Cancer
Processing	Processing – incorporation into formulation, mixture, or reaction product		General Population	Inhalation – Ambient Air		
			Worker	Dermal	✓	
				Inhalation	✓	✓
		ONU	Inhalation			
		Adhesive and sealant chemical in adhesive manufacturing	General Population	Inhalation – Ambient Air		
			Worker	Dermal	✓	
				Inhalation	✓	✓
		ONU	Inhalation			
		Bleaching agents in textile, apparel, and leather manufacturing	General Population	Inhalation – Ambient Air		
			Worker	Dermal	✓	
	Inhalation			✓	✓	
	ONU	Inhalation				
	Repackaging	Sales to distributors for laboratory chemicals	Worker	Dermal	✓	
			ONU	Inhalation	✓	✓
				General Population	Inhalation – Ambient Air	
Recycling		Recycling	Worker	Dermal	✓	
			ONU	Inhalation	✓	✓
				General Population	Inhalation – Ambient Air	
Distribution in Commerce	Distribution in Commerce	Distribution in commerce	Worker	Dermal		
			ONU	Inhalation	✓	✓
				General Population	Inhalation – Ambient Air	
Industrial Use	Non-incorporative activities	Process aid in: Oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing	Worker	Dermal	✓	
			ONU	Inhalation	✓	
				General Population	Inhalation – Ambient Air	
		Use in construction	Worker	Dermal	✓	
	Inhalation		✓	✓		

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Acute Non-cancer	Cancer
Industrial Use	Non-incorporative activities	Oxidizing/reducing agent; processing aids, not otherwise listed	ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
			Worker	Dermal	✓	
				Inhalation	✓	
			General Population	Inhalation – Ambient Air		
	Industrial products	Paints and coatings; adhesives and sealants; lubricants	Worker	Dermal	✓	
				Inhalation	✓	✓
			General Population	Inhalation – Ambient Air		
		Aerospace use in: paints and coating; adhesives and sealants; lubricants; and foam insulation	Worker	Dermal	✓	
			General Population	Inhalation – Ambient Air		
Commercial Use	Furnishing treatment/care products	Floor coverings; foam seating and bedding products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; cleaning and furniture care products; leather conditioner; leather tanning, dye, finishing impregnation and care products; textile (fabric) dyes; textile finishing and impregnating/ surface treatment products.	Worker	Dermal	✓	
				Inhalation	✓	✓
			General Population	Inhalation – Ambient Air		
	Treatment products	Water treatment products	Worker	Dermal	✓	
				Inhalation		
			General Population	Inhalation – Ambient Air		
	Treatment/care products	Laundry and dishwashing products	Worker	Dermal	✓	
				Inhalation		
			General Population	Inhalation – Ambient Air		

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Acute Non-cancer	Cancer
Commercial Use	Construction, paint, electrical, and metal products	Adhesives and sealants; Paint and coatings	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		✓
	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	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		
	Electrical products	Machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/electronic articles	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation	✓	
	Metal products	Construction and building materials covering large surface areas, including metal articles	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation	✓	
	Automotive and fuel products	Automotive articles and automotive care products; lubricants and greases; fuels and related products	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation	✓	✓
	Agriculture use products	Lawn and garden products	Worker	Dermal	✓	
				Inhalation	✓	
			ONU	Inhalation		
	Outdoor use products	Explosive materials	Worker	Dermal	✓	
				Inhalation		
			ONU	Inhalation		

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Acute Non-cancer	Cancer
Commercial Use	Packaging, paper, plastic, hobby products	Paper products; plastic and rubber products; toys, playground, and sporting equipment	General Population	Inhalation – Ambient Air		
			Worker	Dermal		
				Inhalation		
			ONU	Inhalation		
	General Population	Inhalation – Ambient Air				
	Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
	Packaging, paper, plastic, hobby products	Ink, toner, and colorant products; photographic supplies	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation		
			General Population	Inhalation – Ambient Air		
	Products not described by other codes	Laboratory chemicals	Worker	Dermal	✓	
				Inhalation	✓	✓
			ONU	Inhalation	✓	
General Population			Inhalation – Ambient Air			
Disposal	Disposal	Worker	Dermal	✓		
			Inhalation			
		ONU	Inhalation			
		General Population	Inhalation – Ambient Air			

^a Only Inhalation exposure routes were assessed for ONUs and General Population. Additionally, General Population inhalation exposure routes were assessed using the ambient air pathway and are labeled to reflect the specific route.

^b Grayed-out boxes indicate certain exposure routes that were not assessed because it was determined that there was no viable exposure pathway.

Blank boxes indicate that the particular exposure pathway and human health effect do not significantly contribute to the unreasonable risk.

Table 2-2. Supporting Basis for the Unreasonable Risk Determination for Human Health (Consumer Conditions of Use)

Life Cycle Stage	Category	Subcategory	Population ^{a b}	Exposure Route	Human Health Effects: Acute Non-cancer ^c
Consumer Use	Furnishings 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	Consumer	Dermal	✓
				Inhalation	✓
			Bystander	Inhalation	✓
			General Population	Inhalation – Indoor Air	
	Furnishing treatment/ care products	Fabric, textile, and leather products not covered elsewhere (clothing)	Consumer	Dermal	
				Inhalation	✓
			Bystander	Inhalation	
	Treatment products	Water treatment products	Consumer	Dermal	
				Inhalation	
			Bystander	Inhalation	
	Treatment/ care products	Laundry and dishwashing products	Consumer	Dermal	
				Inhalation	
	Construction, paint, electrical, and metal products	Adhesives and sealants; paint and coatings	Consumer	Dermal	✓
				Inhalation	✓
	Construction, paint, electrical, and metal products	Construction and building materials covering large surface areas, including wood articles; construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	Bystander	Inhalation	✓
			Consumer	Dermal	✓
				Inhalation	✓
	Electrical products	Machinery, mechanical appliances, electrical/ electronic articles; other machinery, mechanical appliances, electronic/ electronic articles	General Population	Inhalation – Indoor Air	
			Consumer	Dermal	
				Inhalation	
Automotive and fuel products	Automotive articles and automotive care products; lubricants and greases; fuels and related products	Bystander	Inhalation		
		Consumer	Dermal	✓	
			Inhalation	✓	
		Bystander	Inhalation	✓	

Life Cycle Stage	Category	Subcategory	Population ^{a b}	Exposure Route	Human Health Effects: Acute Non-cancer ^c	
Consumer Use	Agriculture use products	Lawn and garden products	Consumer	Dermal		
				Inhalation		
				Bystander	Inhalation	
	Packaging, paper, plastic, hobby products	Paper products; plastic and rubber products; toys, playground, and sporting equipment	Consumer	Dermal		
				Inhalation	✓	
			Bystander	Inhalation	✓	
			General Population	Inhalation – Indoor Air		
	Hobby products	Arts, crafts, and hobby materials	Consumer	Dermal	✓	
				Inhalation	✓	
			Bystander	Inhalation	✓	
	Packaging, paper, and plastic	Ink, toner, and colorant products; photographic supplies	Consumer	Dermal	✓	
				Inhalation	✓	
Bystander			Inhalation	✓		

^a Only inhalation exposure routes were assessed for Bystander.

^b Typically, “Consumer” represents “Adult” or “Youth” age groups; “Bystander” typically represents “Child” and “Infant” age groups. “Infant” represents ages 0–2; “Child” represents ages 3–10; “Youth” represents ages 11–20; and “Adult” represents ages 21+.

^c Grayed-out boxes indicate certain exposure routes that were not assessed because it was determined that there was no viable exposure pathway. Blank boxes indicate that the particular exposure pathway and human health effect do not significantly contribute to the unreasonable risk.