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Unreasonable Risk Determination of the Draft Risk Evaluation for Formaldehyde

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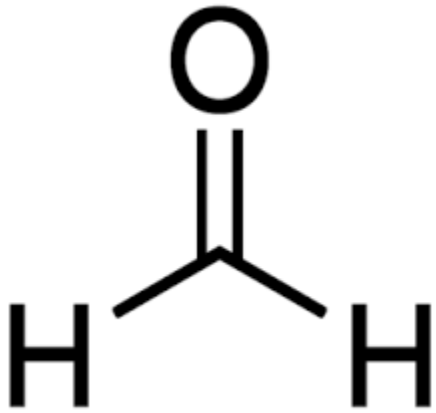

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1 RISK EVALUATION SCOPE

The Toxic Substances Control Act (TSCA) draft risk evaluation of formaldehyde comprises several human health 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. In some cases, individual assessments were completed jointly under TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These modules are shown in dark gray.

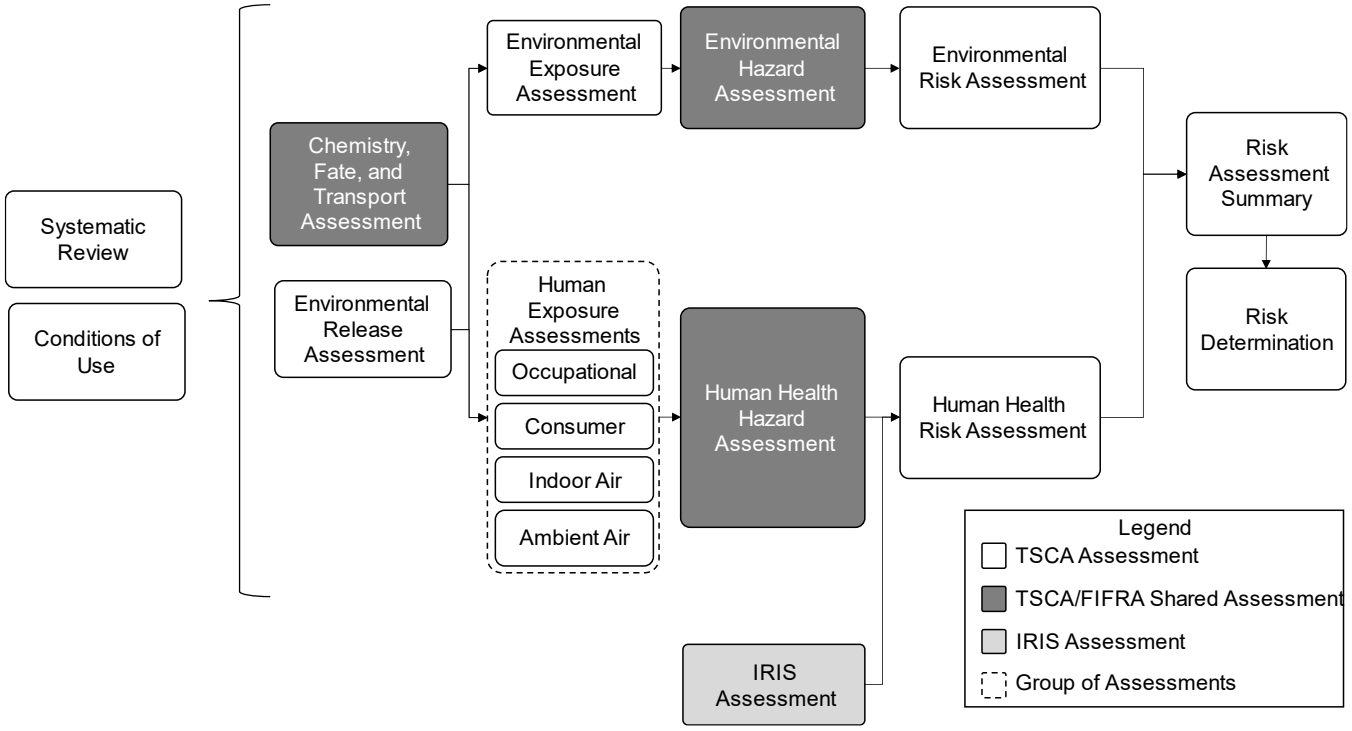

Figure 1-1. Risk Evaluation Document Summary Map

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 identified by EPA as relevant to the risk evaluation, under the TSCA conditions of use (COUs).

EPA is preliminarily determining that formaldehyde presents an unreasonable risk of injury to human health under the COUs. Risk of injury to the environment does not contribute to EPA's preliminary determination of unreasonable risk. This draft unreasonable risk determination is based on the information in previous sections of the modules and documents that comprise this draft risk evaluation and the appendices and supporting documents in accordance with TSCA section 6(b), as well as (1) the best available science (TSCA section 26(h)), (2) weight of the scientific evidence standards (TSCA section 26(i)), and (3) relevant implementing regulations in 40 CFR part 702.

Formaldehyde is found nearly everywhere. Living things—plants, animals, and people—produce and release formaldehyde through natural life (biogenic) processes. Formaldehyde is also produced when other chemicals break down 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 is also used to make many things, including composite wood products, plastics, paints, adhesives, and sealants. Over time, formaldehyde can be released from these products and articles. The formaldehyde sources that EPA evaluates in this draft risk evaluation involve, in general, the production and use of products that are subject to TSCA (as opposed to those products that are excluded from TSCA, such as pesticides). The unique challenge associated with this evaluation is that the formaldehyde released from commercial activities and products that are subject to TSCA is mixed in with the naturally-formed formaldehyde released from all the activities and processes mentioned above.

This draft risk evaluation attempts to understand whether the risk from specific activities subject to TSCA (*i.e.*, the conditions of use) contribute to the unreasonable risk presented by formaldehyde. And the risk estimates from some COUs representing workplaces clearly indicate that the direct use of formaldehyde of those COUs contributes to the unreasonable risk of formaldehyde. However, EPA also acknowledges that it is often difficult to understand what contribution various conditions of use are making to the total level of formaldehyde to which a person is exposed in any given place at any given time.

Taking that context into consideration, as well as the uncertainties in the overall risk estimates, EPA examined whether the contribution of formaldehyde exposure from a COU was greater than or within typical expected exposures from indoor air to inform EPA's preliminary determination of whether that COU contributes to unreasonable risk. In this preliminary determination of formaldehyde unreasonable risk:

1. EPA has a high level of certainty that 41 occupational COUs and has less certainty that 5 additional occupational COUs contribute to unreasonable risk due to non-cancer effects, specifically sensory eye irritation associated with **acute inhalation** of formaldehyde;
2. EPA has a high level of certainty that 7 consumer COUs contribute to the unreasonable risk due to non-cancer effects, specifically sensory eye irritation associated with **acute inhalation** of formaldehyde;
3. EPA has a high level of certainty that 10 occupational COUs and has less certainty that 35 additional occupational COUs contribute to the unreasonable risk due to non-cancer effects,

specifically respiratory and non-respiratory health effects in workers, including reduced pulmonary function, increased asthma prevalence, reduced asthma control, allergy-related conditions, male and female reproductive toxicity, and developmental effects, associated with **chronic inhalation** exposures;

4. EPA is less certain about the contribution from 3 consumer COUs to the unreasonable risk due to non-cancer effects, specifically respiratory and non-respiratory health effects, including reduced pulmonary function, increased asthma prevalence, reduced asthma control, allergy-related conditions, male and female reproductive toxicity, and developmental effects, associated with **chronic inhalation** exposures; and
5. EPA is less certain about the contribution from 1 occupational COU to the unreasonable risk of formaldehyde due to nasopharyngeal **cancer** from chronic inhalation exposures.

In this preliminary risk determination EPA has high level of certainty of the contribution to the unreasonable risk of formaldehyde from a COU when the risk from such COU is much greater than the risk expected from the formaldehyde based on monitored concentrations in the indoor air, and EPA is less certain of the contribution by the COU when the risk from the COU is within the expected risk based on monitored concentrations in the indoor air. In addition, most of the occupational and consumer COUs (47 and 7, respectively) contribute to the unreasonable risk due to non-cancer effects, specifically dermal sensitization associated with **acute dermal** exposure, meaning that skin contact can result in an allergic response.

Taking those uncertainties into consideration, in this preliminary determination EPA is concluding that the following COUs contribute to the unreasonable risk (see Table 2-1 and Table 2-2 for further detail regarding the contribution from each COU):

- 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; and
    - 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; and

    - 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; and
    - oxidizing/ reducing agent; processing aids, not otherwise listed
- Industrial use – chemical substances in industrial products – paints and coatings; adhesives and sealants; lubricants
- 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; and
    - 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);
    - Laundry and dishwashing products;
    - 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; and
    - Ink, toner, and colorant products; photographic supplies
- Disposal

In this preliminary determination, EPA concludes that the following COUs are not expected to 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 machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/electronic articles; and
- Consumer use in lawn and garden products.

Whether EPA makes a determination of unreasonable risk for a particular chemical substance under amended TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. In this draft risk evaluation, the Agency describes the strength of the scientific evidence supporting the exposure assessment as robust, moderate, slight, or indeterminate. When the assessment is supported by robust evidence, overall confidence in the exposure assessment is high; when supported by moderate evidence, overall confidence is medium; when supported by slight evidence, overall confidence is low. The Agency also evaluated the weight of scientific evidence supporting hazard assessment and dose response. This draft risk evaluation discusses the weight of scientific evidence and overall confidence in the exposure assessment as well as the hazard assessment in the *Draft Human Health Risk Assessment for Formaldehyde*. The *Draft*

Environmental Risk Assessment for Formaldehyde 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 are discussed in the *Draft Chemistry, Fate, and Transport Assessment for Formaldehyde*. These and other formaldehyde risk evaluation "modules" as well as scoping, assessments, and other documents and spreadsheets can be accessed in the docket EPA-HQ-OPPT-2018-0438.

In the formaldehyde unreasonable risk determination, EPA considered risk estimates with an overall confidence rating of low, medium, or high. In general, the Agency makes an unreasonable risk determination based on risk estimates that have an overall confidence rating of medium or high, since those confidence ratings indicate the scientific evidence is adequate to characterize risk estimates despite uncertainties. For COUs that had a low confidence rating, EPA is concluding at this time that these COUs do not contribute to the unreasonable risk of formaldehyde.

If in the final TSCA risk evaluation for formaldehyde, EPA determines that formaldehyde presents an unreasonable risk of injury to health or the environment under the COUs, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with formaldehyde under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that formaldehyde no longer presents such risk. EPA 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.

2.1 Unreasonable Risk to Human Health

This assessment provides 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). 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 addition, the risk estimates are based on exposure scenarios with monitoring data that likely reflects existing requirements, such as those established by EPA (*i.e.*, National Emission Standards for Hazardous Air Pollutants [NESHAP] under the Clean Air Act), OSHA (*i.e.*, formaldehyde standard), or industry or sector best practices.

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. For example, before determining whether a COU contributed to the unreasonable risk of formaldehyde to the general population, the Agency compared the exposures and risk estimates for people living and working near formaldehyde release sources (fenceline populations) with risk estimates from "background" air concentrations of

formaldehyde (*i.e.*, ambient or outdoor air that includes formaldehyde typically released from "biogenic" or other non-TSCA sources).

2.1.1 Populations and Exposures EPA Assessed to Determine Unreasonable Risk to 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. With respect to health endpoints upon which EPA is basing this preliminary unreasonable risk determination, the Agency has medium or high confidence in the following point of departures (PODs): (1) nasopharyngeal cancer due to chronic inhalation; (2) non-cancer effects (sensory irritation) due to acute inhalation; (3) non-cancer respiratory effects (reduced pulmonary function, allergy-related conditions, asthma, and sensory irritation) due to chronic inhalation; and (4) non-cancer effects (sensitization) due to acute dermal exposure. EPA evaluated risk from inhalation and dermal exposure of formaldehyde to workers as well as inhalation exposures to ONUs. The Agency evaluated risk from inhalation and dermal exposure to consumer users and risk from inhalation exposure to bystanders. Finally, EPA also evaluated risk from inhalation exposure to the general population.

Oral exposures were not assessed quantitatively as there is no supporting evidence that the oral route is a reasonably foreseen route of exposure for occupational and general populations ((see *Draft Human Health Risk Assessment for Formaldehyde*). 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 (see *Draft Consumer Exposure Assessment for Formaldehyde*). Descriptions of the data used for human health exposure and human health hazards are provided in the *Draft Human Health Risk Assessment for Formaldehyde*. Uncertainties for overall exposures and hazards are presented in the Draft Human Health Risk Assessment for Formaldehye and summarized separately in the Occupational, Consumer, Indoor Air, and Ambient Air Exposure Assessments Modules, and are considered in this preliminary unreasonable risk determination.

2.1.2 Summary of Unreasonable Risks to Human Health

EPA is preliminarily determining that the unreasonable risks presented by formaldehyde are due to

- non-cancer effects in workers from inhalation and acute dermal exposures;
- cancer effects for some workers from inhalation exposures under one condition of use;
- non-cancer effects in occupational non-users (ONUs) from inhalation exposures; and
- non-cancer effects in consumers and bystanders from inhalation and acute dermal exposures.

Table 2-1 and Table 2-2 provide further detail regarding which COUs contribute to the above health effects.

EPA's exposure and overall risk characterization confidence levels are summarized in the Draft Human Health Risk Assessment for Formaldehyde as are health risk estimates for workers, including ONUs, the general population, consumers, and bystanders

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 subpopulation(s) (PESS) people who are expected to have greater exposure to formaldehyde, such as workers exposed to formaldehyde, 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 Draft Human Health Risk Assessment for Formaldehyde). 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, nasal damage. A full PESS analysis is in Appendices C.1 and C.2 of the *Draft 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 levels whereas risk estimates at the central tendency exposure are generally estimates of average or typical exposure. EPA aggregated exposures across certain routes and exposure scenarios for consumers and bystanders for COUs with quantitative risk estimates. The uncertainty factors of 10 (acute inhalation due to sensory irritation and acute dermal due to sensitization) and 3 (chronic inhalation due to respiratory effects) for human variability that EPA applied to MOEs accounts for increased susceptibility of populations such as children and elderly populations. EPA also generally relies on high-end exposure levels to make an unreasonable risk determination to capture vulnerable populations that are expected to have higher exposures. For cancer, although there is likely to be variability in susceptibility across the human population, EPA did not identify specific human groups that are expected to be more susceptible to cancer following formaldehyde exposure. Therefore, for cancer risk, EPA is using central tendency risk estimates as staring point to inform the risk determination. More information on how EPA characterized sentinel and aggregate risks is provided in the Human Health Risk Assessment, Section 4.3.

2.1.4 Unreasonable Risk in Occupational Settings

Based on the occupational risk estimates and related risk factors, EPA is preliminarily determining that the non-cancer risks from worker acute inhalation and dermal exposure to formaldehyde in occupational settings contribute to the unreasonable risk presented by formaldehyde. EPA is also preliminarily determining that chronic inhalation exposures to formaldehyde workers and in occupational settings contribute to the unreasonable risk presented by formaldehyde. Cancer risks in excess of the benchmark ($1x10^{-4}$) were identified for one COU for worker chronic inhalation exposure: *automotive care products; lubricants and greases; fuels and related products*. Products under this commercial COU include polishes, waxes, and other detailing products such as a vinyl coatings, greases and other lubricants used in the maintenance of automobiles, machinery, and other equipment. EPA did not make a preliminary risk determination for one COU that presents slight evidence and therefore was of low confidence.

For COUs assessed, worker risks were evaluated using the central tendency and high-end estimates to account for susceptible populations that may be exposed while working. In a majority of the COUs, non-cancer risks were found for both central tendency and high-end exposures, while cancer risks were mainly found for high-end exposures. There were no COUs assessed qualitatively for the occupational analysis.

EPA analyzed the occupational scenarios using a time weighted average for a typical 8-hour shift as well as a 12-hour shift. The risk determination is only based on a time weighted average for 8-hours as this is the most common scenario and also represents a more conservative estimate of risk to account for susceptible populations. 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. For three COUs, (i) *manufacturing;* (ii) *processing as a reactant;* and (iii) *processing, incorporation into an article: additive in rubber product manufacturing*, EPA had specific ONU data, and these COUs were evaluated using the ONU high-end exposures. Additionally, EPA evaluated dermal exposures only for workers since ONUs are not expected to directly handle formaldehyde.

Non-cancer risk estimates were calculated from acute and chronic exposures. These terms are in reference to the duration of exposure to formaldehyde. Acute refers to an exposure time frame of 24 hours or less (15 minutes for inhalation) and chronic refers to an exposure time frame of greater than three months. Chronic cancer risk estimates include 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.

EPA considered other sources of formaldehyde in the outdoor and indoor environments to provide a rational context for interpreting the inhalation risk estimates of the occupational uses. For example, biogenic sources of formaldehyde result in outdoor air concentrations of about 0.28 µg/m^3; the maximum monitored ambient air concentration of formaldehyde was 60.1 µg/m^3 and the maximum modeled formaldehyde concentration was 50.5 µg/m^3.The monitored indoor air concentrations of formaldehyde (collected from March 2018 to June 2019) range from 0.27 to 124.2 µg/m^3 for all homes, with 95% of homes having concentrations below ~40 µg/m^3, and other reports suggest candles, incense, cooking and wood combustion activities can emit formaldehyde with concentrations up to 44.2 µg/m^3. Across all conditions of use, full work shift (8 to 12 hours) inhalation exposure concentrations of formaldehyde were between 7.5 to 17,353.3 µg/m^3 for workers and ONUs. Therefore, some inhalation exposure concentrations for workers and ONUs are within the outdoor and indoor air concentrations, and some, are greater than what would be expected from total indoor and outdoor exposures. In this preliminary risk determination EPA has high level of certainty of the contribution of an occupational COU when the risk from such occupational COUs is much greater than the risk expected from the formaldehyde based on monitored concentrations in the indoor air, and EPA is less certain of the contribution by the occupational COU when the risk from the COU is within the expected risk based on monitored concentrations in the indoor air. Most of the occupational COUs contribute to the unreasonable risk presented by formaldehyde due to acute dermal exposures at the workplace.

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

2.1.5 Unreasonable Risk to Consumers

Based on the consumer risk estimates and related risk factors, EPA is preliminarily determining that non-cancer risks from acute inhalation exposure to formaldehyde for consumer users and bystanders and chronic inhalation for consumers contribute to the unreasonable risk of formaldehyde. 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. Several of the consumer COUs assessed indicated that the consumer dermal exposures contribute to the unreasonable risk of formaldehyde. In addition, chronic risk was not assessed for some COUs because EPA does not expect consumers to use the products or articles containing formaldehyde for a length of time that would result in chronic exposure to formaldehyde. EPA is not finding that cancer risk due to chronic inhalation exposures to consumers and bystanders contribute to the unreasonable risk of formaldehyde.

Consumers and bystander risks were evaluated for consumer COUs that represent specific age groups. Typically, consumers are adults since most 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 appropriate 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 it is unclear how a consumer exposure would occur during a normal use of an electronic product, such as a circuit board component located within an electronic product. 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 (see Human Health Risk Assessment Module).

For all of the consumer COUs, EPA evaluated the risk to consumers and bystanders using the high-end exposures to account for vulnerable populations that are expected to have higher exposures to certain uses, such as children with asthma.

Similar to occupational COUs, EPA considered other sources of formaldehyde in the outdoor and indoor environment to provide a rational context for interpreting the inhalation risk estimates of the consumer uses. For example, biogenic sources of formaldehyde result in outdoor air concentrations of about 0.28 $\mu g/m^3$; the maximum monitored ambient air concentration of formaldehyde was 60.1 $\mu g/m^3$ and the maximum modeled formaldehyde concentration is 50.5 $\mu g/m^3$; and the monitored indoor air concentrations of formaldehyde (collected from March 2018 to June 2019) range from 0.27 to 124.2 $\mu g/m^3$ for all homes, with 95 percent of homes having concentrations below ~40 $\mu g/m^3$, and other reports suggest candles, incense, cooking and wood combustion alone can emit formaldehyde with concentrations up to 44.2 $\mu g/m^3$. In this preliminary determination, EPA has high level of certainty to the contribution of a consumer COU when the risk from such consumer COU is much greater than the risk expected from the formaldehyde in the indoor air, and EPA is less certain of the contribution by the consumer COU when the risk from the COU is within the expected risk from indoor air. Most of the consumer COUs contribute to the unreasonable risk presented by formaldehyde due to acute dermal exposures.

EPA has high 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 *Draft Human Health Risk Assessment for Formaldehyde*.

2.1.6 Unreasonable Risk to the General Population

Based on the risk estimates calculated using releases from manufacturing, processing, and industrial uses of formaldehyde, and related risk factors, EPA is preliminarily determining that there are no cancer risk effects that contribute to the unreasonable risk of formaldehyde to the general population, including people living or working near facilities (fenceline populations) from the ambient air. In addition, EPA is preliminarily determining that there are non-cancer risk effects to the general population due to chronic inhalation exposure from consumer products in residences and automobiles for four of the consumer COUs assessed which contribute to the unreasonable risk of formaldehyde in indoor air.

For members of the general population exposed due to releases from the COUs, EPA considers a cancer risk benchmark range of 1×10^{-4} to 1×10^{-6}; however, the benchmark is not considered a "bright-line" and other risk related factors were considered. EPA considered other sources of formaldehyde in the outdoor and indoor environment to provide a rational context for interpreting the risk estimates to the general population. For example, EPA also considered the biogenic sources which result in outdoor air concentrations of about 0.28 µg/m^3, and the estimated annual ambient (outdoor) air concentration near releasing facilities, which ranged from 0.0001 to 5.75 µg/m^3 for formaldehyde COUs. EPA also considered concentrations of formaldehyde monitored in ambient air, which ranged from below the method detection limit to 60.1 µg/m^3 and a median value of 1.6 µg/m^3.

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.

Inhalation – Ambient Air

EPA is using the results from IIOAC modeling in the formaldehyde ambient air assessment to determine whether there is unreasonable risk under the COUs to individuals living 100 to 1,000 m from industrial facilities that report air releases of formaldehyde attributable to its domestic manufacturing, import, processing, and industrial COUs. The population living or working within 100 to 1,000 m of the facilities (or fenceline population) are considered PESS and would represent the highest general population exposed to formaldehyde. EPA did not include other commercial COUs of formaldehyde in its ambient air assessment because those commercial releases associated with commercial COUs are generally lower than industrial releases (for example commercial uses related to adhesives and sealants, construction and building materials, automotive care products).

The maximum outdoor air concentration near releasing facilities from the COUs is up to 5.7 µg/m^3, which is below the maximum monitored ambient air concentration of 60.1 µg/m^3. These data suggest that formaldehyde contributions from the COUs are not substantially higher than formaldehyde concentrations that are expected to occur due to background levels. As a result, EPA has preliminarily determined that no formaldehyde COUs contribute to the unreasonable risk of formaldehyde for cancer to the general population. Cancer inhalation risk estimates from IIOAC modeling and from AirToxScreen modeling of biogenic and secondary formation sources are presented in the *Draft Human Health Risk Assessment for Formaldehyde*. EPA's confidence in inhalation risk estimates for cancer risk is moderate at both 100 and 1,000 m.

For one COU, *distribution in commerce*, EPA did not find any information to evaluate releases via ambient air. EPA also did not expect this COU to be similar to other COUs evaluated and therefore could not use similar data.

EPA has high confidence in the overall characterization of exposures for this ambient air exposure assessment due to the use of environmental release data from multiple sources. The greatest uncertainty is associated with the contribution to the total formaldehyde in ambient monitoring data from the COUs due to the contributions from biogenic sources and other background sources. More information on EPA's confidence in these risk estimates and the uncertainties associated with them can be found in the Draft Human Health Risk Assessment Module.

Inhalation – Indoor Air

EPA estimated cancer and non-cancer risks in indoor air for four consumer COUs via the inhalation pathway in two common indoor environments: automobile and residential. These COUs were chosen because they represent the most common products found in these two indoor environments. 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 (residential);
- Fabric, textile, and leather products not covered elsewhere (clothing) (residential and automobile);
- 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 (residential);
- Paper products; Plastic and rubber products; Toys, playground, and sporting equipment (residential).

EPA considered available indoor air monitoring data as well as air concentrations modeled based on emissions associated with the four COUs assessed, as described in the *Draft Indoor Air Exposure Assessment for Formaldehyde*. The cancer risk estimates are based on indoor monitoring data based on the assumptions that those concentrations represent an average exposure over a 78-year lifetime. The basis for chronic non-cancer and cancer risk estimates for indoor air were designed to estimate concentrations at the central tendency because this represents the most common scenario in an indoor environment.

The monitored indoor air concentrations of formaldehyde (collected from March 2018 to June 2019) range from 0.27 to 124.2 µg/m3 for all homes, with 95 percent of homes having concentrations below ~40 µg/m3, and other reports suggest candles, incense, cooking and wood combustion can emit formaldehyde with concentrations up to 44.2 µg/m3. The risk estimates in the indoor 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.

The data used for cancer risk estimates was based on monitoring conducted before the Formaldehyde Emissions Standards for Composite Wood Products final rule pursuant to Title VI of TSCA that was enacted in 2018. TSCA Title VI reduces exposure to formaldehyde emissions from certain composite wood products such as hardwood plywood, medium density fiberboard, and particleboard. By including certain requirements for these composite wood products such as product-testing requirements, labeling, recordkeeping, and import certification, TSCA Title VI ensures that hardwood plywood, medium-density fiberboard, and particleboard products sold, supplied, offered for sale, imported to, or

manufactured in the United States comply with EPA's emission standards. In addition, by March 2024, laminated products—a type of product in which a wood veneer is applied to a composite wood core—will be considered hardwood plywood, significantly expanding the scope of TSCA Title VI to further reduce formaldehyde emissions from composite wood products. Similarly, the chronic non-cancer risk estimates for indoor air are based on studies with medium level of confidence regarding the use of the COU-specific emission rates, and the transformation of formaldehyde once it is released from the articles. Therefore, in this preliminary determination, EPA is finding that the COUs related to exposure in residences from wood articles does not contribute to the unreasonable risk of formaldehyde. In addition, in this preliminary determination, EPA finds that based on the risk estimates of the other COUs evaluated, those COUs do not contribute to the unreasonable risk of formaldehyde based on chronic inhalation exposures to the general population.

EPA's overall confidence in the indoor air consumer analysis was medium. More information on EPA's confidence in these risk estimates and the uncertainties associated with them can be found in the *Draft Human Health Risk Assessment for Formaldehyde* of the draft risk evaluation.

2.2 Unreasonable Risk to the 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 to Determine Unreasonable Risk to the Environment

For terrestrial organisms, EPA evaluated exposures via air. EPA 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 high confidence in environmental releases for industrial COUs[1] and low to medium confidence in commercial COUs. Environmental fate and transport data indicate formaldehyde does not bioaccumulate. EPA concluded that risk to terrestrial organisms via the dietary pathway is not indicated. EPA has high confidence in this assessment conclusion.

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

2.2.2 Summary of Unreasonable Risks to the Environment

EPA quantitatively assessed risk via the ambient air pathway for the COUs evaluated and is preliminarily identifying:

- no indication of risk to terrestrial mammals through air exposure because air concentrations are much lower than the most sensitive toxicity value;
- no indication of risk to other terrestrial taxa, because even though no inhalation toxicity data are available for other terrestrial species, there are orders of magnitude difference in the toxicity and exposure for mammals; and
- no indication of risk to plants from formaldehyde exposures in ambient air because air concentrations are an order of magnitude less than the most sensitive toxicity value.

EPA qualitatively assessed risk via the surface water, dietary, and land pathways and concluded that these were not relevant pathways of exposure and is preliminarily identifying:

- 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. EPA has high confidence in its environmental assessment conclusion.

2.2.3 Basis for Unreasonable Risk of Injury to the Environment

Based on the draft risk evaluation for formaldehyde—including the risk estimates, the environmental effects of formaldehyde, the exposures, physical-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 EPA 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 the *Draft 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 draft unreasonable risk determination of injury to human health and the environment presented in this draft formaldehyde risk evaluation. In these tables, a checkmark (✓) indicates how the COU 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 1, for this draft 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 *Draft 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 Draft Unreasonable Risk Determination for Human Health (Occupational Conditions of Use)

✓ EPA has high level of certainty of the contribution to the unreasonable risk

♦ EPA has less certainty of the contribution to the unreasonable risk

Life Cycle Stage	Category	Subcategory	Population	Exposure Route[a]	Human Health Effects[b]		
					Acute Non-cancer	Chronic 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	Use in adhesives and sealant chemicals	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation			
			General Population	Inhalation – Ambient Air			
		Use as an intermediate	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation			
			General Population	Inhalation – Ambient Air			
		Use as a functional fluid	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation			
			General Population	Inhalation – Ambient Air			
			Worker	Dermal	✓		

Life Cycle Stage	Category	Subcategory	Population	Exposure Route[a]	Human Health Effects[b]		
					Acute Non-cancer	Chronic Non-cancer	Cancer
Processing	Processing – reactant	Processing aids, specific to petroleum production in all other basic chemical manufacturing		Inhalation	✓	♦	
			ONU	Inhalation			
			General Population	Inhalation – Ambient Air			
		Bleaching agent in wood product manufacturing	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			
			General Population	Inhalation – Ambient Air			
		Paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace)	Worker	Dermal	✓		
				Inhalation	✓	✓	
			ONU	Inhalation		✓	
			General Population	Inhalation – Ambient Air			
		Additive in rubber product manufacturing	Worker	Dermal			
				Inhalation	✓		
			ONU	Inhalation			
			General Population	Inhalation – Ambient Air			
		Adhesives and sealant chemicals in wood product manufacturing	Worker	Dermal	✓		
				Inhalation	✓	✓	

Life Cycle Stage	Category	Subcategory	Population	Exposure Route[a]	Human Health Effects[b]		
					Acute Non-cancer	Chronic Non-cancer	Cancer
Processing			ONU	Inhalation	✓	✓	
			General Population	Inhalation – Ambient Air			
	Processing – incorporation into formulation, mixture, or reaction product	Petrochemical manufacturing	Worker	Dermal	✓		
				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			
		Solvents (which become part of a product formulation or mixture) in paint and coating manufacturing	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Processing aids, specific to petroleum production	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Paint additives and coating additives not described by other categories	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Processing for use as an intermediate	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		

Life Cycle Stage	Category	Subcategory	Population	Exposure Route[a]	Human Health Effects[b]		
					Acute Non-cancer	Chronic Non-cancer	Cancer
Processing	Processing – incorporation into formulation, mixture, or reaction product		General Population	Inhalation – Ambient Air			
		Solid separation agents in miscellaneous manufacturing	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Agricultural chemicals (nonpesticidal)	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Surface active agents in plastic material and resin manufacturing	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Ion exchange agents in adhesive manufacturing and paint and coating manufacturing	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Lubricant and lubricant additive in adhesive manufacturing	Worker	Dermal	✓		
				Inhalation	✓	♦	

Life Cycle Stage	Category	Subcategory	Population	Exposure Route[a]	Human Health Effects[b]		
					Acute Non-cancer	Chronic Non-cancer	Cancer
Processing	Processing – incorporation into formulation, mixture, or reaction product		ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Plating agents and surface treating agents in all other chemical product and preparation manufacturing	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Soap, cleaning compound, and toilet preparation manufacturing	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Laboratory chemicals	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Adhesive and sealant chemical in adhesive manufacturing	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
		Bleaching agents in textile, apparel, and leather manufacturing	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation	✓		
			General Population	Inhalation – Ambient Air			
	Repackaging	Sales to distributors for laboratory chemicals	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route[a]	Human Health Effects[b]		
					Acute Non-cancer	Chronic Non-cancer	Cancer
			General Population	Inhalation – Ambient Air			
	Recyling	Recycling	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation			
			General Population	Inhalation – Ambient Air			
Distribution in Commerce	Distribution in Commerce	Distribution in commerce	Worker	Dermal			
				Inhalation	✓	✓	
			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	✓		
				Inhalation		✓	
			ONU	Inhalation		✓	
			General Population	Inhalation – Ambient Air			
		Use in construction	Worker	Dermal	✓		
				Inhalation	✓	✓	
			ONU	Inhalation		✓	
			General Population	Inhalation – Ambient Air			
		Oxidizing/reducing agent; processing aids, not otherwise listed	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation			
			General Population	Inhalation – Ambient Air			
	Industrial products	Paints and coatings; adhesives and sealants; lubricants	Worker	Dermal	✓		
				Inhalation	✓	✓	
			ONU	Inhalation		✓	

Life Cycle Stage	Category	Subcategory	Population	Exposure Route[a]	Human Health Effects[b]		
					Acute Non-cancer	Chronic Non-cancer	Cancer
			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	✓	✓	
			ONU	Inhalation		✓	
	Treatment products	Water treatment products	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation			
	Treatment/ care products	Laundry and dishwashing products	Worker	Dermal	✓		
				Inhalation			
			ONU	Inhalation			
	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		Worker	Dermal	✓		
				Inhalation	✓	♦	

Life Cycle Stage	Category	Subcategory	Population	Exposure Route[a]	Human Health Effects[b]		
					Acute Non-cancer	Chronic Non-cancer	Cancer
Commercial Use		Construction and building materials covering large surface areas, including metal articles	ONU	Inhalation			
	Automotive and fuel products	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			
	Packaging, paper, plastic, hobby products	Paper products; plastic and rubber products; toys, playground, and sporting equipment	Worker	Dermal			
				Inhalation			
			ONU	Inhalation			
	Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation		♦	
	Packaging, paper, plastic, hobby products	Ink, toner, and colorant products; photographic supplies	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation			
	Products not described by other codes	Laboratory chemicals	Worker	Dermal	✓		
				Inhalation	✓	✓	
			ONU	Inhalation		✓	
Disposal	Disposal	Disposal	Worker	Dermal	✓		
				Inhalation	✓	♦	
			ONU	Inhalation			
			General Population	Inhalation – Ambient Air			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route[a]	Human Health Effects[b]		
					Acute Non-cancer	Chronic Non-cancer	Cancer

[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.

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

✓ EPA has high level of certainty of the contribution to the unreasonable risk

♦ EPA has less certainty of the contribution to the unreasonable risk

Life Cycle Stage	Category	Subcategory	Population[ab]	Exposure Route	Human Health Effects[c]	
					Acute Non-cancer	Chronic Non-cancer
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	✓	
			General Population	Inhalation – Indoor Air		
	Treatment products	Water treatment products	Consumer	Dermal		
				Inhalation		
			Bystander	Inhalation		
	Treatment/ care products	Laundry and dishwashing products	Consumer	Dermal	✓	
				Inhalation		
			Bystander	Inhalation		
	Construction, paint, electrical,	Adhesives and sealants; paint and coatings	Consumer	Dermal	✓	
				Inhalation	✓	♦
			Bystander	Inhalation	✓	

Life Cycle Stage	Category	Subcategory	Population[ab]	Exposure Route	Human Health Effects[c]	
					Acute Non-cancer	Chronic Non-cancer
Consumer Use	and metal products					
	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	Consumer	Dermal	✓	
				Inhalation	✓	
			Bystander	Inhalation	✓	
			General Population	Inhalation – Indoor Air		
	Electrical products	Machinery, mechanical appliances, electrical/ electronic articles; other machinery, mechanical appliances, electronic/ electronic articles	Consumer	Dermal		
				Inhalation		
			Bystander	Inhalation		
	Automotive and fuel products	Automotive care products; lubricants and greases; fuels and related products	Consumer	Dermal	✓	
				Inhalation	✓	
			Bystander	Inhalation	✓	
	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.

Life Cycle Stage	Category	Subcategory	Population[ab]	Exposure Route	Human Health Effects[c]	
					Acute Non-cancer	Chronic Non-cancer

[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.