MEMORANDUM

SUBJECT: Updated Draft Risk Calculation Memorandum

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1 Purpose

The purpose of this memorandum is to provide updated draft formaldehyde margin of exposure (MOE) calculations for an acute inhalation point of departure (POD) of 0.3 ppm for sensory irritation and an uncertainty factor of 1 (1×) as described in the Federal Register Notice (FRN) Formaldehyde; Updated Draft Risk Calculation Memorandum; Notice of Availability. The memo includes MOEs for workers, residential indoor air, residential ambient air, and consumers. These calculations revise the "risk characterization" or section 4 of the final risk evaluation available in the public docket (EPA-HQ-OPPT-2018-0438). In addition to this memo, the docket contains several supplemental risk calculators to provide risk estimates for occupational, consumer, and general population exposures. Based on an evaluation of the best available science, and multiple independent peer review records, this memo does not rely on the EPA Integrated Risk Information System (IRIS) cancer inhalation unit risk (IUR) values.

2 Methodology

The occupational, indoor air, outdoor air, and consumer risk calculators have been modified to include risk estimates that utilized both an acute inhalation POD of 0.3 ppm (370 $\mu g/m^3$) and an uncertainty factor (UF) of 1 as cited in the Federal Register Notice Formaldehyde; Updated Draft Risk Calculation Memorandum; Notice of Availability. The risk calculators continue to rely on the occupational, indoor air, outdoor air, and consumer exposure estimates provided in the risk evaluation (RE) for formaldehyde (U.S. EPA, 2024c).

In implementing the revised draft POD, the risk calculators for occupational, indoor air, outdoor air, and consumer exposures adhered to the same methods outlined in the risk evaluation and are therefore not described in this revised draft. See the *Revised Draft Human Health Risk Assessment for Formaldehyde* (also called "Human Health Risk Assessment") for details.

3 Results

3.1 Worker

Acute risk estimates for workers and occupational non-users (ONUs) are based primarily on monitoring samples measured for short period of times (15 to <330 minutes) expected to be peak exposure events, as available. Air concentration ranged up to a central tendency of $2,002 \,\mu\text{g/m}^3$ (1.6 ppm) to a high-end of 209,815 $\,\mu\text{g/m}^3$ (171 ppm). These values are the same as reported in the RE and can be found in the *Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024e).

3.1.1 Manufacturing and Processing COUs

The short-term risk estimates, utilizing an acute inhalation POD of 0.3 ppm (370 $\mu g/m^3$) and a benchmark margin of error (MOE) of 1 for conditional of use (COUs) during lifecycle stages of Manufacturing and Processing, are presented below in Figure 1. This figure revises Figure 4-1 from Section 4.2.1.1.1 for the human health risk assessment TSD (<u>U.S. EPA, 2024c</u>). Nine of the 10 central tendency estimates are above the benchmark (highest MOE: 8.7). The central tendency risk estimate for the manufacturing COU falls below the benchmark, with an MOE of 0.5. All high-end risk estimates are below the benchmark MOE.

Compared to the final RE, the only notable change for COUs during lifecycle stages of Manufacturing and Processing, pertains to the COUs listed below. These COUs were initially associated with central tendency risk estimates below the benchmark MOE. However, using a POD of 0.3 ppm, the central tendency risk estimates are now above the benchmark MOE of 1.1 Note that the reported risk estimates also encompass ONUs² as the Agency did not identify specific short-term monitoring data for these types of workers. As such, the Agency used the central tendency of the risk estimates to represent ONUs.

- Processing incorporation into article adhesives and sealant chemicals in wood product manufacturing; plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing
- Processing recycling

The high-end risk estimates for these two listed COUs continue to remain below the benchmark MOE for all COUs during lifecycle stages of Manufacturing and Processing.

¹ This list of COUs do not include COUs where no unreasonable risks were determined due to slight confidence (*i.e.*, a slight weight of scientific evidence conclusion for occupational exposure), even though risk estimates may have changed from below the benchmark MOE to above the benchmark MOE.

² ONUs are employed persons who do not directly handle the chemical substance but may be indirectly exposed to it as part of their employment due to their proximity to the substance.

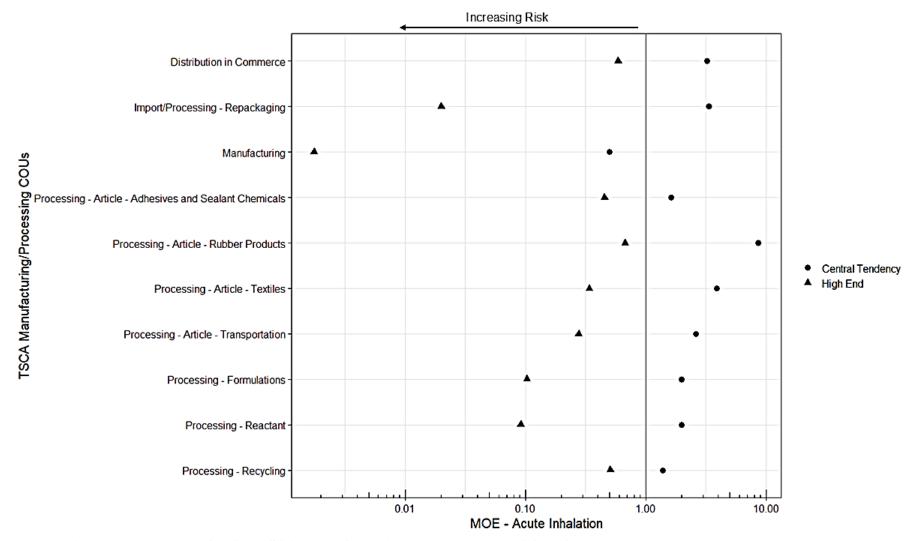


Figure 1. Acute Inhalation MOE for TSCA Manufacturing and Processing COUs for Formaldehyde
Acute non-cancer MOE risk estimates with lower MOE values indicate increased risks. For COUs with multiple OESs or estimation approaches, the estimate with the highest high-end value was illustrated

3.1.2 Industrial or Commercial COUs

Figure 2 presents the risk estimates for the COUs under the lifecycle stages of *industrial or commercial use*. Thirteen of the 18 central tendency estimates are above the benchmark MOE (highest MOE: 174). However, five COUs—namely Automotive care products; Construction and building (metal); Machinery, mechanical; Paints, coatings, adhesives (IU, CU); and Water treatment products—fall below the benchmark; this finding is consistent with the final RE for these five COUs.

Compared to the final RE, there are only three notable changes for COUs under the lifecycle stages of Industrial or Commercial Use. These COUs are listed below. Initially, the COU listed below was associated with a central tendency risk estimate below the benchmark MOE. However, using a POD of 0.3 ppm (370 μ g/m³) the central tendency risk estimate now is above the benchmark MOE. As before, these risk estimates also represent ONUs, as the Agency did not identify monitoring data specific to ONUs, including:

• Commercial use – chemical substances in products not described by other codes – laboratory chemicals.

In addition, the COUs listed below initially had high-end risk estimates that were below the benchmark MOE. However, using a POD of 0.3 ppm the high-end risk estimates are now above the benchmark MOE for workers including ONUs, including the following:

- Industrial use non-incorporative activities oxidizing/reducing agent, processing aids, not otherwise listed; and
- Commercial use chemical substances in agriculture use products lawn and garden products.

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¹ These lists of conditions of use (COUs) do not include COUs where no unreasonable risks were determined due to slight confidence (*i.e.*, a slight weight of scientific evidence conclusion for occupational exposure), even though risk estimates may have changed from below the benchmark MOE to above the benchmark MOE.

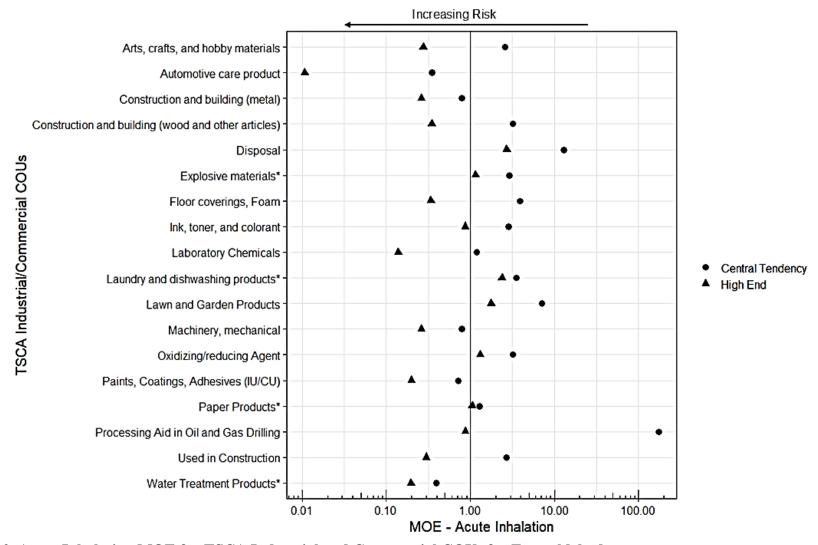


Figure 2. Acute Inhalation MOE for TSCA Industrial and Commercial COUs for Formaldehyde

Acute non-cancer MOE risk estimates with lower MOE values indicate increased risks. For COUs with multiple occupational exposure estimates (OESs) or estimation approaches, the estimate with the highest high-end value was illustrated.

^{*:} indicates COUs for which the respective scenarios have a slight weight of scientific evidence conclusion for the OES as detailed in the final RE. Note: Automotive care products, Lawn and garden products, Processing aid in oil and gas drilling, and Water treatment products COUs are modeled exposures.

3.2 Consumer

In the final RE, EPA concluded that estimated risks to consumers were below the benchmark for all COUs. The Agency characterized risk for acute inhalation and dermal sensitization for consumers who use products and articles containing formaldehyde. This section outlines the results from the final RE and the updated draft risk calculations for acute inhalation.

The Agency used the Consumer Exposure Model (CEM) to estimate formaldehyde concentrations in consumer products. The exposure concentration estimates derived from CEM were based on safety data sheets (SDS) identified in the Use Report for Formaldehyde (CAS RN 50-00-0) and Paraformaldehyde (CAS RN 30525-89-4) with updated Information from the following: Chemical Data Reporting (2016–2019), Toxics Release Inventory (2020), and Clean Water Act permit discharges (2021). Additional searches were also conducted to identify and refine the chemical concentration of formaldehyde in consumer products and articles for the assessed COUs. These estimates are all presented in the *Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a).

Risk estimates for consumer exposures for all TSCA COUs are based on a 15-minute peak concentration of formaldehyde in air from active use of associated consumer products and articles. In the final RE, exposure concentrations from COUs ranged from 220 to $16,450 \, \mu g/m^3 \, (1.8 \times 10^{-1} \, \text{to} \, 1.3 \, \text{ppm})$. The highest modeled exposure concentrations attributable to TSCA COUs came from Adhesives and sealants; paint and coatings.

With the POD of 0.3 ppm, the acute MOEs range from 0.02 to 1.67 for consumer users of products and articles (Figure 3). Most consumer COUs are below the benchmark MOE of 1, but as mentioned previously, these estimates do not change the conclusions of the final RE.

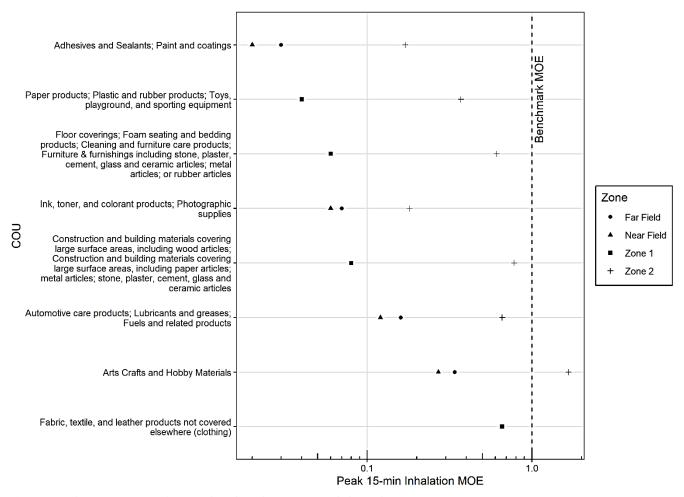


Figure 3. Acute Inhalation MOE for Consumer COUs for Formaldehyde

3.3 General Population

3.3.1 Indoor Air

There are no appreciable changes to the overall assessment conclusion using a POD of 0.3 ppm for indoor air scenarios. However, for completeness, EPA is providing risk estimates using the POD of 0.3 ppm $(370 \,\mu\text{g/m}^3)$ and a benchmark MOE of 1.

The Agency used CEM and Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) to estimate formaldehyde concentrations in the indoor environment. The exposure concentration estimates derived from CEM were based on safety data sheets (SDSs) identified in the Use Report for Formaldehyde (CAS RN 50-00-0) and Paraformaldehyde (CAS RN 30525-89-4) with updated Information from: Chemical Data Reporting (2016–2019), Toxics Release Inventory (2020), and Clean Water Act permit discharges (2021). Additional searches were also conducted to identify and refine the chemical concentration of formaldehyde in article formulation for the assessed COUs. In contrast, formaldehyde concentration estimates derived from IECCU are based on emission factors identified through readily available literature as explained in the *Risk Evaluation for Formaldehyde – Systematic Review Protocol* (U.S. EPA, 2024f). All indoor air exposure concentration estimates can be found in the *Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d).

Acute risk estimates for indoor air exposures are based on 15-minute peak formaldehyde concentrations from passive use of consumer articles. These exposures ranged from 5.4×10^{-5} to 1.2×10^{-1} ppm (0.007–142 µg/m³). The highest modeled (non-aggregate) exposures are reported for the following COUs: Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; Metal articles; and Stone, plaster, cement, glass and ceramic articles.

These concentrations are lower than the acute inhalation POD of 0.3 ppm (370 μ g/m³) with MOEs ranging from 2.6 to 52,638 for indoor residential settings (Figure 4). Consequently, no risk estimates fall below the benchmark MOE.

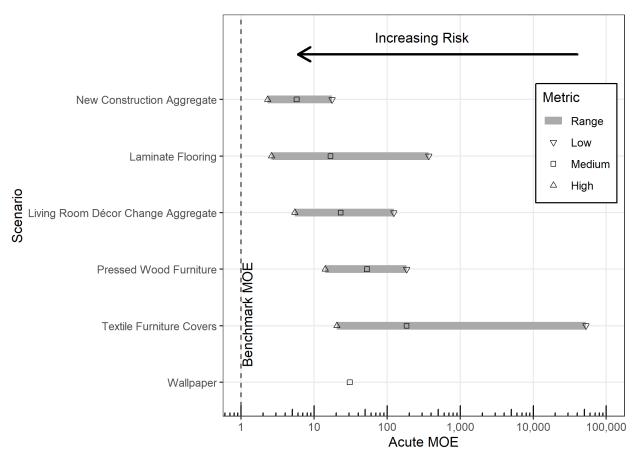


Figure 4. Acute Inhalation MOE for Indoor Air

3.3.2 Ambient Air

In the final RE, the Agency did not determine that acute exposure to formaldehyde in ambient air resulting from COUs would significantly contribute to the unreasonable risk of formaldehyde. As such, there are no appreciable changes to the overall assessment conclusions using a POD of 0.3 ppm. However, for transparency risk estimates using the POD of 0.3 ppm (370 μ g/m³) and a benchmark MOE of 1 are reported.

Acute risk estimates for ambient air for COUs and combustion are based on the maximum release scenarios and the 95th percentile of modeled daily average exposure concentrations 100 m from a releasing facility. The Agency uses these high-end, daily average modeled concentration as this period is the shortest time step modeled by the Integrated Indoor-Outdoor Air Calculator's (IIOAC) and used as a surrogate for a 15-minute exposure. EPA describes its assumptions associated with using daily average

concentration as a surrogate for 15-minute exposure and possible over or underestimation of exposures and associated risks in the final RE. Ambient air concentrations ranged from 0.0004 to $66.2~\mu g/m^3$ and 61 to $662~\mu g/m^3$. The highest modeled daily average exposures attributable to COUs are associated with wood product manufacturing and paper manufacturing industry sectors. Daily average exposures primarily attributable to combustion sources, such as airplanes, on-site vehicles, process heaters, turbines, and reciprocating internal combustion engines (RICE) ranged from 2 to $662~\mu g/m^3$. The highest of these concentrations were estimated for Wholesale and Retail Trade as well as the Oil and Gas Drilling, Extraction, and Support Activities industry sectors.

The acute risk estimates, utilizing an acute inhalation POD of 0.3 ppm $(370 \,\mu\text{g/m}^3)$ and a benchmark MOE of 1 for COUs from non-combustion sources, range from 5.5 to 2,239 (Figure 5). These risk estimates are above the benchmark of 1.

Risk estimates for combustion sources range from 0.6 to 2. MOEs for Industrial use – non-incorporative activities – processing aids, Processing – incorporation into an article – adhesives and sealant chemicals, and Processing – reactant – functional fluids COUs are no longer below the benchmark. Risk estimates for Commercial use – chemical substances in automotive and fuel products – automotive care products, lubricants and greases, fuels and related products; Manufacturing – importing; Processing – incorporation into a formulation, mixture, or reaction product – intermediate; and Processing – repackaging COUs are below the benchmark.

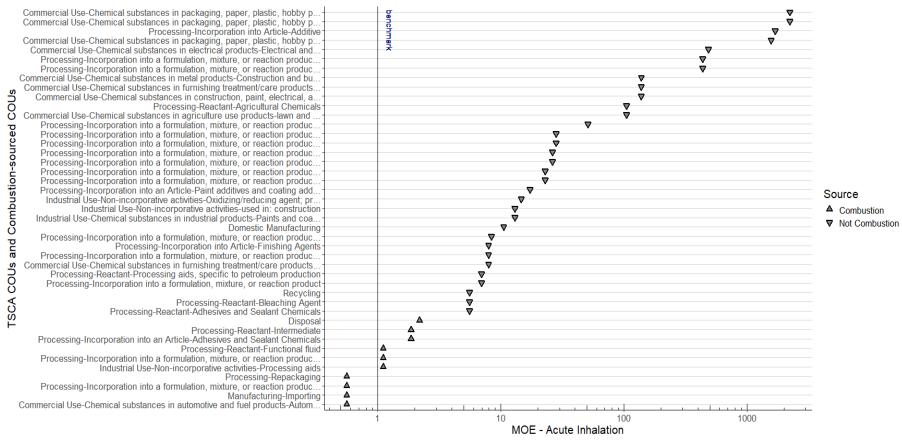


Figure 5. Acute Inhalation MOE for Outdoor Air

4 Acute Inhalation Risk Characterization Conclusions

This memo provides formaldehyde MOE calculations for an acute inhalation POD of 0.3 ppm for sensory irritation, using an uncertainty factor of 1 (UF = 1) for workers, consumers, and the general population. It is intended to revise the risk evaluation for formaldehyde. Other durations and routes are not covered in this memo. The results presented herein are not expected to alter the overall risk assessment conclusions or the determination that formaldehyde presents an unreasonable risk of injury to human health because other health effects are considered (*i.e.*, dermal sensitization).

For COUs that the Agency found significantly contribute to the unreasonable risk presented by formaldehyde in the final Risk Evaluation for Formaldehyde, the revised draft POD and corresponding uncertainty factor impacts the inhalation findings for five COUs for workers and three COUs for ONUs where either the central tendency estimate is no longer below the benchmark, or both the central tendency and the high-end estimates are no longer below the benchmark. These COUs are shown below in Table 1 and Table 2.

Table 1. Acute MOE Calculations for Workers Where Central Tendency Risk is No Longer Below the Benchmark

COU	Updated Draft Central Tendency MOE for Acute Inhalation (UF = 1)	Updated Draft High- End MOE for Acute Inhalation (UF = 1)	Risk Evaluation Central Tendency MOE for Acute Inhalation (UF = 3)	Risk Evaluation High-End MOE for Acute Inhalation (UF = 3)
Lawn and garden products	7.18	1.77	11.9	2.95
Oxidizing/reducing agent	3.24	1.31	5.40	2.18
Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	2.00	0.10	2.3	0.20
Recycling	1.38	0.51	2.31	0.85
Laboratory chemicals	1.98	0.10	1.19	0.23

Table 2. Acute MOE Calculations for ONUs Where Central Tendency Risk is No Longer Below the Benchmark

COU	Updated Draft Central Tendency MOE for Acute Inhalation (UF = 1)	Updated Draft High- End MOE for Acute Inhalation (UF = 1)	Risk Evaluation Central Tendency MOE for Acute Inhalation (UF = 3)	Risk Evaluation High-End MOE for Acute Inhalation (UF = 3)
Laboratory chemicals	1.19	0.23	1.19	0.14
Recycling	1.38	0.51	2.31	0.85
Adhesives and sealant chemicals in wood product manufacturing; plastic material (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	1.62	0.46	2.70	0.76

As noted in Section 3.3.2, the Agency did not identify risk for the general population from outdoor air exposures to formaldehyde that would significantly contribute to the unreasonable risk determination for formaldehyde. The revised draft POD and corresponding uncertainty factor impact three COUs where the MOE estimate is no longer below the benchmark. These COUs are presented in Table .

Table 3. Acute MOE Calculations for the General Population Living 100 m Away from Release Where Risk is No Longer Below the Benchmark

COU	Updated Draft MOE for Acute Inhalation (UF = 1)	Risk Evaluation High-End MOE for Acute Inhalation (UF = 3)
Industrial use – non-incorporative activities – processing aids	1.10	1.84
Processing – incorporation into a formulation, mixture, or reaction product – processing aids, specific to petroleum production	1.10	1.84
Processing – reactant – functional fluid	1.10	1.84

5 References

- U.S. EPA. (2024a). Consumer Exposure Assessment for Formaldehyde. (EPA-HQ-OPPT-2018-0438-0180). Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0438-0180
- <u>U.S. EPA.</u> (2024b). Human Health Hazard Assessment for Formaldehyde. Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0438
- <u>U.S. EPA.</u> (2024c). Human Health Risk Assessment for Formaldehyde. Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0438
- U.S. EPA. (2024d). Indoor Air Exposure Assessment for Formaldehyde. (EPA-HQ-OPPT-2018-0438-0183). Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0438-0183
- U.S. EPA. (2024e). Occupational Exposure Assessment for Formaldehyde. Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. https://www.regulations.gov/docket/EPA-HO-OPPT-2018-0438
- <u>U.S. EPA.</u> (2024f). Risk Evaluation for Formaldehyde Systematic Review Protocol. Washington, DC: Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention. https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0438

Appendix A Updated Draft Risk Calculation Tables

Table_Apx 1. Updated Draft Central Tendency and High-End MOE Estimates for Acute Inhalation by Workers

COU	Draft Central Tendency MOE for Acute Inhalation (UF = 1)	Draft High End MOE for Acute Inhalation (UF = 1)
Automotive care product	0.35	0.01
Water treatment products*	0.39	0.20
Manufacturing	0.50	0
Paints, coatings, adhesives (IU/CU)	0.72	0.20
Machinery, mechanical	0.79	0.26
Construction and building (metal)	0.79	0.26
Laboratory chemicals	1.19	0.14
Paper products*	1.29	1.06
Processing – recycling	1.38	0.51
Processing – article – adhesives and sealant chemicals	1.62	0.45
Processing – reactant	1.98	0.09
Processing – formulations	1.98	0.1
Processing – article – transportation	2.61	0.28
Arts, crafts, and hobby materials	2.61	0.28
Used in construction	2.68	0.3
Ink, toner, and colorant	2.85	0.87
Explosive materials*	2.92	1.15
Construction and building (wood and other articles)	3.22	0.35
Distribution in commerce	3.22	0.59
Oxidizing/reducing agent	3.24	1.31
Import/processing – repackaging	3.34	0.02
Laundry and dishwashing products*	3.56	2.39
Processing – article – textiles	3.92	0.34
Floor coverings, foam	3.92	0.34
Lawn and garden products	7.18	1.77
Processing – article – rubber products	8.70	0.67
Disposal	12.88	2.71
Processing aid in oil and gas drilling	174.42	0.87

^{*:} indicates COUs for which the respective scenarios have a slight weight of scientific evidence conclusion for the occupational exposure estimate (OES) as detailed in the final RE

Table_Apx 2. Updated Draft Acute Inhalation MOE for Low, Medium, and High Exposure Scenarios for Residential Indoor Air COUs

COU Subcategory	Scenario	Level	Draft Acute Inhalation MOE (UF = 1)
Construction and		High	2.6
building materials	Laminate Flooring	Medium	16.7
covering large surface areas, including wood		Low	368.5
articles; construction		High	2.3
and building materials		Medium	5.8
covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	New Construction Aggregate	Low	17.5
Fabric, textile, and	Textile Furniture Covers	High	20.5
leather products not		Medium	184.2
covered elsewhere		Low	52,638.0
Floor coverings; foam		High	14.2
seating and bedding	Pressed Wood Furniture	Medium	52.6
products; cleaning and furniture care products;		Low	184.2
furniture and furnishings		High	5.4
including stone, plaster,		Medium	23.0
5	Living Room Décor Change Aggregate	Low	122.8
Paper products; plastic and rubber products; toys, playground, and sporting equipment	Wallpaper	N/A	30.7

Table_Apx 3. Acute Inhalation MOE Estimates for Combustion-Sourced and Non-Combustion-Sourced Formaldehyde in Ambient Air Based on the Maximum Release Scenarios and the 95th Percentile IIOAC-Modeled Daily Average Exposure Concentrations at 100 m from a Releasing Facility

COU	Source	Draft Acute Inhalation MOE (UF = 1)
Commercial use – chemical substances in automotive and fuel products-automotive care products; lubricants and greases; fuels and related products	Combustion	0.56
Manufacturing – importing	Combustion	0.56

COU	Source	Draft Acute Inhalation MOE (UF = 1)
Processing – incorporation into a formulation, mixture, or reaction product – intermediate	Combustion	0.56
Processing – repackaging	Combustion	0.56
Industrial use – non-incorporative activities – processing aids	Combustion	1.10
Processing – incorporation into a formulation, mixture, or reaction product – processing aids, specific to petroleum production	Combustion	1.10
Processing- reactant - functional fluid	Combustion	1.10
Processing – incorporation into an article-adhesives and sealant chemicals	Combustion	1.86
Processing – reactant – intermediate	Combustion	1.86
Disposal	Combustion	2.18
Processing – reactant – adhesives and sealant chemicals	Not combustion	5.55
Processing – reactant – bleaching agent	Not combustion	5.55
Recycling	Not combustion	5.55
Processing – incorporation into a formulation, mixture, or reaction product	Not combustion	6.95
Processing – reactant – processing aids, specific to petroleum production	Not combustion	6.95
Commercial use – chemical substances in furnishing treatment/care products – floor coverings; Foam seating and bedding products	Not combustion	7.95
Processing – incorporation into a formulation, mixture, or reaction product – bleaching agents	Not combustion	7.95
Processing – incorporation into article – finishing agents	Not combustion	7.95
Processing – incorporation into a formulation, mixture, or reaction product – agricultural chemicals (nonpesticidal)	Not combustion	8.39
Domestic manufacturing	Not combustion	10.54
Industrial use – chemical substances in industrial products – paints and coatings; adhesives and sealants; lubricants	Not combustion	13.03
Industrial use-non-incorporative activities – used in: construction	Not combustion	13.03
Industrial use – non – incorporative activities – oxidizing/reducing agent; processing aids, not otherwise listed (e.g., electroless copper plating)	Not combustion	14.69

COU	Source	Draft Acute Inhalation MOE (UF = 1)
Processing – incorporation into an article – paint additives and coating additives	Not combustion	17.27
Processing – incorporation into a formulation, mixture, or reaction product – paint additives and coating additives not described by other categories	Not combustion	22.90
Processing – incorporation into a formulation, mixture, or reaction product – surface active agents	Not combustion	22.90
Processing – incorporation into a formulation, mixture, or reaction product – ion exchange agents	Not combustion	26.28
Processing – incorporation into a formulation, mixture, or reaction product – solvents (which become part of a product formulation or mixture)	Not combustion	26.28
Processing – incorporation into a formulation, mixture, or reaction product – other: laboratory chemicals	Not combustion	28.08
Processing – incorporation into a formulation, mixture, or reaction product – plating agents and surface treating agents	Not combustion	28.08
Processing – incorporation into a formulation, mixture, or reaction product – solid separation agents	Not combustion	51.13
Commercial use – chemical substances in agriculture use products – lawn and garden products	Not combustion	105.07
Processing – reactant – agricultural chemicals	Not combustion	105.07
Commercial use – chemical substances in construction, paint, electrical, and metal products – adhesives and sealants; paint and coatings	Not combustion	138.55
Commercial use – chemical substances in furnishing treatment/care products – construction and building materials covering large surface areas	Not combustion	138.55
Commercial use – chemical substances in metal products – construction and building materials covering large surface areas, including metal articles	Not combustion	138.55
Processing – incorporation into a formulation, mixture, or reaction product – adhesive and sealant chemicals	Not combustion	436.85
Processing – incorporation into a formulation, mixture, or reaction product – lubricant and lubricant additive	Not combustion	436.85
Commercial use – chemical substances in electrical products – electrical and electronic products	Not combustion	487.96
Commercial use – chemical substances in packaging, paper, plastic, hobby products – ink, toner, and colorant products; photographic supplies	Not combustion	1,579.43

COU	Source	Draft Acute Inhalation MOE (UF = 1)
Processing – incorporation into article – additive	Not combustion	1,698.44
Commercial use – chemical substances in packaging, paper, plastic, hobby products – arts, crafts, and hobby materials	Not combustion	2,239.11
Commercial use – chemical substances in packaging, paper, plastic, hobby products – paper products; plastic and rubber products; toys, playground, and sporting equipment	Not combustion	2,239.11

Table_Apx 4. Updated Draft Acute Inhalation MOE Estimates for Consumer COUs

COU Subcategories	Scenario	Zone	Draft Acute Inhalation MOE (UF=1)
Arts crafts and hobby materials	Craft Paint	Near-Field	0.27
Arts crafts and hobby materials	Craft Paint	Far-Field	0.34
Arts crafts and hobby materials	Craft Paint	Zone 2	1.67
Adhesives and sealants; paint and coatings	Glues and Adhesives	Near-Field	0.02
Adhesives and sealants; paint and coatings	Glues and Adhesives	Far-Field	0.03
Adhesives and sealants; paint and coatings	Glues and Adhesives	Zone 2	0.17
Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	Building / Construction Materials – Wood Articles: Hardwood Floors	Zone 1	0.08
Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	Building / Construction Materials – Wood Articles: Hardwood Floors	Zone 2	0.78
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	Foam seating (residential)	Zone 1	0.06
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	Foam seating (residential)	Zone 2	0.61
Fabric, textile, and leather products not covered elsewhere (clothing)	Seat Covers (automobile)	Zone 1	0.66

COU Subcategories	Scenario	Zone	Draft Acute Inhalation MOE (UF=1)
Automotive care products; Lubricants and greases; Fuels and related products	Lubricants non- spray	Near-Field	0.12
Automotive care products; Lubricants and greases; Fuels and related products	Lubricants non- spray	Far-Field	0.16
Automotive care products; Lubricants and greases; Fuels and related products	Lubricants non- spray	Zone 2	0.66
Ink, toner, and colorant products; Photographic supplies	Liquid photographic processing solutions	Near-Field	0.06
Ink, toner, and colorant products; Photographic supplies	Liquid photographic processing solutions	Far-Field	0.07
Ink, toner, and colorant products; Photographic supplies	Liquid photographic processing solutions	Zone 2	0.18
Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	Rubber Articles (residential)	Zone 1	0.04

Appendix B Occupational Exposure Value

B.1 Occupational Exposure Value Derivation

EPA calculated an occupational exposure value for consideration of formaldehyde inhalation exposure in workplace settings (see Section B.2). This updated draft occupational exposure value derivation applies the 0.3 ppm POD and uncertainty factor of 1. This calculated value may be used to support risk management efforts for formaldehyde under TSCA section 6(a), 15 U.S.C. §2605.

EPA calculated an acute occupational exposure value of 0.3~ppm ($614~\mu\text{g/m}^3$) that is intended to protect workers and ONUs against sensory irritation effects resulting from acute occupational exposures. As noted in the revised draft human health hazard TSD for the risk evaluation for formaldehyde, this sensory irritation effect appears to be more responsive to exposure concentration than duration. Therefore, the occupational exposure value (OEV) applies to all durations of exposure and serves as the short-term exposure value. Use of this OEV is health-protective against other effects, including cancer as described in the Federal Register Notice Formaldehyde; Updated Draft Risk Calculation Memorandum; Notice of Availability.

Of the identified occupational monitoring data for formaldehyde, there have been measured workplace air concentrations below the calculated exposure values. A summary table of available monitoring methods from the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) is included below in Section B.B.3. The table covers validated methods from governmental agencies and is not intended to be a comprehensive list of available air monitoring methods for formaldehyde. The calculated exposure values are above the limit of detection (LOD) and limit of quantification (LOQ) using at least one of the monitoring methods identified.

OSHA set a permissible exposure limit (PEL) as an 8-hour TWA for formaldehyde of 0.75 ppm in 1992 (https://www.osha.gov/annotated-pels), with an action level of 0.5 ppm. In addition, OSHA has set a short-term exposure limit (STEL) of 2 ppm. OSHA's PEL must undergo both risk assessment and feasibility assessment analyses before selecting a level that will substantially reduce risk under the Occupational Safety and Health Act. Other international regulatory bodies such as the European Union established an occupational exposure regulatory limit of 0.3 ppm (European Chemicals Agency, http://echa.europa.eu/).⁴

There are also recommended exposure limits established for formaldehyde by other governmental agencies and independent groups. The American Conference of Governmental Industrial Hygienists (ACGIH) set a Threshold Limit Value (TLV) at 0.1 ppm TWA and 0.3 ppm STEL in 2017. This chemical also has a NIOSH Recommended Exposure Limit (REL) of 0.016 ppm TWA and 15-minute Ceiling limit of 0.1 ppm (https://www.cdc.gov/niosh/npg/).

B.2 Occupational Exposure Value Calculations

This appendix presents the calculations used to estimate occupational exposure values using inputs derived in this risk evaluation. The human health hazard value used in this equation is based on the acute inhalation hazard value identified in the Federal Register Notice.

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⁴ https://echa.europa.eu/substance-information/-/substanceinfo/100.000.002.

Occupational Exposure Value

The occupational exposure value (EV_{acute}) was calculated as the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures using Equation_Apx 1:

Equation_Apx 1.

$$EV_{acute} = \frac{Hazard\ Value_{acute}}{Benchmark\ MOE_{acute}} = \frac{0.3\ ppm}{1} = 0.3\ ppm = 368\ \frac{\mu g}{m^3}$$

Where:

Benchmark MOE_{acute} = Acute non-cancer benchmark margin of exposure, based on the

total uncertainty factor of 1 selected in the FRN.

 EV_{acute} = Exposure limit based on acute effects

Hazard Value_{acute} = Human hazard value for acute occupational exposure

scenarios

Unit conversion:

1 ppm = $1,228 \mu g/m^3$ (based on molecular weight of 30.026 g/mol for formaldehyde)

B.3 Summary of Air Sampling Analytical Methods Identified

EPA conducted a search to identify relevant NIOSH and OSHA analytical methods used to monitor for the presence of formaldehyde in air (see Table_Apx). This table covers validated methods from governmental agencies and is not intended to be a comprehensive list of available air monitoring methods for formaldehyde. The sources used for the search included the following:

- 1. NIOSH Manual of Analytical Methods (NMAM), 5th Edition;
- 2. NIOSH NMAM 4th Edition; and
- 3. OSHA Index of Sampling and Analytical Methods.

Notably, the limit of detection provided is based on the recommended volume. The specific limit of detection may vary depending on the time sampled and flowrate used.

Table_Apx 5. Limit of Detection (LOD) and Limit of Quantification (LOQ) Summary for Air Sampling Analytical Methods Identified

Air Sampling Analytical Methods ^a	Year Published	\mathbf{LOD}^b	LOQ	Notes	Source
NIOSH Method 2016	2016	0.012 ppm	N/A	Estimated LOD is 0.07 µg/sample. The working range is 0.012 to 2.0 ppm for a 15-L sample.	NIOSH Manual of Analytical Methods (NMAM 2016)
NIOSH Method 2541 ^c	1994	0.24 ppm	N/A	Estimated LOD is 1 µg/sample. The working range is 0.24 to 16 ppm for a 10-L sample.	NIOSH Manual of Analytical Methods, 4th Edition (NMAM 2541)
NIOSH Method 3500 ^d	1994	0.02 ppm	N/A	Estimated LOD is 0.5 µg/sample. The working range is 0.02 to 4 ppm for an 80-L sample.	NIOSH Manual of Analytical Methods, 4th Edition (NMAM 3500)

Air Sampling Analytical Methods ^a	Year Published	\mathbf{LOD}^b	LOQ	Notes	Source
NIOSH Method 5700 ^e	1994	0.0004 mg/m ³ (0.0003 ppm)	N/A	Estimated LOD is 0.08 µg/sample. The working range is 0.0004 to 3.8 mg/m³ for a 1,050-L sample. Used for determination of formaldehyde in both textile and wood dusts.	NIOSH Manual of Analytical Methods, 4th Edition (NMAM 5700)
OSHA Method 52	1989	16 ppb	16 ppb	Detection limit and reliable quantification limit is 482 ng per sample (16 ppb for 24 L)	OSHA Index of Sampling and Analytical Methods (OSHA 52)
OSHA Method 1007 ^f https://www.osha.gov/sites/default/files/met/hods/osha-1007.pdf	2005		1.88, 5.68, or 0.58 ppb (Sampler – ChemDisk- AL, UMEx 100, DSD- DNPH, respectively)	Method reports LOD/LOQ of overall procedure as 0.56/1.88 ppb for ChemDisk-AL samplers, 1.70/5.68 ppb for UMEx 100 samplers, and 0.17/0.58 for DSD- DNPH samplers	OSHA Index of Sampling and Analytical Methods (OSHA 1007)

ppm = parts per million; ppb = parts per billion; ppt = parts per trillion

^a EPA has additional air sampling methods targeted for measurement of ambient and indoor air, the methods listed in this table are air sampling for occupational exposures.

^b These sources cover a range of LOD including both below and above the preliminary occupational exposure value.

^c The method is suitable for the simultaneous determinations of acrolein and formaldehyde.

^d This is the most sensitive formaldehyde method in the NIOSH Manual of Analytical Methods and is able to measure ceiling levels as low as 0.1 ppm (one 5-liter sample). It is best suited for the determination of formaldehyde in area samples.

^e Results should be considered separately from vapor-phase formaldehyde exposure; Method measures both "released" and formaldehyde equivalents.

^fRecommends use of OSHA Method 52 when monitoring exposures resulting from the use of formalin solutions.