



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0438; FRL-11608-04-OCSP]

Formaldehyde; Risk Evaluation under the Toxic Substances Control Act (TSCA); Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is announcing the availability of the final risk evaluation under the Toxic Substances Control Act (TSCA) for formaldehyde. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the conditions of use. The Agency used the best available science to prepare this final risk evaluation and has determined, based on the weight of scientific evidence, that formaldehyde presents an unreasonable risk of injury to human health. Under TSCA, EPA must initiate risk management actions to address the unreasonable risk.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0438, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information: Jeffery Putt, Existing Chemical Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3703; email address: formaldehydeTSCA@epa.gov.

For general information: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general and may be of particular interest to those involved in the manufacture (defined under TSCA section 3(9) to include import), processing, distribution in commerce, use, and disposal of formaldehyde, related industry trade organizations, non-governmental organizations with an interest in human and environmental health, state and local governments, Tribal Nations, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. As such, the Agency has not attempted to describe all the specific entities that this action might apply to. If you need help determining applicability, consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

The Agency conducted this risk evaluation under TSCA section 6, 15 U.S.C. 2605, which requires that EPA conduct risk evaluations on chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations. Each risk evaluation must be conducted consistent with the best available science, be based on the weight of the scientific evidence, and consider reasonably available information, pursuant to 15 U.S.C. 2625(h), (i), and (k). See also the implementing procedural regulations at 40 CFR part 702.

C. What action is the Agency taking?

EPA is announcing the availability of the final risk evaluation under TSCA for formaldehyde. The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without

consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the conditions of use. EPA has used the best available science to prepare this final risk evaluation and based on the weight of scientific evidence, determined that formaldehyde poses unreasonable risk to human health. Upon a determination of unreasonable risk, EPA must initiate risk management action as required pursuant to 15 U.S.C 2605(a) to address the unreasonable risk.

For more information about the TSCA risk evaluation process for existing chemicals, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>.

II. Background

A. What is Formaldehyde?

Formaldehyde is a colorless, flammable gas at room temperature and has a strong odor. Formaldehyde is found nearly everywhere. People and animals produce and release formaldehyde. Formaldehyde is produced when organic material including leaves, plants, and woodchips decay. Formaldehyde is also produced and released into the air from combustion activities like burning fuel (*e.g.*, exhaust from cars, airplanes), gas/wood burning (furnaces and stoves), and forest fires, burning candles, and smoking. Finally, formaldehyde is released into the air from industrial and commercial operations when produced or used to make many products or articles including composite wood products and other building materials, plastics, pesticides, paints, adhesives, and sealants. Industry uses formaldehyde due to its ability to combine and react with many other chemical substances and make resilient structures that are widely used in manufacturing. Information from the 2016 Chemical Data Reporting (CDR) for formaldehyde indicates that the reported production volume is between 1 billion and 5 billion pounds per year (manufacture and import).

Short-term inhalation exposure to high levels of formaldehyde can cause sensory irritation such as eye and respiratory irritation. Short-term skin contact can cause sensitization.

Exposure over longer periods can also cause respiratory effects and cancer. The complex toxicology and exposure profiles for formaldehyde presented unique challenges for this evaluation. As required under TSCA section 6(b)(4)(A), EPA evaluated the risks from formaldehyde under its conditions of use, including the intended, known and reasonably foreseen circumstances under which the chemical is manufactured, processed, distributed in commerce, used or disposed of. EPA did not evaluate risk from sources of formaldehyde exposure excluded from TSCA jurisdiction.

B. Risk Evaluation of Formaldehyde

In December 2019, EPA designated formaldehyde as a High Priority Substance for risk evaluation under TSCA (Ref 1.). A draft scope of the formaldehyde risk evaluation was published in April 2020 (Ref 2.) and after receiving public comment, EPA issued the final scope of the formaldehyde risk evaluation in September 2020 (Ref 3.). In March 2024, EPA released a draft risk evaluation for public comment and scientific peer review (Ref 4.).

EPA leveraged work products and resources across the agency in its development of the draft risk evaluation under TSCA, including consideration of hazard information from EPA's Integrated Risk Information System (IRIS) Toxicological Review of Formaldehyde-Inhalation. A draft version of the IRIS document was published in April 2022 and finalized in August 2024. The draft IRIS document was the subject of external peer review by the National Academies of Sciences, Engineering, and Medicine (NASEM).

In addition, EPA leveraged multiple federal advisory committees and their reports to support the external peer review of formaldehyde during the TSCA risk evaluation process, including NASEM, the Human Studies Review Board (HSRB) and the TSCA Science Advisory Committee on Chemicals (SACC).

The final formaldehyde risk evaluation comprises a series of technical support documents. Each document contains sub-assessments that inform adjacent, "downstream" documents. These documents address comments from both the public and peer reviewers. The

components of the risk evaluation, including (but not limited to) each technical support document and responses to peer review and public comments, are available in the docket.

III. Unreasonable Risk Determination

EPA has determined that formaldehyde presents an unreasonable risk of injury to human health under the conditions of use. The unreasonable risk to human health presented by formaldehyde is due to non-cancer effects in workers and consumers from acute dermal and inhalation exposures, and due to cancer effects in workers from long-term inhalation exposure.

EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk determination for formaldehyde.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory actions to the extent necessary so that formaldehyde no longer presents an unreasonable risk under the conditions of use. The Agency expects to focus its risk management action on the TSCA conditions of use that significantly contribute to the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to contribute significantly to unreasonable risk and may select from among a suite of risk management approaches based on requirements in TSCA section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) contributing significantly to unreasonable risk, even if the upstream activities do not contribute significantly to the unreasonable risk.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket,

even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. *Federal Register*. 84 FR 71924, December 30, 2019 (FRL-10003-15).

2. EPA. Draft Scopes of the Risk Evaluations to be Conducted for Seven Chemical Substances under the Toxic Substances Control Act; Notice of Availability. *Federal Register*. 85 FR 22733, April 23, 2020 (FRL-10008-05).

3. EPA. Final Scopes of the Risk Evaluations To Be Conducted for Twenty Chemical Substances Under the Toxic Substances Control Act; Notice of Availability. *Federal Register*. 85 FR 55281, September 4, 2020 (FRL-10013-90).

4. EPA. Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Notice of Availability, Public Meetings and Request for Comment. *Federal Register*. 89 FR 18933, March 15, 2024 (FRL-11608-03-OCSP).

5. EPA. Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Request for Nominations of ad hoc Expert Reviewers. *Federal Register*. 88 FR 88910, December 26, 2023 (FRL-11608-01-OCSP).

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 30, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024-31571 Filed: 1/2/2025 8:45 am; Publication Date: 1/3/2025]