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Dated: January 4, 2021.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0238; FRL-10017-46]

1,4-Dioxane; Final Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the final Toxic Substances Control Act (TSCA) risk evaluation of 1, 4-dioxane. The purpose of conducting risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation, without consideration of costs or other nonrisk factors. EPA has determined that specific conditions of use of 1, 4-dioxane present an unreasonable risk of injury to health or the environment. For those conditions of use for which EPA has found an unreasonable risk, EPA must take regulatory action to address that unreasonable risk through risk management measures enumerated in TSCA. EPA has also determined that specific conditions of use do not present

an unreasonable risk of injury to health or the environment. For those conditions of use for which EPA has found no unreasonable risk of injury to health or the environment, the Agency's determination is a final Agency action and is issued via order in the risk evaluation.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0238, is available online at <http://www.regulations.gov> or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Public Reading Room are closed to visitors with limited exceptions. The EPA/DC staff continue to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Yvette Selby-Mohamadu, Office of Pollution Prevention and Toxics (7403M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-5245; email address: selby-mohamadu.yvette@epa.gov.

For general information contact: 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. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of interest to persons who are or may be interested in risk evaluations of chemical substances under TSCA, 15 U.S.C. 2601 *et seq.* Since other entities may also be interested in this final risk evaluation, the EPA has not attempted to describe all the specific entities that may be affected by this action.

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

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence and consider the reasonably available information. 15 U.S.C. 2625(h), (i), and (k). TSCA section 6(i) directs that a determination of "no unreasonable risk" shall be issued by order and considered to be a final Agency action, while a determination of "unreasonable risk" is not considered to be a final Agency action. 15 U.S.C. 2605(i).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) Integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i) through (ii) and (iv) through (v). Each risk evaluation

must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

The statute requires that the risk evaluation process be completed within a specified timeframe and provide an opportunity for public comment on a draft risk evaluation prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4).

Subsection 5.4.1 of the final risk evaluation for 1, 4-dioxane constitutes the order required under TSCA section 6(i)(1), and the “no unreasonable risk” determinations in that subsection are considered to be a final Agency action effective on the date of issuance of the order. In conducting risk evaluations, “EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use within the scope of the risk evaluation” 40 CFR 702.47. Under EPA’s implementing regulations, “[a] determination by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluation, does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order.” 40 CFR 702.49(d). For purposes of TSCA section 19(a)(1)(A), the date of issuance of the TSCA section 6(i)(1) order for 1, 4-dioxane shall be at 1:00 p.m. Eastern time (standard or daylight, as appropriate) on the date that is two weeks after the date when this notice is published in the **Federal Register**, which is in accordance with 40 CFR 23.5.

C. What action is EPA taking?

EPA is announcing the availability of the risk evaluation of the chemical substance identified in Unit II. In this risk evaluation, EPA has made unreasonable risk determinations on some of the conditions of use within the scope of the risk evaluation for this chemical. For those conditions of use for which EPA has found an unreasonable risk of injury to health or the environment, EPA must initiate regulatory action to address those risks through risk management measures enumerated in 15 U.S.C. 2605(a).

EPA also is announcing the availability of the information required to be provided publicly with each risk evaluation, which is available online at <http://www.regulations.gov> in the dockets identified. 40 CFR 702.51. Specifically, EPA has provided:

- The scope document and problem formulation (in Docket ID No. EPA-HQ-OPPT-2016-0723);

- Draft risk evaluation, supplemental analysis to the draft risk evaluation, and final risk evaluation (in Docket ID No. EPA-HQ-OPPT-2019-0238);

- All notices, determinations, findings, consent agreements, and orders (in Docket ID No. EPA-HQ-OPPT-2019-0238);

- Any information required to be provided to the Agency under 15 U.S.C. 2603 (in Docket ID No. EPA-HQ-OPPT-2016-0723 and Docket ID No. EPA-HQ-OPPT-2019-0238);

- A nontechnical summary of the risk evaluation (in Docket ID No. EPA-HQ-OPPT-2019-0238);

- A list of the studies, with the results of the studies, considered in carrying out each risk evaluation (Risk Evaluation for 1, 4-dioxane) in Docket ID No. EPA-HQ-OPPT-2019-0238);

- The final peer review report, including the response to peer review and public comments received during peer review (in Docket ID No. EPA-HQ-OPPT-2019-0238); and

- Response to public comments received on the draft scope, the draft risk evaluation and the supplemental analysis to the draft risk evaluation (in Docket ID No. EPA-HQ-OPPT-2019-0238).

II. TSCA Risk Evaluation

A. What is EPA’s risk evaluation process for existing chemicals under TSCA?

The risk evaluation process is the second step in EPA’s existing chemical review process under TSCA, following prioritization and before risk management. As this chemical is one of the first ten chemical substances undergoing risk evaluation, the chemical substance was not required to go through prioritization (81 FR 91927, December 19, 2016) (FRL-9956-47). The purpose of conducting risk evaluations is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, not consider costs or other nonrisk factors, use reasonably available information and approaches in a manner that is consistent with the requirements in TSCA for the use of the best available science, and ensure decisions are based on the weight of the scientific evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out in 40 CFR part 702 and summarized on EPA’s website at [http://](http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca)

www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca. As explained in the preamble to EPA’s final rule on procedures for risk evaluation (82 FR 33726, July 20, 2017) (FRL-9964-38), the specific regulatory process set out in 40 CFR part 702, subpart B is being followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

Prior to the publication of this final risk evaluation, a draft risk evaluation was subject to peer review and public comment and a supplemental analysis to the draft risk evaluation was subject to public comment. EPA reviewed the report from the peer review committee and public comments and has amended the risk evaluation in response to these comments as appropriate. The public comments, peer review report, and EPA’s response to comments is in Docket ID No. EPA-HQ-OPPT-2019-0238. Prior to the publication of the draft risk evaluation, EPA made available the scope and problem formulation, and solicited public input on uses and exposure. EPA’s documents and the public comments are in Docket ID No. EPA-HQ-OPPT-2016-0723. Additionally, information about the scope, problem formulation, and draft risk evaluation phases of the TSCA risk evaluation for this chemical is available at EPA’s website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-14-dioxane>.

B. What is 1, 4-dioxane?

1,4-dioxane is used primarily as a solvent in a variety of commercial and industrial applications like in the manufacture of other chemicals, as a processing aid, a laboratory chemical, and in adhesives and sealants. 2016 CDR data shows that there were two manufacturers producing or importing 1,059,980 pounds of 1,4-dioxane in the U.S. in 2015.

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

Andrew Wheeler,
Administrator.

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