



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018- 0443; FRL-12964-01-OCSP]

**Octamethylcyclotetrasiloxane (Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-)**

**(D4); Draft Risk Evaluation under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) is announcing the availability of and seeking public comment on a draft risk evaluation under the Toxic Substances Control Act (TSCA) for Octamethylcyclotetrasiloxane (Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-) (D4) (CASRN 556-67-2). 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 under the conditions of use (COUs), including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, and without consideration of costs or non-risk factors. EPA used the best available science to prepare this draft risk evaluation and to preliminarily determine, based on the weight of scientific evidence, that D4 poses unreasonable risk to human health and the environment driven primarily by certain conditions of use analyzed in the draft risk evaluation.

**DATES:** Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0443, online at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more

information about dockets generally, is available at <https://www.epa.gov/dockets>.

## **FOR FURTHER INFORMATION CONTACT:**

*For technical information:* Scott Drewes, 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) 564-8833; email address: [drewes.scott@epa.gov](mailto:drewes.scott@epa.gov).

*For general information:* The TSCA-Hotline, Goodwill of the Finger Lakes, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto: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, use, and disposal of D4, 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 is conducting 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 the 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, and not consider costs or non-risk

factors. 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 and seeking public comment on a draft risk evaluation under TSCA for D4. This draft risk evaluation was developed in response to a manufacturer request. 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 under the conditions of use, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, and without consideration of costs or non-risk factors. EPA has used the best available science to prepare this draft risk evaluation and, based on the weight of scientific evidence, to preliminarily determine that D4 poses unreasonable risk to human health and/or the environment.

*D. What should I consider as I prepare my comments?*

1. *Submitting CBI.* Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703, as applicable.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

## **II. Background**

*A. What is D4?*

D4 is a common name for octamethylcyclotetrasiloxane (CASRN 556-67-2). It is a colorless, volatile, oily liquid primarily used to make silicone chemicals. D4 commercial uses include but are not limited to adhesives and sealants, automotive care products, paints and coatings, and other plastic and rubber products. D4 is also used as an ingredient in consumer

products (i.e., cosmetics, medical devices, and food contact materials) regulated by the Federal Food, Drug, and Cosmetic Act (FFDCA) [21 U.S.C. 321]. D4 is not reported to the Toxics Release Inventory, National Emission Inventory, or to the Discharge Monitoring Report system. D4 is found in various environmental media including air, water, sediment, soil, and biota.

#### *B. Summary of Activities for the Risk Evaluation of D4*

On March 19, 2020, EPA received a manufacturer request, pursuant to 40 CFR 702.37, to conduct a risk evaluation for D4 (Docket ID: EPA-HQ-OPPT-2018-0443) through the American Chemistry Council's Silicones Environmental, Health, and Safety Center. (Ref. 1) In October 2020, EPA granted the manufacturer request for risk evaluation for D4. In September 2021, EPA published and sought public comment on the draft scope of the D4 risk evaluation (Ref. 2), and, after considering public comments, issued the final scope in March 2022 (Ref. 3). These documents, other supporting documents, and public comments are in the docket at <https://www.regulations.gov>.

Additionally, in 2014, EPA issued an enforceable consent agreement (ECA) requiring five manufacturers of D4 to submit testing data to help the agency better understand the amount of D4 released into the environment and the quantity of D4 in water, sediment and aquatic organisms. The signatory companies completed the ECA testing requirements in September 2017. The information gathered by the ECA was used in conjunction with other available data to assess exposures and risks due to environmental releases from D4. The final test report can be found in multiple sections in the docket (EPA-HQ-OPPT-2012-0209).

### **III. Request for Comment**

EPA seeks feedback on the assessment of risk presented in the draft risk evaluation for D4, a copy of which is available in the docket, and encourages all potentially interested parties, including individuals, governmental and non-governmental organizations, non-profit organizations, academic institutions, research institutions, and private sector entities to comment on the draft risk evaluation. To the extent possible, the Agency asks commenters to please cite

any public data related to or that support comments provided, and to the extent permissible, describe any supporting data that is not publicly available.

EPA welcomes specific input on each section of the draft risk evaluation, particularly input on the following:

- evaluation and use of the D4 physiologically based pharmacokinetic model;
- identification of hazards relevant to human health and ecological risk assessment;
- whether and how exposure controls and personal protective equipment are used for each of the COUs;
- information on environmental release of D4, including media of release and facility-specific receiving waterbodies;
- information to inform estimates of dermal exposures for workers;
- information to inform exposures of occupational non-users in the assessment;
- handling of uncertainties associated with exposure and release assessments;
- bioaccumulation, bioconcentration, biomagnification, and potential trophic transfer, including the selection of the bioconcentration factor to estimate human exposure from fish consumption;
- consideration of aggregate exposure and risk; and,
- any other information that may inform the assumptions used for modeling each of the COUs.

#### **IV. Next Steps**

EPA will consider comments received from the public and SACC on the draft risk evaluation and will issue the final risk evaluation for D4. A separate forthcoming *Federal Register* notice will announce the peer review by the SACC.

Under TSCA section 6, EPA must determine in the final risk evaluation, based on the weight of scientific evidence, whether or not the chemical presents an unreasonable risk to health or the environment under the chemical's conditions of use. This includes consideration of risks

to potentially exposed susceptible subpopulations (PESS) who may be at greater risks than the general population, such as children and workers. TSCA prohibits EPA from considering non-risk factors (e.g., costs/benefits) during risk evaluation.

If EPA determines that a chemical presents an unreasonable risk to health or the environment, the chemical will move to risk management action under TSCA section 6(a) for the relevant conditions of use.

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

## **V. 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. Manufacturer Request for Risk Evaluation under the Toxic Substances Control Act: Octamethylcyclotetra-siloxane (D4): Notice of Availability. *Federal Register*. 85 FR 36586, June 17, 2020 (FRL-10010-49).
2. EPA. Octamethylcyclotetra-Siloxane (D4); Draft Scope of the Risk Evaluation to Be Conducted Under the Toxic Substances Control Act; Notice of Availability and Request for Comments. *Federal Register*. 86 FR 50347, September 8, 2021 (FRL-8850-01-OCSP).
3. EPA. Final Scope of the Risk Evaluation to Be Conducted Under the Toxic Substances Control Act: Octamethylcyclotetra-siloxane (D4). Notice. *Federal Register*. 87 FR 12696, March 07, 2022 (FRL-8850-02-OCSP).

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

Dated: September 12, 2025.

**Nancy B. Beck,**

*Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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