



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2025-1610; FRL-12975-01-OCSPP]

Octamethylcyclotetrasiloxane (D4); Draft Risk Evaluation; Science Advisory Committee on Chemicals (SACC) Peer Review; Notice of SACC Meeting; Availability of Draft Documents and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is announcing that there will be two virtual public meetings of the Science Advisory Committee on Chemicals (SACC). On November 18, 2025, a preparatory meeting for the SACC to consider the scope and clarity of the draft charge questions for the peer review; and on December 2 through 5, 2025, a peer review meeting for the SACC to consider the octamethylcyclotetrasiloxane (D4) draft risk evaluation, technical support documents, and public comments. EPA is also announcing the availability of and soliciting public comment on the draft documents and charge questions that will be provided to the SACC for this peer review. The draft risk evaluation and technical support documents were prepared under the Toxic Substances Control Act (TSCA) and will be submitted to the SACC for peer review.

DATES:

Preparatory Public Meeting:

Meeting date: November 18, 2025, 1:00 p.m. to approximately 4:00 p.m. (EST).

Registration: To request time to present oral comments during the preparatory meeting, you must register by noon (12:00 p.m. EST) on November 11, 2025, and submit a written version of your oral comments by noon (12:00 p.m. EST) on November 14, 2025. For those not making oral comments, registration will remain open through the end of this meeting on November 18, 2025.

SACC Peer Review Public Meeting:

Meeting dates: December 2 through 5, 2025, 10:00 a.m. to approximately 5:00 p.m. (EST).

Registration: To request time to present oral comments during the SACC peer review meeting, you must register by noon (12:00 p.m. EST) November 25, 2025, and submit a written version of your oral comments by noon (12:00 p.m. EST) on November 28, 2025. For those not making oral comments, registration will remain open through the end of this meeting on December 5, 2025.

Comments: Submit written comments on the draft risk evaluation, technical support documents, and charge questions that will be provided to the SACC for this peer review on or before November 4, 2025.

Special Accommodations: To allow sufficient time for EPA to process your request for special accommodations before both the preparatory and SACC peer review meetings, please submit the request at least ten business days in advance of the relevant meeting.

ADDRESSES:

Comments: Submit written comments, identified by docket identification (ID): EPA-HQ-OPPT-2025-1610, through <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Members of the public should also be aware that personal information included in any written comments may be posted on the internet at <https://www.regulations.gov>. Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

Meeting(s) registration: Online registration for the preparatory meeting will be available in October 2025. Online registration for the SACC peer review meeting will be available in November 2025. Please refer to the SACC website at <https://www.epa.gov/tsca-peer-review>.

After registering, you will receive the webcast and streaming service meeting links and audio teleconference information.

Special accommodation requests: To request an accommodation for a disability, please contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

Designated Federal Official (DFO): Dr. Alaa Kamel, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-5336 or call the SACC main office: (202) 564-8450; email address: kamel.alaa@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

EPA is announcing that there will be two virtual public meetings of the SACC. On November 18, 2025, a preparatory meeting for the SACC to consider the scope and clarity of the draft charge questions for the peer review; and on December 2 through 5, 2025, a peer review meeting for the SACC to consider the D4 draft risk evaluation, technical support documents, and public comments. EPA is also announcing the availability of and soliciting public comment on the draft documents and charge questions that will be provided to the SACC for this peer review.

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

EPA established the SACC in 2016 in accordance with TSCA, 15 U.S.C. 2625(o), to provide independent advice and expert consultation with respect to the scientific and technical aspects of issues relating to the implementation of TSCA. The SACC operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. 10, and supports activities under TSCA, 15 U.S.C. 2601 *et seq.*, the Pollution Prevention Act, 42 U.S.C. 13101 *et seq.*, and other applicable statutes.

C. 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, processing, distribution, and disposal of the subject chemical substances, and/or those interested (including members of at-risk communities, non-governmental organizations, and federal, state, and local officials) in the assessment of risks involving chemical substances and mixtures regulated under TSCA.

D. What should I consider as I submit my comments to EPA?

1. *Submitting CBI.* Do not submit CBI or other sensitive information to EPA through <https://www.regulations.gov> or email. To include information in your comment that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting that information.

2. *Tips for preparing comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>. See also the instructions in Unit III.C.

E. How can I stay informed about SACC activities?

You may subscribe to the following listserv for alerts regarding this and other SACC-related activities: https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_101.

II. Background

A. What is the purpose of the SACC?

The SACC provides independent advice and recommendations to EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA. The SACC is composed of experts in toxicology, environmental risk assessment, exposure assessment, and related sciences (e.g., chemistry, biology, toxicology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, physiologically based pharmacokinetic (PBPK) modeling, computational

toxicology, epidemiology, environmental fate, and environmental engineering and sustainability). When needed, the SACC committee will be assisted by *ad hoc* reviewers with specific expertise in the topics under consideration.

B. Why is EPA conducting these risk evaluations?

TSCA requires EPA to conduct risk evaluations on high-priority chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations.

The purpose of conducting risk evaluations is to determine whether a chemical substance presents an unreasonable risk to human health or the environment under the conditions of use (COUs). These evaluations include assessing risks to relevant potentially exposed or susceptible subpopulations. As part of this process, EPA: (1) Integrates hazard and exposure assessments using the best available science that is reasonably available to assure decisions are based on the weight of the scientific evidence, and (2) Conducts peer review for risk evaluation approaches that have not been previously peer reviewed. For more information about the three stages of EPA's process for ensuring the safety of existing chemicals (i.e., prioritization, risk evaluation, and risk management), go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals>.

C. Why did EPA develop these documents?

D4 (CASRN 556-67-2) is a colorless, volatile oily liquid with an annual total production volume in the United States in 2020 between 250 and 500 million pounds (lb.). The primary uses for D4 are to make other silicone chemicals with commercial uses including but not limited to adhesives and sealants, automotive care products, paints and coatings, and other plastic and rubber products. On March 19, 2020, EPA received a manufacturer request for a risk evaluation of D4 from Dow Silicones Corporation, Elkem Silicones USA Corporation, Evonik Corporation, Momentive Performance Materials, Shin-Etsu Silicones of America, Inc., and Wacker Chemical Corporation through the American Chemistry Council's (ACC's) Silicones Environmental,

Health, and Safety Center (SEHSC). In October 2020, EPA notified ACC SEHSC that the Agency had granted their manufacturer requested risk evaluation.

EPA is submitting the draft risk evaluation of D4 and associated technical support documents for external peer review. The draft risk evaluation includes analyses of physical and chemical properties, environmental hazard and risk, the fate and transport in the environment, releases to the environment, exposure to workers, and the general population, including potentially exposed susceptible subpopulations, and human health hazard and risk characterization for workers and the general population.

EPA is not developing charge questions for all aspects of the risk evaluation but is instead focusing its charge to the SACC on specific scientific areas that need peer review. Many of the methods and analyses used in this risk evaluation are not novel and have been reviewed in the development of the tools and approaches used in various agency work products or in previous TSCA assessments.

D. What is the topic of the planned SACC peer review?

On September 10, 2025, EPA requested nominations of scientific and technical experts to be considered as *ad hoc* reviewers assisting the SACC with the peer review of the draft risk evaluation of D4 under TSCA (<https://www.epa.gov/chemicals-under-tsca/epa-requests-nominations-peer-reviewers-tsca-risk-evaluation-d4>). These nominations will help the agency in selecting approximately seven to eight *ad hoc* reviewers to assist the SACC with their review. The SACC and *ad hoc* reviewers will provide feedback on novel approaches, unique exposure analyses and other calculations, and selection of key hazard endpoints for D4 as follows:

- Identification of hazards relevant to human health risk assessment.
- Evaluation and use of the D4 physiologically based pharmacokinetic (PBPK) model.
- Handling of uncertainties associated with exposure and release assessments.
- Characterization of bioaccumulation, bioconcentration, biomagnification, and potential trophic transfer.

- Human fish consumption for the general population and potentially exposed or susceptible subpopulations.

- Identification of hazards relevant to ecological risk assessment.

III. Virtual Public Meetings of the SACC

A. What is the purpose of the virtual public meeting(s)?

The purpose of the preparatory meeting is for the SACC to consider and ask questions regarding the scope and clarity of the draft charge questions. The purpose of the peer review meeting is for the SACC to consider, and peer review the draft risk evaluation and technical support documents. These public meetings are part of the SACC's peer review of the Agency's methods and novel analyses for the D4 draft risk evaluation. The agenda for these meetings will be posted in the docket and will also be available through the SACC website.

EPA will consider recommendations from this SACC review and public comments in the development of the TSCA risk evaluations and may inform other EPA efforts related to the assessment and regulation of the chemical substances. The Agency will be seeking SACC review of its data analyses and methodologies relevant to human health hazard and exposure analyses that have not been previously peer reviewed.

B. How can I participate in the virtual public meetings?

To participate in these virtual public meetings, you must register online to receive the webcast and streaming service meeting links and audio teleconference information for each meeting. Online registration will be available approximately one month prior to the meetings and will remain open through the end of the meetings. To make oral comments during one of these meetings, follow the instructions in this document.

C. How can I access the documents?

The draft risk evaluation, technical support documents, and draft charge questions are available in docket ID: EPA-HQ-OPPT-2025-1610. EPA will include additional meeting background materials as they become available, (e.g., SACC members and the meeting agenda)

in the docket and through the Peer Review of the Draft Risk Evaluation for Octamethylcyclotetrasiloxane (D4) website at <https://www.epa.gov/tsca-peer-review/peer-review-draft-risk-evaluation-octamethylcyclotetrasiloxane-d4>.

D. How can I provide comments?

To ensure proper receipt of comments, it is imperative that you identify docket ID: EPA-HQ-OPPT-2025-1610 in the subject line on the first page of your comments and follow the instructions in this document.

1. *Written comments.* Submit written comments by the deadlines set in the **DATES** section of this document and as described in the **ADDRESSES** section of this document.

2. *Oral comments.* To request time to present oral comments during one of the virtual public meetings, you must register online by the deadlines set in the **DATES** section of this document. Oral comments during the peer review meeting are limited to five minutes unless arrangements have been made with the DFO, within the constraints of the meeting agenda, prior to November 21, 2025. In addition, each speaker should submit a written copy of their oral comments and any supporting materials (e.g., presentation slides) to the DFO prior to the meetings for distribution to the SACC by the deadlines set in the **DATES** section of this document.

IV. Next Steps

After the peer review meeting, the SACC will prepare the meeting minutes and final report document summarizing its recommendations to EPA, which will also be available in the docket and through the SACC website. EPA will consider the SACC recommendations and public comments to complete the risk evaluation and unreasonable risk determinations under TSCA for this chemical substance. Under TSCA, EPA must then initiate risk management actions to address the unreasonable risk it identified.

Authority: 15 U.S.C. 2625(o); 5 U.S.C. 10.

Dated: September 16, 2025.

Nancy B. Beck,

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

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