Octamethylcyclotetra- siloxane (D4); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA)
Response to Comments

Docket Number: EPA-HQ-OPPT-2018-0443
October 15, 2020

Overview

Under 40 CFR 702.37(e)(3), EPA is required to assess whether the circumstances identified in a manufacturer request for a risk evaluation constitute conditions of use (as defined under TSCA section (3)(4) and implementing regulations (40 CFR 702.33)), and whether those conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will also assess what, if any, additional conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance, and conduct these evaluations based on the same considerations applied in the same manner as it would for a risk evaluation for a high-priority substance in the EPA-initiated risk evaluation process. No later than 60 business days after receiving a manufacturer request for risk evaluation that EPA has determined to be facially complete (meeting the criteria set forth in 40 CFR 702.37(e)(1)), EPA is required to submit for publication the receipt of the request in the Federal Register, open a public docket for the request (which must contain the manufacturer request and EPA's possible additional conditions of use), and provide no less than 45 calendar days for public comment.

This document includes EPA's responses to comments received during the public comment period (June 17, 2020 to August 3, 2020) for docket number EPA-HQ-OPPT-2018-0443 (Octamethylcyclotetra- siloxane (D4)); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA)), submitted by 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 Silicones Environmental, Health, and Safety Center (SEHSC). During the public comment period, the public submitted comments and information relevant to the requested risk evaluation.

The Agency received nine public comments related to the manufacturer request for risk evaluation for D4. After careful review, the Agency determined that all of these comments are substantively or procedurally relevant. All comments received are identified by docket identification (ID) number EPA-HQ-OPPT-2018-0443 and are available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0443-0002.

1. General Comments

Comment: Several commenters stated support for SEHSC's request for an assessment of D4 and strongly encouraged EPA to conduct a timely, transparent, and scientifically sound risk assessment. Multiple commenters stated that D4 is a critical building block of silicone polymers used in: the auto industry (EPA-HQ-OPPT-2018-0443-0006, EPA-HQ-OPPT-2018-0443-0014); medical devices (EPA-HQ-OPPT-2018-0443-0007); cleaning products (EPA-HQ-OPPT-2018-

0443-0008); the semiconductor industry (EPA-HQ-OPPT-2018-0443-0009); transportation, building and construction, health care, and electronics (EPA-HQ-OPPT-2018-0443-0011); and personal care products (EPA-HQ-OPPT-2018-0443-0012).

Response: EPA appreciates the comments supporting the risk evaluation process and continues to implement the requirements of the "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" (Risk Evaluation Rule) (40 CFR Part 702), by which EPA seeks to "ensure that it is able to focus on conducting a timely, relevant, high-quality, and scientifically credible evaluation of a chemical substance as a whole, and that it always includes an evaluation of the conditions of use that raise greatest potential for risk. EPA wants also to ensure that the Agency can effectively assess, and where necessary, regulate chemical substances, within the statutory deadlines. These same principles will also serve to guide EPA's implementation of the procedures" (82 FR 33726, 33728 (July 20, 2017)).

Comment: One commenter (EPA-HQ-OPPT-2018-0443-0013) strongly recommends against the use of the draft risk evaluation included in SEHSC's "Manufacturer Request for a Risk Evaluation of D4" to inform any EPA processes regarding D4 moving forward.

Response: All risk evaluations, whether EPA-initiated or manufacturer-requested, will be conducted in the same manner following the procedures in EPA's risk evaluation regulations. EPA is using the systematic review process described in the Application of Systematic Review in TSCA Risk Evaluations document to guide the process of screening reasonably available information, including information already in EPA's possession, for use and inclusion in the risk evaluation. If EPA determines, in screening and evaluation of the information presented in SEHSC's "Manufacturer Request for a Risk Evaluation of D4," that information in SEHSC's draft risk evaluation is of adequate quality and relevance, EPA plans to include that information in a draft risk evaluation for D4.

2. Conditions of Use

Comment: One commenter (EPA-HQ-OPPT-2018-0443-0009) describes the semiconductor industry's manufacturing process and the conditions of use of D4 in semiconductor manufacturing. The commenter stated that this industry's use of D4 is unique and should not be bundled with other, dissimilar uses of D4.

Response: The Agency appreciates the comment and plans to add this as an example further characterizing the electrical and electronic products condition of use in the draft scope document conditions of use (COU) table for D4. As EPA conducts its analysis during the risk evaluation process, EPA will follow-up with the commenter as necessary to further refine its understanding of the use.

Comment: One commenter (EPA-HQ-OPPT-2018-0443-0010) stated that, "the more specific COU presented in the EPA Table can reasonably be considered included in the more general categories presented in the MRRE."

Response: The Agency appreciates the information on the additional conditions of use proposed for inclusion within the scope of a risk evaluation for the chemical substance.

3. Comments Related to Risk Determination

Comment: One commenter (EPA-HQ-OPPT-2018-0443-0010) stated that, "the more specific COU identified by EPA would not lead to levels of exposure to workers, consumers, the general public, or the environment beyond those addressed in the draft risk evaluation included in the [SEHSC Manufacturer Request for a Risk Evaluation of D4]."

Response: The Agency appreciates this feedback from potentially affected industry. During the risk evaluation process, EPA will determine, utilizing the best available science and the weight of scientific evidence (TSCA sections 26(h) and (i)), and based on reasonably available information (TSCA section 26(k)), whether or not the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. EPA will consider all reasonably available information on exposures submitted in the draft risk evaluation prepared by SEHSC, obtained by EPA (e.g., through the systematic review process), and received in public comments.

Comment: One commenter (EPA-HQ-OPPT-2018-0443-0009) describes the complete reaction of D4 during its use in the semiconductor industry along with the, "totally enclosed RF PECVD processes," and recommends based on the information they provided that, if EPA were to proceed with a risk evaluation of D4, "EPA conclude the semiconductor industry's use of D4 does not pose a risk to human health or the environment."

Response: The Agency appreciates this feedback from potentially affected industry. During the risk evaluation process, EPA will determine, utilizing the best available science and the weight of scientific evidence (TSCA sections 26(h) and (i)), and based on reasonably available information (TSCA section 26(k), whether or not the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. EPA will consider all reasonably available information on exposures and hazards submitted in the draft risk evaluation prepared by SEHSC, obtained by EPA (e.g., through the systematic review process), and received in public comments.

4. Need for a Science-Based Assessment

Comment: A commenter (EPA-HQ-OPPT-2018-0443-0011) stated, "[i]t is critical that the oversight of D4 production and manufacturing is guided by a science-based assessment of a robust data set, and not a biased selection of a few studies that do not capture actual risk to humans or the environment. Regulating silicone materials without credible and complete scientific evidence would be a huge mistake and costly for consumers who benefit from their wide applications every day."

Comment: Another commenter (EPA-HQ-OPPT-2018-0443-0012) stated they, "strongly support science-based regulation which is founded on weight of evidence and robust risk assessments utilizing relevant and reliable data." They further "believe that such risk assessments are paramount to consumer and environmental safety."

Response: In regard to science-based decision-making, TSCA risk evaluations are conducted using best available science, and the weight of scientific evidence, TSCA sections 26(h) and (i) respectively, and involve the consideration of reasonably available information in accordance with TSCA section 26(k).

The draft scope document will include a description of such reasonably available information, including relevant information in databases containing publicly available, peer-reviewed literature and gray literature (i.e., the broad category of data/information sources not found in standard, peer-reviewed literature databases), and data and information submitted under TSCA sections 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions. EPA will seek public comment on the draft scope document and draft risk evaluation and consider information submitted by commenters. The draft risk evaluation will also be peer reviewed.

5. Comments Related to Risk Management

Comment: One commenter (EPA-HQ-OPPT-2018-0443-0014) stated that it is important that EPA,

> "make clear, affirmative findings – both 'unreasonable risk' determinations, as well as 'no unreasonable risk' determinations. To ensure that states do not override EPA's risk evaluation findings and preempt federal determinations, EPA must address all conditions of use, including articles, and develop a regulatory and administrative record that ensures federal preeminence. In making these determinations for articles and components, EPA must give due consideration to two specific sections of the Toxic Substance Control Act (TSCA) that recognize the unique circumstances associated with articles and replacement parts.
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> TSCA Section §6(c)(2)(E) directs EPA to recognize that articles generally present a low risk of exposure potential relative to the chemical(s) bound up in the article and directs EPA to restrict the use of articles only to the extent necessary to address any risk specifically identified for that article(s).[3] If an article in and of itself does not present an unreasonable risk, then it should be determined to not present an unreasonable risk, and EPA's findings should be clearly stated.
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> Similarly, TSCA §6(c)(2)(D) requires EPA to 'exempt replacement parts for complex durable goods' from a §6 rulemaking unless 'the Administrator finds such replacement parts contribute significantly to the risk identified in a risk evaluation conducted under section (b)(4)(A).' As with articles, we request that when making this determination, EPA clearly state a no unreasonable risk determination."

[3] TSCA Section §6(c)(2)(E): '…the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or the category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).'

Response: The final risk evaluation for D4 will include risk determinations for each condition of use within the scope of the risk evaluation, in accordance with TSCA section 6(b)(4)(A) and 40 CFR 702.47.

EPA notes that TSCA section 6(c)(2)(D) (replacement parts) and (E) (articles) applies to risk management under TSCA section 6(a), which is subsequent to the risk evaluation process under TSCA section 6(b). If unreasonable risks are identified for conditions of use of the chemical substance during the risk evaluation process, then any risk management rulemaking will consider replacement parts and articles, to the extent provided under TSCA sections 6(c)(2)(D) and (E), respectively.

Comment: A commenter (EPA-HQ-OPPT-2018-0443-0009) believes, "there are several risk-based exemptions that EPA should consider during risk management, including a *de minimis* exemption, exclusion of impurities and byproducts, and a research and development exemption."

Response: EPA notes that this comment applies to risk management under TSCA section 6(a), which is subsequent to the risk evaluation process under TSCA section 6(b). As such, these comments are not relevant to the present manufacturer requested risk evaluation for D4. As these exemptions and exclusions relate to this risk evaluation, EPA notes, as explained in the preamble to the Risk Evaluation Rule, that it will conduct risk evaluations in a fit-for-purpose manner and will refine, as necessary, its evaluations for one or more conditions of use in any risk evaluation. When information and analysis are sufficient to make a risk determination using assumptions, uncertainty factors, and models or screening methodologies, EPA may decide not to refine its analysis further.