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Comments on the Octamethylcyclotetra-siloxane (D4) TSCA Review
Docket ID: EPA-OPPT-2018-0443

The American Consumer Institute (ACI) is a nonprofit 501(c)(3) education and research organization. Its mission is to identify, analyze, and protect the interests of consumers in legislative and rulemaking proceedings. ACI supports market-driven solutions that improve consumer welfare and maximize economic growth.

ACI is submitting these comments regarding the Environmental Protection Agency's (EPA) released draft risk evaluation for octamethylcyclotetrasiloxane (D4). The EPA, however, did not fully utilize that evaluation and preliminarily concludes that D4 poses risks in certain circumstances.

EPA's risk evaluation has the potential to affect manufacturing, the marketplace, and consumers. It is essential that this evaluation reflects the full breadth of available and relevant scientific evidence. How EPA characterizes D4's risk could have far-reaching and potentially unintended consequences. A determination of negative health risks without evaluating all the evidence, could needlessly affect U.S. manufacturing, impose costs across supply chains, and lead to inferior products.

Background

The chemical compound D4 is used in countless applications to produce silicone polymers. Its versatility makes it indispensable in diverse industries as a basic building block for silicones used in shampoos, moisturizers, cleaners, sealants, adhesives, paints, electronics, kitchenware, laptops, cell phones, and medical devices. Thousands of everyday products benefit from some level of D4. Its resistance to heat and moisture makes it vital in multiple high-tech and consumer-oriented industries. The substance is employed in the manufacturing process but is only present at very low (trace) levels in the end products.

The silicone industry proactively submitted D4 as part of a Manufacturer-Requested Risk Evaluation (MRRE) to determine if the chemical poses unreasonable risks to human health or the environment. This opportunity was provided to chemical manufacturers by Congress in the 2016 amended Toxic Substances Control Act (TSCA) which gives the EPA enhanced authority to assess and regulate both new and existing industrial chemicals. The silicone industry's goal has been to address potential risks and support the responsible use of D4 in its numerous applications.

In October 2020 the EPA decided to grant the industry's request for evaluation.[1] The Silicones Environmental, Health and Safety Center (SEHSC) closely collaborated with EPA to design a monitoring program and provide exposure data to help conduct a scientifically sound risk assessment, the first and only instance of an organization to make such a request supported by a complete risk evaluation.

SEHSC remains confident that no regulatory restrictions for D4 are warranted. Independent peer-reviewed studies of the monitoring program data conclude D4 poses negligible risk to the environment.[2] The safety of cyclosiloxanes like D4 has been confirmed by independent expert panels, including the European Scientific Committee for Consumer Safety, the United States Cosmetics Review Panel, and Health Canada.[3]

However, EPA's initial findings differ from this evidence. The September 2025 release of the draft risk evaluation preliminarily determines that D4 presents unreasonable risk of injury to human health, with risk to workers from 23 conditions of use (COUs) and risk to consumers from one COU.[4] EPA also concludes that D4 presents an unreasonable risk to the environment from seven COUs.

EPA Did Not Use SEHSC Draft Risk Evaluation

The silicones industry had included in its submission for a D4 risk evaluation all the items specified in EPA's Risk Evaluation Procedural Rule in addition to a comprehensive draft risk evaluation. SEHSC's request notably included a thorough and complete draft of human health and environmental risk evaluation prepared in accordance with EPA guidance.

In 2020, before any testing occurred, Senior SEHSC Director Karluss Thomas affirmed his confidence in D4's safety: "Based on SEHSC's thorough risk evaluation submitted to EPA, the scientific evidence continues to confirm that no regulatory restrictions on D4 are warranted," adding "SEHSC looks forward to a timely, transparent, and scientifically sound risk determination for D4."[5] SEHSC was ready to address any technical questions EPA might have while conducting its D4 risk evaluation.

EPA has deviated from TSCA statute and regulations. EPA's draft D4 risk evaluation reflects a significant expansion in scope from the D4 Final Scope document, containing 27 changes to the COUs which were not previously listed in the published document, as required by TSCA. Adjusting COUs changes exposure scenarios, safety requirements, and ultimately the conclusions of risk evaluations by transforming a chemical's risk profile and compliance requirements. EPA did not notify the public nor provide an opportunity to comment on the changes prior to their publication.

[1] Global Silicones Council, "SEHSC Welcomes EPA-Granted Manufacturer-Requested Risk Evaluation of D4," News Release, October 7, 2020, https://globalsilicones.org/news/sehsc-welcomes-epa-granted-manufacturer-requested-risk-evaluation-of-d4/#:~:text=Greater%20than%2099%20percent%20of,emissions%20and%20improve%20energy%20efficiencies
[2] Josie Nutz et al., "Use of Multiple Lines of Evidence to Provide a Realistic Toxic Substances Control Act Ecological Risk Evaluation Based on Monitoring Data: D4 Case Study," Science of the Total Environment, Volume 636, September 15, 2018.
[3] Pierre Germain, Karluss Thomas, Tomonobu Noguchi, "Frequently Asked Questions — D4, D5 & D6," Global Silicones Council, January 2020, https://globalsilicones.org/wp-content/uploads/2020/11/FAQ-D4-D5-D6.pdf.
[4] U.S. Environmental Protection Agency, "Draft Risk Evaluation for Octamethylcyclotetrasiloxane," September 2025, https://www.epa.gov/system/files/documents/2025-09/01.-d4.-draft-risk-evaluation.-public-release.-sept-2025_2.pdf.
[5] Global Silicones Council, News Release, October 2020.

To meet its obligations under TSCA, EPA must consider the draft risk evaluation SEHSC prepared in accordance with EPA guidance and was included in the MRRE request. TSCA mandates the use of the best available science and a weight-of-evidence approach, which includes consideration of multiple sources of information and lines of evidence. The EPA did not do this.

The testing was imprecise. EPA significantly overestimated the amount of D4 in its modeling. Real-world environmental monitoring data—that SEHSC developed with EPA—show actual D4 levels are much lower than EPA's models predict. Some of the health effects in EPA's human health risk determination are based on high-dose animal studies with exposure levels significantly higher than what humans would actually encounter.

EPA also admits "these preliminary risk determinations do not reflect the use of personal protective equipment (PPE)" for COUs with unreasonable risk to workers, even though such procedures were outlined when the MRRE request was submitted.[6] Accurately characterizing D4's potential human health risk requires considering existing workplace safety measures already in use, including PPE.

D4 Around the World

Several countries have already weighed in on D4's potential environmental hazard; some have concluded that D4 poses minimal risk.

Australia has assessed a range of silicone materials, including D4, and found no significant human health risks. Based on their assessment, Australia did not propose any regulatory restrictions on the use of these materials.[7] They concluded that "the direct risks to aquatic life from exposure to these chemicals at expected surface water concentrations are not likely to be significant."

Environment Canada, having reviewed the environmental data available for D4, determined that it may be harmful to the environment but is not harmful to human health.[8] Therefore, Canada has not imposed any product use or concentration restrictions on the use of D4 in any application; they only require certain facilities that use D4 to prepare a "pollution prevention plan" to minimize the release of D4 in industrial processes.

Both countries used a weight-of-evidence approach and real-world exposure data. The governments came to a comprehensive and robust conclusion by considering various types of data and evaluating the quality and reliability of each piece of evidence before synthesizing the information to inform a final judgment.

[6] U.S. Environmental Protection Agency, "Risk Evaluation for Octamethylcyclotetrasiloxane (D4)," October 2025, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-octamethylcyclotetrasiloxane-d4#background.
[7] Global Silicones Council, "Australia Siloxane Evaluations," Accessed November 21, 2025, https://globalsilicones.org/regulation/australia/.
[8] Global Silicones Council, "Canada Siloxane Evaluations," Accessed November 21, 2025, https://globalsilicones.org/regulation/canada/.

Using a different approach, the European Union (EU) came to a different conclusion and their authorities determined that D4 met existing Persistent, Bioaccumulative and Toxic (PBT) criteria under the EU's chemical management program, placing restrictions and limited use on the substance.[9]

The Global Silicones Council (GSC) contends that the EU's assessment of D4 did not consider all available evidence, ignoring technical input from leading academic experts; the D4 designation as environmentally harmful "is an unfortunate consequence of the EU's flawed regulatory evaluation for these silicone materials" and would be "inconsistent with sound science."[10] The EU's conclusions are out of step with regulatory outcomes for the same substances in other regions of the world.

Since the EU did not adequately consider all the available information, the GSC filed legal challenges in the EU. GSC members believe that the chemical management apparatus failed to follow the requirements to consider all the available evidence and properly assess D4.

D4 should not suffer the same fate in the U.S.

Restricting D4 Affects Manufacturers and Consumers

D4's unique properties make it a crucial intermediate in silicone manufacturing and its utilization in countless fields like medicine, safety, cosmetics, energy, engineering, construction, and technology cannot be overstated. Its removal or restriction in the market would have significant impacts on the chemical industry and consumer products, and manufacturers would be required to reformulate their products with alternative ingredients to meet regulatory compliance.

Banning or limiting D4 would force manufacturers to invest in new production methods, inflicting costs as they investigate new processes and products. Reformulation and testing costs could potentially lead to increased product prices for consumers. Requiring unnecessary regulations that impose burdensome and costly compliance obligations would also reverberate across the value chain and consumer markets.

Changes in manufacturing processes could potentially lead to short-term price fluctuations, product delays, or shortages as supply chains adapt. Those that rely on certain products could be forced to go without or find alternative options.

Substituting other compounds with D4 could also completely alter the composition, quality, and performance of the products that rely on it. D4 provides unmatched characteristics of durability, stability, and heat resistance. Ultimately, alternative ingredients could mean inferior goods which could affect consumer satisfaction.

[9] Global Silicones Council, "Frequently Asked Questions: EU's D4, D5, D6 Authorization Draft Recommendation," November 2020, https://globalsilicones.org/wp-content/uploads/2020/11/GSC-Authorization-FAQ.pdf#:~:text=No%20country%20or%20region%20outside%20of%20the,not%20warrant%20regulatory%20restrictions%20on%20any%20products..
[10] Ibid.

The increased costs, restrictions, product shortages, and weakened product performance would undermine U.S. manufacturing, eroding America's leadership in advanced materials. Such regulatory uncertainty would negatively impact research and development investments in next-generation technologies and shift innovation, jobs, and production overseas. America must remain competitive, strengthen domestic manufacturing, and protect U.S. jobs.

In essence, removing D4 from the market would necessitate a broad and costly industrial transition.

Conclusion

D4 is a critical intermediate in silicone production, enabling the durability, stability, and performance of thousands of everyday and advanced products. Restricting its use would not only undermine consumer welfare and product quality but also erode America's competitiveness in materials innovation and impose significant costs throughout supply chains.

To meet its obligations under TSCA, EPA must ground its final risk evaluation in the best available science, apply a transparent weight-of-evidence approach, and fully consider the comprehensive evaluation submitted by SEHSC. A balanced, science-based determination will safeguard consumer interests, protect U.S. manufacturing, and ensure that regulatory decisions enhance—rather than hinder—economic growth and innovation.

Thank you for the opportunity to submit these comments.

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