



August 3, 2020

Ms. Yvette T. Collazo
Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

**Re: Docket ID: EPA-HQ-OPPT-2018-0443, Document # 2020-13037
Attn: Bethany Masten (masten.bethany@epa.gov)**

Dear Ms. Collazo:

I write on behalf of the American Consumer Institute Center for Citizen Research (ACI), a 501(c)(3) non-partisan research and educational institute, with the mission to identify, analyze, and project the interests of consumers in selected legislative and rulemaking proceedings in matters that affect consumers.

ACI submits these comments in response to the request of the Silicones Environmental, Health and Safety Center (SEHSC) of the American Chemistry Council (ACC) for the U.S. Environmental Protection Agency (EPA) to conduct a chemical risk evaluation of D4 (octamethylcyclotetrasiloxane; CASRN: 55-67-2).

We very much support the request for EPA to conduct a timely, transparent, and scientifically-sound risk assessment of D4.

D4 is a critical building block of silicone polymers, and the derived products from a variety of industries including, but not limited to, transportation, building and construction, health care, and electronics, provide vital societal benefits. D4 plays a

prominent role in medical innovation¹ in the United States, while in the energy sector² D4's value to consumers and the environment is substantial.

While we acknowledge that silicones have been extensively studied and that more than 1,000 studies³ have been conducted to assess the safety of silicones relative to workers, consumers, the environment and manufacturing processes, we believe a comprehensive risk-based evaluation of D4 under EPA guidance would further corroborate the safety of silicones in their diverse and important applications.

A science-based evidence approach⁴ rooted in “mathematical theories of probability and in scientific methods for identifying causal links between adverse health effects and different types of hazardous activities”⁵ has been a cornerstone of U.S. environmental policy⁶ for decades now.

D4 has been one of the most extensively studied⁷ chemicals widely-used in consumer products and industrial applications and the EPA has demonstrated interest in this chemical substance for almost a decade now. In light of EPA's track record in conducting risk evaluations on chemical substances guided by high scientific standards, we strongly support the EPA granting this Manufacturer Request for Risk Evaluation.

¹ Liam Sigaud, “Unnecessary Regulations On Silicone Could Put Patients In Jeopardy,” June 18 2018, *Daily Caller*, Available at

<https://dailycaller.com/2018/06/18/unnecessary-regulations-on-silicone-could-put-patients-in-jeopardy/>.

² Liam Sigaud, “Efforts to Ban Silicone Hamper Energy and Environmental Goals,” July 9, 2018, *Real Clear Energy*, Available at

https://www.realclearenergy.org/articles/2018/07/09/efforts_to_ban_silicone_hamper_energy_and_environmental_goals.html.

³ American Chemistry Council, Silicones Environmental, Health, and Safety Center, Research: *Science, Health and Safety*, <https://sehsc.americanchemistry.com/Research-Science-Health-and-Safety/>.

⁴ Also adopted by Canada and Australia.

⁵ Gurjar, B.R. and Mohan, M., 2002. Environmental risk analysis: problems and perspectives in different countries. *RISK*, 13, p.1. Available at

<https://scholars.unh.edu/cgi/viewcontent.cgi?article=1483&context=risk>.

⁶ In 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act — which mandates risk-based chemical assessments — received strong bipartisan support. See

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>.

⁷ The safety of D4 in personal care products has been confirmed by independent expert scientific panels, including the United States Cosmetics Review Panel and Health Canada. Additional risk assessments for D4 have been published in the peer reviewed literature (see Gentry, R., Franzen, A., Van Landingham, C., Greene, T., Plotzke, K. 2017, “A global human health risk assessment for octamethylcyclotetrasiloxane (D4),” *Tox Let* 279,(2017, 23-41; Nusz J., Fairbrother A., Daley J., Burton G.A., 2018, “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* 636:1382–1395; Woodburn et al. 2018; Woodburn, K.B., R.M. Seston, J. Kim, and D.E. Powell, 2018, “Benthic invertebrate exposure and chronic toxicity risk analysis for cyclic volatile methylsiloxanes:” and “Comparison of hazard quotient and probabilistic risk assessment approaches,” *Chemosphere*, 192: 337-347).

Conducting a timely risk assessment of D4 will further help provide clarity for consumers and business owners on this substance.

It 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.

Thank you for your consideration of these comments.

Respectfully submitted,

Krisztina Pusok



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