



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 26, 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Karluss Thomas
American Chemistry Council
Silicones Environmental Health, and Safety Center

Dear Mr. Thomas,

Thank you for your March 28, 2018 letter regarding the completion of a risk evaluation for Octamethylcyclotetrasiloxane (D4).

Under amended TSCA, EPA is now directed to evaluate existing chemicals for unreasonable risk of injury to health or the environment. The law mandates the process by which EPA must evaluate existing chemicals, and the timelines for which these actions must be completed. The first step is a 9- to 12-month prioritization process involving risk-based screening of hazard and exposure potential to determine if the chemical is high- or low-priority for risk evaluation. If the chemical is designated as high-priority, it moves directly into risk evaluation, where within three and a half years, EPA must determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. By statute, EPA must have 20 high-priority risk evaluations ongoing by December 2019; therefore, EPA plans to begin prioritization between December 2018 and March 2019. EPA is in the process of determining how chemicals will be selected for prioritization. If D4 were to be one of the first chemicals selected for prioritization, and if it were determined to be a high-priority chemical, a risk evaluation would be completed no later than June 2023.

An alternative route for a chemical to be evaluated for risk is the TSCA provision under which manufacturers may request that a chemical they manufacture undergo an EPA-conducted risk evaluation. The final risk evaluation rule (Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 FR 33726, June 22, 2017), defines the form and manner under which these requests must be made to the Agency, along with EPA's process to accept a request and begin the risk evaluation. If a request is granted, the Agency will begin the risk evaluation, which must be completed within three and a half years. This method bypasses the 9- to 12-month prioritization process. Note that EPA will not initiate a manufacturer requested risk evaluation until the finalization of the fees rule.

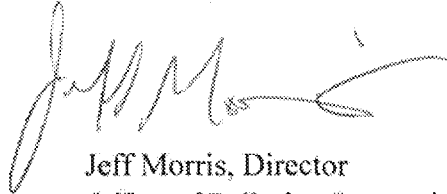
Additionally, you could provide a draft risk evaluation with, or without, a manufacturer request for risk evaluation. On June 22, 2017 EPA published guidance to assist interested persons in developing and submitting a draft risk evaluation. EPA would consider this draft risk

evaluation as reasonably available information to be considered, along with other information, in an EPA-conducted risk evaluation.

You cite TSCA section 26(p)(2), which allows the Agency to initiate, continue, or complete a risk evaluation prior to the completion of policies, procedures and guidance required, as a mechanism by which a risk evaluation on D4 could be expedited. You note that 40 CFR 702.35 states that risk evaluations initiated prior to the effective date of the rule will be conducted in accordance with the rule to the maximum extent practicable. However, although EPA has received information through implementation of the enforceable consent agreement, OCSPP has not initiated a D4 risk assessment.

Thank you for your letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Morris", with a long horizontal flourish extending to the right.

Jeff Morris, Director
Office of Pollution Prevention and Toxics