



Manufacturer-Requested Risk Evaluation of D4 – FAQs

When did SEHSC make the request of EPA and when did EPA grant SEHSC’s request to conduct a risk evaluation of D4 under the Toxic Substances Control Act?

SEHSC submitted its risk evaluation request – an opportunity afforded to chemical manufacturers by Congress in the 2016 amended TSCA law – to EPA on February 3, 2020 and received a notification of the submission being facially complete from the Agency on April 7, 2020. SEHSC received an official notification that EPA had granted its request for a D4 risk evaluation on October 6, 2020.

What is included in SEHSC’s risk evaluation request for D4?

SEHSC’s submission included all the items specified in EPA’s Risk Evaluation Procedural Rule as well as a comprehensive draft risk evaluation for D4. This draft evaluation included an assessment of hazard and exposure under conditions of use for both human health and the environment.

How did the industry determine what data to include in its request to EPA?

The submission was prepared to satisfy the data requirements set forth for manufacturer requests for risk evaluations in EPA’s “Procedures for Chemical Substance Risk Evaluations” Rule. SEHSC’s submission included a scientifically robust draft risk evaluation under specified conditions of use prepared in accordance with EPA’s “Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act.”

How did SEHSC’s D4 monitoring program contribute to the industry’s submission?

Exposure data collected during the rigorous D4 environmental monitoring program, designed in collaboration with EPA, was a critical component of the draft risk evaluation’s environmental assessment. In addition, SEHSC included in the submission to EPA an independent, peer-reviewed ecological risk evaluation that incorporated those data and was published in the scientific journal, *Science of the Total Environment*, in September 2018.

Why is it important that EPA use exposure data in its assessment of D4?

The data collected as part of the D4 environmental monitoring program – as well as other environmental and human health safety data on D4 – should assist the Agency in performing a risk-based evaluation of the substance, using the best available scientific data, consistent with its statutory mandate under TSCA. While modeling of D4 concentrations in environmental media may be appropriate in certain circumstances, the monitoring data allows EPA to assess the risks associated with D4 using ‘real-world’ measured concentrations as opposed to using estimates of exposure derived from computer models.

Proactive; External Use

Have other authorities evaluated the safety of D4 for human health?

Human health risk evaluations for D4 have been conducted by regulatory authorities in Canada, Australia, and the UK. In addition, expert scientific panels including the U.S. Cosmetic Ingredient Review and the EU Scientific Committee on Consumer Safety has also assessed the human health risks associated with D4. All these evaluations concluded that there is no risk to human health from D4 when used appropriately.

What will be the silicones industry’s role in EPA’s evaluation of D4?

While it is the responsibility of EPA to evaluate the risks associated with D4 in accordance with its conditions of use, SEHSC is committed to working collaboratively with the Agency during its evaluation to serve as a technical resource and to answer any questions associated with the information that has been provided by SEHSC to inform the Agency’s assessment of D4.

How much did SEHSC pay EPA?

The risk evaluation was initiated upon payment of an initial fee as established under EPA’s TSCA Fee Rule. This amount was \$1.25 million, which corresponds to 2/3 of 50 percent of EPA’s expected actual cost to complete the risk evaluation (i.e., ~2/3 of 50% of \$3.88 million). Following completion of the risk evaluation, the companies will be responsible for any additional amounts up to a total 50% of actual costs.

Now that EPA has granted SEHSC’s request, how long will the Agency’s evaluation of D4 take?

Once EPA grants the request and industry submits an initial fee payment, EPA must initiate the risk evaluation. Under TSCA, EPA must complete the risk evaluation “as soon as practicable” but no more than three and a half years after initiating the evaluation. EPA’s timely risk evaluation and determination for D4 would provide clarity and benefit to consumers, businesses, and the environment.

What is the next step for the EPA?

According to the 2016 statute, in February 2021 EPA was to provide SEHSC and the public with a draft “Scope of the risk evaluation” document that would lay out the EPA’s process and informational needs to evaluate D4. Specifically, the scope document would include the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations that EPA plans to consider in conducting the risk evaluation for D4.

EPA issued the draft scope document on September 8, 2021 and provided a 45-day comment period. SEHSC submitted its comments by the deadline of October 25, 2021. EPA issued the final scope document on March 7, 2022.

For more information about SEHSC’s D4 monitoring program, please visit: [ECA FAQ](#).