



SEHSC
Silicones Environmental,
Health, and Safety Center

September 16, 2016

Ms. Kara Steward
Washington Department of Ecology
Hazardous Waste & Toxics Reduction Program
P.O. Box 47600
Olympia, WA 98504-7600

Re: Children's Safe Products Reporting Rule, Chapter 173-334 WAC - Review of the inclusion of D4 as an Endocrine Disruptor on the existing list of Chemicals of High Concern to Children (WAC-173-334-130)

Dear Ms. Steward:

The Silicones Environmental Health and Safety Center (SEHSC) of the American Chemistry Council (ACC) submits the following information in response to the Washington Department of Ecology's request for comment on revisions to the State's Children's Safe Products (CSP) Reporting Rule and the proposed list of Chemicals of High Concern to Children (CHCC). Included in this proposed list is octamethylcyclotetrasiloxane, (known as D4 - CAS # 556-67-2) because of its alleged endocrine disruptor (ED) characteristics. SEHSC strongly disagrees with this categorization and asserts that the science clearly illustrates that D4 lacks the potential for endocrine disruption in humans. SEHSC also believes that the references that the Department of Ecology (referred to as Ecology) cited as the basis for the listing of D4 as an ED were not subjected to a weight of evidence approach and in some cases are simply incorrect.

SEHSC understands that initially Ecology based its list of chemicals identified as EDs on a European Union list but now recognizes "that research into the endocrine disrupting effects of chemicals is evolving rapidly, and questions have been raised about the use of the European Union list of endocrine disruptors for selecting CHCCs."¹ To our knowledge, there is no European Union list of endocrine disruptors, but only a proposed candidate list for possible further evaluation. D4 does not appear on this list.² To define a substance as an endocrine disruptor by the widely accepted World Health Organization/United Nations Environmental Program (WHO/UNEP) definition³ requires identifying a causal link between an endocrine mode of action and an adverse effect in a whole organism. A weight of evidence process must

¹ Children's Safe Products Act Rationale for Chemicals listed under Reporting Requirements
<http://www.ecy.wa.gov/programs/hwtr/rtt/cspa/pdf/cspa-rationale-intro.pdf>

² <http://eng.mst.dk/topics/chemicals/endocrine-disruptors/the-eu-list-of-potential-endocrine-disruptors>

³ WHO/IPCS. 2002. Global assessment of the state-of-the-science of endocrine disruptors. WHO/PCS/EDC/02.2.
http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/

be used to evaluate all relevant data to determine endocrine disrupting potential, and more than one study is needed to define an endocrine disruptor. The description that the chemicals included on the CHCC list for endocrine disruption have been shown to “disrupt the endocrine system based on the results of one or more relevant assays,” particularly when the response in the assay does not equate to an adverse effect or is only a biomarker response, is misleading and scientifically unjustified. While it is conceivable that a compilation of selected substances may be required for government prioritization purposes, the purpose and context of the compilation must be clearly communicated so that this screening “compilation list” does not become a *de facto* classification for endocrine disrupting chemicals, and is not misused to ban or restrict valuable substances that can be used safely.

There are five citations⁴ used to provide the rationale for including D4 on the CHCC list. Two of them are government reports, while the other three are published screening studies, all of the same study type. The citation used to classify D4 for endocrine disruption is a report developed in 2002 by BKH⁵ under contract to DG Environment of the European Commission. It was prepared as one step in a process to develop a “priority list of substances for further evaluation of their role in endocrine disruption” and is not a listing of endocrine disrupting substances. D4 is actually not listed in this document. Ecology relies on the Danish Ministry of Environment⁶ survey to substantiate exposure. D4 is listed in the Danish database of chemicals as being present in only a very limited number of consumer products but this database does not indicate any potential risk associated with its presence.

The three published studies are all of one type of assay, the rodent uterotrophic assay. This assay is designed to be especially sensitive for detecting the potential to act like the female hormone, estrogen. The rodent uterotrophic assay is one of the 11 screening assays used in Tier 1 of the US Environmental Protection Agency’s Endocrine Disruptor Screening Program (EDSP)⁷ to identify the potential to interact with the endocrine system of humans and wildlife. This assay is used with the rest of the screening battery, as well as other scientifically relevant information, to identify substances that need further study to determine if the potential endocrine interaction leads to an adverse effect.

In those three studies, D4 exhibited very weak endocrine activity and only at very high doses – doses to which humans can never, even accidentally, be exposed. As discussed in those papers, the endocrine activity of D4 detectable in these sensitive rat assays is hundreds of thousands of times weaker than that of the naturally occurring estrogen and up to 200 times weaker than natural plant estrogens found in the human diet, such as in soy (phytoestrogens). The very weak activity exhibited by D4 indicates virtually no potential for estrogen activity in humans because it would be overwhelmed by the existing natural estrogens in the body which are present at much higher levels in humans than in rats. D4 exhibits no potential androgenic or progesterone-like activity or the ability to alter the activity of natural androgen or progesterone. There are no indications of a significant or sustained effect on the thyroid gland or the

⁴ <http://www.ecy.wa.gov/programs/hwtr/rtt/cspa/pdf/556672.pdf>

⁵ http://ec.europa.eu/environment/archives/docum/pdf/bkh_main.pdf

⁶ http://www.mst.dk/English/Chemicals/Consumer_Products/Surveyson-chemicals-in-consumer-products.htm

⁷ <https://www.epa.gov/endocrine-disruption>

thyroid-sensitive tissues, offspring growth or developmental endpoints in male or female rats even when exposed to the highest achievable inhalation concentration of D4.⁸

We acknowledge that endocrine disruption is an issue of significant public, political, and scientific interest, but we believe that any chemicals policy should be based on a clear and comprehensive evaluation of current science. SEHSC is committed to relying on a weight of evidence approach to inform the responsible use of silicones and more specifically the use of D4. Given that D4 is not included in either of the referenced reports used as the rationale for categorization, and there is no indication that D4 would have the potential to cause adverse effects on the endocrine system in humans, SEHSC respectfully requests that the Washington Department of Ecology remove D4 from its CHCC list.

Thank you.

Sincerely,

Karluss Thomas,
Senior Director
Silicones, Environmental, Health, and Safety Center

<http://www.americanchemistry.com>

The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an \$801 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

<https://sehsc.americanchemistry.com>

Operating as an ACC sector group, SEHSC promotes the safe use of silicones through product stewardship, outreach and environmental, health and safety research. Silicones are among the most extensively studied materials used in consumer and industrial applications today. More than 1,000 studies have been conducted by silicone manufacturers to assess the safety of silicones relative to workers, consumers, the environment and manufacturing processes. The results of this continuous research and testing demonstrate the safety of silicones in their diverse and important applications.

⁸ Quinn AL, Regan JM, Tobin JM. 2007. *In vitro* and *in vivo* evaluation of the estrogenic, androgenic and protestagenic potential of two cyclic siloxanes *Toxicol Sci.* 96:145-153.