American Chemistry Council | SEHSC Silicones Environmental, Health, and Safety Center

February 8, 2019

Brendan Atwood
Vermont Department of Health (VDH)
108 Cherry Street,
PO Box 70
Burlington, VT 05402
ATTN: Public Comment

Subject: **SEHSC Comments on Proposed Changes to the Vermont Chemical of High Concern in Children's Products Rule**

Dear Mr. Atwood:

The Silicones Environmental, Health, and Safety Center (SEHSC) of the American Chemistry Council (ACC) appreciates the opportunity to comment on the proposed changes to the Vermont Chemicals of High Concern in Children's Products rule (Proposed Rule). SEHSC's comments focus on the following items:

- Proposed definitions to clarify meaning of certain key terms used in the Proposed Rule
- Request for delisting of octamethylcyclotetrasiloxane (D4) from the Chemicals of High Concern to Children (CHCC) list.

Proposed Definitions to Clarify Meaning of Certain Key Terms

Several key terms in the provisions regarding "Evaluation of Chemicals for Listing as a Chemical of High Concern to Children" (i.e., section 9.0) should be defined to help foster clarity, consistency and transparency in regulatory decisions under the Proposed Rule. Below we offer proposed definitions for the following terms: "credible, scientific evidence"; "weight of credible, scientific evidence"; "demonstrated"; and "authoritative governmental entity or accredited research university".

We note that certain of these (or very similar) terms were recently defined by the U.S. Environmental Protection Agency (US EPA) in a rulemaking to implement its obligations under the amended federal Toxic Substances Control Act.[1] Specifically, in its "Procedures for Chemical Substance Risk Evaluations" EPA defines the terms "Weight of scientific evidence" and "best available science." SEHSC believes that incorporating similar definitions here will help clarify for all parties the intended basis of decisions under this Proposed Rule and will have the collateral benefit of helping foster consistent, science-based decision making at the state and federal level.

SEHSC proposes the following definitions be added to Section 4.0 of the Proposed Rule:

4.10 "Credible, scientific evidence" means science that is reliable and unbiased; it involves the use of supporting studies conducted in accordance with sound and objective science

[1] See 82 Fed. Reg. 33726 (July 20, 2017).

practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

4.11 "Weight of credible, scientific evidence" means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

4.12 "Demonstrated" means a weight of credible, scientific evidence evaluation based on credible, scientific information that considers risk.

With respect to "demonstrated," which appears in Section 9.1.1 of the Proposed Rule, it is important to recognize that government entities and other bodies may conduct scientific evaluations and/or make regulatory determinations using fundamentally different approaches. Those approaches can result in significantly different conclusions regarding the chemical substance at issue.[2] In some instances, a governmental authority or other body may simply adopt or incorporate by reference determinations or chemical lists put forth by other entities irrespective of whether those determinations or lists reflect weight of credible, scientific evidence reviews or risk-based determinations by the authoring party.

The intent of the proposed definition of "demonstrated" is to emphasize that in making listing/de-listing determinations, it is important that the Commissioner account for the varying approaches used by other entities and base its decisions on a weight of credible, scientific evidence review that considers risk. The Commissioner should not simply adopt another entity's characterization of the chemical if that characterization itself was not based on a weight of credible, scientific evidence review that considered risk. Otherwise, the Commissioner would be inappropriately delegating its responsibility for determining whether a substance qualifies as a CHCC.
If the proposed definition of "demonstrated" is not adopted, then, at a minimum, the language in 9.1.1 and 10.2.1 should be modified to reflect that Vermont would preferentially defer to those entities that conduct scientific evaluations using a risk-based, weight of evidence approach.

4.13 "Authoritative Governmental Entity or Accredited Research University" means an entity who conducts scientific evaluations on the basis of a risk-based approach, utilizing the weight of scientific evidence that considers exposure.

SEHSC urges the Vermont Department of Health (VDH) to adopt these clarifying definitions to ensure that sound science is utilized to justify additions and deletions to the VT CHCC list.

Request for Delisting of D4

First, as a brief background, D4 is a chemical intermediate that is primarily used to produce silicone polymers. These silicone polymers are used in many products in which they provide unique performance characteristics that enable innovation in transportation, electronics, building and construction materials, and life-saving health care applications. Silicone polymers

[2] For example, pursuant to the amended TSCA, the United States, and, in particular, the US EPA has embraced risk as the philosophical underpinning for its chemical safety determinations. Likewise, national authorities in Canada and Australia utilize risk as the basis for their chemical safety evaluations. Risk-based approaches consider exposure and utilize weight-of-evidence in their assessment of risk.

contribute to weight reduction in automobiles, which results in increased fuel efficiency and lower pollutant emissions. Silicone polymers protect electronic components against heat, shock, and contaminants which is critical for ensuring the long-term stability and performance of increasingly small, portable, and sophisticated electronic devices such as mobile phones, tablet computers, and global positioning systems. Silicone polymers are used widely in construction because they bond with many materials including concrete, glass, granite, marble, aluminum, steel, and plastics, are durable and resist decay caused by extreme weather conditions, moisture, or sunlight, and silicone polymers make buildings energy efficient by preventing humidity and hot or cold air from coming through joints and cracks. Silicones are hydrophobic, hypoallergenic, and non-reactive with most chemicals. Their chemical stability, durability, and elastic nature can make silicone polymers ideal for use in applications involving implantation in the human body.

D4 was designated as a CHCC in Act 188, which provides the statutory basis for the Proposed Rule[3], and appears in the list of CHCC in section 5.0 of the Proposed Rule. The Vermont Department of Health D4 fact sheet notes that D4 is an endocrine disruptor and has reproductive, respiratory, lung, and liver effects. The fact sheet also indicates that D4 is classified as a persistent, bioaccumulative, and toxic chemical by the European Chemicals Agency (ECHA).

D4 is not an endocrine disruptor, and does not pose a risk to human health

D4 is not classified as an endocrine disruptor by the European Union. The citation used in the VDH D4 fact sheet to support D4's classification as an endocrine disruptor by the European Union is a report developed in 2002 by BKH[4] 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. In addition, D4 does not actually appear in the document or in the annexes to the document. To define a substance as an endocrine disruptor by the widely accepted World Health Organization/United Nations Environmental Program (WHO/UNEP) definition[5] 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 be used to evaluate all relevant data to determine endocrine disrupting potential, and more than one type of study is needed to define an endocrine disruptor. The published studies associating D4 with endocrine activity in vivo are all of one type of assay, the rodent uterotrophic assay. This assay is designed to be especially sensitive for identifying chemicals with the potential to act like the female hormone 17β-estradiol based on the potency with which the chemical elicits a uterotrophic response (increase in weight of the uterus). The rodent uterotrophic assay is one in the battery of 11 screening assays used in Tier 1 of the US Environmental Protection Agency's Endocrine Disruptor Screening Program (EDSP)[6] to identify the potential to interact with the endocrine system of humans and wildlife. This assay should be used only in the context of other assays in 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. The several different types of studies published on D4 endocrine activity have all found that D4 lacks sufficient potency to act like the female hormone 17β-estradiol. These

[3] See 18 V.S.A. Chapter 38A, §1773(a).
[4] http://ec.europa.eu/environment/archives/docum/pdf/bkh_main.pdf
[5] 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
[6] https://www.epa.gov/endocrine-disruption

findings demonstrate that there is no weight of evidence to support a designation of D4 as an endocrine disruptor.

In the published uterotrophic studies, D4 produced a uterotrophic effect only at very high doses, indicative of insufficient potency to act like the female hormone 17β-estradiol. Chemicals with such low potency cannot act as estrogens in humans because they are overwhelmed by the existing natural estrogens in the body, which are present at much higher levels in humans than in rodents. D4 exhibits no estrogenic activity in male rats and has shown no potential to produce androgenic or progesterone-like activity or to alter the activity of natural androgen or progesterone. There are no indications of a significant or sustained effect on the thyroid gland, on thyroid hormone action or thyroid-sensitive tissues, on offspring growth or developmental endpoints in male or female rats, even when exposed to the highest achievable inhalation concentration of D4.[7]

Given that D4 is not included in the referenced report used as the rationale for categorization as an endocrine disruptor, and there is no indication that D4 would have the potential to cause adverse effects on the endocrine system in humans, D4 should not be considered an endocrine disruptor by Vermont.

The health hazards noted in the VDH D4 fact sheet, including the liver and lung impacts, reproductive effects, and respiratory irritation, were all assessed as part of Health Canada's robust human health evaluation of D4. In consideration of those potential effects, and a number of others, Canada concluded that D4 "is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health".[8] The Australian Department of Health also evaluated the human health effects of D4 and reached a similar conclusion ("…the public risk from this chemical is not considered to be unreasonable"). [9] The concentrations of D4 measured in perfume, toys, children's cosmetics and articles, fish, sediment, indoor air and dust, outdoor air, and drinking and surface water that are cited in the Vermont D4 fact sheet were all well below concentrations associated with adverse effects in laboratory studies. A scientifically-credible assessment of the risks associated with D4, where exposure is appropriately considered, reveals that D4 does not pose a risk to human health or the environment.

The Weight of Scientific Evidence demonstrates that D4 is not a PBT

Using a weight of evidence approach to assess the PBT characteristics of D4 demonstrates it is not a PBT. The bio-concentration factor (BCF) or log Kow are the criteria that are frequently used to assess whether a compound is bioaccumulative in regulatory evaluations. These criteria were developed to assess bioaccumulative behavior for a specific class of carbon-based chemistry and were not intended to be used exclusively for assessing bioaccumulative behavior for all chemistries. D4 is silicon-based, highly volatile, and non-water soluble, so D4's environmental fate characteristics do not lend themselves to using the current PBT criteria that were intended only to screen for a potential environmental concern. In addition, it is widely recognized that the original purpose for identifying bioaccumulative compounds was to prevent environmental exposure to compounds that bio-magnify in food webs.[10] Accordingly, there was an intent to identify compounds for which environmental exposure would lead to progressively

[7] 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.

[8] http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2481B508-1

[9] https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=2031#cas-A_556-67-2

[10] http://chm.pops.int/TheConvention/ThePOPs/tabid/673/Default.aspx

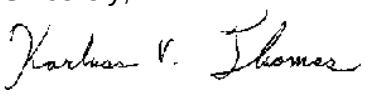
higher concentrations in organisms as you move up the food chain to top predators and humans. Published field studies[11] consistently show that environmental exposure to D4 does not result in its bio-magnification, and exhibits the opposite phenomenon, bio-dilution. Because D4 does not bio-magnify in the food web (the original intent of identifying bioaccumulative compounds) it should not be considered bioaccumulative.

Regarding toxicity, concentrations of D4 measured in the environment are lower than the concentrations of D4 associated with effects in organisms in laboratory studies. A hallmark of using a risk-based approach to assess the potential harm associated with a compound is the consideration of environmental exposure. D4 has been measured in surface waters, sediment, and biota.[12] These exposures are well below those concentrations where effects have been seen in laboratory experiments. Consequently, D4 should not be considered toxic at environmentally-relevant concentrations. Because D4 is not bioaccumulative or toxic, it should not be considered a PBT. Both Canada and Australia have evaluated the PBT properties of D4, and each concluded that D4 failed to meet all the criteria for PBT substances.

Washington State Removed D4 from its Chemical of High Concern (CHCC) Listing
It is noteworthy that Washington State removed D4 from its CHCC listing. Vermont's Act 188 notes that "it is the policy of the state to attempt, when possible, to regulate toxic chemicals in a manner that is consistent with regulation of toxic chemicals in other states." Within this context, SEHSC encourages VDH to review the recent Washington Department of Ecology decision to remove D4 from its CHCC list based on consideration of "credible peer-reviewed scientific information documenting why D4 failed to meet the criteria required for inclusion on the list (WAC 173-334-070 4(c))." In its explanatory note, Washington stated that it "had conducted a detailed review and analysis of the information and references"….. Including "recent studies"… to reach its conclusion to delist D4 from its CHCC list. The state of Oregon has followed Washington in removing D4 from its listing of chemicals of concern.

SEHSC believes that D4 does not meet the legislative and regulatory criteria for inclusion on the CHCC list. Including D4 on the CHCC list will provide no measurable benefit to human health or the environment in Vermont and could create the false impression that D4 is unsafe. Moreover, because governmental authorities and legislative/regulatory bodies often enact laws and promulgate regulations that incorporate by reference the lists of other authorities, being inappropriately included on even one list can have unintentional consequences.

Sincerely,



Karluss Thomas
SEHSC Senior Director

ACC is a national trade association representing companies engaged in the business of chemistry. The Council's mission is to advocate on behalf of its members to foster innovation in manufacturing, high-tech jobs, and to enhance safety through the products of chemistry and investment in research. The Council is committed to sustainable development by fostering progress in the economy, environment and society.

SEHSC represents the manufacturers of silicone materials and promotes the safe use of silicones through product stewardship, outreach and environmental, health and safety research. This research must rely on a risk-based and weight-of-evidence methodology to accurately determine classifications of silicone materials.

[11] Borga, 2012; Hori, 2013; McGoldick, 2014; Nusz, 2018; Powell, 2018; Powell, 2018a

[12] Burkhard, 2011; Borga, 2012; McGoldick, 2014; Nusz, 2018; Powell, 2018; Powell, 2018a; Wang, 2013