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

July 14, 2023

Washington Department of Ecology
Hazardous Waste and Toxics Reduction Program
Safer Products for Washington Program

Submitted via Ecology comment portal

Subject: **SEHSC Comments on the "Draft Identification of Priority Chemicals Report to the Legislature: Safer Products for Washington Cycle 2, Implementation Phase 1"**

The Silicones Environmental, Health, and Safety Center (SEHSC) of the American Chemistry Council (ACC) appreciates the opportunity to provide comments regarding the "Draft Identification of Priority Chemicals Report to the Washington State Legislature" which "identifies priority chemicals and chemical classes for the first phase of the second cycle of Safer Products for Washington (SPW) implementation." As discussed further below, SEHSC is requesting that certain siloxanes (i.e., hexamethylcyclotrisiloxane (D3) octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5), and dodecamethylcyclohexasiloxane (D6)) be excluded from the priority chemicals and chemical classes list under SPW. Listing D3, D4, D5, and D6 is unwarranted and would not help to make consumer products in Washington safer which is the fundamental purpose of the underlying law (i.e., Toxic Pollution law) that directed the Department of Ecology (referred to as Ecology) to establish the SPW program.

Priority Chemical List under SPW

Ecology is proposing to add D3, D4, D5, and D6 to the priority chemicals list based on its conclusion that these substances are a concern for sensitive species and sensitive populations because of their hazards and exposure potential. According to Ecology, D3, D4, D5, and D6 are "persistent, likely bioaccumulative, and toxic [PBT] chemicals that have high production volumes, potential disproportionate exposures, and hazards that can impact sensitive species and populations." SEHSC strongly disagrees with this characterization and a determination that these substances meet the statutory criteria for identification of priority chemicals under the SPW. We believe that the best available science supports that D3, D4, D5, and D6 are safe for human health and the environment when used in their intended applications.

Global Regulatory Assessments

Many of the references cited in this proposal to support the inclusion of D3, D4, D5, and D6 in the priority chemicals list are based on the European Union's (EU) hazard-based approach for assessing substances deemed to have PBT properties. Europe's chemicals management approach does not allow for the consideration of risk (exposure data) in their environmental assessment of PBT chemicals.

In regions where a risk-based approach is used, even if the substances are deemed to meet some of the PBT criteria, there is still consideration of risk and exposure data in their environmental and health assessments. For example, Canada[1] and Australia[2] have evaluated the PBT properties of D4, D5, and D6, and each concluded that the substances failed to meet all the criteria for PBT substances.

Monitoring studies conducted by academic experts, government scientists, and industry consistently demonstrate that the concentrations of the substances measured in the environment are significantly less than toxicological thresholds of concern. These monitoring data were considered by regulators in Australia and Canada as part of their risk-based chemical assessments.

The human health risk assessments for D3, D4, D5, and D6 in Canada[3] and for D4, D5, and D6 in Australia[4] resulted in regulatory determinations that the substances were safe for human health. The human health risk assessments for the substances in Australia and Canada considered reproductive and development effects, carcinogenicity, and endocrine impacts. These assessments also included consumer and workplace exposures to the substances. SEHSC urges Ecology to use a risk-based approach as the basis for priority listing decisions. By doing so, Ecology would follow an international consensus in the scientific community and acknowledgement by international regulatory authorities that risk to human health and the environment should be the basis for whether a substance meets regulatory scrutiny. [5]

Use of monitoring and exposure data to assess risk contradicts Ecology's assertion that D3, D4, D5, and D6 have "potential disproportionate exposures" and "pose a risk to sensitive populations and species."

D3, D4, D5, and D6 are not PBTs and are not a concern to sensitive populations and species

In its draft proposal, Ecology notes that "cVMS are not on the state's PBT list (WAC 173-333-310)." Yet in this same proposal, Ecology is proposing to add D3, D4, D5,and D6 to the priority chemical list due to the impact these substances could have on sensitive populations and species because of their PBT properties. SEHSC urges Ecology to refer to its own ruling under related programs as well as the science provided below to conclude that D3, D4, D5, and D6 do not meet the PBT criteria as defined by the Washington statute (WAC 173-333-320), do not pose a concern to sensitive populations and species and should not be included in the SPW priority chemical list.

> Persistence: On persistence, it is important to consider the overall distribution and fate of D3, D4, D5, and D6 in the environment, which is dictated by their unique physico-chemical properties due mainly to the inorganic backbone chain of Si-O-Si units. D3, D4, D5, and D6 are predominately released to air and will partition readily to air when released to other compartments where they are degraded more rapidly than in other

[1] http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2481B508-1; https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=13CC261E-1; https://www.canada.ca/en/health-canada/services/chemical-substances/challenge/batch-2/d6.html

[2] https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-ii-environment-assessments/cvms

[3] http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2481B508-1; https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=13CC261E-1; https://www.canada.ca/en/health-canada/services/chemical-substances/challenge/batch-2/d6.html

[4] https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-ii-environment-assessments/cvms

[5] https://c.ymcdn.com/sites/www.setac.org/resource/resmgr/publications_and_resources/pbtpopsexecutivesummary.pdf

matrices. Therefore, the presence of D3, D4, D5, and D6 in the environment is much shorter than the classical vP chemicals and would be considered easily reversible (removed from the environment) if sources were to cease (Kim et al, 2018)[6].

Bioaccumulation: The bio-concentration factor (BCF) or log Kow are screening criteria that are frequently used to assess whether a compound is bioaccumulative in regulatory evaluations. These criteria were developed to assess bioaccumulative behavior for carbon-based chemistry and were not intended to be used exclusively for assessing bioaccumulative behavior for all chemistries. D3, D4, D5, and D6 are silicon-based, highly volatile, and non-water soluble, so their environmental fate characteristics do not lend themselves to using the current PBT screening criteria that were intended only to screen for a potential to be a bioaccumulative substance in the environment. 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.[7] Accordingly, there was an intent to identify compounds for which environmental exposure would lead to progressively higher concentrations in organisms as you move up the food chain to top predators and humans. Published field studies[8] consistently show that environmental exposure to D4, D5, and D6 does not result in bio-magnification, and exhibits the opposite phenomenon, bio-dilution. Because D4, D5, and D6 do not bio-magnify in the food web (the original intent of identifying bioaccumulative compounds) they should not be considered bioaccumulative. Since D3 is not stable in the environment, it would not be available for exposure and therefore could not bioaccumulate.

Toxicity: Regarding toxicity, environmental monitoring demonstrates concentrations of D4, D5, and D6 measured in the environment are lower than the concentrations of D4, D5, and D6 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, D5, and D6 have been measured in surface waters, sediment, and biota.[9] These exposures are well below those concentrations where effects have been seen in laboratory experiments. Consequently, D4, D5, and D6 should not be considered toxic at environmentally relevant concentrations. For D3, even though there have been some reports of presence in the environment, it is more likely that presence of D3 in those samples are due to challenges with the analytical method that can often lead to the formation of D3 during the analysis[10].

Because D4, D5, and D6 are not bioaccumulative or toxic, they should not be considered PBTs. Both Canada and Australia evaluated the PBT properties of D3, D4, D5, and D6, and each concluded that the substances failed to meet all the criteria for PBT substances.

State Determinations

In 2017/18, the Washington State Department of Ecology and the Oregon Department of Health both decided to remove D4 from their chemicals of high concern (CHCC) listings based on consideration of “credible peer-reviewed scientific information documenting that D4 does not

[6] Chemosphere. 2018 Mar;195:325-335. doi: 10.1016/j.chemosphere.2017.12.071. Epub 2017 Dec 12. PMID: 29272801.
[7] http://chm.pops.int/TheConvention/ThePOPs/tabid/673/Default.aspx
[8] Borga, 2012; Hori, 2013; McGoldick, 2014; Nusz, 2018; Powell, 2018; Powell, 2018a
[9] Burkhard, 2011; Borga, 2012; McGoldick, 2014; Nusz, 2018; Powell, 2018; Powell, 2018a; Wang, 2013
[10] https://www.sciencedirect.com/science/article/pii/S0048969722053748?via%3Dihub

meet the criteria required for inclusion on the list (WAC 173-334-070 4(c))." In its explanatory note, Ecology 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 followed Ecology in removing D4 from its listing of chemicals of concern. In addition, neither state includes D3, D5, or D6 on their chemicals of concern lists. Also, the Massachusetts Toxic Use Reduction Institute (TURI) evaluated D4 and D5 and did not recommend adding the substances to its Toxic Use Reduction Act (TURA) list[11].

These risk determinations illustrate that D3, D4, D5, and D6 are safe for human health and should not be considered priority chemicals under the SPW.

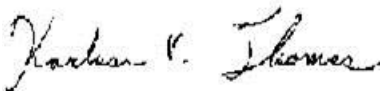
Silicones provide innumerable benefits to society

D3, D4, D5, and D6 are chemical intermediates that are 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 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. Ecology should not include D3, D4, D5, and D6 as priority chemicals under the SPW, to ensure that Washington State citizens can continue to benefit from the unique performance characteristics of silicones in all the products they use daily.

SEHSC believes that including D3, D4, D5, and D6 on the priority chemical list will provide no measurable benefit to consumers of products in Washington State and could create the false impression that they are unsafe.

We would very much appreciate the opportunity to meet with you and your staff to more fully discuss these comments and our position that D3, D4, D5, and D6 do not meet the criteria established under the SPW as chemicals that pose a concern to sensitive populations and species and should not be included on the SPW priority chemical list. Please let us know when you might be available for a meeting.

Sincerely,



Karluss Thomas
SEHSC Senior Director

[11] Assessment of Alternatives to Perchloroethylene for the Dry Cleaning Industry. 2012. / TURI Guides to Safer Chemicals / TURI Publications / TURI - TURI - Toxics Use Reduction Institute

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.