



June 14, 2019

Jan Malcom  
Commissioner  
Minnesota Department of Health  
625 N. Robert St.  
St. Paul, MN 55155-2538

David Bell  
Research Scientist  
Toxic Free Kids

Subject: SEHSC Petition to Delist Silicone Substances from the Minnesota Chemicals of High Concern List under the Toxic Free Kids Act

Dear Commissioner Malcolm and Mr. Bell:

The Silicone Environmental, Health, and Safety Center (SEHSC) of the American Chemistry Council (“ACC” or the “Council”) understands that the Minnesota Toxic Free Kids (TFK) Act (Minnesota Statutes 116.9401 to 116.9407) requires that its Chemicals of High Concern (CHC) list must be reviewed and updated by the Minnesota Department of Health (MDH) every 3 years.

As part of this update, SEHSC on behalf of its members, proposes the inclusion of clarifying definitions of key terms and the removal of D4, D5, D6, L3, M4Q, MDnM-hydride, and Cyclotetrasiloxane, hexamethyl, diphenyl from the Minnesota CHC list as they do not satisfy the statutory criteria for listing.

### **Proposed Definitions to Clarify Meaning of Certain Key Terms**

To enhance clarity, consistency and transparency in MDH’s decisions regarding the identification and listing of CHC under Minn. Stat. 116.9402, we recommend that MDH incorporate the following definitions of certain key terms into its approach to identifying CHC.

- Definitions: “credible scientific evidence” to mean “science that is reliable and unbiased; it involves the use of supporting studies conducted in accordance with sound and objective science 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).”<sup>1</sup>
- “known or suspected with a high degree of probability” means “those decisions and determinations achieved through a weight of scientific evidence evaluation that considers risk.”

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<sup>1</sup> This definition draws from U.S. Environmental Protection Agency’s (EPA’s) definition of “best available science” in 40 C.F.R 702.33 as applied EPA’s conduct of risk evaluations under the amended Toxic Substances Control Act.

- “weight of scientific evidence” means “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.”<sup>2</sup>

SEHSC believes that incorporating these definitions into MDH’S approach will help clarify for all parties the intended basis of decisions regarding CHC listings and will have the collateral benefit of helping foster consistent, science-based decision making at the state and federal level.

SEHSC urges Minnesota to adopt these clarifying definitions to ensure that sound science is utilized to justify additions and deletions to the Minnesota CHC list.

**L3 (CAS # 107-51-7), M4Q (CAS # 3555-47-3), MDnM-hydride (CAS # 69430-47-3), and Cyclotetrasiloxane, hexamethyl, diphenyl, (CAS # 33204-76-1)**

L3, M4Q, MDnM-hydride, and Cyclotetrasiloxane, hexamethyl, diphenyl were included on the Minnesota CHC list on the basis that they are purported persistent (P), bioaccumulative (B), and toxic (T) substances. The government of Canada conducted a robust risk-based human health and environmental assessment for these substances utilizing a weight of evidence approach. Canada did not conclude that these compounds were PBT. Canada also concluded that none of the substances<sup>3</sup> are entering the environment in a quantity or concentration or under conditions that have or may have immediate or long-term harmful effects on the environment or its biological diversity. For human health, Canada concluded that L3, M4Q, MDnM-hydride and Cyclotetrasiloxane, hexamethyl, diphenyl are 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. Canada is the only federal, state, or international regulatory authority that has developed a regulatory human health and environmental risk assessment for these substances. Consequently, none of these substances meet the statutory criteria for being identified as a chemical of high concern in Minnesota, and should be removed from the Minnesota CHC List. It is also noteworthy that the State of Maine has removed L3 from its Chemical of Concern list on the basis of the Canadian L3 evaluation.

The prioritization process in Canada identified compounds as “high priorities” for assessment when screening criteria identified them as potential persistent (P), bioaccumulative (B), and toxic (T) compounds. The prioritization process in Canada was never intended to be a final determination of the PBT properties of substances; rather it was a process to identify those compounds that were priorities for conducting definitive human health and environmental regulatory risk evaluations for the substances. Canada’s final screening assessments for L3, M4Q, MDnM-hydride, and Cyclotetrasiloxane, hexamethyl, diphenyl concluded that none of the compounds posed a significant risk to human health or the environment.

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<sup>2</sup> This definition aligns with the EPA definition of the term in 40 C.F.R. 702.33.

<sup>3</sup> <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2F7C2533-1>  
<http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=19584F14-1>  
<http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=C630CD3B-1>  
<https://www.canada.ca/content/dam/eccc/documents/pdf/pded/rs4/Rapid-screening-substances-limited-general-population-exposure.pdf>

## D5 (CAS# 541-02-6) and D6 (CAS# 540-97-6)

Both D5 and D6 were included on the Minnesota CHC list on the basis that they are purported PBT substances. Regulatory evaluations for D5 and D6 have been conducted by three international regulatory authorities including Australia, Canada, and the European Union (EU). Neither Australia nor Canada concluded that D5 and D6 meet all of the regulatory criteria for being considered PBTs. For D5 and D6, Canada concluded that both substances were P but neither meet the regulatory criteria for being considered B, or T.<sup>4</sup> Australia concluded that D5 met the regulatory criteria for being P and B, but not T. Similar to Canada, Australia concluded that the regulatory criteria was met for P, but not B or T for D6.<sup>5</sup> In addition, the Maine Department of Environmental Protection removed D6 from its CHC list because they asserted that D6 “no longer met the criteria associated with this listing.”

More importantly, an international consensus has emerged in the scientific community where risk to the environment should be the primary basis for whether a substance merits regulatory scrutiny<sup>6</sup>. It has become widely recognized that persistence and bioaccumulation are exposure characteristics that should be considered in the context of a compound’s environmental exposure, and the likelihood that the compound can elicit toxic effects at the concentrations it is present in the environment. Persistence and bioaccumulation should not be used as surrogates for risk to the environment. International regulatory authorities have also acknowledged the importance of using a risk-based approach for identifying compounds that pose a risk to the environment. Both Canada and Australia used a risk-based approach for assessing the environmental risks associated with D5 and D6. Australia assessed the environmental risks associated with a number of siloxanes, including D5 and D6, and concluded ‘the direct risks to aquatic life from exposure to siloxanes at expected surface water concentrations are not likely to be significant’.<sup>7</sup> Canada also used a risk-based approach for assessing the environmental risks associated with D5 and D6. For D5, Canada concluded that it does not pose a danger to the environment, and that projected future uses of D5 will not pose a danger to the environment. Canada concluded that D6 is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends.<sup>8</sup>

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<sup>4</sup> <http://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>

<sup>5</sup> <https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-ii-environmental-assessments/cvms>

<sup>6</sup> [https://c.ymcdn.com/sites/www.setac.org/resource/resmgr/publications\\_and\\_resources/pbtpopsexecutivesummary.pdf](https://c.ymcdn.com/sites/www.setac.org/resource/resmgr/publications_and_resources/pbtpopsexecutivesummary.pdf)

<sup>7</sup> <https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-ii-environmental-assessments/cvms>

<sup>8</sup> <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=515887B7-1>

The EU concluded that D5 and D6 were very Persistent (vP) and very Bioaccumulative (vB).<sup>9</sup> The EU has maintained a hazard-based approach for assessing the environmental risks associated with chemicals in commerce. The EU did not consider environmental exposure in its evaluation of D5 and D6, and used P and B as surrogates for actual environmental risk. As a consequence of its hazard-based approach for assessing environmental risk, the EU concluded that both D5 and D6 pose a risk to the environment and imposed restrictions on their use in commerce. Neither Canada nor Australia has imposed restrictions on the use of D5 or D6 in commerce. The EU is the only regulatory authority that has imposed restrictions on the use of any silicone material in commerce.

Because its hazard-based approach is out of step with the broader scientific community and conflicts with the risk-based assessments for D5 and D6 conducted by Canada and Australia, SEHSC believes the EU D5 and D6 assessments should be disqualified from consideration in Minnesota for determining whether the substances merit inclusion on the Chemical of High Concern list on the basis that the EU determinations did not utilize a risk-based approach for evaluating their risks to the environment. Consequently, neither D5 nor D6 should be considered as meeting the statutory criteria for being a CHC in Minnesota.

#### **D4 (CAS# 556-67-2)**

D4 is included on the Minnesota Department of Health CHC list as a purported endocrine disruptor and a PBT substance, based on determinations by the EU, Canada and Washington.

D4 is not an endocrine disruptor, and does not pose a risk to human health. Contrary to the Minnesota CHC listing note, D4 is not classified as an endocrine disruptor by the European Union (EU). Rather the reference that is cited refers to an EU “priority list of substances identified for further evaluation of their role in endocrine disruption.” To define a substance as an endocrine disruptor by the widely accepted World Health Organization/United Nations Environmental Program (WHO/UNEP) definition 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 primarily 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 17 $\beta$ -estradiol based on the potency with which the chemical elicits an 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) 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 17 $\beta$ -estradiol. The US EPA has determined that D4 lacks the potential for bioactivity via estrogen pathways and a recent peer-reviewed evaluation demonstrated that the potency of D4 is 1 – 2 orders of magnitude below the minimum potency that could be relevant to humans. These findings demonstrate that weight of evidence is inconsistent with a designation of D4 as an endocrine disruptor.

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<sup>9</sup> [https://echa.europa.eu/documents/10162/23665416/rest\\_d4\\_d5\\_bd\\_draft\\_10832\\_en.pdf/cc2e98e6-cb89-7f73-aced-19da652037b3](https://echa.europa.eu/documents/10162/23665416/rest_d4_d5_bd_draft_10832_en.pdf/cc2e98e6-cb89-7f73-aced-19da652037b3)

In addition, Minnesota Statutes at Section 116.9402, notes that it will consider determinations made by state agencies including the Washington Department of Ecology (Ecology). Washington State removed D4 from its CHCC listing 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.

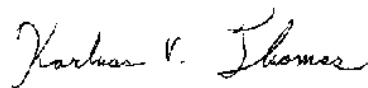
Using a hazard-based regulatory approach, the EU concluded that D4 was PBT and vP, vB. For the reasons cited previously, the EU evaluation of D4 should not be considered relevant to Minnesota’s identification of CHC’s. Therefore, D4 should not be included as a CHC in Minnesota.

Using a risk-based approach, both Canada and Australia evaluated the PBT properties of D4. Canada concluded that D4 was P and T with uncertain B,<sup>10</sup> while Australia concluded that D4 was P and B, with uncertain T. Neither Canada nor Australia concluded that D4 meets all of the regulatory criteria for being P, B, and T. In its regulatory assessment of the environmental risks associated with a number of siloxanes including D4, Australia concluded ‘the direct risks to aquatic life from exposure to siloxanes at expected surface water concentrations are not likely to be significant’.

## Summary

SEHSC believes that D4, D5, D6, L3, M4Q, MDnM-hydride, and Cyclotetrasiloxane, hexamethyl, diphenyl do not merit inclusion on the Minnesota Chemical of High Concern (CHC) list. Maintaining these substances on the Minnesota CHC list will provide no measurable benefit to human health or the environment in Minnesota and could create the false impression that these substances are unsafe.

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 material.*

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<sup>10</sup> <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2481B508-1>