Frequently Asked Questions
Canadian Assessment of L2, L4, L5, D3, dvTMDS, and Cyclomethicone

What materials were assessed by Canada?
Six silicone materials were assessed by Canada authorities, including Hexamethyldisiloxane (L2), Decamethyltetrasiloxane (L4), Dodecamethylpentasiloxane (L5), Cyclotrisiloxane (D3), Divinyltetramethyldisiloxane (dvTMDS), and Cyclomethicone. The Canadian Chemicals Management Plan referred to these materials collectively as the "Siloxanes Group."

What is the Canadian Chemicals Management Plan?
The Canadian Chemicals Management Plan, or CMP, is a systematic program that evaluates the safety of chemicals in commerce in Canada. The CMP is highly regarded by scientific experts as a world-class, risk-based program that effectively evaluates chemicals using the weight-of-evidence approach and appropriate consideration of exposure.

How are these siloxanes used in Canada?
In Canada, L2, L4, L5, and D3 are used in a host of products such as cosmetics, electronics, medical devices, adhesives and sealants, as well as in industrial applications such as paints and coatings.

Why did Canada assess this group of siloxanes?
These silicone materials were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of Canada's 1999 chemicals management law, known as the Canadian Environmental Protection Act (CEPA). As such, Canadian regulators conducted a screening assessment of these materials to determine if they posed a risk to human health and the environment.

Who in Canada conducted the assessment?
Staff in the CEPA Risk Assessment Program at Environment and Climate Change Canada and Health Canada conducted the scientific evaluation of this group of siloxanes. Both the human and ecological portions of the assessment underwent external review and/or consultation.

What data were considered?
This screening assessment includes consideration of information for each of these substances on chemical properties, environmental fate, hazards, uses and exposures, including additional information submitted by stakeholders.

When was the assessment conducted and finalized?
Relevant data were identified up to December 2017. Environment and Climate Change Canada and Health Canada published its draft evaluation on June 1, 2019, and according to press reports, the final assessment is expected in June 2020.

What did Canadian regulators conclude about these silicone materials' environmental impact?
Based on all available scientific evidence, Canada has concluded that the materials are "unlikely to be causing ecological harm." In addition, authorities concluded that these materials are not considered toxic under CEPA because they "are 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."

What did Canadian regulators conclude about these silicone materials' impact on human health?
Based on all available scientific evidence, regulators determined that these siloxane materials "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."

Has Canada studied other silicone materials?
In January 2009, Environment Canada identified octamethylcyclotetrasiloxane (D4), decamethylpentacyclosiloxane (D5), and dodecamethylcyclohexasiloxane (D6) as priorities for regulatory evaluation on the basis of hazard screening criteria. Further to a comprehensive screening assessment of these materials, Canada has not imposed any use restrictions or concentration-based restrictions on D4, D5, or D6 for any product in Canada. In 2015, Environment and Health Canada published their final screening assessment for L3, which concluded that the substance is not entering the environment in a way that constitutes a danger in Canada to human health or the environment. Consequently, L3 has not been subject to any regulatory restrictions in Canada. For more information about Canada's assessment of silicone materials, please visit: https://globalsilicones.org/canada-siloxane-evaluations.

Have other countries come to similar conclusions about siloxanes?
In 2018, Australia's Department of the Environment and Energy assessed D3, D4, D5, D6, D7, and cyclomethicone and concluded, "[t]he direct risks to aquatic life from exposure to these chemicals at expected surface water concentrations are not likely to be significant." Regulators also found that these materials posed no risk to human health. As such, Australia has not proposed any regulatory restrictions on the use of any of these silicone materials

Have other countries come to different conclusions about siloxanes?
The European Union (EU) is the only regulatory authority that has imposed restrictions on the use of any silicone material in commerce. It has imposed a wash-off personal care products restriction on D4, D5 and listed D4, D5 and D6 as SVHC substances. The EU has maintained a hazard-based approach for assessing the environmental risks associated with chemicals in commerce. The EU did not consider exposure in its evaluation of silicone materials.

On the contrary, we believe that in order to enable effective decision making to protect human health and the environment, a risk-based approach needs to be employed, where **both exposure and hazard** are evaluated using all relevant and reliable sources of information.