Frequently Asked Questions – D4, D5 & D6
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1. What are silicones?

Silicones are high-performance polymers that can take a variety of physical forms that may range from solids to water-thin liquids and semi-viscous pastes, greases and oils. They have revolutionized thousands of products that add quality to life in terms of performance, comfort and safety. Additionally, they reduce the cost of household and personal care products that consumers use every day.

In the kitchen and throughout the home, silicones are known for their versatility and convenience. Silicone kitchenware is durable, easy to clean, lightweight and stain-resistant. In the household, silicones are used as antifoams in detergents, which enable lower washing temperatures, thereby saving energy. Silicones spread easily and protect surfaces, making them an ideal component for polishes or cleaning agents for household surfaces.

In aerospace applications, silicone products increase the lifespan of vital components, while in railway locomotives they provide tough, long-lasting motor insulation and lubricants for bearings.

They are employed as sealants for windows, as caulking for bridges and bathroom tiles, as coatings to protect facades and historical monuments, as coolants in transformers, as protective encapsulating material for semiconductors in electronics and as foam-control agents in the manufacture of many types of products.

Silicones are also used in a wide range of health care and medical applications. They serve as coatings for hypodermic needles, ensure high oxygen permeability in hydrogel contact lenses, are used in tubing in a wide range of medical devices including insulin pumps, and are particularly suitable in prosthetic devices due to their hypoallergenic properties and a wide range of beneficial physical properties, helping millions of people in their daily lives.

In electronic devices, their high temperature resistance and heat dissemination are essential to provide high-functioning, small devices with the cushioning they need to function.

2. What are D4, D5 and D6?

Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5) Dodecamethylcyclo-hexasiloxane (D6) are cyclosiloxanes, and basic members of the silicone family, serving as the building blocks for many silicones. They are used to create a diverse range of silicone materials (polymers) that provide beneficial characteristics to a wide variety of applications and products, including construction, electronics, engineering, health care and personal care among others. D4, D5 and D6 are most frequently used as raw materials, meaning that the substance is employed in the manufacturing process but is only present at very low (trace) levels in the end products.

3. Are D4, D5 and D6 safe for the environment and/or human health?

Yes. D4, D5 and D6 are safe for the environment and for human health, when used for their intended purposes.

Silicones are not new on the market. In fact, they have been used for more than six decades. Still, observed levels monitored in a wide variety of temperatures and surroundings do not give rise to any concern. The many years of use have therefore not led to any environmental concern, and based on the observed data the industry does not expect this to change. Multiple lines of evidence show the environmental levels are not increasing even though uses of silicones have considerably grown over years.

Large volumes of monitoring data collected by the global silicones industry, academic experts/institutes and governmental regulatory agencies globally, continue to demonstrate that D4, D5 and D6 are not found at, nor are likely to be found at, levels that pose a risk to the environment. Since they are volatile, the majority of D4, D5 and D6 are released to the atmosphere or will evaporate quickly into the atmosphere if released in other media. Once in the atmosphere, D4, D5 and D6 break down due to natural, physical processes.

With respect to D5, these conclusions were confirmed by an independent panel of scientists in **Canada**. The "Board of Review" reviewed all the scientific literature on D5, leading the Canadian Environment Minister to decide that no action was needed to limit the use of the substance. In addition, Environment Canada, having reviewed the environmental data available for D4, has not imposed any product use or concentration restrictions on the use of D4 in any application. Health Canada also has declared D4, D5 and D6 safe for human health.

These findings were confirmed by **Australian** regulators for a series of siloxanes, including D3, D4, D5, D6, D7, and cyclomethicone. The Australian assessment concluded: "[t]he direct risks to aquatic life from exposure to these chemicals at expected surface water concentrations are not likely to be significant." Although most of these substances are known or expected to be persistent in the sediment compartment, Australia, using a risk-based assessment approach, concluded that these silicone materials don't pose risks to the environment and has not proposed any regulatory restrictions on the use of any of the materials.

Independent scientists and regulatory agencies have also evaluated how consumers and workers can be exposed to D4, D5 and D6 and concluded that there is no risk to human health. Links to these scientific studies can be found on www.cyclosiloxanes.org/science

4. What do PBT and vPvB stand for?

PBT and vPvB stand for "Persistent, Bioaccumulative and Toxic" and "very Persistent and very Bioaccumulative".

5. What is the current regulatory status of D4, D5 and D6?

Country/Region	**Use restrictions**
Europe	Wash-off personal care products restriction (D4, D5); D6 expected to be added to restriction in January 2019. Leave-on personal care and other consumer/professional products restriction proposal (D4, D5 and D6) under public consultation in Q1 2020. D4, D5, D6 listed as SVHC in June 2018.
Canada	None
United States	None
Japan	None
Australia	None

In Europe, a restriction on the use of D4 and D5 was adopted under the European Union's Chemicals management program (REACH) in May 2017 and published in the EU Official Journal in January 2018. The scope of the restriction is limited to wash-off cosmetic products with a D4 or D5 concentration equal to or greater than 0.1% by weight of either substance. All companies that place products on the market that are within the restriction scope must comply with the requirements set forth in this restriction by January 31, 2020. In January 2019, the European Chemicals Agency (ECHA) proposed a new restriction, on the use of D4, D5 and D6 in leave-on personal care and consumer and professional products in concentrations equal to or greater than 0.1% w/w of each substance.

To assess the impact of these restrictions, and in cooperation with several European Member States, the silicones industry began monitoring the amount of D4 and D5 being released into domestic wastewater treatment plants (WWTPs) in 2018. The silicones industry amended the monitoring in 2019 to include D6, once the new restriction was proposed. This monitoring is a surrogate for estimating consumer use of products containing D4, D5 and D6, although it will also capture some professional uses when releases are to water going to domestic WWTPs. Monitoring results indicate that D4 and D5 wastewater treatment plant influent concentrations are well below the baseline levels predicted, and in the case of D4, already consistent with the predicted post-restriction concentrations. For D6, concentrations are below the predicted pre-restrictions and post-restriction levels at all WWTPs for the "leave-on personal care product proposed restriction." These concentrations are lower than assumed by EU authorities in implementing restrictions and suggest that those restrictions were unnecessary.

In April 2017, the European Chemicals Agency (ECHA) published its intention to assess the need for further restriction of D4 and D5 in leave-on personal care products and other consumer/professional uses (e.g. dry cleaning, waxes and polishes, washing and cleaning products) in concentrations greater than 0.1%. In January 2018, the Commission requested adding D6 to the scope of this restriction, and to the scope of the 'wash-off' restriction. The restriction proposal on D4, D5, and D6 in leave-on products, as well as the addition of D6 to the scope of the 'wash-off' restriction was released in 2019 and is under public consultation. The proposed restriction has not yet been finalized nor approved and may be further amended based on additional information provided during subsequent public consultation or based on the opinion of ECHA's Committees. A final decision is expected in 2020.

In 2017, Germany conducted an additional Risk Management Option Analysis (RMOA) for D4 and D5 and concluded that, when compared against existing regulatory criteria, D4 and D5 meet the criteria for PBT/vPvB and vPvB respectively. In 2018, a similar vPvB conclusion was reached by ECHA for D6. Member States subsequently decided in June 2018 that these substances should be included on the list of Substances of Very High Concern (SVHC).

An SVHC listing is not a ban or restriction on the use of D4 D5 and D6 or any silicone polymers that contain D4, D5 and D6. Formal identification of PBT/vPvB properties carries communication and risk management measure obligations only.

The EU made its determinations based on the REACH PBT/vPvB criteria. The REACH criteria to assess bioaccumulation were intended only to be used for organic (carbon-based) substances, not inorganic substances. D4, D5 and D6 have an inorganic backbone and are unique hybrid inorganic-organic substances. Therefore, the criteria used to assess whether D4, D5 and D6 are bioaccumulative do not reflect the unique chemistry of siloxanes.

The European PBT guidelines allow for consideration of the weight of scientific evidence. The silicones industry believes that up-to-date scientific evaluations using the weight-of-evidence method conclude that D4, D5, and D6 do not behave as PBT or vPvB in the environment.

In Canada, Environment Canada carried out a thorough investigation to determine whether D4, D5 and D6 warrant environmental regulatory measures. With respect to D5, the Canadian Environment Minister established a first-ever Board of Review to advise him based on the newly available science whether D5 could pose a risk to the environment. Following a scientific review process that included formal hearings and a rigorous examination of all the relevant scientific information related to D5's behavior in the environment and any potential danger posed by the substance, the Board concluded in late October 2011 that "siloxane D5 does not pose a danger to the environment or its biological diversity." Furthermore, the Board added that, "based on the information presented, siloxane D5 will not pose a danger to the environment or its biological diversity in the future". In February 2012, the Canadian Environment Minister accepted the Board of Review's findings and removed D5 from a proposed list of toxic substances under CEPA.
For D6, the Government of Canada's final assessment concludes that "exposure to D6 is not considered to be harmful to human health or to the environment". In addition, Environment Canada, having reviewed the environmental data available for D4, has not imposed any product concentration restrictions on the use of D4 in any application.

In fact, Environment Canada/Health Canada conducted a comprehensive surveillance program in Ontario and Quebec and monitored levels of D4 and D5 in waste water treatment plants influents and effluents receiving waters. They found that the removal efficiency of siloxanes in all WWTPs is very high and that there is no risk posed by D4 and D5 to aquatic and sediment-dwelling organisms.

In the United States, SEHSC submitted the final results of its D4 environmental monitoring program to the U.S. Environmental Protection Agency (EPA) in September 2017. SEHSC directly worked with EPA over several years to design and wholly fund the complex environmental monitoring program, which consisted of collecting samples from 14 sites across the country. Actual environmental concentrations measured in samples collected will facilitate EPA's environmental risk assessment for D4.

An independent expert published an evaluation of the environmental risks associated with D4 using data from the silicones industry/EPA collaborative monitoring program. The assessment concluded that D4 poses no unreasonable environmental risk in the US. Based on this independent assessment of the data, SEHSC continues to believe that no regulatory restrictions are needed. In January 2020, SEHSC submitted a request to EPA to conduct a risk evaluation of D4 under the Toxic Substances Control Act and looks forward to a timely, transparent, and scientifically sound risk determination for D4 by the EPA.

In Japan the government chemical review for D4, D5, and D6 was conducted in December 2017 under the Chemical Substance Control Law (CSCL). As a result, D4 was assigned to the CSCL "monitoring Chemicals" category because of the need for some additional ecotoxicity data, and D6 was included in the "monitoring chemicals" category because of the need for additional ecotoxicity and health data. Substances are included in this category if they are determined to be "persistent" and "bio-accumulative", but there are no restrictions on their use. No change was recommended for D5. Based on safety data, D5 continues to be managed under the CSCL General Chemical category. The effective date for the categorization was April 2018.

The environment monitoring data for D4, D5 and D6 conducted in Tokyo Bay indicates that these substances do not build up in the food chain. The silicone industry in Japan is requesting that Japanese regulators provide for risk assessments for monitoring chemicals. The silicone industry strongly believes that risk–based assessments will demonstrate that D4 and D6 do not pose risks to human health or the environment and should therefore be managed under Japan's General Chemical category.

In Australia, Australia's Department of the Environment and Energy carried out a risk assessment for a range of silicone materials which concluded in 2018. Australia's assessment focused on a series of siloxanes, including D3, D4, D5, D6, D7, and cyclomethicone. The

assessment concluded: “[t]he direct risks to aquatic life from exposure to these chemicals at expected surface water concentrations are not likely to be significant.” Based on this conclusion, Australia has not proposed any regulatory restrictions on the use of any of the materials. Health assessments have also been completed with no significant identified human health risks.

In China
In December, 2017, the Ministry of Environmental Protection (the “MEP”) drafted a Catalogue on Prioritized Chemicals (First Batch) which included D4. The Silicone Industry requested that D4 be removed from the current draft of China’s priority chemical list and the MEP agreed to the request. The Silicone Industry provided a proposal to conduct a D4 environmental risk assessment to understand potential risks, if any, associated with releases of D4. The Silicone Industry believes that a D4 risk assessment in China should be completed before any regulatory decisions for D4 are made. The data and information resulting from this assessment should inform the need for prioritization of further assessment or any preventive risk management for D4.

In early 2018, GSC entered into a tri-party agreement with the China Association of Fluorine and Silicone Industry (CAFSI) and the MEP’s Solid Waste and Chemical Management and Technology Center (SCC), to conduct an environmental risk evaluation of D4 in China. The risk evaluation is expected to be completed by May, 2020.

6. Would there be any socio-economic impacts of a regulatory decision on D4, D5 or D6?

Yes. D4, D5 and D6 play a key role in the production of silicones that are beneficial to society. Undue regulation of D4, D5 and D6 would have serious negative consequences on important applications in the fields of medicine, safety, energy, engineering, construction and technology.

A disproportionate decision would put jobs and economic growth at risk. The global silicones industry is responsible for the manufacture of products with an economic value of over €10 billion ($12 billion) in Europe and North America, and the global silicones industry sustains thousands of jobs directly, contributing to jobs in downstream firms that employ millions of people.

7. Why do some regulatory agencies consider D4, D5 and D6 as PBT and vPvB, respectively, but the industry believes that no further regulation is needed?

The silicones industry is convinced, based on all available science, that D4, D5 and D6 are safe for human health and the environment. Independent scientists have confirmed this position. Therefore, the industry believes that D4, D5 and D6 should not be regarded or regulated as PBTs/vPvBs. The most recent scientific studies on this topic are regularly uploaded to www.cyclosiloxanes.org/science.

The safety of cyclosiloxanes has been confirmed by independent expert panels, including the European Scientific Committee for Consumer Safety, the United States Cosmetics Review Panel, and Health Canada. Environmental monitoring data from locations in North America, Europe, and Japan show that D4, D5 and D6 do not build up in the food chain. Very low to no detectable levels of D4, D5 or D6 are found in water, soil or sediment at locations away from human populations, based on monitoring data from the Arctic. Municipal environmental monitoring data collected by the global silicones industry and governmental regulatory agencies demonstrate that D4, D5 and D6 are not found at, nor are likely to be found at, levels that pose any risk.

In Europe, the existing criteria for assessing whether a substance is PBT or vPvB under REACH do not allow for accurate evaluation of silicon-based substances. Current criteria are based on

organic substances, and therefore are inappropriate to predict the behavior of siloxanes, which have an inorganic backbone and are unique hybrid inorganic-organic substances. The criteria therefore over-predict the potential bioaccumulation and concentration of siloxanes in the environment. In our view and the view of many leading scientific experts, D4, D5 and D6 do not behave as PBT or vPvB substances in the environment.

The silicones industry will continue to work with regulatory authorities on the development of regulatory assessments and associated management measures that minimize environmental impacts, and that facilitate innovation, job-creation, and economic growth.

8. What do you mean when you say that "D4, D5 and D6 are safe for human health and the environment when used as intended"?

What we mean is that science and reliable monitoring data demonstrate that D4, D5 and D6 are safe for humans and the environment and may be used with confidence in their current and intended applications.

In fact, the Silicones Industry has committed to several long term voluntary monitoring initiatives to better understand the presence and behavior of siloxanes in the environment. Findings from these initiatives illustrate that none of the levels detected posed a risk to aquatic organisms and no significant concentration trend was detectable at any of the four locations (no environmental concentration increase was found over the course of the monitoring program).

In addition, D4, D5 and D6 have been subject to dozens of scientific studies showing that they are safe for human health.

Like all chemical products, this doesn't mean that these substances can be handled irresponsibly. Our members provide all the necessary information and guidance to their customers to ensure that they will use these substances appropriately (e.g. through safety data sheets). Provided that such basic and necessary precautions are followed, D4, D5 and D6 are perfectly safe.

Our approach is supported by Responsible Care®, which is the chemical industry's global, voluntary initiative under which companies, through their national associations, work together to continuously improve their health, safety and environmental performance, and to communicate with stakeholders about their products and processes. All the leading silicone manufacturers fully support Responsible Care®.

9. How can the concerns raised by governmental risk assessments of D4, D5 and D6 best be addressed?

The silicones industry recommends addressing any such concerns through voluntary and targeted risk-management measures, in dialogue with authorities.

In order to consider all the data available on these unique hybrid inorganic-organic substances and appropriately address the concerns raised by some scientists regarding their persistence (P) and bioaccumulation (B) assessment, the industry believes that we need to find an appropriate platform to resolve scientific divergences and remaining uncertainties. This will allow for an in-depth review of the science available on these substances in line with advancements in the academic understanding of persistence and bioaccumulation since the criteria were developed**.**

Up-to-date scientific data demonstrate that these unique chemicals behave differently from what is predicted under current PBT regulatory criteria; the methods used to assess P and B may need to be reviewed and updated, a position supported by several eminent scientific experts from around the world.

The silicones industry is committed to responsible stewardship and will continue to promote environmental responsibility through developing and supporting independent science and

monitoring studies. The industry will also continue to work closely with regulatory authorities around the globe to ensure that silicones can continue to be used with confidence, preserving and fostering the innovation made possible by the unique characteristics of these materials.

10. Is the industry undertaking any concrete measures to reduce the environmental impact of D4, D5 and D6?

As part of the silicones industry's on-going effort to minimize our environmental footprint, we are cooperating actively with authorities around the world to determine the necessary measures to effectively address any environmental concerns in relation to these substances.

We provide additional data from environmental **monitoring** studies and research, such as a comprehensive long-term monitoring program to assess the presence of D4, D5 and D6 in different locations worldwide. We have established a robust monitoring program to evaluate the effectiveness of the newly published REACH restriction in wash-off personal care products.

The industry also collaborated with external experts and developed a **guidance** document on emissions management.

Other measures include a program to support the widespread use of waste handling and disposal practices for D4, D5 and D6 at processing and formulation sites, and improvements in the removal of D4, D5 and D6 in effluent discharge.

Furthermore, the Global Silicones Council released a study assessing the full life cycle of silicones, siloxanes and silanes with respect to greenhouse gas emissions, and found that the use of these products can help save, on average, nine times the amount of greenhouse gases required to manufacture them.

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