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Questions & Answers for cyclic siloxanes D4, D5 and D6 for communication to customers

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What are silicones?

“Silicone” is a generic term referring to a class of synthetic polymers. They have an inorganic silicon–oxygen (Si–O) backbone with at least one organic group attached to the silicon atom via a direct carbon–silicon bond. Silicones are defined as inorganic or hybrid substances.

<https://globalsilicones.org/explore-silicones/what-are-silicones/>

<https://www.silicones.eu/science/production/chemistry-polymerisation/>

Silicones are used in hundreds of applications where their special performance is required. They are used as adhesives, in the production of insulation materials, they provide unique sensory benefits, and they have excellent mechanical, optical and thermal resistance among many other properties. They are used, for example, in medical technologies, renewable energy and energy saving solutions, cosmetics and cleaning products, as well as in digital technologies, construction and transportation.

What are D4, D5 and D6 and where are they used?

D4 (Octamethylcyclotetrasiloxane), D5 (Decamethylcyclopentasiloxane), and D6 (Dodecamethylcyclohexasiloxane) are types of cyclic siloxanes, which are a type of silicone compound. They are essential building blocks to create a diverse range of silicone materials in a variety of products, including personal care and cosmetics items, construction, electronics, engineering, health care, as well as in industrial applications such as lubricants and coatings. These products provide unique and beneficial characteristics that can not be achieved by any other material.

D4, D5 and D6 are most frequently used as chemical intermediates, i.e. the substances are used in the manufacturing process, but are only present as minor impurities in the final products.

What does SVHC mean and how does it relate to D4, D5 and D6?

SVHC stands for “Substance of Very High Concern”. D4, D5 and D6 have been identified as “Substances of Very High Concern” by the European Chemicals Agency (ECHA) since 2012. They were added to the Candidate List of SVHCs.

Who made the SVHC decision for D4, D5 and D6?

The decision to identify D4, D5, D6 as SVHCs was made by the European Chemicals Agency (ECHA) Member States Committee (MSC), which is composed of experts nominated by EU Member States and ECHA.

The MSC members were asked to review the technical dossiers submitted by Germany for D4 and D5, and by ECHA for D6, as well as the comments received during the public consultation. The mandate of these experts is to assess and confirm the scientific basis underpinning the SVHC proposals, and not to assess the potential impact.

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Why were D4, D5 and D6 listed as SVHC?

Based on the criteria used in REACH, D4 meets the criteria for persistent, bioaccumulative and toxic (PBT) substances, and D5 and D6 meet the criteria for very persistent, very bioaccumulative (vPvB) substances.

In addition, D5 and D6 are classified as PBT if they contain more than 0.1% of D4.

This led to a nomination to the list of SVHCs by EU Member States.

What does it mean in practice that D4, D5 and D6 are listed as SVHC?

An SVHC listing is not a ban on the use of silicone polymers. Nor is it a ban or a restriction on the use of D4, D5 and D6 'as such'. Silicone polymers can be used safely in all products.

The formal identification of PBT/vPvB properties entails obligations of communication and risk management measure. The complexity of this information varies according to the actors in the supply chain:

- Silicone manufacturers must implement risk management measures at their sites and recommend to downstream users to minimize exposure and emissions throughout the lifecycle of the substance resulting from the manufacture or identified use. The relevant safety data sheets will be updated by the individual companies without undue delay, as appropriate (substances and mixtures, if the substance is present individually at levels $\geq 0.1\%$).
- Suppliers of articles (finished articles as placed on the market after processing and treatment, including those that are partly based on silicone) containing D4, D5 or D6 at concentrations above 0.1% (weight by weight), either intentionally added as an ingredient or present as an impurity, must provide their customers (industry, professional users, distributors) with sufficient information to allow safe use of the article. This information must include at least the name of the substance.
- Consumers can request similar information and have the right to receive a response within 45 days of receiving the request.
- Producers or importers of articles have to notify ECHA if their article contains D4, D5 or D6 in a total quantity of more than one ton per producer or importer per year and in a concentration of more than 0.1% (weight by weight, per substance). Notifications must be submitted no later than 6 months after the inclusion on the candidate list. Notification is not required if exposure of humans and the environment to the substance can be excluded during the use and disposal of the article.

The notification needs to include the following information:

- the identity and contact details of the company,
- the identity of the substance and its registration number, if available,
- the tonnage range of the substance in the notified article(s),
- a brief description of the use(s) of the substance in the article(s) and of the uses of the article(s).

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Find more information about the obligations resulting from inclusion of SVHCs in the [candidate list](#).

This [website](#) explains the notification process for substances in articles.

On what basis did the EU make its PBT/vPvB determinations for D4, D5 and D6?

The EU made its determinations based on the REACH PBT/vPvB criteria.

The REACH criteria for assessing bioaccumulation should only be used for organic (carbon-based) substances, not inorganic substances. D4, D5 and D6 have an inorganic part in the molecule.

Therefore, the criteria used to assess whether D4, D5 and D6 are bioaccumulative do not reflect the unique chemistry of siloxanes. In fact, recent scientific studies have concluded that these regulatory criteria are not appropriate for assessing the behaviour of siloxanes in the environment.

The criteria for assessing bioaccumulation focus on one factor only, namely bioconcentration.

As a result, the bioconcentration factor data were weighted stronger than the non-bioconcentration data – for example, the trophic magnification data (data measuring the average relative increase (decrease) in concentration of a substance over an entire food chain). By not applying a robust scientific weight-of-evidence determination, weighing all available data and considering the unique properties of siloxanes, the scientific assessment of D4, D5 and D6 was effectively biased.

Member States Committee experts considered the field data as inconclusive at this stage. However, real-world monitoring data show that D4, D5 and D6 do not bioaccumulate in the environment. These data are important because monitoring data provide evidence of the actual levels of a given substance in the environment. Real-world data allow scientists to assess actual exposure levels, and these data can be used to refine and better calibrate predictive models that might otherwise be suitable for use with silicone materials.

In the case of D4, D5 and D6, the methodology based on bioconcentration factors may significantly overestimate bioaccumulation, but there is also a risk of underestimating bioaccumulation in the case of other substances. Accurate PBT/vPvB assessment based on the best available science should be the overriding policy driver.

We believe that the REACH criteria do not allow the full range of relevant scientific evidence to be considered and that not all relevant scientific evidence was thoroughly considered before the decision was taken.

What restrictions exist for D4, D5 and D6?

In January 2018, a restriction on the use of D4 and D5 was published in the EU Official Journal (Regulation (EC) No. 2018/35). The scope of the restriction is limited to wash-off cosmetic products with a concentration of D4 or D5 equal to or greater than 0.1% by weight of either substance.

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This restriction targets at emissions to water, which has been identified as a potentially critical compartment and will apply from the end of January 2020. Industry has accepted the restriction as a proportionate measure and has committed to support it and monitor its effects in the environment.

In April 2017, the European Chemicals Agency (ECHA) published an intention to extend the restriction of D4 and D5 to leave-on personal care products and other consumer / professional products. D6 was later added to this intention. The restriction dossier was published in January 2019. Following the public consultation on [Annex XV report](#) the SEAC draft opinion was published on 5 December 2019. In March 2020 the Committee for Socio-economic Analysis (SEAC) has adopted its [final opinion](#) supporting ECHA's proposal to restrict the placing on the market of D4, D5 and D6 as substances, as constituents of other substances, or in mixtures in a concentration equal to or greater than 0.1 % weight by weight of each substance.

The [extended restriction](#) was finalized in April and came into force in May 2024.

What are the exemptions to the extended restriction?

In the [Annex XVII](#) of the extended restriction various exceptions are listed for the use of D4, D5 and D6 in industrial uses and for residues in silicone polymer mixtures.

By way of derogation, the restriction shall not apply to the placing on the market of D4, D5 and D6 for the following [industrial uses](#) (*paragraph 4a*):

- as a monomer in the production of silicone polymer,
- as an intermediate in the production of other silicone substances,
- as a monomer in polymerisation,
- in the formulation or (re)packing of mixtures,
- in the production of articles,
- in non-metal surface treatment.

Additionally, derogations are listed for the following applications (please check full description in *paragraphs 4b-d, 5 and 7*):

- devices for treatment and care of scars and wounds, prevention of wounds and the care of stoma (D5 and D6),
- cleaning/restoration of arts and antiques (D5 only),
- laboratory reagents under controlled conditions (D4, D5, D6),
- as a constituent of a silicone polymer on its own,
- as a constituent of a silicone polymer in a mixture derogated under *paragraph 6*,
- cosmetic products not covered in restriction (limited until 6 June 2027)
- dry cleaning systems with D5 as a solvent in strictly controlled closed systems for textile, leather, and fur, where the cleaning solvent is recycled or incinerated,

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In addition, by way of derogation, the restriction shall not apply to the placing on the market of mixtures that contain D4, D5 or D6 as residues from silicone polymers, under the following conditions (*paragraph 6*):

- a) D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in adhesion, sealing, gluing and casting;
- b) D4 in a concentration equal to or less than 0,5 % by weight, or D5 or D6 in a concentration equal to or less than 0,3 % by weight of either substance in the mixture for use as protective coatings (including marine coatings);
- c) D4, D5 or D6 in a concentration equal to or less than 0,2 % by weight of the respective substance in the mixture, for use as devices as defined in Article 1(4) of Regulation (EU) 2017/745 and in Article 1(2) of Regulation (EU) 2017/746, other than the devices referred to in paragraph 6(d);
- d) D5 in a concentration equal to or less than 0,3 % by weight in the mixture or D6 in a concentration equal to or less than 1 % by weight in the mixture, for use as devices as defined in Article 1(4) of Regulation (EU) 2017/745, for dental impression;
- e) D4 in a concentration equal to or less than 0,2 % by weight in the mixture, or D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture for use as silicone insoles for horses, or as horseshoes;
- f) D4, D5 or D6 in a concentration equal to or less than 0,5 % by weight of the respective substance in the mixture, for use as adhesion promoters;
- g) D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in 3D-printing;
- h) D5 in a concentration equal to or less than 1 % by weight in the mixture or D6 in a concentration equal to or less than 3 % by weight in the mixture, for rapid prototyping and mould making, or high performance uses stabilised by quartz filler;
- i) D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture, for use in pad printing, or manufacturing of printing pads;
- j) D6 in a concentration equal to or less than 1 % by weight of the mixture, for professional use in the cleaning or restoration of art and antiques.

What is the consequence of the extended restriction for Evonik's products?

The majority of Evonik's products are being used in an industrial environment and are not affected by the current restriction on consumer and professional products.

Many of the products are being used as additives in single-digit percentage concentrations in our customers' formulations and already contain less than 0,1 % w/w of each of the cyclic siloxane. Therefore, the concentrations in the final products are below the limit value and not affected by the restriction.

In the few cases where there is an impact, we will work closely with our customers to find the best way for our products in the various applications.

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What does the authorization of D4, D5 and D6 mean for silicone polymers?

On 14 April 2021, ECHA announced its recommendation to add D4, D5 and D6 to REACH Annex XIV to the authorization list (Annex XIV). This recommendation follows D4, D5 and D6 inclusion in the REACH Candidate List in 2018 and is part of standard REACH procedure.

According to the background documents for authorization intention the volumes of imported polymers have not been considered for priority assessment. It is also recognized, that siloxane cyclic are used as precursors for polymers and can remain as impurities with concentrations >0.1% in the silicone polymer. The use of such polymers would also not require authorization. Thus, it can be concluded that D4, D5 and D6 as impurities of polymers are out of scope of the intended authorization recommendations by ECHA.

Are D4, D5 and D6 POPs (Persistent Organic Pollutants)?

ECHA has launched on 15 June 2023 a public [consultation](#) on a draft scientific dossier to assess whether D4, D5 and D6 meet the scientific [criteria](#) to be listed under the Annex B¹ of the Stockholm Convention's Persistent Organic Pollutants (POP). The consultation is open for comments until 10 August 2023. This is not a decision that D4, D5 and D6 meet the POP criteria nor that they should be listed under the Convention at this stage.

Currently, scientific discussions are ongoing as to whether these substances meet the criteria of the Convention, such as the long-range transport potential (LRT) and back-deposition to remote areas. In collaboration with authorities and other stakeholders, the industry is organising a comprehensive field study in the Antarctic region to assess whether D4, D5 and D6 can be transported and accumulate in remote environments. Initial results are expected in Q3 2024. In addition, a second study is being conducted with the Norwegian Air Institute (NILU) in the Arctic, with initial results expected in Q4 2023.

What does it mean in practice if D4, D5 and D6 will be added to ANNEX B of Stockholm Convention?

This question could not be answered in detail at this stage. However, there are several risks related to the proposal of listing these substances.

The EU Commission has confirmed that their intention is to propose a listing under the Stockholm Convention to stop direct uses of D4, D5, D6 in consumer applications globally, while protecting polymer production, transportation and availability via a broad acceptable purpose for the use of these substances as transported intermediates for polymer production.

¹ Annex B of the Stockholm Convention lists the specific chemicals that are considered POPs and subject to restrictions and control measures.

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For context, direct (non-intermediate) uses of these substances account for less than 2% of global use, while >98% is used for polymer production (intermediate use). Therefore, such a broad acceptable purpose would apply to >98% of the uses of these substances. No acceptable purpose has ever been granted under the Stockholm Convention that would allow a broad intermediate use accounting for most of the quantities of a given substance.

A final recommendation to achieve a broadly acceptable purpose for transported intermediates will ultimately be made by the Stockholm Convention's Persistent Organic Pollutants Review Committee (POPRC). Past and current practice in the POPRC shows that stakeholder negotiations drive exemptions to a very granular level, regardless of the original intentions of the proposal. The POPRC must submit its recommendation to the involved parties (COP) for a final decision. The COP can follow this recommendation in full, in part or not at all. It is very difficult (even for the EU) to predict the outcome of a proposal, as the listing is the result of political bargaining between parties. The Commission indicated that on-site intermediate uses of D4, D5, D6 would be automatically exempted as closed-system site-limited intermediates (CSSLI). However, the Stockholm Convention does not define CSSLI conditions, leaving their definition to individual Parties.

The standard used in Europe is 'Strictly Controlled Conditions' (SCC). In the EU, SCC are defined in Article 18(4) (a) to (f) of the REACH Regulation. To our knowledge, no other Party has set specific requirements for how CSSLI should be implemented within their jurisdiction.

In a Stockholm listing scenario, such stringent measures would need to be applied at D4, D5, D6 manufacturing sites but also at the downstream user sites using these substances to make silicone polymers. The cost of implementing such stringent emission control measures would likely drive many players out of the market.

A POP listing would also have a negative impact on the production and use of silicone polymers, as D4, D5, D6 residues in polymers would be restricted or banned. The Stockholm Convention generally exempts POPs present as "unintentional trace contaminants" (UTCs) in products and articles from the requirements of Annexes A and B. However, there is no precise definition of UTCs. This means that Parties will have to implement their own definitions and thresholds for UTC exemptions to enable an effective implementation of the Convention. While the EU Commission could set a UTC limit value of 0.1% in the EU, to reflect the concentration limits set under REACH (with which industry is working towards and will meet at the latest by the time the REACH restriction comes into force), there is no guarantee that other Parties will not set more stringent limits. This would lead to distortions in the market for silicone polymers, which would be subject to different regulations in different countries.

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Would a POP listing have an impact on the recycling of silicone waste?

A POP listing of D4, D5, D6 would automatically trigger registrations or bans that would affect the ability to ship, recycle, and safely manage waste. For example, the Stockholm Convention and the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal have a joint mandate on POPs waste and have agreed to cooperate closely in establishing the levels of destruction and irreversible transformation necessary to ensure that the characteristics of POPs do not persist. The EU's POPs Regulation (Regulation 2019/1021) stipulates that POPs can only be recovered from the waste that is intended for destruction. Recycling of silicones will only be technically and economically viable at large economies of scale, with transport of the waste streams secured globally and across Europe. With a listing of D4, D5, D6 under the Stockholm Convention and, subsequently under the Basel Convention, this transport would only be viable if: a) residues are set a minimum of 0.1% by weight under the Basel Convention, and b) under a listing under the Stockholm Convention, exemptions are included to produce D4, D5, D6 through recycling processes. These two conditions are essential but extremely difficult to secure in a highly uncertain negotiation of both treaties, which the EU Commission would trigger by listing D4/D5/D6 POPs.

"Allowed" concentrations of POP content in waste – so-called low-persistent-organic-pollutant content (LPC) – are defined in the General Technical Guidelines for the environmentally sound management of wastes. If COM were unable to secure workable LPC values, all waste containing silicone polymers from D4, D5, D6 would be incinerated. Industry would not be able to recycle devices with silicone parts, volatile materials containing D4, D5, D6, and silicone polymers with residues below 0.1% w/w. There is a clear risk that a POP listing of D4, D5, D6 will hamper and impede recycling.

Have other countries considered real-world data as part of their assessment?

In both countries [Canada and Australia](#), government authorities have evaluated the environmental impact of D4, D5 and D6, and in each instance, regulators have relied on all available science and risk-based evaluations that consider weight-of-evidence. As a result, both countries decided not to restrict the use of these substances in commerce. The US is also considering an evaluation of D4 and has worked collaboratively with industry to provide the exposure data requested by the US EPA (Environmental Protection Agency) for its assessment.

What are the socio-economic consequences of an SVHC decision?

Identifying D4, D5 and D6 as SVHCs is damaging to investments, innovation and competitiveness, as it causes considerable uncertainty for customers at a global level.

Silicone polymers rely on D4, D5 and D6 as building blocks (monomers) for their manufacture. Silicone materials are widely used and difficult to substitute due to their durable, safe and highly effective mechanical, optical and thermal properties. Critical applications include construction, transportation, lighting, alternative energy, cosmetics, cleaning, electronics and medical uses.

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It is important to note that the listing of D4, D5 and D6 as SVHC candidates does not constitute a ban on the manufacture or use of silicones or on the use of D4, D5 and D6 "as such". Are there alternatives to silicones with similar properties?

Siloxanes are a group of substances characterized by a chain of alternating silicon (Si) and oxygen (O) atoms. Because siloxanes have an inorganic backbone, they are different from organic (carbon-based) substances. The structure and functionality of these chemical compounds determine the specific combination of properties of siloxanes including high propensity to repel water, low water solubility and volatility.

Siloxanes are a key element in the production of silicones. Silicone materials offer several useful properties, including thermal stability (high and low temperature), resistance to oxidation, ozone, UV exposure, good wetting, spreading, and flow, low electrical conductivity, and water repellency (among many others). While alternative materials may offer one or a few of these properties, there are no alternative materials that can offer the same combination of unique properties.

In addition, the use of silicones, siloxanes and silane products leads to a reduction in greenhouse-gas emissions that outweighs the impact of production and end-of-life disposal by a factor of 9. In other words, for every ton of CO₂ emitted, the use of silicones enables a saving of nine times that amount. This is at the top of the range of previous estimates made for chemical applications across the board.

Silicones can still be used as the SVHC identification of D4, D5 and D6 does not constitute a ban or a restriction on silicone polymers or on the use of D4, D5 and D6 "as such".

Can silicones be used safely?

Yes, silicones can be used safely in all products. Silicones remain safe when used as intended. Silicones are not new to the market.

In fact, they have been in use for more than six decades. If they were indeed very persistent and bioaccumulative, we would expect to see very high and increasing levels in the environment as their use has increased significantly over time – but the levels observed in a wide range of temperatures and surroundings are extremely low (close to the detection limit).

The many years of use have therefore not led to any environmental concerns and, based on the observed data, we do not expect this to change. Several lines of evidence show the environmental levels are not increasing.

The PBT criteria under REACH rely predominantly on laboratory-based testing and do not consider these real-life data. However, in order to comply with the officially recognized PBT designation, the silicone industry is committed to minimize emissions at all levels. A first step is the development of an emissions management guide to support our value chain manage emissions.

In addition, the silicone industry is in the process of establishing a voluntary product stewardship program that goes beyond regulatory requirements. Monitoring results show that the concentrations of D4 and D5 in wastewater are already typically below the predicted baseline, and in the case of D4, already in line with the predicted post-restriction levels.

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What is the importance of silicones for Evonik and what does that mean for the Evonik products?

For the vast majority of Evonik's products D4 and D5 are used only as reactive substances e.g., in the production of polymers. We have already optimized our production processes in recent years to minimize the residual content of D4 and D5 in our products.

Many of Evonik's products are being used as additives in single-digit percentage concentrations in our customers formulations. And most of our products already contain less than 0.1 % of each of the cyclic siloxane. We clearly expect to continue to serve these applications, as the socio-economic benefits clearly outweigh the potential reduction in emissions. We will present such socio-economic arguments to the authorities.

Together with the silicone industry, Evonik is assessing future scenarios. Although the industry is working intensively with legislative bodies to avoid unnecessary and disproportionate regulations, Evonik cannot rule out restrictions on the direct use of cyclic siloxanes and on the content of cyclic siloxanes in consumer and professional products. Evonik believes that this may force us to further reduce the content of cyclic siloxanes in consumer and professional products e.g., in household care products. This could be required in about 3 years. We will work closely with our customers to determine the best way forward for our products in the various applications.

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What is the position of Evonik?

Evonik is a member of Silicones Europe and Global Silicones Council (GSC) and supports the position that the current regulatory activities are disproportionate and not justified for the protection of the environment. The industry's conclusion is based on the unique properties and behaviour of cyclic siloxanes. The silicone industry is committed to responsible stewardship and is determined to address environmental risks by developing and supporting independent scientific and monitoring studies to inform and guide measures. The industry will continue to work closely with regulators and downstream users around the globe to ensure that silicones can continue to safely deliver all the benefits and innovations for which they are used with confidence. Due to the specifics of silicone chemistry, it is not possible to produce silicone polymers and silicone copolymers under industrial conditions with 'zero D4 / D5'. During polymerization a certain amount of cyclic siloxanes remains unreacted and can only be subsequently reduced afterwards to certain levels, depending on the polymers and the processing conditions.

In general, we confirm that Evonik is fully committed to silicone technology and is working hard with the authorities to define a reasonable way forward that allows the continued use of silicone products and their special properties.

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Where can I find further information?

ECHA Restrictions

- Wash-off Personal Care products:
<https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e182463cd3>
- Leave-on Personal Care and other consumer and professional products:
<https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade>
- ECHA Annex XV report:
<https://echa.europa.eu/documents/10162/039f5415-d7a2-b279-d270-0d07e18f6392>

SVHC

- RMOA:
<https://echa.europa.eu/rmoa>
- SVHC candidate list
<https://echa.europa.eu/candidate-list-table>
- SVHC legal obligations
<https://echa.europa.eu/candidate-list-obligations>

Authorization

- Background document for octamethylcyclotetrasiloxane (D4):
<https://echa.europa.eu/documents/10162/7cc92a5f-ca14-f23b-ac4d-fdd8c6471ab5>
- Background document for decamethylcyclopentasiloxane (D5):
<https://echa.europa.eu/documents/10162/58d230eb-6cbc-f2c1-3bed-2ddf408329c2>
- Background document for dodecamethylcyclohexasiloxane (D6):
<https://echa.europa.eu/documents/10162/da907b89-f29d-6e65-db94-8e9777addacd>

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Silicones Europe & Global Silicones Council

- SVHC statement:
<https://www.silicones.eu/the-addition-of-d4-d5-and-d6-to-the-candidate-list-under-reach-is-disproportionate-and-endangers-critical-beneficial-uses/>
<https://globalsilicones.org/regulation/eu/substances-of-very-high-concern/>
- Properties and behaviour of cyclic siloxanes in the environment
<https://www.silicones.eu/science/environment/>
<https://globalsilicones.org/safety/environment/>
- Monitoring study
https://www.silicones.eu/wp-content/uploads/2023/02/silicone-research_an-industry-commitment.pdf
- Toolbox for minimizing environmental emissions
https://www.silicones.eu/wp-content/uploads/2023/02/Cyclosiloxanes_Toolbox_Version-Nov-2019.pdf