

Restriction and authorisation of cyclic siloxanes D4, D5, D6 under REACH

Dear Customer,

In the last weeks we received several requests regarding the restriction and authorisation of the cyclic siloxanes D4, D5 and D6 under REACH. Therefore, we would like to take the opportunity to explain the background of the current situation as well as work of CES-Silicones Europe in this context.

In the course of the REACH registration process European authorities concluded, that D4 fulfils the screening criteria for persistent, bioaccumulative and toxic (PBT) as well as very persistent and very bioaccumulative (vPvB) and D5 for vPvB substances. Therefore a [restriction](#) was proposed for so called wash-off Personal Care products to limit the concentration of D4 and D5 to less than 0.1 % in the end-product. This restriction aims at emissions to water, which was identified as a potentially critical compartment and is effective since end of January 2020. The Industry has accepted the restriction as a proportionate measure, is [committed to support](#) it and [monitor](#) the effect in the environment.

In April 2017, following a request from the European Commission, ECHA published an additional [restriction intention](#) for leave on personal care products and other consumer and professional products (e.g. dry cleaning, waxes and polishes, washing and cleaning products) containing D4/D5/D6 in concentrations > 0.1%. In addition, wash off and rinse off cosmetic products containing D6 in concentrations > 0.1% shall not be placed on the market. The restriction dossier was published in January 2019. After the public consultation on [Annex XV report](#) the SEAC draft opinion was published on 5 December 2019. It concluded that the restriction proposed on D4, D5 and D6 is the most appropriate EU wide measure to address the identified risks, as concluded by RAC.

On 16 March 2020, ECHA announced that 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 consolidated RAC/SEAC opinion has not yet been made available but based on our information it should be in line with last draft. The EU Commission should prepare its legislative proposal between May and August 2020. Should the Council and the European Parliament not oppose the proposal, the restriction will be adopted. Based on usual timelines, we expect it to be published in the Official Journal in late 2020.

In August 2017 the German authorities launched a Risk Management Option Analysis ([RMOA](#)) for D4 and D5. In their report, which was published in January 2018, the German authorities noted their intent to propose a candidate listing of D4 and D5 as Substances of Very High Concern (SVHC) under REACH. In parallel, the European Commission requested ECHA to develop a SVHC candidate proposal for D6. In June 2018 the Member State Committee agreed to add D4, D5 and D6 to the [SVHC candidate list](#). The listing has no direct impact on the use of these products, but companies may have [legal obligations](#) regarding provision of data for safe handling and use as well as minimisation of release. These obligations, which are effective from the date of inclusion, refer not only to the listed substances on their own or in mixtures but also to their presence in articles with concentrations above 0.1% w/w.

Following standard REACH procedures, ECHA identified D4, D5 and D6 as potential priorities for inclusion in the Authorisation list (Annex XIV). The draft recommendation does not cover all uses but only those that are in scope of an authorisation and are not part of the REACH restrictions. Some uses appear not to be in the scope of authorisation, such as – to the extent they fall under the generic exemptions from authorisation requirement – uses as laboratory reagent and uses as intermediate in e.g. the manufacture of silicone polymers. According to the silicone industry understanding of ECHA's [background documents](#) this means that the following uses remain in scope of a potential authorization:

- non-intermediate direct uses to manufacture formulations in industrial settings (intentional use of D4/5/6) including formulations for export outside of Europe
- industrial uses of the substances as such, or of formulations with D4, D5 or D6 as components, where concentrations levels are 0.1% (w/w) or above per substance

This also means that unintentionally added impurities in polymers are out of scope and are not considered by ECHA in their calculations of the volumes. A public consultation has been launched by ECHA to gather input on whether these substances should be included in the final recommendation list. The consultation will run until 5th of June 2020. However, please note that ECHA's recommendation is a preliminary step and the final decision to propose substances for authorization lies with the European Commission.

It is obvious that European authorities see the need to regulate uses of cyclic siloxanes, which is in contrast to the activities in other countries like [Australia](#), [Canada](#) and the [US](#), who concluded that the risks associated with cyclic siloxanes in the environment warrant only minor actions like minimizing releases from industrial sources.

Evonik is a member of CES–Silicones Europe and GSC–Global Silicones Council and supports the [position](#) that the ongoing regulatory activities are disproportionate and not warranted for protection of the environment. Industry bases their conclusion on the unique [properties and behaviour](#) of cyclic siloxanes. The silicones industry is committed to responsible stewardship and is determined to address environmental risks through developing and supporting independent science and [monitoring studies](#), which [inform and guide measures](#). The industry will continue to work closely with regulatory authorities and with downstream users around the globe to ensure that silicones can continue to provide 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 will remain unreacted and can only be reduced afterwards to certain levels, which depend on the polymers and work-up conditions.

Situation at Coating Additives business line of Evonik Operations GmbH

Cyclic siloxanes are essential raw materials for tailoring polysiloxane backbones resulting in high performing additives for the Coating and Inks industry. Therefore their presence cannot be avoided completely. However, in our continuous improvement process Coating Additives strives to minimize the residual content of cyclic siloxanes in our products. After the recent regulatory changes we have intensified our efforts to further reduce the contents of remaining siloxanes and continue to work on this topic.

Legislative bodies like the German Environmental Agency (Umweltbundesamt – UBA) and the European ECHA have clearly expressed, that their regulatory initiatives aim at a) restricting uses of cyclic siloxanes as formulation ingredients (direct use, which means intentional addition of cyclic siloxanes), b) the information of the value chain about contents of one or more cyclic siloxanes above 0,1 %, c) the minimization of the release of cyclic siloxanes from products for consumer and professional use and d) minimization of emissions of cyclic siloxanes into the environment from industrial processes.

Evonik in line with the Silicone Industry is assessing future scenarios. Although Industry works intensively with legislative bodies to avoid unnecessary and disproportionate rules, Evonik cannot exclude the restrictions for direct use of cyclic siloxanes and for the content of cyclic siloxanes in consumer and professional products.

In general, we confirm that Evonik is fully committed to Silicone technology and is working hard to define jointly with authorities a reasonable path forward, which allows to continue to use Silicone products and their special properties.

Many of Evoniks products are being used as additives in single digit percentage concentrations in our customers formulations. And most of our products contain already less than 0.1 % of each of the cyclic siloxanes. We clearly expect that we can continue to serve these applications, as the socio-economic benefit clearly outweighs the potential reduction of emissions. We will provide such socio-economic arguments to the authorities.

CES-Silicones Europe informed several downstream user organizations of silicones about the current situation and asked for support by stressing benefits of silicone polymers which are based on cyclic siloxanes as raw material. We would highly appreciate your support in reinforcing these messages with the relevant stakeholders in preparation for the public consultation.

We realize this information cannot be comprehensive and answer all questions. Please feel free to contact us in case you need more information or assistance:
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Sincerely yours,

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Annex:

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/10162/1d2e92dc-c1c6-3baf-8baa-83f61dfb13e2>

SVHC

- RMOA:
<https://echa.europa.eu/rmoa>
- SVHC candidate list
<https://echa.europa.eu/documents/10162/2be7bcbf-f797-c28c-2c67-939664155c7c>
- SVHC legal obligations
<https://echa.europa.eu/candidate-list-obligations>

Authorisation

- Draft background document for octamethylcyclotetrasiloxane (D4):
<https://echa.europa.eu/documents/10162/a737ece5-ca1e-2e13-a097-7ca38c6e2afa>
- Draft background document for decamethylcyclopentasiloxane (D5):
<https://echa.europa.eu/documents/10162/84e15bf2-5bd9-cfba-070e-87d6e097750f>
- Draft background document for dodecamethylcyclohexasiloxane (D6):
<https://echa.europa.eu/documents/10162/5cc7bce1-8822-9be1-096e-abba10516dd2>

Activities outside of Europe

- Australia:
<https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-ii-environment-assessments/cvms#Key>
- Canada
<https://www.canada.ca/en/health-canada/services/chemical-substances/challenge/batch-2.html>
- US
https://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=CASNO&p_value=556-67-2

CES-Silicones Europe

- SVHC statement:
<https://www.silicones.eu/industry-update/statement-the-addition-of-d4-d5-and-d6-to-the-candidate-list-under-reach-is-disproportionate-and-endangers-critical-beneficial-uses/>
- Properties and behaviour of cyclic siloxanes
<https://www.silicones.eu/the-science-behind-silicones-the-substances-used-to-manufacture-them/environment-a-key-priority-for-the-silicones-industry/>
- Monitoring study
<https://www.silicones.eu/industry-update/lorem-ipsum-dolor-sit-amet-consectetur-adipiscing-elit/>
- Toolbox for minimising environmental emissions
https://www.silicones.eu/wp-content/uploads/2019/01/Cyclosiloxanes_Toolbox_Version-Nov-2019.pdf