EU Regulatory update on D4, D5 and D6 (22 June 2018)

This document provides an update on recent European regulatory developments on Cyclosiloxanes D4, D5 and D6 following their listing as Substances of Very High Concern.

Background

Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6) are used to create a diverse range of silicone materials that provide beneficial characteristics to a wide variety of applications and products across sectors, including construction, electronics, engineering, health care, cosmetics and personal care. D4, D5 and D6 are most frequently used as chemical intermediates, meaning that the substances are employed in the manufacturing process but only present at low levels in the end products.

REACH restriction on D4 and D5 – “wash-off” cosmetic products

In January 2018, a restriction on the use of D4 and D5 was published in the EU Official Journal (Regulation (EC) No. 2018/35).
Scope of the restriction: only wash-off cosmetic products with a D4 or D5 concentration equal to or greater than 0.1% by weight of either substance.
The transition period for full compliance by all actors in the supply chain is February 2020.
ECHA is currently assessing whether to add D6 to the scope of this restriction. A proposal to this effect is expected in January 2019.

REACH restriction proposal for D4 and D5 for direct uses in consumer and professional products (no decision taken)

In April 2017, the European Chemicals Agency (ECHA) published a restriction intention addressing D4 and D5 in leave-on personal care products and other consumer/professional products (e.g. dry cleaning, waxes and polishes, washing and cleaning products) in concentrations greater than 0.1%. D6 was later added to this intention. The preparatory work is on-going, with a restriction proposal expected from ECHA in January 2019.

Substances of Very High Concern (SVHC)

In February 2018, Germany filed a dossier proposing that D4 and D5 be identified as Substances of Very High Concern (SVHC) under REACH, on the basis of their Persistent, Bioaccumulative and Toxic (PBT) and very Persistent, very Bioaccumulative (vPvB) properties. ECHA developed a similar dossier for D6 on request of the European Commission.
Public consultation on the three dossiers and referral to the ECHA Member States Committee (MSC) followed.

In spite of the scientific evidence presented, the MSC decided to identify D4, D5 and D6 as SVHCs at their June 12-14 meeting. As a result, the inclusion of these substances in the ‘Candidate list’ has to be expected on 28 June.

The silicones industry strongly believes Candidate Listing of these substances is disproportionate and unjustified. The decision does not take full account of the whole body of scientific evidence, should have recognised already applicable and on-going regulatory activities, and puts at risk numerous beneficial uses including in the healthcare, electronic and energy efficiency sectors.
The evidence demonstrates that these unique chemicals behave differently in the environment from what is predicted under current PBT and vPvB REACH criteria. CES continues to collect real-world monitoring data to further establish that D4, D5, and D6 are not found in the environment at concentrations that merit further regulatory action.

**Consequences of SVHC listing for downstream users**

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.

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

- Silicone manufacturers will need to implement on site, and recommend to downstream users, risk management measures which minimize exposure and emissions, throughout the lifecycle of the substance that results from the manufacture or identified use.
  - To meet this objective, CES – Silicones Europe is currently working with independent experts to produce an emissions management guide, which will be ready in Q4 2018.
  - The relevant safety data sheets will be updated by individual companies without undue delay, as applicable (substances and mixtures, when the substance is individually present at levels ≥ 0.1%).

- Suppliers of articles\(^1\) (final articles as placed on the market after processing and treatment, including those that are part silicone) containing D4, D5, or D6 in a concentration above 0.1% (weight by weight), either intentionally added as an ingredient or present as an impurity), will need to provide sufficient information to their customers (industry, professional users, distributors) to allow safe use of the article. This information must contain as a minimum the name of the substance.

- Consumers can request similar information and have the right to receive an answer within 45 days of the receipt of the request.

- Producers or importers of articles have to notify ECHA if their article contains D4, D5, or D6 in articles totalling over one tonne per producer or importer per year and in a concentration above 0.1% (weight by weight, per substance). The notifications must be submitted no later than 6 months after the inclusion on the candidate list. No notification is 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)

The following website explains the obligations resulting from inclusion of SVHCs in the Candidate List: https://echa.europa.eu/candidate-list-obligations

The following website explains the notification process for substances in articles: https://echa.europa.eu/support/dossier-submission-tools/reach-it/notifying-substances-in-articles

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\(^1\) The ECHA guidance document on substances in articles includes more information to clarify what constitutes an article.
Note that there is no proposal at this time to move the substances to Authorisation List (Annex XIV), which would ban direct, intentional uses of the substances unless an authorisation is granted.

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 and their innovation potential preserved.

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