

## Restriction of D4 and D5 in Personal Care Products in Europe

Octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) have been added to REACH annex XVII restricted substances list (entry 70) by COMMISSION REGULATION (EU) 2018/35 on 10 Jan 2018. D4 and D5 may not be placed on the market in wash-off cosmetic products in a concentration equal to or greater than **0.1%** by weight of either substance, after **31 January 2020**. Note that this refers to the finished formulation – not the amount of D4/D5 in the raw material. All dimethicones and dimethicone-derived products such as silicone glycols and amodimethicones contain some level of D4/D5. The regulation does not apply to non-wash off products.

Substance	Conditions of Restriction
<b>Octamethylcyclotetrasiloxane</b> EC number: 209-136-7, CAS number: 556-67-2	1. Shall not be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0.1 % by weight of either substance, after 31 January 2020.
<b>Decamethylcyclopentasiloxane</b> EC number: 208-746-9, CAS number: 541-02-6	2. For the purposes of this entry, “wash-off cosmetic products” means cosmetic products as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009 that, under normal conditions of use, are washed off with water after application.’

D4 also appears on the Annex II List of Prohibited Substances Prohibited in Cosmetic Products. However, this applies only to the intentional addition of D4. D4 can be present in cosmetic product formulations is when it is technically unavoidable when following good manufacturing practices.

## Why Are D4 and D5 Restricted?

D4 and D5 are cyclosiloxanes mainly used as monomers for silicone polymer production. They also have a direct use in personal care products. D4 has been identified as a persistent, bioaccumulative and toxic (PBT) and very persistent very bioaccumulative (vPvB) substance. D5 has been identified as a vPvB substance.

Due to concerns that D4 and D5 may have the potential to accumulate in the environment and cause effects that are unpredictable and irreversible in the long-term, ECHA’s Risk Assessment (RAC) and Socio Economic Assessment (SEAC) Committees agreed with the UK’s proposal to restrict D4 and D5 in **wash-off personal care products** in June 2016 since they may go down the drain and enter lakes, rivers, and oceans.

## What does this mean for PEL-SIL products?

Because D4 and D5 are present at low concentrations in Elé Corporation’s PEL-SIL products, and because these products are themselves usually only a minor constituent of personal care formulations, it is unlikely in most cases that the 0.1% threshold will be crossed. It is advisable however, to be aware of the D4/D5 content of all raw materials and finished formulations.