CTPA Position on a REACH Restriction on the Cyclic Siloxanes D4, D5 and D6 in Leave-On Cosmetic Products

CTPA is the UK trade association representing all types of companies making, supplying and selling cosmetic and personal care products. The Association's role is to advise member companies about the strict legal framework for cosmetics, to represent industry views to UK Government and external stakeholders and provide the science behind cosmetic products and their safety to the media.

1. Summary

- **An EU REACH restriction on D4 and D5 is already in force in the UK, which limits the maximum concentration of D4 and D5 in wash-off cosmetic products to 0.1%.**
- **D4 is already banned in all cosmetic products (May 2019) owing to a CMR classification.**
- **Emissions of cyclic siloxanes from leave-on cosmetic products form a tiny fraction of emissions to the aquatic environment.**
- **The UK Competent Authority's 2015 Annex XV dossier concluded that a restriction on wash-off products only was sufficient to manage any risk.**
- **Data from environmental monitoring studies demonstrate that the existing restriction on wash-off products has significantly reduced the level of cyclic siloxanes in the aquatic environment.**
- **The proposed EU restriction on leave-on products will further reduce emissions, albeit by a small amount. Further action in the UK is therefore unnecessary.**
- **D5 and D6 are very important ingredients in a wide range of cosmetic products owing to their unique set of properties, which cannot be fully replicated by alternative ingredients. Substituting these ingredients will reduce product performance, and in some cases product availability, with no benefit to the environment.**
- **An understanding of consumer acceptability, and willingness to pay for, the reduction in product performance from a UK restriction of D5 and D6 in leave-on cosmetic products is essential to understand and take into account possible societal costs.**

Implementing a restriction on D4, D5 and D6 on leave-on cosmetic products in the UK will reduce the availability and performance of important cosmetic products for consumers, incur significant costs to business, whilst providing no tangible benefit to the environment.

2. Relative importance of leave-on vs wash-off cosmetic products for emissions of cyclic siloxanes

The Annex XV dossier created by the UK (HSE, 2015) in support of the wash-off REACH restriction on D4 and D5 calculated a "release to waste water of < 1000 tonnes/year for D5 and < 15 tonnes/year for D4 in wash-off Personal Care Products (PCPs), and ca. < 25 tonnes/year for D5 and < 1 tonnes/year for D4 in leave-on PCPs (the figures for leave-on PCPs may be over-estimates)". **Therefore, for D5, emissions from leave-on personal care products only account for approximately 2.5% of the total emissions from personal care products.**

The UK dossier considered that the most appropriate risk to be addressed was from wash-off personal care products, not leave-on personal care products: "The releases from leave-on PCPs are relatively much smaller, and may also be over-predicted … Consequently, the focus of this proposal for EU-wide measures to minimise environmental risks is on wash-off PCPs. Preventing release to water from direct use in wash-off PCPs would reduce releases to surface waters by at least 70 per cent for D4 and 95 per cent for D5."

D4, D5 and D6 tend to be distributed mainly in air (> 95%) and air is considered their final environmental compartment (Bridges and Solomon, 2016). Therefore, it is important to consider if release of these substances to air has any impact on humans or the environment. With substances that are found in the air it is important to consider near- and far-field effects. For near-field and the potential for risk to humans, a number of human health risk assessments have been completed and the safety of D4, D5 and D6 has been confirmed by international regulatory authorities and independent expert panels, including the United States Cosmetics Review Panel (CIR, 2009), Environment and Climate Change Canada and Health Canada (2012, 2019), and the Government of Australia (NICNAS, 2018).

A risk assessment report conducted by Peter Fisk Associates on behalf of Silicones Europe (CES) (Fisk and Gebbink, 2019) which was submitted to the public consultation on the Annex XV dossier, concludes that "given that the substances are PBT/vPvB on the basis of persistence in aquatic sediment, it could be concluded that the 'risk' indicated by ECHA from the substances in the air compartment and the pelagic water compartment are very low and do not merit further regulation to control such a low risk."

ECHA's Annex XV dossier (ECHA 2019) for the leave-on restriction confirms that "Releases to the atmosphere, although relatively greater than those to the aquatic compartment, are not as closely associated with the PBT/vPvB hazard as those releases that occur to the aquatic compartment."

3. Impact of the Wash-Off Restriction on D4 and D5 Emissions

The development of an additional restriction in the UK on leave-on products would need to take into account the reduction in D4 and D5 emissions caused by the existing published restriction on wash-off products.

The cosmetics Industry would like to reiterate the significant decline of emissions to the aquatic environment following the introduction of the D4 and D5 wash-off REACH restriction in January 2018 (2018/35/EC). This is supported by environmental monitoring data submitted to ECHA as part of the public consultation on the Annex XV dossier.

Monitoring data:

The silicone industry had initiated an EU-wide monitoring programme in 2017 to measure the volume of D4 and D5 entering Wastewater Treatment Plants (WWTPs) treating mainly domestic wastewater, which contain releases from the use of personal care products and other domestic and professional products. The programme intended to understand the impact of the wash-off restriction.

The following table presents a comparison of measured releases to WWTPs with estimates in the ECHA Dossier (CES 2019):

	ECHA dossier (tons/year)		**Measured (tons/year)**
	Low	**High**	
D4	19	36	13
D5	140	491	280

Initial results from the monitoring study found that measured releases of D4 were well below the low scenario estimated in the ECHA dossier. This is to be expected following the classification of D4 as a CMR substance under the Classification, Labelling and Packaging (CLP) Regulation and its subsequent ban in cosmetic products, which cosmetic companies had been preparing for since 2016.

The measured tonnages include the contribution from **both** wash-off and leave-on cosmetic products, whereas the estimation in the ECHA dossier only includes leave-on cosmetic products. **Therefore, the ECHA estimates for both D4 and D5 emissions caused by leave-on cosmetic products are overestimated.**

In addition, a pilot study to evaluate the feasibility of sampling and analysing D6 in wastewater was performed in a WWTP in the UK. The concentration in the influent was in the range of 1 µg/l (0.53 – 1.25µg/l).

Habits and practices data:

An assessment was conducted of the fraction of the cosmetic ingredient, D5, that might be released to wastewater following application of those products (Franco and van Egmond 2020). This assessment integrates all available data from the literature as well as the consumer habits and practices in a comprehensive probabilistic exposure assessment.

The report (Crème Global and Cosmetics Europe 2019) estimates that 11700 tonnes of D5 were used in leave-on cosmetic products in 2018. In order to assess the fraction of D5 that is released to wastewater following product application, the following parameters were considered.

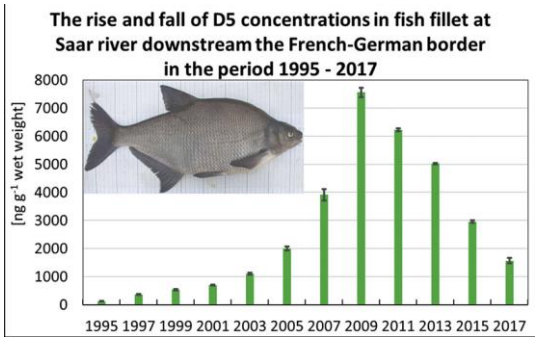
1. Amounts of D5 in leave-on cosmetic products used by the European population.
2. Duration between product application and wash-off.
3. Kinetics of D5 evaporation from skin/hair following product application.

The results of the assessment are as follows:

	Wash-off cosmetics	**Leave-on cosmetics**
Fraction of D5 released to wastewater following application of cosmetics	701.1 t/y (RAC opinion)	43 t/y (Crème-Cosmetics Europe assessment)
Corresponding D5 concentration in influent of wastewater treatment plants	38 µg D5/L (Crème-Cosmetics Europe assessment)	2.3 µg D5/L (Crème-Cosmetics Europe assessment)

The results demonstrate that the emissions from leave-on cosmetic products into wastewater are significantly lower than from wash-off products owing to evaporation of D5 from products during the period they remain on the skin or hair. **Therefore, the already-published restriction on D4 and D5 in wash-off products is the most appropriate risk management measure.**

In addition, a retrospective analysis of cyclic volatile methylsiloxanes in archived German fish samples (Radermacher *et al,* 2020) covering a period of two decades has shown a rise in D5 levels peaking between 2007 and 2011 followed by a rapid decline. **Reformulation of wash-off consumer products may be contributing to this decline.** The downward trend is expected to continue following the deadline for the wash-off restriction which was January 2020. As a result, the cosmetics industry believes that this significant reduction should be taken into account, demonstrating that cosmetic leave-on products are not a significant source of aquatic emissions. **Additional monitoring studies should be conducted prior to instigating any restriction development on leave-on cosmetic products in the UK.**



from Radermacher *et al* 2020

4. Ban of D4 in all Cosmetic Products

D4 is classified under the Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation) as CMR (Reprotoxic) Category 2. CMR substances are banned in cosmetics unless specific exemption criteria are fulfilled. Exemption criteria have not been fulfilled for D4 and **in May 2019, a ban on making available any cosmetic product containing D4 was introduced in the UK and EU.**

5. Reformulation challenges and loss of product performance

D5 and D6 are used across a variety of different leave-on cosmetic products, notably in the skincare, leave-on haircare, and deodorant categories.

Replacing D5 and D6 in different personal care product types needs to be addressed on a case-by-case basis and requires a new formulation approach with the creation of a new product architecture in order to achieve a product which matches the desired performance characteristics and sensory benefits of a specific original siloxane-containing finished product, which is a major reformulation.

Throughout the development of the EU REACH Restrictions, the European cosmetics industry has gathered information on multiple aspects for D5 specifically, including the availability of alternative ingredients. It is clear that there is no universal and direct one-for-one substitute for D5 used in personal care products that could effectively duplicate all the specific product performance characteristics. D5 has a unique combination of properties in regard to its spreadability, smoothness, lack of irritation potential, lack of odour and ideal volatility. Potential alternatives cannot fulfill all of these characteristics. From a safety perspective, several alternatives are unfeasible due to human or environmental safety concerns, or lack of data.

In addition, an industry survey found that in the majority of cases, the unit price of the alternative substances is higher than that of D5.

6. Socioeconomic considerations

A report (Wood 2019) has estimated the cost of the leave-on restriction for the cosmetics sector to be €855 million per year across the EU. This is significantly higher than the €63 to €73 million estimated in ECHA's Annex XV dossier. Costs of a similar restriction in the UK are expected to be proportional to these EU costs.

The report estimates that the reformulation costs associated with a move away from the use of D5 in cosmetic products could be as follows:

	Mean	Low	High
Number of D5-containing products requiring reformulation	26,500	12,600	45,300
Total reformulation cost (€ million)	€3,300	€700	€6,800
Equivalent annual cost (€ million)	€740	€160	€1,530

Source: Reconsile SEA reports

During the development of the UK's Annex XV dossier for a REACH restriction on D4 and D5 in wash-off cosmetic products, the impact of a reduction in product performance in terms of cost was conducted. Such an assessment was not conducted during the development of ECHA's Annex XV dossier for leave-on products. Owing to the lack of one-to-one replacement ingredients and alternative ingredients with the same high performance, **it would be essential to conduct a similar assessment when considering a UK-specific restriction, for a more complete understanding of the socioeconomic costs of a restriction.**

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