Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background Document

to the Opinion on the Annex XV dossier proposing restrictions on
Octamethylcyclotetrasiloxane (D4)
Decamethylcyclopentasiloxane (D5)
Dodecamethylcyclohexasiloxane (D6)

ECHA/RAC/[Opinion No ECHA/RAC/RES-O-0000006700-80-01/F]
ECHA/SEAC/[Opinion No (reference code to be added after the adoption of the SEAC opinion)]

EC Numbers	CAS Numbers
209-136-7	556-67-2
208-764-9	541-02-6
208-762-8	540-97-6

Draft

Version n. 1

5 December 2019

BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON
D4, D5 and D6

Change history

Revision n.	Reason for change	Date	Prepared by
1	The Annex XV restriction report becomes the Background document to RAC and SEAC opinions on D4, D5 and D6. It includes revisions based on the comments received during the consultation.	05/12/2019	Dossier Submitter

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Summary

The cyclosiloxanes octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) are cyclic volatile methyl siloxane (cVMS) substances with four, five and six siloxane groups, respectively. They are manufactured and used in a variety of sectors in the European Economic Area. There are four production sites in the EU, producing up to 200 000 tonnes per annum (tpa) of D4, 50 000 tpa of D5 and 6 000 tpa of D6. The substances are mainly used as monomers for the production of silicone polymers but are also used as substance on their own or in the formulation of various mixtures that are subsequently used by consumers and professionals. The silicone polymers are not specifically targeted by this restriction proposal but they may be inadvertently impacted if they are also found in the same mixtures as the intentionally used substances, or if they are the main component(s) of mixtures covered by the scope of the restriction. D4, D5 and D6 may be impurities in silicone polymers, therefore the impact of a restriction on the uses of D4, D5 and D6, also includes an assessment of the impact on relevant uses of silicone polymers and if necessary action is taken to mitigate any significant impacts.

Since the restriction for D4 and D5 in wash-off[1] cosmetic products, which entered into force on 30 January 2018 and applies from 31 January 2020, the identified uses for the substances have been revised. However, the use in cosmetic products is still the most important one both in leave-on and wash-off products (the latter mainly related to D6). Other, non-cosmetic product uses, include dry cleaning (only for professional use), detergent, household care, and vehicle maintenance products (professional and consumer use), pharmaceuticals (professional and consumer use), medical devices, head-lice treatment (consumer use) and cleaning of art and antiques (professional use).

D4, D5 and D6 were identified by ECHA's Member State Committee as SVHC substances with PBT/vPvB properties. PBT/vPvB substances give rise to specific concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are difficult to reverse even when releases cease. Therefore, the risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way, e.g. by derivation of risk characterisation ratios. Emissions and subsequent exposure, in the case of a PBT/vPvB substance, are therefore considered as a proxy for risk.

The total releases to the environment from the uses of D4, D5 and D6 have been estimated to be approximately 18 000 tpa. The Dossier Submitter has also estimated that the steady-state stock of D4, D5 and D6 that remains in the environment associated with these releases is approximately 500 tonnes. Despite the existing restriction on D4 and D5 in wash-off cosmetics, the wide-dispersive use of D4, D5 and D6 in cosmetic products remains the main source of releases; other uses contribute to overall releases, but are relatively much less significant.

[1] 'Wash-off cosmetic products' means 'cosmetic products' as defined in Article 2(1)(a) of Regulation EC No 1223/2009 that, under normal condition of use, are washed off with water after application. They can be considered as a sub-category of rinse-off cosmetics.

'Rinse-off product' means a cosmetic product which is intended to be removed after application on the skin, the hair or the mucous membranes (Regulation (EC) No 1223/2009 – Preamble to Annexes II to VI). Rinse-off products include wash-off products, but not all rinse-off products are considered to be wash-off products, such as tissues, pads and wipes.

The Dossier Submitter concluded that the risk associated to the use of D4, D5 and D6 in consumers and professional products is not adequately controlled and needs to be addressed. Therefore, an analysis of risk management options (RMOs) was conducted to identify the most appropriate measure to address these risks. The Dossier Submitter has further concluded that action is required on a Union-wide level and that the proposed restriction is the most appropriate measure.

Products containing these substances are formulated and used throughout the EU/EEA, resulting in releases throughout the EU/EEA. Thus, only action on a Union-wide basis would effectively reduce the environmental exposure to D4, D5 and D6 in the EU, limit the potential for trans-boundary exposure to D4, D5 and D6 from EU sources and avoid trade and competition distortions.

The proposed restriction is estimated to cost in total €703 million[2] for cosmetic products, assuming a 5-year transitional period. Best estimates of the cost per kg of releases prevented are €4 for all releases (to air and water) and €1 400 for releases to water alone. The cost per kg of preventing releases that will remain in the environment, which is considered by the Dossier Submitter to be the most appropriate measure for these substances, is estimated to be €104 per kg.

Although significant emission reductions (ca. 90%) could be obtained through the Annex XV restriction proposal on the use of D4, D5 and D6, emissions will not totally cease as releases will remain from uses of silicone polymers where the concentration of D4, D5 and D6 is below the limit proposed in the restriction.

Alternatives to D4, D5 and D6 exist for the majority of the identified uses. The reformulation or transition to alternatives is considered to be feasible if sufficient transition time is given. For a number of consumer and professional uses, there are already alternative mixtures available on the market that do not use D4, D5 and D6. When the use of alternatives would not result in an overall reduction in risk, or where the restriction would appear to be disproportionate from society's perspective, the Dossier Submitter has proposed derogations from the proposed restriction.

The Dossier Submitter has identified several uses of silicone polymers in mixtures that potentially contain relatively high concentrations of D4, D5 and D6 as impurities (mixtures containing silicone polymers used as medical devices and as sealants used in the construction sectors). As these specific applications may be inadvertently impacted by the restriction, the Dossier Submitter is proposing specific and targeted derogations for these applications. Information was submitted during the consultation to allow for the proposal of dedicated concentration limits for some of these applications to ensure they are not affected by the restriction. Information on what would be a suitable concentration limit to avoid these impacts is still lacking for some others. For those uses, the Dossier Submitter considers therefore that the need for a different concentration limit could be further considered if additional information is submitted during the consultation on SEAC's draft opinion to justify it.

The scope of the proposed restriction is clear and unambiguous: it covers the uses of D4, D5 and D6 as a substance or in mixtures used by consumers and professionals. Industrial

[2] 20-year NPV value

uses and use in articles are out of scope.

Standardised laboratory methods for measuring D4, D5 and D6 in cosmetic products (and environmental samples) have been developed in response to the restriction proposal in wash-off products, suggesting that the restriction is practical and monitorable both for cosmetic products and other uses of D4, D5 and D6 in mixtures. In addition, for cosmetic products, a simple preliminary check if the restricted substances are included can already be done by reading the INCI ingredients list on cosmetics packaging. Nevertheless, this label reading should not replace laboratory testing, as this method might not be 100% reliable.

The presence of cosmetics on the market containing D4, D5 and D6 could be monitored using databases or applications such as the ones that were used as sources for this Annex XV report preparation. Mystery shopping campaigns could also be used for the same purposes. Additionally, Voluntary Industry programmes on waste water treatment plants (WWTP) monitoring on D4, D5 could be expanded with D6.

Overall, the proposed restriction is considered to be a balanced, justified and cost-effective measure. The proposed restriction is also considered to be implementable, enforceable, manageable, and monitorable.

Proposed restriction

The proposed restriction aims at expressing the intention of the Dossier Submitter. The final legal wording will be ultimately decided by the European Commission after receiving the Committees' opinions, and should take into account the existence of entry 70 in Annex XVII which is already restricting the use of D4, and D5 in wash-off cosmetics.

Brief title: Restriction of D4, D5 and D6 in consumer and professional products

Proposed restriction:

Designation of the substances, of the group of substances or of the mixture	**Conditions of restriction**
a) Octamethylcyclotetrasiloxane EC Number: 209-136-7 CAS Number: 556-67-2 INCI name: Cyclotetrasiloxane or Cyclomethicone *Also known as D4.* **b) Decamethylcyclopentasiloxane** EC Number: 208-764-9 CAS Number: 541-02-6 INCI name: Cyclopentasiloxane or Cyclomethicone *Also known as D5.* **c) Dodecamethylcyclohexasiloxane** EC number: 208-762-8 CAS number: 540-97-6 INCI name: Cyclohexasiloxane or Cyclomethicone *Also known as D6.*	1. Shall not be placed on the market: a) As substances. b) As constituents of other substances (except polymers as defined under the REACH Regulation (EC) No 1907/2006), in a concentration equal to or greater than 0.1% w/w. c) As constituents in mixtures in a concentration equal to or greater than 0.1% w/w. 2. Shall not be used: a) As a solvent for the dry cleaning of textiles, leather and fur. 3. This restriction shall come into force: a) On DD/MM/YY [at least 5 years after publication in the Official Journal] for (i) leave-on cosmetic products (as defined in the Regulation (EC) No 1223/2009 – Preamble to Annexes II to VI), (ii) medical devices as defined in the Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745 (iii) medicinal products for human health as defined in EU Directive 2001/83/EC . b) On DD/MM/YY [at least 10 years after publication in the Official Journal] for D5 as a cleaning solvent in the dry cleaning of textiles, leather and fur. c) On DD/MM/YY [at least 2 years after publication in the Official Journal] for all other uses. 4. By way of derogation, paragraph 1 shall not apply to: a) Placing on the market of D4, D5 and D6 for the following uses: - Industrial use as a monomer in the production of silicone polymer - Industrial use as an intermediate in the production of other organosilicon substances - Industrial use as a monomer in emulsion polymerisation - Industrial use in formulation and/or (re-)packing of mixtures - Industrial production of articles - Industrial use in non-metal surface treatment - Industrial use as laboratory reagent in Research & Development activities

Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
	b) Placing on the market of D5 and D6 for use as medical devices, as defined in Directive 93/42/EEC or in the Regulation (EU) 2017/745, for the (i) treatment/care of scars and wounds, (ii) prevention of wounds, and (iii) care of stoma. c) Placing on the market of D5 for professional use in the cleaning or restoration of art and antiques. 5. In addition, by way of derogation, paragraph 1 shall not apply to the placing on the market of mixtures that contain silicone polymers with residues of: a) D4 or D5 or D6 in a concentration equal to or less than 1% w/w, for use as adhesives or sealants *that cure in situ* b) D5 in a concentration equal to or less than 0.2% w/w or D6 in a concentration equal to or less than 1% w/w, for use as medical devices (as defined in Directive 93/42/EEC or in the Regulation (EU) 2017/745) for dental impression. c) D4 in a concentration equal to or less than 0.3% w/w for use as protective coatings. d) D5 in a concentration equal to or less than 1% w/w or D6 in a concentration equal to or less than 3% w/w, for (i) rapid prototyping and mould making, and (ii) high performance uses stabilised by quartz filler. e) D4 or D5 or D6 in a concentration equal to or less than 0.2% w/w, for use as medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745. 6. By way of derogation, paragraphs 1 and 2 shall not apply to: a) Use of D5 in strictly controlled closed dry cleaning systems for textile, leather and fur where the cleaning solvent is recycled or incinerated.

Report

1. Problem analysis

1.1. Background

Octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) are cyclic volatile methyl siloxane (cVMS) substances with four, five and six dimethyl siloxane groups, respectively. They are high production volume substances whose hazard assessment and risk management has been subject to ongoing activities within the EU for several years. The key activities and decisions that have preceded the preparation of this Annex XV report are briefly outlined below to provide context and orientation for this report.

In April 2015, at the request of the Executive Director of ECHA[3], the ECHA Member State Committee (MSC) gave an opinion on the persistency and bioaccumulation properties of D4 and D5. The MSC opinion concluded that both D4 and D5 met the REACH Annex XIII criteria for a vPvB substance[4]. This opinion was not a formal SVHC identification, but was used as the basis for the hazard assessment[5] in an Annex XV restriction proposal prepared by the UK, also submitted in April 2015, on the use of D4 and D5 in 'wash-off' cosmetic products. After the proposal was evaluated[6] by ECHA's scientific committees for risk (RAC) and socio-economic analysis (SEAC), the Commission published a decision amending Annex XVII of REACH, adopting the proposed restriction, in January 2018[7,8].

In December 2016, the European Commission requested ECHA[9] to prepare an Annex XV restriction dossier for uses of D4 and D5 in leave-on cosmetics and in other consumer or professional products that were not covered by the UK's proposal[10]. The request from the Commission noted that the evaluation of the UK Annex XV restriction report on wash-off products by RAC had not been able to exclude a potential risk from the use of D4 and D5 in leave-on cosmetic products. These products had been excluded during the development of the UK Annex XV restriction report on wash-off products on the basis that the UK's analysis had considered that releases to the aquatic compartment from these uses were negligible and that releases to air were not associated with a risk that was not controlled. The Commission considered that risks from the use of D4 and D5 in leave on cosmetic

[3] https://echa.europa.eu/documents/10162/13641/annex_1_eds_request_to_msc_on_d4_and_d5_en.pdf

[4] https://echa.europa.eu/documents/10162/13641/art77-3c_msc_opinion_on_d4_and_d5_20150422_en.pdf

[5] D4 also meets the Annex XIII T criterion on the basis of a harmonised classification for toxicity to reproduction (category 2). Therefore D4 is also considered as a PBT/vPvB substance.

[6] https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/9444/term

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0035&from=EN

[8] An application has been submitted to the Court contesting the decision of the European Commission: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62018TN0226.

[9] ECHA is also referred to in the report as the 'Dossier Submitter'

[10] https://echa.europa.eu/documents/10162/13641/echa_commission_request_en.pdf

products needed to be further assessed and, if necessary, a proposal for an additional restriction prepared.

A call for evidence to support the preparation of this second Annex XV dossier was open on the ECHA website from 03/05/2017 to 03/08/2017. Comments were received from various stakeholder organisations, principally Cosmetics Europe and Silicones Europe (CES).

In November 2017, the 17th meeting of the ECHA PBT expert group discussed the bioaccumulation properties of dodecamethylcyclohexasiloxane (D6), a structurally similar cVMS substance, and supported a proposal by the UK that the substance meets the Annex XIII criteria for a vPvB substance[11].

In February 2018, the European Commission requested that ECHA include D6 within the scope of their ongoing Annex XV report preparation for uses of D4 and D5 on the basis that the use of D6 may pose the same risk to the environment and that the uses were, on the basis of the registration dossiers, similar for the three substances[12]. The submission date for the Annex XV report was extended to allow for additional data gathering, analysis and reporting.

A further, supplementary, call for evidence was open between 02/05/2018 and 18/06/2018 to gather additional information on the uses of D6 in consumer and professional products and clarify some additional specific information requests in relation to uses of D4 and D5.

In June 2018, the MSC agreed that D4[13], D5[14] and D6[15] should be identified as SVHC substances and added to the Candidate List[16]. D4 was identified as a PBT/vPvB substance. D5 and D6 were identified as vPvB substances, but were also considered to be PBT substances where the concentration of D4 (as a constituent) exceeded a concentration limit of 0.1 % (w/w). The SVHC proposals for D4 and D5 were prepared by Germany based on the 2015 MSC opinions. The SVHC proposal for D6 was prepared by ECHA based on a UK PBT assessment.

1.2. General approach to the investigation and analysis

This Annex XV restriction report has been prepared according to the requirements of Annex XV of REACH and with reference to applicable ECHA Guidance. The requests to ECHA from the Commission to develop an Annex XV report and the subsequent discussions between them clearly focus the scope of an investigation, and of any subsequent proposal for a restriction, on the following uses:

[11] https://echa.europa.eu/documents/10162/21877836/pbteg-17_report_en.pdf

[12] https://echa.europa.eu/documents/10162/13641/note_to_echa_annex_xv_d6_en.pdf

[13] https://echa.europa.eu/documents/10162/680ea46d-b626-1606-814e-62f843fe2750

[14] https://echa.europa.eu/documents/10162/1b116de3-d5f9-40a2-d681-2e00d3953a7b

[15] https://echa.europa.eu/documents/10162/81c323a0-f0ce-8375-5091-b08d44f35553

[16] An application has been submitted to the Court contesting the decision of ECHA: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62018TN0519.

- Use of D4, D5 and D6 in 'leave-on cosmetic products'.
- Use of D4, D5 and D6 in 'other consumer or professional products' that were not included in the UK Annex XV restriction report, specifically 'rinse-off cosmetic products' that are not washed-off with water (e.g. impregnated tissues, pads and wipes) but also other products and uses e.g. mixtures used for professional dry cleaning as well as household cleaning, care and maintenance products used by consumers.
- Use of D6 in 'wash-off cosmetic products[17]'.

The Commission's request excludes the industrial uses of D4, D5 and D6 from the Annex XV investigation (such as formulation of mixtures, production of silicone polymers, or production of articles), the industrial uses will therefore not be considered as candidates for restriction.

In addition, for clarification, the Dossier Submitter proposes the terms 'consumer' and 'professional' should be understood as follows:

- According to ECHA Guidance on Information Requirements and Chemical Safety Assessment, chapter R.15, a 'consumer product' is defined as a substance, mixture or article that can be purchased from a retail outlet by members of the general public. In the context of this restriction proposal, medicinal products (with and without prescription) are considered as 'consumer products'.
- The Guidance for Downstream Users defines 'professional users' as users who apply substances in a professional capacity which is not regarded as an industrial use. This includes craftsmen, and service providers that may or may not have a fixed workplace or workshop[18].

In addition to leave-on cosmetic products which, on the basis of the various discussions leading up to the Commission's request, were the primary focus of the Dossier Submitter's investigation, the assessment also considered uses of D4, D5 and D6 in 'other consumer or professional products' not covered by the previous UK Annex XV restriction report (on D4, D5 in wash-off cosmetics).

In line with the request from the Commission, the Dossier Submitter has interpreted this to include 'rinse-off' cosmetic products that are not washed-off after use (such as in impregnated tissues, pads or wipes for the removal of make-up). The Dossier Submitter has also assessed other consumer or professional uses of D4, D5 and D6 (as a substance itself, in a mixture or in an article) that were identified from registration dossiers or from stakeholder feedback, such as in medicinal products and medical devices, household

[17] 'Wash-off cosmetic products' means 'cosmetic products' as defined in Article 2(1)(a) of Regulation EC No 1223/2009 that, under normal condition of use, are washed off with water after application. They can be considered as a sub-category of rinse-off cosmetics.

[18] This life-cycle stage covers all activities of a substance carried out by professional workers. These activities do not take place at industrial sites, and hence the nature of exposure stemming from them is different. The potential group of users is large, and the amount used by a single user is typically low compared to industrial use. This life-cycle stage covers, for example, the activities of craftsmen, cleaners, employees in public administration and the self-employed. However, as the term 'professional users' is not defined in the REACH Regulation the Dossier Submitter notes that it is difficult in some circumstances for enforcement authorities to differentiate between professional and industrial uses.

products, car care products, dry cleaning and in the restoration of antiques and artwork. Further details of these uses are presented in subsequent sections of this report.

In addition to uses in consumer and professional products, D4, D5 and D6 are used as monomers for producing a large variety of silicone polymers, which are further used as substances as such, in mixtures and/or as substances in articles. D4, D5 and D6 are not used as substances as such in articles. However, D4, D5 and D6 can be present at low concentrations (<1 % w/w) in mixtures or articles containing silicone polymers as an impurity i.e. with no intended function. Silicone polymers are extensively used across many different industry sectors, including in the construction (sealants, paints and coatings), automotive (parts and lubricants), electronics, pulp and paper, oil and gas, medical and aerospace/defence sectors. Silicone polymers are often present in consumer and professional products including medicinal products, cosmetic products and in household products.

For the purposes of this Annex XV report, the Dossier Submitter will use the term 'impurities' to more clearly differentiate between an intentional use (where the substance imparts a function) and the presence of an impurity in another substance, or article where there is no function. A similar approach was adopted in the UK Annex XV restriction report on uses of D4 and D5 in wash-off cosmetic products where these impurities are referred to as 'indirect uses'.

However, the Dossier Submitter will estimate the releases of D4, D5 and D6 as an impurity from 'downstream' uses of silicone polymers (i.e. mixtures and articles) to allow an assessment of the effectiveness (also referred to as the risk-reduction capacity) of any proposed restriction on consumer and professional uses of D4, D5 and D6 in relation to overall releases.

Any concentration limit proposed as part of a restriction on consumer and professional uses of D4, D5 and D6 (e.g. 0.1 % w/w) could have an impact on consumer and professional uses of silicone polymers in the event that D4, D5 and D6 would be present above the proposed concentration limit. The concentration limit could also, indirectly, have impacts on the upstream (industrial) uses of D4, D5 and D6 to produce silicone polymers (where it could result in increased requirements for polymer purification, for example). As these are considered to be relevant impacts of a proposed restriction the Dossier Submitter has investigated and assessed these impacts.

In addition, it should be noted that according to the REACH Regulation the identification of D4, D5 and D6 as SVHC substances on the basis of their PBT/vPvB properties obliges manufacturers/importers to implement on site, or recommend to downstream users, risk management measures which minimise exposure and emissions to humans and the environment, throughout the lifecycle of the substance that results from the manufacture or identified use (REACH Annex I, Paragraph 6.5). In addition, the 'right to know' in relation to the presence of SVHC in articles could provide a further incentive to minimise the concentration of D4, D5 and D6 of in articles (REACH Article 7(2) and REACH Article 33).

These existing obligations are relevant to the assessment of the impacts of any proposed restriction and the Dossier Submitter has taken these into account, where relevant.

1.3. Identity of the substance(s), physical and chemical properties

1.3.1. Substance identification

Table 1: Name and numerical identifiers of D4, D5 and D6

	EC number	CAS number	IUPAC name
D4	209-136-7	556-67-2	2,2,4,4,6,6,8,8-octamethyl-1,3,5,7,2,4,6,8-tetraoxatetrasilocane
D5	208-764-9	541-02-6	2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentoxapentasilecane
D6	208-762-8	540-97-6	2,2,4,4,6,6,8,8,10,10,12,12-dodecamethyl-1,3,5,7,9,11-hexaoxa-2,4,6,8,10,12-hexasilacyclododecane

1.3.2. Physical chemical properties

The physical chemical properties most commonly found in the literature are summarised in Table 2 below.

Table 2: Summary of physical chemical properties for D4, D5 and D6

	D4	D5	D6
Molecular weight range	296.6158 g/mol	370 g/mol	444.92 g/mol
Vapour Pressure	132 pa at 25°C	33.2 Pa at 25 °C	4.7 Pa at 25 °C
Water solubility	0.056 mg/L at 23 °C	0.017 mg/L at 23 °C	0.0051 mg/L at 23 °C
K_{OW} (log10 value)	6.49 at 25.1 °C	8.023 at 25.3 °C	8.9 at 23.6 °C
Koc	Log Koc 4.22	Log Koc 5.17	Koc = 7.9E+05 at 20 °C
Henry's law constant	1.21 × 10^6 Pa.m^3/ mol at 21.7°C	3.34 × 10^6 Pa.m^3/ mol at 24.6 °C	2.52 × 10^6 Pa.m^3/ mol at 23.6°C
K_{AW} ((log10 value) Air/water partition coefficient	2.69 at 21.7 °C	3.13 at 24.6 °C	3.01 at 23.6°C
Biodegradability screening test	Under test conditions no biodegradation observed		
Comment	Although log KOW is an important surrogate property for environmental fate assessment, measured data for key end points (e.g. bioaccumulation) are available and therefore preferred.		

Source: UK Annex XV restriction report (UK, 2015)*, MSC opinions of the identification of substances as PBT/vPvB* (ECHA MSC, 2018b) (ECHA MSC, 2018c) (ECHA MSC, 2018a)*, Registration data available from the ECHA website accessed on 26 October 2018*

1.4. Manufacture and uses

1.4.1. Manufacture

According to information in registration dossiers (published on the ECHA website - data extraction on 10/09/2018), the registered tonnage for the substances are as follows:

- Octamethylcyclotetrasiloxane (D4): 100 000 – 1 000 000 tonnes per annum (tpa)
- Decamethylcyclopentasiloxane (D5): 10 000 – 100 000 tpa
- Dodecamethylcyclohexasiloxane (D6): 10 000 – 100 000 tpa

Forty eight registration dossiers have been submitted for D4, 29 for D5 and 11 for D6. By way of a comparison, there were eight registrations for D4 and seven for D5 in 2015 when

the UK was preparing the Annex XV restriction proposal for the use of D4 and D5 in wash-off cosmetic products.

According to registration dossiers, there are four production sites in the EU, producing up to 200 000 tpa of D4, 50 000 tpa of D5 and 6 000 tpa of D6.

1.4.2. Summary of information on uses

1.4.2.1. Information from REACH registrations

Since the preparation by UK of the Annex XV restriction proposal for D4 and D5 in wash-off cosmetic products, the REACH registrants have significantly revised the lists of identified uses for the substances.

The major changes are related to the uses of D4 and D5 in wash-off cosmetic products. In the most recent updates to registration dossiers[19], both the formulation and professional/consumer uses have been removed and replaced by a 'post restriction' scenario (D4 and D5 in wash-off cosmetic only as residual in silicone polymers in a concentration < 0.1%).

In addition, several uses of D4 and D5 have been removed from registrations on the basis that these are now understood not to be uses of the substances as such, but rather uses of silicone polymers that contain residual levels of D4 and D5 as impurities, e.g.:

- Use in electronics applications
- Use of products containing D5 in the textiles industry
- Use in sealants
- Use in coatings
- Use in pulp and paper industry
- Use in oil drilling sector

Instead, a generic use/exposure scenario describing the use of silicone polymers containing residual amounts of monomer has been introduced in the registration of D4 and D5. However, no specific details are provided on the share of silicone polymers used across different sectors, nor the types of silicone polymers that result in releases to the environment (and if there are differences in the releases that occur from different applications).

It should also be noted that the registrants have refined the tonnage associated with some uses. While the tonnage associated with the use in leave-on cosmetic products remains in the same order of magnitude, the total tonnage of D5 in dry cleaning has decreased by 90 percent in the latest registration dossiers (i.e. from <500 tpa to 50 tpa).

1.4.2.2. Information from ECHA call for evidence and other stakeholder discussions

In addition to the information contained in the registration dossiers, the Dossier Submitter has gathered additional information on the uses, releases and exposure via two calls for

[19] D4 joint CSR submitted by the lead on 18 July 2018, and on 6 July 2018 for D5.

evidence, a 'mystery shopping' exercise (COWI, 2018) and a market research exercise (where more than 100 stakeholders were contacted). Further information has also been provided by various actors in the D4, D5 and D6, supply chain, including suppliers, formulators and downstream users.

Additional information has also been obtained from several national consumer associations i.e. Que Choisir in France (Que Choisir, 2018), Forbrugerrådet Tænk in Denmark (Danish Consumer Council THINK Chemicals, 2018) and the Nordic Swan ecolabel (Nordic Swan Ecolabel, 2018). The Dossier Submitter had also acquired an extensive dataset of cosmetic products and their ingredients from CosmEthics (CosmEthics, 2018).

Through these various consultations, ECHA has identified a new (i.e. non-registered), use of D4 and D5 for the cleaning and restoration of art and antiquities. The use of D4, D5 and D6 in firefighting foams was discussed with industry stakeholders and, although it cannot be definitively ruled out based on these discussions, at present there is no indication that D4, D5 and D6 is used in these products.

Further details on stakeholder consultation is available in Annex E.

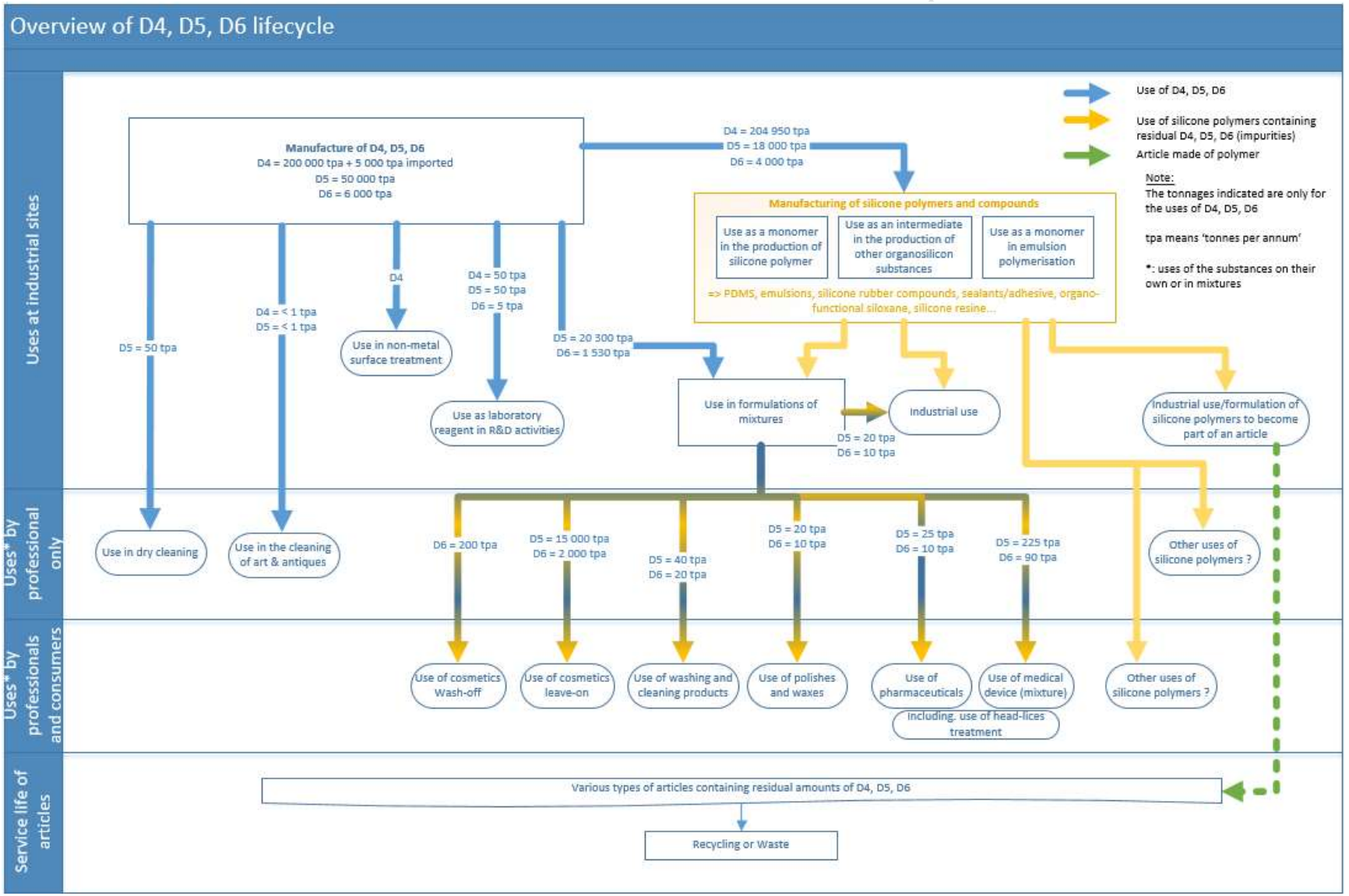
1.4.2.3. Uses overview of D4, D5 and D6 reported in Europe

The major use of D4 and D5 and, to a lesser extent, D6 is as a feedstock (i.e. monomer) for the production of various type of silicone polymers. These silicone polymers have a wide range of uses in industrial, professional and consumer products, including in or as articles.

Other uses of D4, D5 and D6, either as a pure substance or as a component of a mixture, are limited to a relatively low number of specific applications, each of which are further described below (e.g. cosmetic products), as well as in Section 2 of this Dossier. Use in cosmetic products is the most important of them in terms of tonnage.

The life-cycle of D4, D5 and D6 is presented in Figure 1. For completeness, industrial uses such as manufacturing, and formulation into mixtures are presented.

Figure 1: Overview of the lifecycle of D4, D5 and D6



1.4.3. Uses of D4, D5 and D6 in professional and consumer products

The uses of D4, D5 and D6 (as substances as such, or in a mixture) in consumer and professional products in the EU are summarised and presented in Table 3 below. This includes both registered and non-registered uses. The term use refers to where D4, D5 and D6 is intentionally present to impart a function.

Use in cosmetic products is the most important of them in terms of tonnage, and will therefore be further detailed below. Elaborated descriptions of the other, non-cosmetic product uses, are included in the relevant sections of the impact assessment.

During the consultation (#2344), the Dossier Submitter has been informed that Rigid PU foam was not a use of D5, and that the registration dossier will be updated accordingly. This use has therefore been removed from the list of uses.

Table 3: Uses of D4, D5 and D6

Use	D4	D5	D6	Comments
Dry cleaning		✓		Only for professional use
Leave-on cosmetic products	✓	✓	✓	Professional and consumer use According to Registrants and Cosmetics Europe, D4 is not used by the European cosmetics industry. Nevertheless, market surveys performed by the Dossier Submitter have demonstrated the presence of D4 on the labelling of cosmetics placed on the market in Europe.
Wash-off cosmetic products			✓	Professional and consumer use Restriction implemented re. the use of D4 and D5 in wash-off cosmetics (EIF 31.01.2018)[20]
Detergent, household care, and vehicle maintenance products		✓	✓	Professional and consumer use It includes liquid formulations as well as waxes and polishes.
Pharmaceuticals[21]		✓	✓	Professional and consumer use It is not always easy to distinguish between a pharmaceutical and a medical device (especially for topical uses), therefore the three uses will be assessed together as 'pharmaceutical products and medical devices'
Medical devices		✓	✓	
Head-lice treatment		✓		
Cleaning of art and antiques	✓	✓		Only for professional use

[20] (EU) 2018/35 - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0035&from=EN

[21] REACH title VIII (Restriction) is applicable to medicinal products and medical devices (no exemption granted according to REACH Article 2)

1.4.3.1. Cosmetic products (D4, D5 and D6)

EU Cosmetics Regulation allocates cosmetic products into one of two groups, based on how they are intended to be used: leave-on products[22] and rinse-off products[23]. This distinction underpins how their safety for consumers is assessed.

Ingredients[24] in cosmetic products are identified using 'INCI names' (International Nomenclature Cosmetic Ingredient). INCI names are systematic names that are internationally recognised to identify cosmetic ingredients. They are developed by the International Nomenclature Committee (INC) and published in the International Cosmetic Ingredient Dictionary and Handbook, as well as in the European Cosmetics Ingredient database (COSING).

D4, D5 and D6 are identified with the following INCI names:

- cyclotetrasiloxane for D4
- cyclopentasiloxane for D5
- cyclohexasiloxane for D6
- cyclomethicone for a blend of D4, D5 and D6 (cf. Annex B; Johnson et al., 2011).

D4, D5 and D6 are odourless, colourless, non-oily fluids that perform three main technical functions in cosmetic products: hair-conditioning agents, skin-conditioning agents (emollient) and a solvent/diluent. The use of D4, D5 and D6 in products is reported to allow the products to spread smoothly and easily on the skin or on hair, providing a silky, luxurious feel during application. They are often used as a carrier/delivery system to uniformly deliver other substances contained in the formulation (e.g. in hair spray gloss, sun-screen, deodorant and antiperspirants) (Gruber James V., 1999).

As a consequence of their high volatility, the use of D4, D5 and D6 in cosmetics products results in rapid product drying (CfE1#465 and CfE2#791), which is a beneficial property; particularly for deodorants and skin-care products.

The use of D4 and D5 in wash-off cosmetic products[25], which can be considered as a sub-category of rinse-off cosmetic products, has already been restricted under REACH. Therefore, these uses are not considered further in this report. However, the use of D6 in

[22] 'Leave-on product' means a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes (Regulation (EC) No 1223/2009 – Preamble to Annexes II to VI).

[23] 'Rinse-off product' means a cosmetic product which is intended to be removed after application on the skin, the hair or the mucous membranes (Regulation (EC) No 1223/2009 – Preamble to Annexes II to VI). Rinse-off products include wash-off products, but not all rinse-off products are considered to be wash-off products, such as tissues, pads and wipes.

[24] 'Ingredient' means any substance or mixture intentionally used in the cosmetic product during the process of manufacturing. The following shall not, however, be regarded as ingredients: (i) impurities in the raw materials used; and (ii) subsidiary technical materials used in the mixture but not present in the final product.

[25] 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.

these type of cosmetic product is assessed as it is not presently restricted for that use.

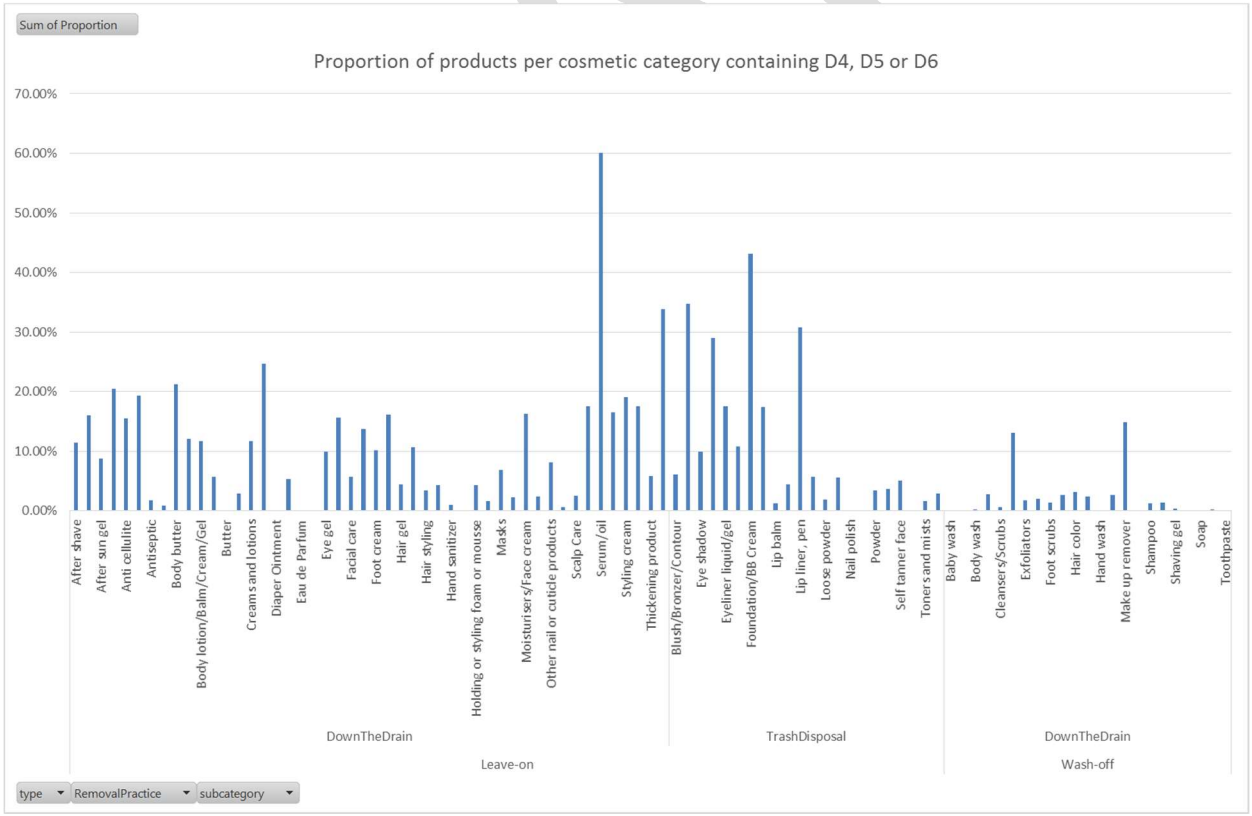
According to the information provided by Cosmetics Europe (CfE1#465), D4 is only infrequently used as an ingredient in cosmetic products, although it is present as an impurity of other raw materials, i.e. D5, D6 and silicone polymers (cf. details in Annex A and B).

Nevertheless, the ECHA mystery shopping exercise (COWI, 2018), as well as the information gathered from consumer associations (Que Choisir, 2018; Danish Consumer Council THINK Chemicals, 2018); CosmEthics, 2018) have consistently reported the presence of D4 on the labels of cosmetic products placed on the market in Europe, as well as the presence of cyclomethicone, which is a blend of D4, D5 and D6 according to the European Cosmetics Ingredient database (COSING) maintained by the European Comission.

D5, conversely, is widely used in certain leave-on cosmetic product categories as a substance. D6 is also used in certain categories of rinse-off and leave-on cosmetics, but to a lesser extent than D5.

Figure 2 below gives an overview of the proportion of products per cosmetics category containing at least one of the cyclosiloxanes. This information was gathered during the market research exercise and is consistent with information provided by Cosmetics Europe in their response to the call for evidence (CfE1#465). Detailed figures are available in Annex A.

Figure 2: Proportion of products per cosmetics category containing D4, D5 and D6



Source: Based on data from CosmEthics (CosmEthics, 2018). *Data are broadly consistent with data provided by*

other stakeholders (COWI, 2018; Que Choisir, 2018; Danish Consumer Council THINK Chemicals, 2018)[26]

In addition, Table 4 gives an overview of the maximum concentration encountered in certain types of cosmetic products.

Table 4: Concentration of D5 and D6 in cosmetic products categories

	Use of D5 (excluding wash-off products)		**Use of D6 (rinse-off and leave-on products)**
Product category	Median reported average concentration (%w/w) [1]	Maximum concentration reported (%w/w) [1]	Maximum concentration reported (%w/w) [2]
Skin care products	5 %	90 %	18%
Make up and make up removing products	10 %	90 %	18%
Deodorant and antiperspirants	10 %	60 %	18%
Hair care (leave-on)	20 %	95 %	18%
Others [3]	5 %	75 %	50 %
Wash-off	NA	NA	18%
Wipes	No information	No information	8 %

Source: Cosmetics Europe ((CfE1#465) and (CE, 2018b)*) and literature review* (Johnson et al., 2011)

Notes:

[1]: information provided by Cosmetics Europe (CfE1#465) based on a survey to Cosmetics Europe members performed mid-2017, covering the year 2016. 75 companies, representing 64% of the EU cosmetics market, participated in the survey. The max concentrations indicated are in line with the US assessment report for D5 (Johnson, 2009)*.*

[2]: information provided by Cosmetics Europe (CE, 2018b) *based on a survey to Cosmetics Europe members performed in 2018, covering the year 2017. 29 companies, including SMEs and nine major multinational companies participated in the survey. The max concentrations indicated are in line with the US assessment report for D6* (Johnson, 2009) *which was indicating a maximum concentration of 48%.*

[3]: this includes products intended for application on the lips, sun protection products, products for tanning without sun, etc.

1.4.3.2. Other uses

For brevity, the other identified uses of D4, D5 and D6, other than in cosmetic products, are further detailed in the relevant sections of Section 2 on impact assessment.

1.4.4. Uses of silicone polymers

The term silicone polymers refers to silicone fluids, emulsions, elastomers, rubbers, gels and resins. These various silicone polymer types have a very wide range of uses in many thousands of applications, including as rubber; elastomers; for coatings and sealants; antifoams; flow and/or gloss improvers in alkyd paints and varnishes; softening, waterproofing and wetting agents in textile manufacturing; components of polishes and

[26] Information gathered during the ECHA market study from four different sources between February and October 2018 (CosmEthics, 2018; COWI, 2018; Que Choisir, 2018; Danish Consumer Council THINK Chemicals, 2018). The data from the different sources are broadly consistent. It was also assumed that the uses of the substances would be identified on cosmetic product labels by the following INCI names: cyclotetrasiloxane or cyclomethicone for D4, cyclopentasiloxane or cyclomethicone for D5, and cyclohexasiloxane or cyclomethicone for D6.

other surface treatment formulations; lubricants, greases, anti-adhesion coatings and mould release agents; paper coatings; hydraulic, dielectric and heat transfer fluids; and consumer products such as personal, household, and automotive care products (Andriot et al., 2007).

Silicone polymers may be modified with specific functional groups for a myriad of additional applications. Silicone polymers are used to manufacture articles or parts of articles.

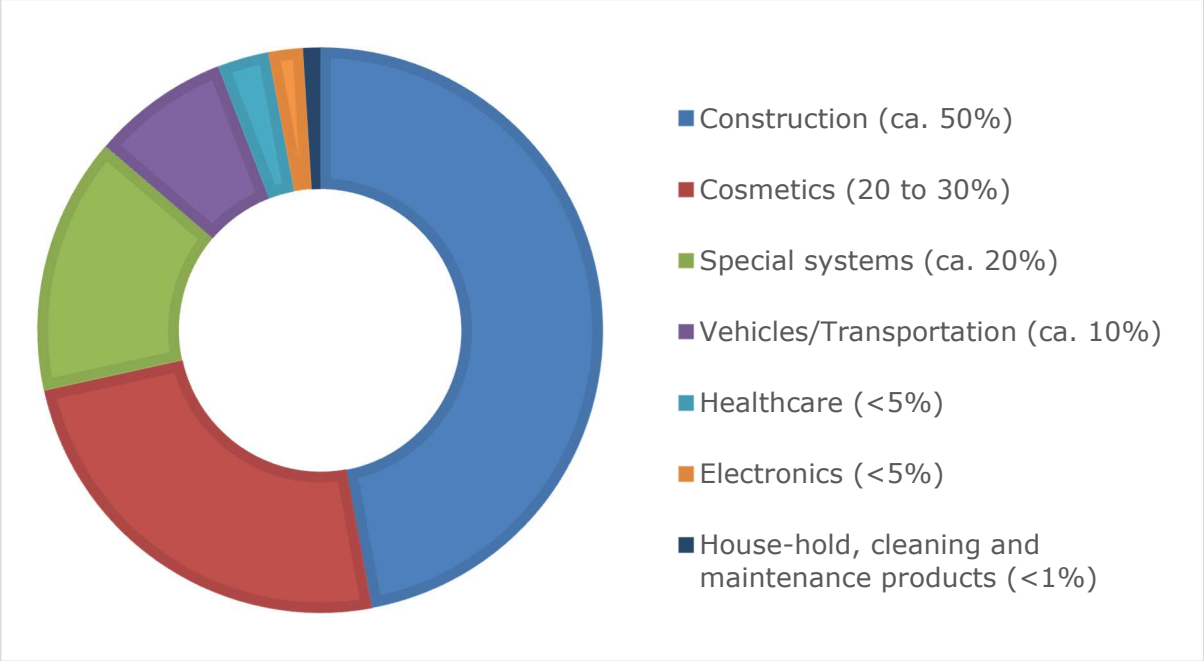
Since D4, D5 and D6 are key monomers used to produce silicone polymers, and due to the character of the thermodynamic equilibrium of the condensation-polymerisation process for poly(dimethyl)siloxanes, it is not technically possible to produce silicone polymers with 'zero content of D4, D5 and D6' using conventional production techniques (CfE2#788; CES, 2018b).

In addition, under certain conditions (high temperatures, presence of certain types of fillers), silicone polymers can break down resulting in low concentration of D4, D5 and D6; within the polymer matrix. This is termed a 'reversion process' (CES, 2018b; Camino et al., 2001; Camino et al., 2002).

Therefore, as a result of both of these processes, silicone polymers can contain residual impurities of D4, D5 and D6 and potential release these to the environment.

According to a recent study (AMEC, 2016) on the basic silicone polymers market in Europe, the main consumer and professional uses of silicone polymers can be divided among seven different sectors, as depicted in Figure 3. The uses of silicone polymers in the different sectors are further described in Section 2.7. These uses can also overlap with the intentional uses of the substances.

Figure 3: Split of EU silicone polymer uses between sectors



Source: Graph based on publicly available Global Silicones Council report (AMEC, 2016)

1.5. Risk assessment

1.5.1. Classification and labelling

D4 has a CLP harmonised classification and labelling (index number: 014-018-00-1).

Table 5: Harmonised classification of D4

Hazard class and category	Hazard statement
Repr. 2	H361f***: Suspected of damaging fertility
Aquatic Chronic 4	H413: May cause long-lasting harmful effects to aquatic life

Source: Annex VI to CLP Regulation (EC) 1272/2008

In addition, an update of the harmonised classification and labelling is currently on-going (RAC opinion adopted in March 2018, ATP[27] expected to be published in 2020), which would lead to a D4 classification as Aquatic Chronic 1 (H410) instead of Aquatic Chronic 4 (H413). In addition an M factor (chronic) is proposed to be set to 10.

Despite its harmonised classification as a Reprotoxic category 2, D4 was not banned until now in cosmetics nor restricted according to the Cosmetics Regulation. In 2005, the SCCS (the Scientific Committee for Consumers Safety) concluded that they were:

> *"unable to assess the risk to consumers when octamethylcyclotetrasiloxane (D4) is used in cosmetic products* (SCCS, 2005). *Despite the size of the dossier submitted by industry for evaluation, it is unfortunate that the dossier lacked meaningful information/data on actual consumer exposure to D4".*

In 2010, the SCCS concluded after further investigations that cyclomethicone (D4, D5) used in cosmetics products does not pose a risk for human health. No conclusion was reached for D4 alone (SCCS, 2010).

However, immediately prior to the submission of this Annex XV report, the Dossier Submitter was informed by the Commission that a decision was made in December 2018 to prohibit the use of D4 in cosmetic products[28]. Annex II of the Cosmetic Regulation will therefore be amended. Its adoption is foreseen in May 2019 with no transitional period.[29]

Self-classifications have also been notified to ECHA. The self-classifications are summarised in Table 6.

[27] Amendments to the Regulation on the classification, labelling and packaging of substances and mixtures (CLP), including harmonised C&L, are published via ATP (adaptation to technical and scientific progress).

[28] Early January 2019, a draft Omnibus Regulation amending Annexes II, III and V to the Cosmetics Regulation has been voted and was under scrutiny by the European Parliament and the Council (RegCom number: D054047/05).

[29] This analysis was performed before this decision came to our knowledge. However, given the assumptions used in the analysis (that D4 is not used in cosmetic products), this decision does not affect the conclusions indicated in this Annex XV report.

Table 6: Self-classifications notified to ECHA

Substance	Total number of notifications	Self-classification reported[30]
D4	3 234	Flammable liquid 3 (ca. 75%)
		Aquatic chronic 2 (ca. 5%)
D5	2 930	Aquatic chronic 4 (ca. 5%)
		Eye irritation 2 (ca. 2%)
D6	265	Aquatic chronic 4 (ca. 8%)
		Eye irritation 2 (ca. 8%)

Source: ECHA dissemination website accessed on 14 September 2018

1.5.2. Hazard assessment

On 27 June 2018, D4, D5 and D6 were added to the Candidate List of substances of very high concern (SVHCs) for authorisation on the basis of their PBT/vPvB properties. D4 was identified as a PBT/vPvB substance (ECHA MSC, 2018d). D5 and D6 were identified as vPvB substances, but were also considered to be PBT substances where the concentration of D4 (as a constituent) exceeded a concentration limit of 0.1 % w/w (ECHA MSC, 2018e; ECHA MSC, 2018f).

Further details as the basis for these conclusions are available in the corresponding decisions of the ECHA MSC and support documents available on the ECHA website. Readers are referred directly to these documents for additional information[31].

As D4, D5 and D6 have been identified as having vPvB properties, REACH Annex I paragraph 6.5 requires registrants to implement on site, and recommend to downstream users, risk management measures which minimise exposure and emissions to humans and the environment, throughout the lifecycle resulting from manufacture or identified uses.

1.5.3. Releases to the environment

Releases to the environment from the identified consumer and professional uses of D4, D5 and D6 have, where possible, been estimated quantitatively. This includes releases occurring both from the uses of D4, D5 and D6 as such and also uses of silicone polymers (containing residual amounts of D4, D5 and D6).

The industrial uses of D4, D5 and D6, including formulation uses, are *per se* outside of the scope of this Annex XV report. Nevertheless, in case of a restriction on professional and consumer uses, this will have consequences on the upstream supply chain, i.e. the releases during the formulation life-cycle stage for such uses will be avoided. Therefore, releases from the associated formulation steps have been quantified to assess the impacts of any restriction. Releases related to the manufacture of D4, D5 and D6 as a substance have not been explicitly quantified, as releases from these uses are considered to be negligible as a result of existing operating conditions and risk management measures in place to limit

[30] The proportion of notifications that have reported the self-classification are presented in parenthesis.

[31] D4: https://echa.europa.eu/documents/10162/680ea46d-b626-1606-814e-62f843fe2750

D5: https://echa.europa.eu/documents/10162/1b116de3-d5f9-40a2-d681-2e00d3953a7b

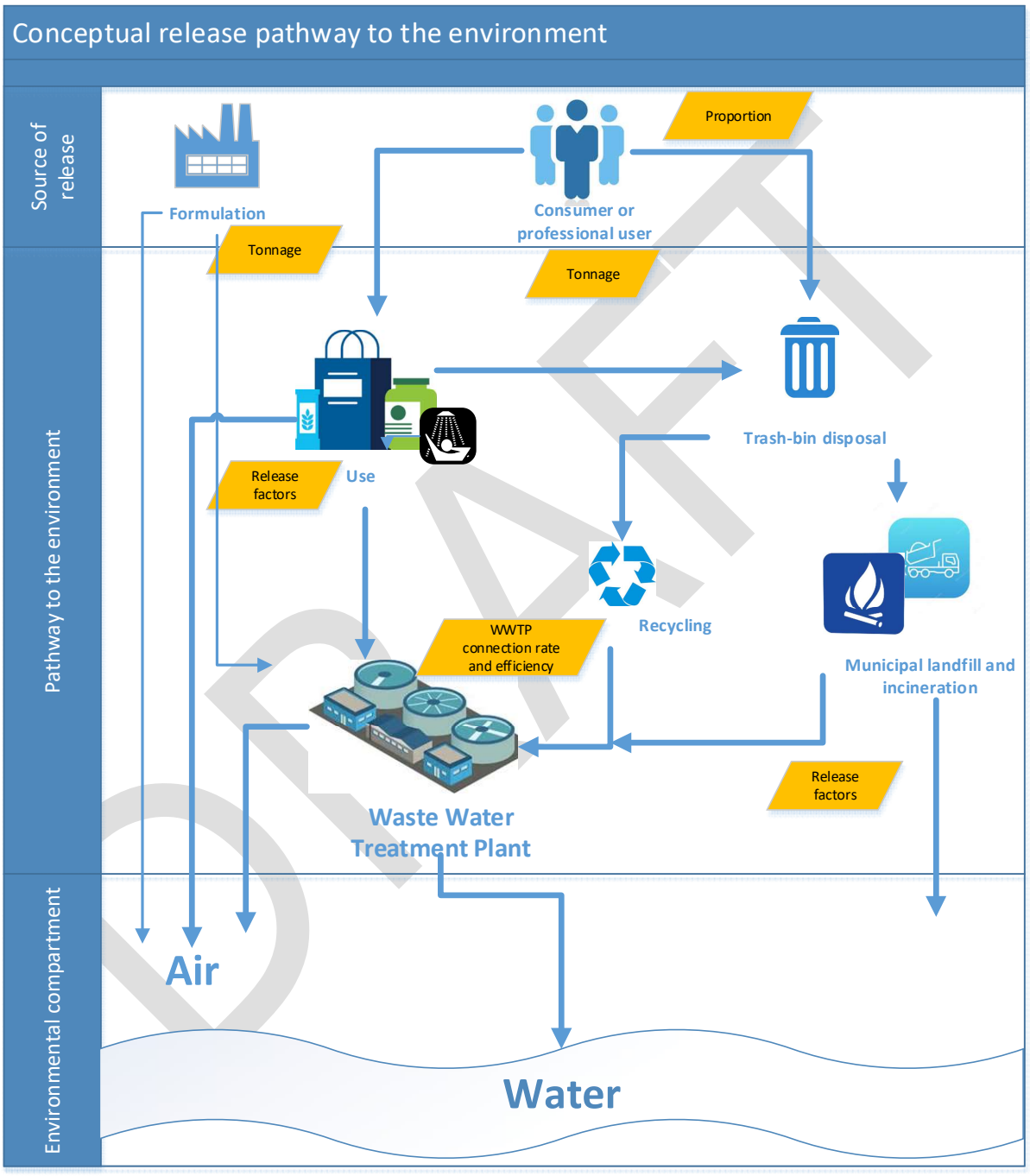
D6: https://echa.europa.eu/documents/10162/81c323a0-f0ce-8375-5091-b08d44f35553

releases to the environment from these sites.

1.5.3.1. Sources and pathways into the environment

D4, D5 and D6 can be released to the environment. The conceptual release and pathways to the environment of D4, D5 and D6, are described in a simplified manner in Figure 4.

Figure 4: Conceptual source, pathway, receptor relationships for uses of D4, D5 and D6



The calculation of releases to the aquatic and air compartments for the various consumer or professional use are based on the following elements:

- The quantity of D4, D5 and D6 used (*TONNAGE*)

- The relevant behaviour of consumers and professionals in terms of product use, including how products are removed from skin and disposed after use (relevant for cosmetic products only) (*RELEASE FACTOR*)
- Where relevant, consumer behaviour in terms of the disposal of unused/out of date products, or product packaging after use (such packaging can contain residual D4, D5 and D6) *(PROPORTION)*
- Waste water treatment plant connection rate *(WWTP connection rate)*
- The partitioning of D4, D5 and D6 during wastewater treatment (i.e. to air/sludge) and the efficiency of degradation, which is different for each substance *(WWTP efficiency).*
- The waste disposal route for articles and product packaging containing residual D4, D5 and D6 (e.g. municipal landfill, municipal incineration or recycling)

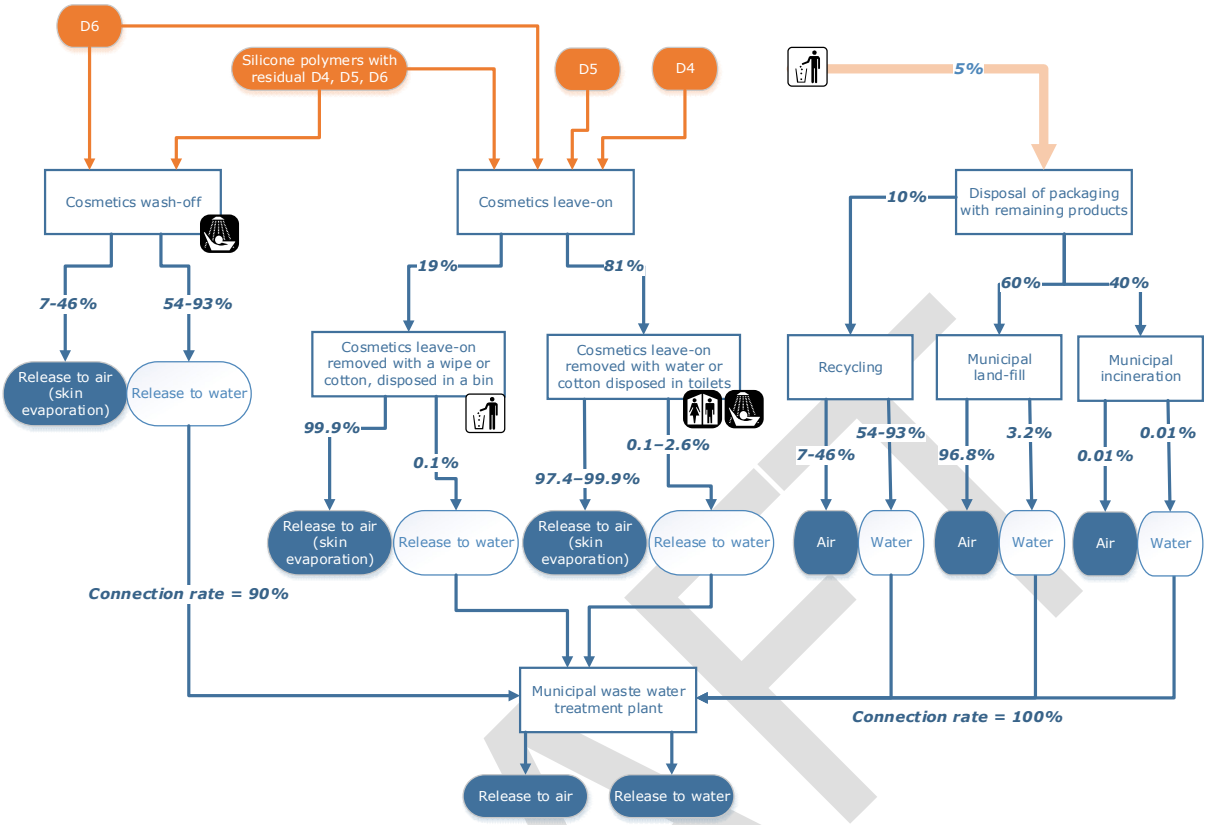
These criteria vary depending on the use and are further described for each use in Annex D. As a range of release factors are reported for some of the sources of releases a series of scenarios were used to characterise the implications of this uncertainty on the release estimates. These scenarios also differentiate to which compartment releases occur, and are further outlined below.

Cosmetic products

In terms of non-intermediate tonnage, the use in cosmetic products is the single most important use of D4, D5 and D6. Recognising the significance of this sector, the sources of release and pathways to the environment for uses of D4, D5 and D6 for cosmetic products are exemplified in below. The release factors applied at each point were identified from various sources, including previous relevant risk management assessments (i.e. those reported in the combined RAC and SEAC opinion on the UK proposal for a restriction on the use of D4 and D5 in wash-off cosmetic products) together with information on consumer behaviour in terms of removal and disposal of leave on cosmetic products after use.

Further information and justification for the selection of release factors for cosmetic products, as well as for the other uses of D4, D5 and D6 assessed, are provided in Annex B.

Figure 5: Conceptual release pathways for consumer and professional uses of cosmetic products



1.5.3.2. Estimated releases

Total releases are reported in two scenarios:

1- **Releases to the aquatic compartment only** (which was the approach adopted by UK in the restriction dossier for D4 and D5 in wash-off cosmetic products) – *'low release' scenario*

2- **Releases to all compartments** (aquatic and atmospheric) – *'high release' scenario*

These two scenarios represent 'low' and 'high' releases scenarios, respectively. The rationale for including/excluding certain compartments from the release estimates in each of the two scenarios recognises the specific fate and behaviour of D4, D5 and D6 in the environment.

Without prejudice to the requirement to minimise releases of PBT/vPvB substances to the environment detailed in Annex I of REACH, the scenarios developed in this assessment acknowledge that D4, D5 and D6 have been identified as PBT/vPvB substances based on their properties in the aquatic compartment. Therefore, releases to this compartment are most well understood to be associated with the PBT/vPvB hazard and potential for risk. 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. As such, the relevance of releases to the atmosphere to the principal benefits of the restriction (the abatement of releases that will result in persistence in the aquatic compartment), and as such their 'weight', could be

considered to be different. This element of the assessment is elaborated in Section 0 of the report.

In addition, within each scenario, a lower and upper range of releases is reported in order to take into account (i) the upper and lower bound release factors adopted by the RAC during their evaluation of the previous restriction proposal on the use of D4 and D5 in wash-off cosmetic products and (ii) the most recent information on releases reported in registration dossiers. Indeed, following the previous restriction proposal on the use of D4 and D5 in wash-off cosmetic products, industry has carried out new measurement campaigns and updated their CSRs. The information on releases (release factors) provided in the most recent CSRs is different from the release factors adopted by RAC, although only modestly different.

Detailed information on the assumptions used to estimate releases for each use is available in Annex D. As there are a number of uncertainties in the input parameters used for calculating releases, a sensitive analysis has been made and is reported in Section 3.

Estimated total releases of D4, D5 and D6, including the releases from the residues in the silicone polymers, are shown in Table 7, and were found to be between 63 and 153 tpa in the 'low release scenario', and between 17 994 and 18 485 tpa in the 'high release scenario'.

Use in cosmetic products contribute the most to overall releases to the environment, irrespective of the scenario. These uses represent 91% of the overall releases, or up to 94% of the total releases when the releases from impurities in silicone polymers used in cosmetic products are also considered.

Table 7: Releases estimates per use

Use	**Use tonnage** [tpa]	**Low release scenario** (water only) [tpa]	**High release scenario** (all compartments) [tpa]
Leave-on cosmetic products (D5 and D6)	17 000	7 - 50	16 399 – 16 641
Pharmaceutical products and medical devices (D5 and D6)	350	6 - 11	273 - 305
Wash-off cosmetic products (D6)	200	12 - 20	55 - 114
Detergents, household care and vehicle maintenance products (D5 and D6)	90	3 - 6	50 - 66
Dry cleaning (D5)	50	0 - 0	46 - 46
Cleaning of art and antiques (D4 and D5)	0.3	–ca. 0	–ca. 0.3
Formulation of mixtures[1]	-	0 - 1	5 - 8
Impurity in silicone polymers[2]	1 613	26 - 50	597 - 707
Impurity in silicone polymers used in cosmetic products	638	6 - 12	567 - 595
Grand Total	**19 940**	**63 - 153**	**17 994 – 18 485**

Notes:
[1]: Industrial life-cycle stage, included for comparative purposes
[2]: Silicone polymers excluding the uses in cosmetics products

Substance-specific estimates (Table 8) identify that D5 is the most important source of releases among the three cyclosiloxanes assessed.

Table 8: Releases estimates per substance and use

Use	Use tonnage [tpa]	Low release scenario (water only) [tpa]	High release scenario (all compartments) [tpa]
D4	**900**	**13 - 26**	**504 - 541**
Cleaning of art and antiques	<1	0 - 0	0 - 0
Presence of impurities in silicone polymers	645	11 - 20	269 - 299
Presence of impurities in silicone polymers used in cosmetic products	255	2 - 5	234 - 242
D5	**16 260**	**26 - 82**	**15 210 – 15 516**
Leave-on cosmetic products	15 000	6 - 44	14 476 – 14 684
Pharmaceutical products and medical devices	250	4 - 8	198 - 219
Detergents, household care and vehicle maintenance products	60	2 - 4	35 - 45
Dry cleaning	50	0 - 0	46 - 46
Cleaning of art and antiques	<1 T	0 - 0	0 - 0
Formulation of mixtures[1]	-	0 - 1	4 - 8
Impurity in silicone polymers	645	10 - 19	225 - 276
Impurity in silicone polymers used in cosmetic products	255	2 - 4	223 - 236
D6	**2 780**	**22 - 44**	**2 279 – 2 427**
Leave-on cosmetic products	2 000	0 - 5	1922 - 1956
Wash-off cosmetic products	200	12 - 20	55 - 114
Pharmaceutical products and medical devices	100	1 - 3	75 - 85
Detergents, household care and vehicle maintenance products	30	1 - 2	15 - 21
Formulation of mixtures[1]	-	0 - 0	0 - 0
Impurity in silicone polymers[2]	323	5 - 9	101 - 131
Impurity in silicone polymers used in cosmetic products	128	1 - 2	108 - 116
Grand Total	**19 946**	**63 - 153**	**18 000 – 18 491**

Notes: [1]: Industrial life-cycle stage, included for comparative purposes,
[2]: Silicone polymers excluding uses in cosmetic products

In addition, as shown in Figure 6 and Table 9, the relative contribution of uses to total releases, as well as the ranking of uses in terms of their contribution to releases, varies considerably depending on the environment compartments considered (aquatic only, or all compartments). However, as outlined above, uses in cosmetic products (including the presence of impurities in cosmetic products) dominate releases to the environment under both the 'low' and 'high' releases scenarios contributing 34-62% and 93-95% under the 'low' and 'high' release scenarios, respectively. Further details of the release estimate calculation are reported in Annex B.

Figure 6: Relative contribution of each use to the overall tonnage and releases

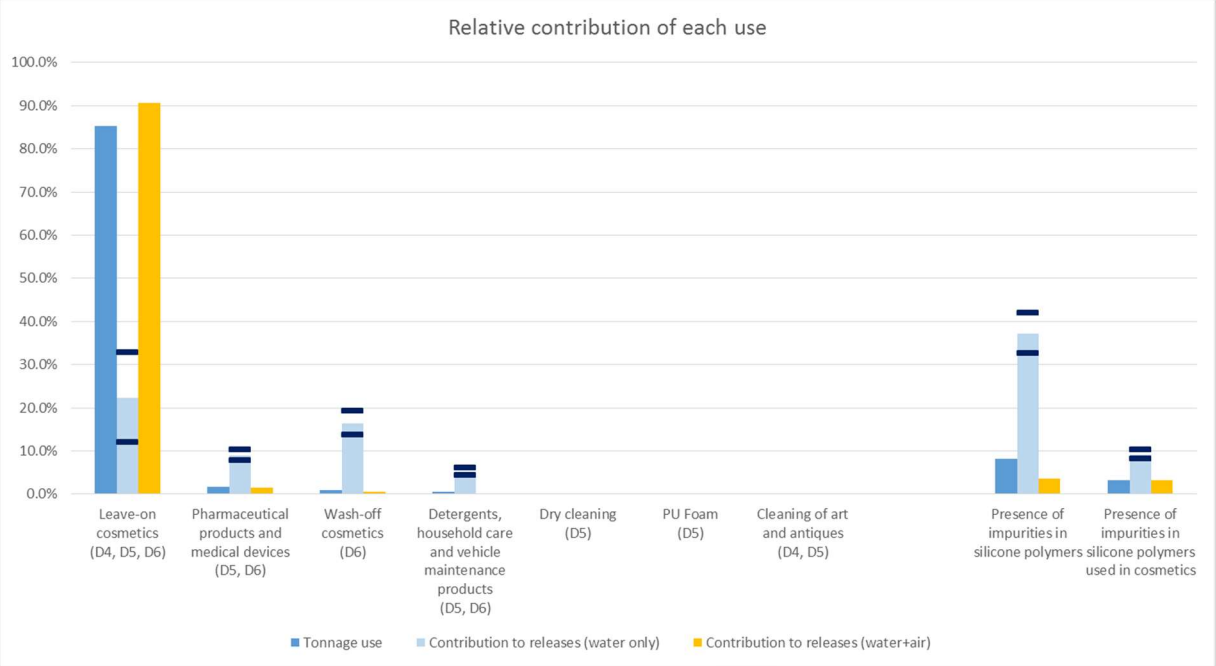


Table 9: Uses ranked according to their contribution to environmental releases

Rank	Releases to aquatic compartment only		Releases to all environment compartments	
	Use	**Proportion**	**Use**	**Proportion**
1	Impurity in silicone polymers	32-42%	Leave-on cosmetic products	90-91%
2	Leave-on cosmetic products	12-33%	Impurity in silicone polymers	Ca. 3%
3	Wash-off cosmetic products	14-19%	Impurity in silicone polymers in cosmetic products	Ca. 3%
4	Impurity in silicone polymers in cosmetic products	8-10%	Pharmaceutical products and medical devices	1.5 - 1.7%
5	Pharmaceutical products and medical devices	8-10%	Wash-off cosmetic products	0.3 – 0.6%

Further analysis of releases from cosmetic products

Cosmetic products represent by far the largest use and releases of D4, D5 and D6 to the environment. Therefore, a more granular analysis of the releases has been made looking across various categories and, where appropriate, sub-categories of cosmetic products, in order to appreciate better the contribution and significance of each of them to releases.

Estimated releases of D4, D5 and D6 from cosmetic products (use and presence as an impurity) are presented in Table 10. Releases were estimated to be between 26 and 83 tpa in the 'low scenario', and between 17 022 and 17 350 tpa in the 'high scenario'.

Looking more specifically at the different cosmetic product categories, it is clear that the *deodorants and antiperspirants* product category and the *leave-on hair styling and hair care* product category contribute the most to the overall releases. These two categories account for approximately 70% of the overall releases from cosmetic products.

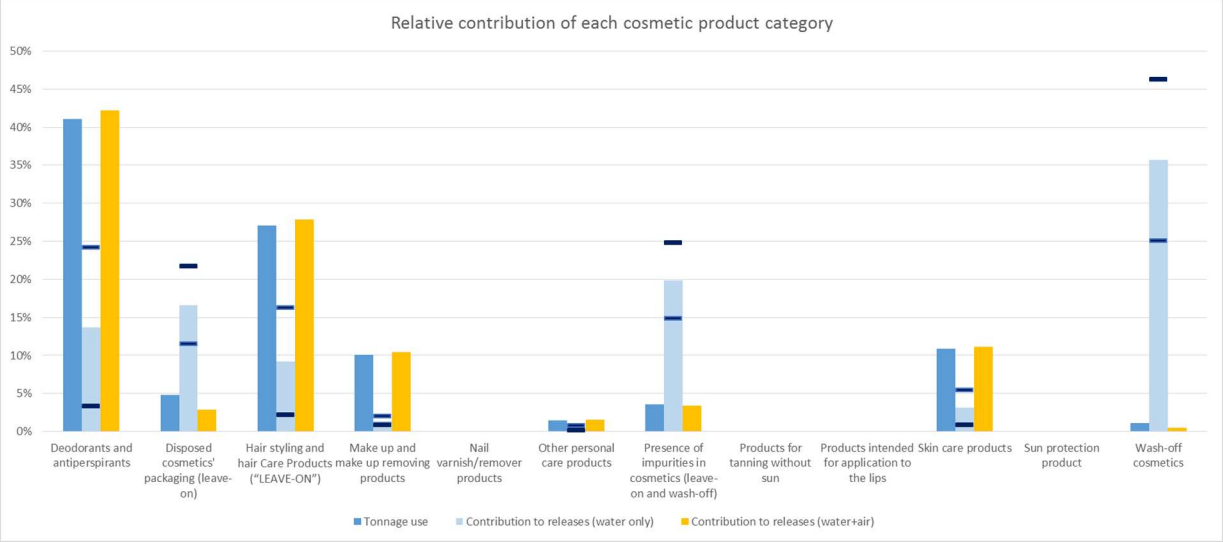
On the contrary, in the case of the 'low scenario', it is the wash-off cosmetics containing D6, and the silicone polymers (with D4, D5 and D6 residues) that have the biggest share in the releases to water.

Table 10: Releases estimates per cosmetic product category and subcategory

Cosmetic product category	**Use tonnage** [tpa]	**Low release scenario** (water only) [tpa]	**High release scenario** (all compartments) [tpa] *(% grand total release)*
Leave-on and rinse-off (excluding wash-off) products (D4, D5 and D6)			
Deodorants and antiperspirants	7 316	0 – 20	7201 – 7310 *(42%)*
Hair styling and hair care products ("LEAVE-ON")	4 831	0 – 13	4754 – 4827 *(28%)*
Skin care products	1 932	0 – 4	1906 – 1931 *(11%)*
Make up and make up removing products	1 794	0 – 1	1784 – 1793 *(10%)*
Disposed cosmetics' packaging (leave-on)	850	5 – 9	479 – 502 *(3%)*
Other personal care products	265	0 - 0	261 – 264 *(2%)*
Nail varnish/remover products	3	0 - 0	2 - 2
Products for tanning without sun	3	0 - 0	2 - 2
Products intended for application to the lips	3	0 - 0	2 - 2
Sun protection products	3	0 - 0	2 - 2
Wash-off products (D6)			
Wash-off cosmetics	200	12 – 20	55 – 114 *(0%)*
Presence of impurities (D6)			
Presence of impurities in cosmetics (leave-on and wash-off)	638	6 – 12	567 – 595 *(3%)*
Grand Total	**17 838**	**26 - 83**	**17 022 – 17 350**

The contribution of an individual product category to overall releases varies significantly depending on whether releases are considered solely to the aquatic environment or to both aquatic and air compartments, as shown in Table 10 and Figure 7. Details on the estimated releases calculation is available in Annex B.

Figure 7: Relative contribution of various cosmetic product categories to the overall tonnage and releases of D4, D5 and D6 from cosmetic products



1.5.4. Environmental fate modelling

Recent research on socio-economic analysis for PBT substances in the REACH Authorisation and Restriction procedures for the European Commission has reported that a 'stock pollution approach' could provide additional useful information within a socio-economic analysis compared to simply considering releases to environmental compartments (Gabbert et al., 2018) and (Gabbert, Hilber, 2016).

Therefore, in addition to the 'low' and 'high' release scenarios, a complementary 'environmental stock' scenario has been developed for D4, D5 and D6. This scenario is based on multi-media environmental fate and distribution modelling using the widely used SimpleBox 4.0 model parametrised with relevant environmental fate parameters for the three substances identified from registration dossiers or the recent SVHC decisions for D4, D5 and D6.

The model takes into account the partitioning behaviour (between environmental compartments e.g. water and sediment) of D4, D5 and D6 as well as the degradation of the substances. In simple terms, the modelling estimates the quantity (mass) of 'undegraded' D4, D5 and D6 remaining in the environment under steady-state conditions assuming the baseline releases estimated in Section 1.5.3.2. Whilst providing useful insights into which compartments would be most affected by releases it is also possible to determine the proportion of annual releases that would remain in the environment at any given moment.

Using these data, the cost-effectiveness of addressing the releases that would remain in the environment can be estimated, similar to how the cost-effectiveness of preventing all releases is calculated. Further details of this approach are provided in Annex B.

SimpleBox has been used to estimate the overall fate and distribution of the total D4, D5 and D6 annual releases, rather than by individual product group[32]. The results are

[32] Further analysis by product group, taking into account the relative proportion of releases that occur to water and air, could be undertaken, if necessary, during the opinion-making phase.

presented in Table 11 and will be used as a complementary approach to calculate the cost effectiveness of the restriction in the socio-economic analysis. This will complement the upper and lower bound to cost-effectiveness calculated considering the 'low' and 'high' release scenarios described in Section 1.5.3.2.

Table 11: Steady-state environmental stock associated uses of D4, D5 and D6

Use	Annual use tonnage [tpa]	Steady-state environmental stock [t]
All uses	19 946	493 - 509
Use in cosmetics only (D4, D5 and D6, and impurities)	17 838	463 - 474

1.5.5. Risk characterisation

D4, D5 and D6 are PBT/vPvB substances and, as such, it is acknowledged that the risks to the environment resulting from their uses, or the uses of silicone polymers, cannot be adequately addressed in a quantitative way using a threshold (e.g. by derivation of a PNEC). Therefore, in the absence of an appropriate threshold, releases of D4, D5 and D6 into the environment are used as a proxy for risk. This approach is consistent with previous Annex XV restriction proposals for other substances for which a risk quotient cannot be derived (e.g. PBT/vPvB substances such as decaBDE, the neurotoxic phenylmercury compounds, PFOA and lead.

Consumer and professional uses of D4, D5 and D6 result in releases to the environment which are dominated by releases from wide-dispersive uses in cosmetic products (under both low and high release scenarios). The Dossier Submitter considers that the risk management measures adopted are not sufficient and that uses of PBT/vPvB substances are not minimised throughout their life-cycle, as required according to paragraph 6.5 of Annex I of REACH. **As such, risks from consumer and professional uses of D4, D5 and D6 are not adequately controlled.**

The reduction of D4, D5 and D6 releases achieved by the proposed restriction will be used as an estimate of the effectiveness (risk reduction capacity) of the proposed restriction.

It should be noted that although releases to the environment will be reduced by any proposed Annex XV restriction on uses of D4, D5 and D6, some releases, i.e. those that originate from impurities in silicone polymers (in any mixtures or article service life), will not be further minimised, where the concentration of D4, D5 and D6 are already below 0.1% w/w in the final product (cf. chapter 2.4 for additional information).

Risks to human health:

ECHA does not have a legal mandate to look at the risk to human health for cosmetic products, so this aspect with regard to the use of D4 will not be addressed in the Annex XV restriction proposal.

On the other hand, risks to the human health related to the use of D4 by professionals in the cleaning of art and antiques may be relevant. However, as this is a niche market, it is not proposed to address these risks in detail in the Annex XV restriction proposal and, alternatively, read-across, where possible, from the existing SCCS opinion of the use of D4 in cosmetic products.

1.6. Justification for an EU wide restriction measure

D4 has PBT and vPvB properties, D5 and D6 have vPvB properties. The three substances fulfil the criteria for Substances of Very High Concern (SVHC) (REACH Article 57).

Products containing these substances are formulated and used throughout the EU/EEA, resulting in releases throughout the EU/EEA.

Thus, Union-wide basis is to effectively reduce the environmental exposure to D4, D5 and D6 in the EU. Action on a Union-wide basis would also limit the potential for trans-boundary exposure to D4, D5 and D6 from EU sources.

Union-wide action is proposed to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States.

1.7. Baseline

The tonnage and releases report in 1.5.3 are the starting point for considering the baseline in this analysis; the assumptions relating to the future trends of the use of D4, D5 and D6. The baseline scenario is compared to the proposed restriction scenario in the impact assessment, in terms of both costs and benefits.

On 27 June 2018, D4, D5 and D6 were identified as SVHC on the basis of their PBT/vPvB properties and added to the Candidate List.

There are some indications that SVHC identification could affect the baseline, mainly for the case of their use in cosmetic products. According to Cosmetics Europe (personal communication), an SVHC listing makes ingredients less attractive for mid- to long-term formulation developments, since there is a perceived threat that they could become subject to REACH Authorisation at any time. Cosmetics Europe also noted that large retailers are increasingly rejecting products that contain ingredients under regulatory scrutiny, even if they are not subject to any restrictions or a ban.

Additionally, there are also mechanisms that operate via consumer demand. For example, Cosmetics Europe report that they have observed that some suppliers have started to offer and market materials marked as 'SVHC-free'. In their experience, once some companies begin using this as a marketing argument, it is likely to create consumer demand such that other companies may feel obliged to follow. The actions of NGOs and consumer associations can also lead to a move away from substances listed as SVHCs, as they will often include them in 'negative lists', and recommend to retailers and consumers not to purchase products containing ingredients from these lists.

The arguments above suggest that there could be a move away from using D4, D5 and D6 in cosmetics (and potentially in other uses) even in the absence of a restriction on this use. However, there is no data that would allow the Dossier Submitter to estimate for what proportion of formulations this could happen voluntarily, or what the timeline would be for those voluntary substitutions.

Therefore, the Dossier Submitter has calculated the impact of the proposed restriction assuming a 'business as usual' baseline scenario, where D4, D5 and D6 would continue to be used at the same quantities as reported today. In this scenario, all of the costs of replacing D4, D5 and D6 would be assumed to be as a result of the proposed restriction. Based on the considerations above this could overestimate the costs of the restriction. As

such, the Dossier Submitter also presents a sensitivity analysis underpinned by a baseline scenario assumption that D4, D5 and D6 would be voluntarily replaced in all cosmetic products over a period of 10 years (see Annex D). The real impacts of a restriction should be expected to be somewhere in between these two scenarios, but there is insufficient information available that would allow to predict precisely where.

The baseline for the cosmetics sector could also be affected by other regulatory activities, such as the adoption of a restriction on the intentional use of microplastics (Annex XV report submitted by ECHA on 11 January 2018), which would also require the reformulation of some cosmetic products. If this restriction were adopted it is likely that some of the costs estimated in this assessment would be overestimates (as reformulation in response to the two regulatory measures is likely to be coordinated, at least to a certain extent). More information is provided in in Section 2.5.3. For clarity, the baseline scenario used for the impact assessment in this report does not incorporate the possibility of a restriction on the intentional use of microplastics.

In addition, it should be noted that Annex I to REACH obliges registrants of PBT/vPvB substances to implement or recommend to downstream users risk management measures that minimise the releases of substances to environmental compartments and the workplace throughout the life-cycle of the substance. Use of a PBT/vPvB substances in a consumer product that is 'widely dispersed' during use (either released to atmosphere or to wastewater), such as a cosmetic product, is unlikely to be consistent with the concept of minimisation. Therefore, it could be argued that the identification of D4, D5 and D6 as SVHC is sufficient justification in itself for producers to reformulate cosmetic products that contain them as ingredients. On this basis, although reformulation costs would arise, any additional restriction on uses of cosmetic (or other widely dispersed consumer product) could be argued to have limited costs and the reformulation should have occurred already under existing legal obligations.

For uses other than in cosmetic products, it will be assumed that the future situation would continue as it is today.

2. Impact assessment

2.1. Analysis of risk management options (RMOs)

As indicated in the previous sections, there are releases to the environment from consumer and professional uses of D4, D5 and D6. These releases are considered to pose a risk that is not adequately controlled.

The Dossier Submitter has conducted an analysis of a series of diverse risk management options to identify the most appropriate one to address the identified risks. This assessment was underpinned by the information on uses, releases and socio-economic impacts, but also by the criteria outlined in Annex XV of REACH for assessing the appropriateness of a REACH restriction: effectiveness, practicality and monitorability.

On the basis of this assessment, the following restriction scenario is proposed as the most appropriate risk management option. The option addresses the identified uncontrolled risks and will ensure a level playing field with imported substances and mixtures:

- Restriction on placing D4, D5 and D6 on the market (concentration limit of 0.1% w/w) in consumer and professional products including justified derogations, and transitional periods of different durations to avoid disproportionate socio-economic impacts.

The risk management options indicated below were also considered, but were not considered to be as appropriate as the option identified above, and were therefore disregarded:

1. Restriction on the placing on the market of all products intended for consumer and professional use containing D4, D5 and D6, with no derogations, nor concentration limit.

2. As per option 1, but with a concentration limit of 0.01% w/w.

3. Restriction on placing D4, D5 and D6 on the market in selected product forms (e.g. only mixtures).

4. Restriction on the placing D4, D5 and D6 on the market in selected sectors or categories of products (e.g. cosmetics, or even specific categories of cosmetics).

5. Restriction on the placing D4, D5 and D6 on the market unless specific labelling product labelling conditions were met.

Each of the above mentioned options was assessed against the main criteria for restriction: effectiveness, practicality and monitorability, which is summarised in the Table 12 below. Additional details are also available in Annex C.

Table 12: Summary of restriction options assessment (comparison to the proposed one)

	Option	Effectiveness[33]	Practicality[34]	Monitorability	Comment
1	No concentration limit	-	-	-	This option is disproportionate in terms of scope and potential cost. It would capture for example, all uses of silicone polymers, and all uses in articles and cured polymers where there is currently no alternative available. Currently available measurement systems may not be able to distinguish the substances from silicone polymer's residues.
2	Conc. limit of 0.01% w/w	-	-	-	Effects would be similar as in option 1.
3	On selected product forms	=	=	=	Elements of this have been used in the proposed restriction option (specific concentration limits to be considered for some mixtures that will cure during use)
4	On specific sectors or categories of products	-	=	=	New uses (or uses the Dossier Submitter may have missed in the analysis) would not be covered by the restriction
5	Labelling with a phrase such as 'contains PBT/vPvB substance concentration > 0.1%', and/or with user instructions to minimise releases	-	=	=	This RMO could result in a decline in the use of D4, D5 and D6 in cosmetics (and potentially in other uses) as consumers/formulators would discriminatue against products with a requirement for this type of label. In this respect effectiveness (and costs) could be equivalent to the proposed restriction. In terms of a requirement for additional user instuctions, given that these substances are released to the atmospheric compartment during use (via evaporation) it is unlikely that user instuctions would be an effective RMM for the majority of uses considered in this report as the conditons of use could not be amended to prevent evaporation (or capture releases).

Note: (+) means better than the proposed restriction option, (-) means less good, and (=) means similar

2.2. Proposed restriction

2.2.1. Definition and scope

Short title:

Restriction of D4, D5 and D6 in consumer and professional products

Scope description:

The proposed restriction aims at expressing the intention of the Dossier Submitter. The final legal wording will be ultimately decided by the European Commission after receiving the Committees' opinions, and should take into account the existence of entry 70 in Annex XVII which is already restricting the use of D4, and D5 in wash-off cosmetics.

[33] Effectiveness: i.e. risk reduction vs proportionality

[34] Practicality: i.e. implementability, enforceability, manageability

Table 13: Proposed restriction

Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
a) Octamethylcyclotetrasiloxane EC Number: 209-136-7 CAS Number: 556-67-2 INCI name: Cyclotetrasiloxane or Cyclomethicone *Also known as D4.* **b) Decamethylcyclopentasiloxane** EC Number: 208-764-9 CAS Number: 541-02-6 INCI name: Cyclopentasiloxane or Cyclomethicone *Also known as D5.* **c) Dodecamethylcyclohexasiloxane** EC number: 208-762-8 CAS number: 540-97-6 INCI name: Cyclohexasiloxane or Cyclomethicone *Also known as D6.*	1. Shall not be placed on the market: a) As substances. b) As constituents of other substances (except polymers as defined under the REACH Regulation (EC) No 1907/2006), in a concentration equal to or greater than 0.1% w/w. c) As constituents in mixtures in a concentration equal to or greater than 0.1% w/w. 2. Shall not be used: a) As a solvent for the dry cleaning of textiles, leather and fur. 3. This restriction shall come into force: a) On DD/MM/YY [at least 5 years after publication in the Official Journal] for (i) leave-on cosmetic products (as defined in the Regulation (EC) No 1223/2009 – Preamble to Annexes II to VI), (ii) medical devices as defined in the Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745, and (iii) medicinal products for human health as defined in EU Directive 2001/83/EC . b) On DD/MM/YY [at least 10 years after publication in the Official Journal] for D5 as a cleaning solvent in the dry cleaning of textiles, leather and fur. c) On DD/MM/YY [at least 2 years after publication in the Official Journal] for all other uses. 4. By way of derogation, paragraph 1 shall not apply to: a) Placing on the market of D4, D5 and D6 for the following uses: - Industrial use as a monomer in the production of silicone polymer - Industrial use as an intermediate in the production of other organosilicon substances - Industrial use as a monomer in emulsion polymerisation - Industrial use in formulation and/or (re-) packing of mixtures - Industrial production of articles - Industrial use in non-metal surface treatment - Industrial use as laboratory reagent in Research & Development activities b) Placing on the market of D5 and D6 for use as medical devices, as defined in Directive 93/42/EEC or in the Regulation (EU) 2017/745, for the (i) treatment/care of scars and wounds, (ii) prevention of wounds, and (iii) care of stoma. c) Placing on the market of D5 for professional use in the cleaning or restoration of art and antiques. 5. In addition, by way of derogation, paragraph 1 shall not apply to the placing on the market of

Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
	mixtures that contain silicone polymers with residues of: a) D4 or D5 or D6 in a concentration equal to or less than 1% w/w, for use as adhesives or sealants *that cure in situ* b) D5 in a concentration equal to or less than 0.2% w/w or D6 in a concentration equal to or less than 1% w/w, for use as medical devices (as defined in Directive 93/42/EEC or in the Regulation (EU) 2017/745) for dental impression. c) D4 in a concentration equal to or less than 0.3% w/w for use as protective coatings. d) D5 in a concentration equal to or less than 1% w/w or D6 in a concentration equal to or less than 3% w/w, for (i) rapid prototyping and mould making, and (ii) high performance uses stabilised by quartz filler. e) D4 or D5 or D6 in a concentration equal to or less than 0.2% w/w, for use as (substance-based) medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745. 6. By way of derogation, paragraphs 1 and 2 shall not apply to: a) Use of D5 in strictly controlled closed dry cleaning systems for textile, leather and fur where the cleaning solvent is recycled or incinerated.

2.2.2. Justification for the proposed restriction

2.2.2.1. Substance identification

In addition to the EC number, CAS number and IUPAC name of the substances to be restricted, it is proposed to also include the substances INCI names in the legal text in order to facilitate the identification of the substances on cosmetic product ingredient lists, and facilitate the enforceability (as a preliminary check) of the restriction for cosmetic products:

- cyclotetrasiloxane for D4
- cyclopentasiloxane for D5
- cyclohexasiloxane for D6
- cyclomethicone for a blend of D4, D5 and D6

2.2.2.2. Product type (cf. scope paragraph 1)

This paragraph sets the scope of the restriction to preven the placing of D4, D5 and D6 on the market as either a substance as such (1a), a constituent in another substance (1b) or in a mixture (1c). The wording proposed corresponds to the standard REACH terminology.

The wording is covering the types of use that have been reported to the Dossier Submitter:

- Paragraph 1a: for uses of D4, D5, D6 as a mono-constituent substance: e.g. D5 for dry-cleaning, D4 and D5 for the cleaning of art and antiques.

- Paragraph 1b: the wording 'Constituent in another substance' is intended to cover instances where D4, D5 and D6 would be an impurity or an additive (i.e. a constituent in the REACH Regulation) in another substance e.g. present as an impurity in another cyclosiloxane such as D7.
- Paragraph 1c: for uses of D4, D5 and D6 in blends/mixtures e.g. D5 and D6 in cosmetic product formulations

In line with the request from the Commission, the restriction proposal is not intended to cover uses of silicone polymers. This is why paragraph 1b specifically exclude polymers (note that according to REACH article 3(5), polymers are substances).

articles are not included in the scope of the proposed restriction by specifically referring to substances and mixtures (cf 1.2).

This scope is considered to be appropriate as, in combination with the derogations set out in paragraphs 4 and 5, it addresses the usesthat are associated with the risk that is not controlled.

2.2.2.3. Concentration limit (cf. scope paragraph 1)

The maximum allowable concentration of D4, D5 and D6 as a constituent in another substance or in a mixture is determined by the specific concentration limit.

The proposed concentration limit of 0.1 % w/w is the same as currently implemented for the restriction of D4 and D5 in wash-off cosmetic products. It is proposed to use the same concentration limit as this will prevent intentional uses of D4, D5 and D6 whilst also facilitating the enforceability of both restrictions.

Standardised analytical methods to verify this concentration in mixtures, including cosmetic products, have been developed to support the implementation of the restriction on wash-off cosmetic products. Similar to the considerations during the development of the restriction on the use of D4 and D5 in wash-off cosmetic products, a lower concentration limit (e.g. 0.01% w/w) would adversely affect the use of silicone polymers in mixtures, which is not the intention of the restriction.

2.2.2.4. Restriction on 'placing on the market' (cf. scope paragraph 1)

'Placing on the market' should be understood as 'placing on the EEA market (i.e. EU + Iceland, Norway and Liechtenstein)' as set under REACH.

Article 3(12) of REACH defines 'placing on the market' as 'supplying or making available, whether in return for payment or free of charge, to a third party. Import is deemed to be placing on the market'.

2.2.2.5. Restriction on 'use as a solvent for the dry cleaning of textiles, leather and fur' (cf. scope paragraph 2, 3b and 6)

Paragraphs 2, 3b and 6 are complimentary and should be understood collectively.

Paragraph 2 and 6 clearly specifies that the restriction is on the **use** of D4, D5 and D6 for the dry cleaning of textiles, leather and fur. This is in order to facilitate the enforcement in dry cleaning shops and facilities, which the Forum had noted in their advice was complicated by reliance only on a restriction on 'placing on the market' (as originally proposed in the Annex XV report).

The derogation proposed in paragraph 6 is a process-limited derogation from the

restriction for D5 only for uses where OC and RMM can be implemented in order to adequately control the risk from the use of D5 in dry-cleaning applications.

Current OCs and RMMs used in dry cleaning result in a large proportion of the tonnage being released to the atmosphere, which could be improved by reducing evaporative losses at the end of the cycle (e.g. by waiting longer to open doors, etc.). The intention of the Dossier Submitter is to propose a derogation that would include a requirement that appropriate OCs and RMMs are identified and put in place in order to (i) recycle or incinerate the washing liquid and (ii) to avoid any release to air or wastewater.

A transition period (e.g. of 10 years) followed by a derogation for use in closed systems could therefore be appropriate.

The wording proposed is by analogy to (i) the concept of strictly controlled conditions for intermediates under REACH, and (ii) from a derogation included in existing restriction entry 46 in Annex XVII (on the use of nonylphenol for industrial washing and cleaning) (e.g. 'closed' processes).

The wording in paragraph 3b and 6 explicitly excludes D4 and D6 from the process-limited derogation as D4 and D6 have not been reported as used for this type of application.

2.2.2.6. Derogations (cf. scope paragraph 4)

For the proposals identified in paragraph 4, the Dossier Submitter considers that sufficient information is available to justify a derogation from the scope of the proposed restriction, as follows:

Derogation for placing on the market for use at industrial sites and transported isolated intermediates (cf. scope paragraph 4a)

The restriction is specifically targeting substances or mixtures intended for end use by the general public or professionals. However, as the terms 'general public' and 'professionals' are not specifically defined under the REACH Regulation, it is proposed to instead indicate that the restriction applies to all placing on the (EEA) market except where a subsequent downstream use takes place at an industrial site[35] (cf. Appendix C1 in the Annex document for additional details on 'use at industrial sites'). The restriction should also not apply when substances or mixtures are transported between industrial sites or where a substance or mixture is imported into the EU for downstream (or intermediate) use at an industrial site. This recognises that raw materials (e.g. silicone polymers) could contain D4, D5 and D6 at concentrations greater than the specific concentration specified in paragraph 1(b).

Table 14 provides a list of registered uses (that are considered to occur at industrial sites) that are intended to benefit from the derogation.

[35] The REACH legal text differentiates between industrial and professional use [activity] in definitions 13, 25 and 35, as well as section 6 of Annex VI. In Annex XVII also the terms "industrial installation" and activity of a "professional outside industrial installations" are used. The Guidance R.12 on Use description (ECHA, 2015) provides a non-exhaustive list of characteristics associated with industrial sites.

Table 14: Uses of D4, D5 and D6 at industrial sites

Use	D4	D5	D6	Comments
Use as a monomer in the production of silicone polymer	✓	✓	✓	According to the CSRs, such uses can happen both at the manufacturing site (of D4, D5 and D6) or at a down-stream user site after transportation. The later type of use cannot benefit from the general restriction exemption for on-site isolated intermediate.
Use as an intermediate in the production of other organosilicon substances	✓	✓	✓	
Use as a monomer in emulsion polymerisation	✓	✓	✓	
Use in formulation and/or (re-)packing of mixtures		✓	✓	Example of applications: cosmetics, pharmaceuticals, medical devices, detergent, household care and vehicle maintenance products, sealants
Production of article	✓	✓	✓	
Use in non-metal surface treatment	✓			
Use as laboratory reagent in R&D activities	✓	✓	✓	
Use in industrial site dry cleaning		✓		This use will not be derogated unless it complies with the derogation conditions set in paragraph 3d

Source: ECHA dissemination website accessed on 4 April 2019

It should be noted that the proposed derogation would continue to allow the direct export of a consumer/professional substance or mixture outside of the EU/EEA (as it would not be placed on the EU/EEA market).

Derogation for placing on the market of D5 and D6 for use as medical devices for the treatment/care of scars and wounds, the prevention of wounds and the care of stoma. (cf. scope paragraph 4b)

Uses of D5 and D6 in high concentration (between 5 and 60% w/w) have been reported for the medical devices (mixtures) used in the treatment/care of scars and wounds, the prevention of wounds, and the care of stoma. These applications have high societal values and the use of D5, D6 and silicone polymers with high concentration of D5 and D6 are recognised as state of the art in the above mentioned treatments. If the use of D5 and D6 would be banned for these applications, there is a risk that functionality could be lost, and that this would affect vulnerable patients such as the elderly, patients with burns, or those with poor medical condition. The tonnages used are expected to be low with a low proportion of releases occurring to water.

The derogation is specifically targeted to D5 and D6 only, because D4 has reprotoxicity properties.

The proposed text of the derogation aims at expressing the intention of the Dossier Submitter. The Dossier Submitter notes that the final legal wording of this derogation could also include reference to the medical devices classification system as defined in Annex VIII to Regulation 2017/745 (cf. section 2.6.4 for further details). Other wording could be used for 'scar', such as 'cicatrix', which is a medical term and may be preferable.

Medical devices are regulated by the EU Regulation (EU) 2017/745 on Medical Devices (aka MDR). This EU regulation repeals the existing directives on medical devices, and active implantable medical devices, and will be applicable from 26 May 2020. Due to the transitional period set in the new Regulation, some devices with certificates issued under the 'old' Directives (MDD and AIMDD) may continue to be placed on the market until 27

May 2024 and made available until 27 May 2025. Therefore the proposed derogation is referring to both legislations: MDR ((EU) 2017/745) and MDD (Directive 93/42/EEC).

Derogation for placing on the market D5 for the professional cleaning or restoration of art and antiques

The releases to the environment associated to these uses are limited (niche market), and the uses have high societal/cultural value: they allow the restoration of antiques, paintings and art that could be damage if other techniques would be used.

The derogation is specifically targeted to D5 only, because D4 is hazardous for human health, and D5 can be used as an alternative to D4.

2.2.2.7. Derogations (cf. scope paragraph 5)

During the preparation of the restriction proposal, and the consultation of the opinion-making phase, the Dossier Submitter has been made aware of uses of silicone polymers in mixtures that potentially contain relatively high concentrations of D4, D5 and D6 as impurities.e.g. mixtures containing silicone polymers used as medical devices such as dental imprints, mixtures containing silicone polymers used as sealants or adhesives in various sectors (construction, medical devices).

The Table 15 summarises the information received in the consultation about the presence of D4 or D5 or D6 above 0.1% in silicone polymers.

Table 15: Overview of presence of D4 or D5 or D6 above 0.1% in silicone polymers (ranges over which data was reported marked in grey)

	0.2%	0.3%	0.5%	0.9%	1%	3%	Derogation paragraph
Wound and stoma (D6)							4b
Wound and stoma (D5)							4b
Medical bonding adhesive							5a
Sealants (D4 or D5)							5a
Sealants (D6)							5a
Sealants and adhesive (D4, or D5 or D6)							5a
Dental impression (D5)							5b
Dental impression (D6)							5b
Protective coating (D4)							5c
Rapid prototyping, mould making (D5)							5d
Rapid prototyping, mould making (D6)							5d
High performance uses stabilised by quartz filler (D5)							5d
High performance uses stabilised by quartz filler (D6)							5d
Skin treatment (topical) (D4, or D5 or D6)							5e

Source: Consultation (data reported as ranges because some data was confidential)

In case of enforcement, inspectors would not be able to distinguish if the presence of D4,

D5 and D6 detected above the concentration limit of 0.1% w/w is due to the presence of D4, D5 and D6 themselves or from the presence of impurities in silicone polymers. As these specific applications may be inadvertently impacted by the restriction, the Dossier Submitter is proposing specific and targeted derogations for these uses.

The available information for these types of mixtures and uses indicates that (i) it is unlikely to be possible to reduce the concentration of D4, D5 and D6 present as an impurity to below 0.1% w/w without adversely affecting the properties of the product itself and (ii) that the removal of the product from the market would have significant negative socio-economic implications.

The current proposal for derogations, including the proposed concentration limit per ingredient, is based on information submitted during the consultation. The proposed concentration limits are applicable to each ingredient as specified in the text.

The proposed text of the derogation aims at expressing the intention of the Dossier Submitter. Some of the subparagraph could be grouped together if needed. The final wording will be decided by the European Commission after receiving the Committees' opinions.

2.2.2.8. Entry into force (cf scope paragraph 3)

Paragraph 3 details the transition periods proposed for different uses, as justified by the socio-economic analysis.Further details are provided in section 0 for leave-on cosmetics, in section 2.6.4 for pharmaceutical products and medical devices and in section 2.6.1 for dry cleaning.

It should be noted that the wording proposed for paragraph 3.a.ii refers to (substance-based) medical devices for topical uses (i.e. 'medical devices that are composed of substances or combinations of substances that are to be introduced into the human body through a natural orifice or applied to the skin and that are absorbed by or locally dispersed in the human body'), e.g. massage gel, lubricants, topical treatment for skin diseases, head lice treatments. Both the MDD (Directive 93/42/EEC) and the MDR ((EU) 2017/745) legislations are mentioned due to the transitional period set in the new Regulation (cf. details in section 2.2.2.6).

The wording proposed for paragraph 3.a.iii is intentionally only referring to human health medicinal products, as the Dossier Submitter has not received any information on potential uses for veterinary medicinal products (defined in EU Directive 2001/82/EC).

According to the proposed wording in paragraph 3.c, wash-off cosmetics containing D6 would have a 2 year transition period.

2.3. Approach to impact assessment

As outlined in Section 1.5.3.2, an examination of the releases of D4, D5 and D6 from different uses shows that by far the greatest amount is released from their use in cosmetic products (leave-on and wash-off). Uses of D4, D5 and D6 in cosmetic products account for 91% of the aggregate releases to the environment (all compartments) from uses of the substances. This increases to approximately 94% of aggregate releases (all compartments) when uses of silicone polymers in cosmetic products, which contain D4, D5 and D6 as impurities, are also included.

Uses of silicone polymers in mixtures and articles are estimated to contribute

approximately 5 % of total releases to the environment of D4, D5 and D6 (all compartments). This suggest that a restriction on remaining consumer and professional uses (as proposed by the Dossier Submitter) will address the majority (95%) of releases of these substances to the environment.

In the majority of cases the concentration of D4, D5 and D6 in mixtures and articles as impurities are reported to be significantly below a concentration of 0.1% w/w. However, there are some applications of silicone polymers where D4, D5 and D6 are reported to be present as impurities at concentrations greater than 0.1% w/w. Stakeholders provided some information indicating that there could be difficulty reducing the concentration of D4, D5 and D6 as impurities in these mixtures to < 0.1% w/w (the concentration limit proposed for 'uses' of D4, D5 and D6) in certain specific end-use products. This was reported to be because the conventional process uses to remove impurities in silicone polymers (vacuum evaporation and moderate heat) would adversely affect the functionality of final products (specifically 'uncured' mixtures for silicone polymers used as sealants in the construction sector would be partially 'cured' using this process).

A variety of other 'minor' uses of D4, D5 and D6 have been identified, each estimated to result in significantly smaller quantity of releases to the environment, such as in dry cleaning and in the cleaning of art and antiques, amongst others.

Given that a single use (i.e. use in cosmetic products) dominates both the tonnage used and the quantities released, the Dossier Submitter has taken the following approach in the socio-economic analysis underpinning the impact assessment.

For cosmetic products, as good quality and detailed information on cost elements was available (albeit with some uncertainties), the Dossier Submitter has undertaken detailed analysis are estimated costs under 'high', 'low', and 'best' cost assumptions. Sensitivity analysis has been undertaken on key uncertainties. It has not been possible to quantify some impacts (e.g. costs to consumers associated with performance loss and consumer valuation of environmental impact). In these instances, a qualitative assessment has been made supported with the available quantitative information.

For other uses of D4, D5 and D6, and uses of silicone polymers, information on potential impacts are presented and summarised, but no quantitative estimates of the cost of a potential restriction were made. This was because (i) the available information suggested that the potential costs were low in comparison to those accruing to the cosmetics industry and (ii) because of the lack of information available to the Dossier Submitter, specifically information on the proportion of products that would be affected by a restriction and/or potential costs.

Therefore, the analysis for other uses is comprised of a summary of the available cost information together with a qualitative assessment of impacts, particularly to identify where a restriction would have a disproportionate impact from a social perspective; and would justify a derogation.

2.4. Impact on the environment (effectiveness/risk-reduction capacity)

2.4.1. Effectiveness and risk reduction capacity of the proposed restriction

Based on the analysis reported in previous sections of this report (Section 1.5.3.2), it can be readily appreciated that the majority of releases of D4, D5 and D6 to the environment (all compartments) can be reduced through an Annex XV restriction focussing on uses.

The Dossier Submitter has also assumed that in case a restriction is adopted on professional and consumer products, this will have consequences on the upstream supply chain, hence the releases to the environment from the formulation steps will also be reduced.

In term of environmental releases, the impact of the restriction could be depicted as shown in the Table 16.

Table 16: Tonnage and releases estimates per use after restriction

Use	Restriction proposal	Impact on the use tonnage [tpa]	Impact on the releases [tpa]
Leave-on cosmetic products (D4, D5 and D6)	Restricted	Reduced to 0	Reduced to 0
Pharmaceutical products and medical devices (D5 and D6)	Restricted except for scars, wound treatments and stoma-care (similar to leave-on)	<50 Worst case estimate based on scarced information received during the consultation[1]	Reduced compared to current releases i.e. < 0.005 - 0.150 (water only) < 47-48 (all compartments)
Wash-off cosmetic products (D6)	Restricted	Reduced to 0	Reduced to 0
Detergents, household care and vehicle maintenance products (D5 and D6)	Restricted	Reduced to 0	Reduced to 0
Dry cleaning (D5)	Process-limited derogation	<50	Reduced to 0
Cleaning of art and antiques (D4 and D5)	Restricted for D4 Derogation for D5	No impact	Remains close to 0
Formulation of mixtures	N.A.	5 000[2]	Releases reduced by ~75% i.e. < 0.05–0.3 (water only) < 1-2 (all compartments)
Impurity in silicone polymers (excluding cosmetics)	N.A.	1 613[3]	Similar to current releases i.e. 26 – 50 (water only) 597 – 707 (all compartments)
Impurity in silicone polymers used in cosmetic products	N.A.	638[2]	Similar to current releases, i.e. 6 – 12 (water only) 567 – 595 (all compartments)

Note:
[1] Based on the derogation proposal, which is limited to scars, wound treatments and stoma-care*. It is assumed that maximum 50 tpa (worst case estimate) of D5 will remains placed on the market in that type of products. This is a conservative approach.*
[2]It is assumed that a proportion of cosmetics containing D5, D6 will still be formulated in Europe and exported directly as of today. This is why the formulated tonnage is not set to zero. This is a conservative approach
[3] It is assumes that the tonnage remains the same or slightly increases if D4, D5 and D6 are replaced by silicone polymers with impurity <0.1%

According to Table 16, a total emissions reduction for all compartments of ca. 93% could be obtained through the Annex XV restriction proposal on the use of D4, D5 and D6 (from releases of 17 994 – 18 485 tpa to releases of 1 212 – 1 352 post restriction). The reduction would be of ca. 50% (from 63 – 153 tpa releases to 32 – 62 tpa releases post restriction) if considering the releases to the aquatic environment only.

It should be noted that emissions of D4, D5 and D6 in the environment will not totally cease and will remain in the following situations:

- Some consumer and professional products that are mixtures will contain silicone polymers with residual amounts of D4, D5 and D6 at concentrations below 0.1%[36]. The resulting emissions would not be affected by the proposed restriction. This would also be the case for articles where the residual amount of D4, D5 and D6 is below 0.1%.

For consumer and professional products that are articles or parts of an article (e.g. rubber and sealants): it might not be possible to reduce residual amounts of D4, D5 and D6 to below 0.1% by additional curing, without affecting the properties of the product itself.

2.4.2. The relative importance of releases to air versus the aquatic compartment

The REACH regulation recognises that the hazard and exposure assessment of PBT/vPvB substances (i.e. substances that fulfil the REACH Annex XIII criteria) cannot be carried out with sufficient reliability for a quantitative characterisation of risks. Therefore, REACH registrants of PBT/vPvB substances are required to undertake an 'emissions characterisation' and implement or recommend to downstream users risk management measures that minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance (REACH Annex I).

Recent restriction proposals under REACH for PBT/vPvB substances (e.g. decaBDE, PFOA and PFOA-related substances, D4 and D5 in wash-off cosmetics) have applied a semi-quantitative approach to socio-economic analysis, based primarily on estimates of 'cost-effectiveness', as recommended by ECHA (ECHA, 2016). The cost-effectiveness metric is typically expressed as the emission reduction achieved by a measure in relation to the compliance costs (e.g. € cost per kg of emission prevented).This is because any quantification of the impact arising from the exposure to PBT/vPvB substances in the environment is not currently possible from a methodological perspective.

[36] It includes also mixtures that are made of silicone polymers with residual amounts of D4, D5 and D6 above a concentration of 0.1%: after formulation and dilution with other ingredients, the residual amounts of D4, D5 and D6 in the final products used by the consumers and professionals could be in concentrations below 0.1%.

The semi-quantitative cost-effectiveness approach advocated by ECHA in restrictions or applications for authorisation of PBT/vPvB substances acknowledges that it is not currently possible to weight the damage potential/impacts of different PBT/vPvB substances.

Annex I of REACH does not differentiate between the environmental compartments that should be considered when undertaking an emission characterisation or minimising releases for a PBT/vPvB substance. Given that it is not possible to derive a PNEC for a PBT/vPvB substance a risk is considered to occur in any compartment that a PBT/vPvB substance is released to. However, it is recognised that individual PBT/vPvB substances may have significantly different fate and behaviour in different environmental compartments and may, as a result, pose different levels of risk in different environmental compartments.

For example, the UK's proposal for a restriction on the use of D4 and D5 in wash-off cosmetic products was supported by a socio-economic analysis that was primarily comprised of a cost-effectiveness analysis limited to releases to the aquatic compartment.

The UK's approach was based on an understanding, described in the Background Document for the restriction proposal), that releases of D4 and D5 to the atmosphere were unlikely to result in significant (re)deposition to surface media, despite their relatively long atmospheric half-lives. The Background Document reports that D4 and D5, based predominantly on modelling studies, are thought to remain in the atmospheric compartment after release until they are degraded (behaving as, what are termed, 'flyers'). As such, in the absence of any evidence of adverse effects on air-breathing organisms, their impact within the atmospheric compartment was considered to be negligible.

This conclusion has been challenged by a study that described deposition of D4, D5 and D6 during the arctic winter and subsequent bioaccumulation in plants and animals (Sanchis, et al., 2015a), although it should be noted that this findings of this study are themselves subject to challenge within the scientific community (Warner, et al., 2015; Mackay, et al., 2015; Sanchis, et al., 2015a).

Although the RAC opinion on the UK restriction proposal considered that the Sanchis et al. (2015a) study was insufficient to prove that deposition was occurring, its opinion noted that on the basis of the large tonnages of these substances released to the atmospheric compartment only low rates of deposition would be necessary to result in a concern.

D4, D5 and D6 are persistent in the aquatic compartment and bioaccumulation and trophic magnification have been observed in some aquatic food chains. Therefore, the key impacts that would be addressed by a proposed restriction would appear to be those that occur in the aquatic compartment. Therefore, it could be argued that the cost-effectiveness of the restriction should be based on releases that occur only to the aquatic compartment, as per the UK proposal on the use of D4 and D5 in wash-off cosmetic products.

Given the relative scale of aquatic to atmospheric releases for the uses of D4, D5 and D6 considered in this assessment such as approach ought to be considered as a 'low' release scenario for cost-effectiveness calculations and would correspond to an upper bound cost effectiveness estimate for the proposed restriction (where the proposed restriction is least favourable from a cost-effectiveness perspective).

Alternatively, releases to all environmental compartments can be considered in a 'high' release cost-effectiveness scenario. Although consistent with REACH, this scenario does not take into account that a proportion of D4, D5 and D6 released to the atmospheric

environment will degrade in this compartment without partitioning (deposition) to the aquatic or terrestrial compartment. This scenario can be considered to result in a lower bound cost-effectiveness estimate (where the proposed restriction is most favourable from a cost-effectiveness perspective.

As part of the preparation of this Annex XV report the Dossier Submitter consulted the ECHA PBT Expert Group (PBT EG) to solicit its views on the appropriateness of the two cost-effectiveness scenarios outlined above. No consensus emerged from this consultation, although many members considered that releases to the atmospheric compartment for these substances should not be excluded from a cost-effectiveness analysis *a priori*, but rather considered carefully within a form of tiered assessment. Several members acknowledged that, based on the specific fate and behaviour of D4, D5 and D6, releases to different compartments ought to be given different 'weights', with releases to the aquatic compartment given greatest weight. Several members suggested that some form of multi-media environmental fate modelling could be explored, that would allow an assessment of the significance of atmospheric releases to the presence of D4, D5 and D6 in the aquatic compartment.

Therefore, based on the feedback received from the PBT EG, the environmental stock modelling reported in Section 1.5.4 was undertaken, and cost-effectiveness estimates derived from this approach should be considered to be complementary to those derived from the more conventional high and low release scenarios conducted according to the conventional approach to PBT/vPvB substances in restrictions.

The estimates of environmental stock reported in Section 1.5.4 are not intended to be definitive estimates the environmental behaviour of D4, D5 and D6 but rather indicative estimates of the proportion of substance releases that remains 'undegraded' in the environment after relevant fate processes are taken into account. Nevertheless, such an approach clearly represents a more refined estimate of relevant quantities upon which to estimate cost effectiveness than that afforded by an approach based on either releases to the aquatic compartment or the atmosphere.

Cost effectiveness estimates based on releases that would remain in the environment are underpinned by the quantity of releases (to the environment as a whole) that would remain undegraded in the environment after taking into account relevant degradation and fate processes (at steady state). As such, it may be considered as a more suitable basis upon which to estimates cost-effectiveness, at least for these substances, when compared to the high and low release scenarios. Nevertheless the high and low release scenarios remain useful to establish the upper and lower extremes of cost-effectiveness.

2.5. Impact on cosmetic products

2.5.1. Economic impacts

In general terms, this analysis follows the approach used by the UK Annex XV restriction proposal for the use of D4 and D5 in wash-off cosmetics (UK, 2015). However, the Dossier Submitter has deviated from some of the key assumptions used in that assessment. In some cases that is because there is more accurate information available today than was available to the UK at the time. In others, it is because in the assumptions used by the UK were acknowledged to be overestimates. Where this was the case, the Dossier Submitter has opted to present an analysis based on more realistic assumptions.

The Dossier Submitter considers the following broad categories of impacts arising from a restriction on cosmetic products:

- Reformulation costs
- Raw material costs
- Costs associated with performance loss
- Consumer valuation of environmental benefits

The following sections set out the key assumptions used, with reference made to those used in the UK Annex XV restriction report. Further detailed assumptions and calculations are covered in Annex D.

2.5.1.1. Reformulation costs

If a restriction prevents the use of D4, D5 and D6 above a concentration of 0.1% w/w in cosmetic products, companies producing them will have to reformulate their products to remove D4, D5 and D6 if they want to continue placing them on the market. The key assumptions for these costs are described below.

The Dossier Submitter notes that cosmetic product reformulation costs are also analysed in the Annex XV restriction report proposing a restriction on the intentional use of 'microplastics'. Where possible, the methodology and underpinning assumptions used in the two assessments are the same.

A) Number of total cosmetic product formulations on the EU/EEA market

The EC impact assessment of the cosmetics industry estimates 300 000 cosmetic product formulations on the EEA market (EC, 2008). This estimate has been updated for the purposes of this assessment based on information from Cosmetics Europe (CE, 2018) and results in an estimate of 430 000 formulations[37]. Only some of these formulations will contain D4, D5 and D6, and would thus be affected by the proposed restriction.

B) Costs per reformulation

The UK Annex XV restriction report presented an extensive review of available information on reformulation costs and common practices of reformulation in the cosmetics sector. It considered cost estimates provided by Cosmetics Europe and those in a 2002 report by

[37] The number of 'larger companies' and 'SMEs' active in the EA/EEA market was updated based on more recent data. The number of formulations per company was kept the same.

RTI prepared for the US Food and Drug Administration (RTI, 2002). These included several kinds of estimates (the cosmetics industry presented data for major reformulations for large and small companies, while the RTI study presented costs for reformulating a major ingredient, as well as a critical and non-critical minor one).

Based on these data, the UK assessment assumed that replacing D4 and D5 in cosmetics would require a major reformulation in all cases, and chose to use a central cost estimate of €350 000 per reformulation, which corresponds to the lower bound estimate presented by Cosmetics Europe for major reformulations (large companies) and also the estimate by RTI for reformulating a major ingredient.

The UK considered these costs could be overestimates, and there are several sources of information to support this conclusion. For example, data from the impact assessment report on simplification of the Cosmetics Directive (EC, 2008) shows that out of the estimated 300 000 cosmetic product formulations on the EU market at the time, 2/3 belonged to SMEs. The cost estimates provided by Cosmetics Europe themselves for major reformulations done by smaller companies are €30 000 - €50 000 per item. A simple weighted average would hence result in an estimate for reformulation costs of €135 000 - €200 000 per item, which is significantly lower than the € 350 000 assumed in the UK assessment. However, the Dossier Submitter notes that there are also indications that smaller companies may be more likely to be in the 'natural segment', and therefore less likely to own formulations containing siloxanes, so using a simple weighted average may not be appropriate.

Additional preliminary calculations based on industry R&D spending also suggest that the costs per reformulation assumed in the UK assessment may be an overestimate. According to EuroStat, the cosmetics industry spent €1.3 billion on R&D in 2014. Cosmetics Europe assume that spending on R&D is about 5% of turnover (CE, 2018a), resulting in a total of €2.35 million R&D spending for 2017. Assuming that all R&D is used for reformulation (i.e., excluding new product development), that minor reformulations are about 10 times less costly than major ones, and that the same share of annual major and minor reformulations holds as in the UK assessment (every year 5% of formulations undergo major reformulation and 15% undergo minor ones, see below for details), the cost per major reformulation would be between €47 000 and €84 000, while for minor ones this would be €4 700 to €8 400.

Based on these data, the Dossier Submitter will assume that reformulation costs are indeed different for large companies and SMEs. A cost per reformulation of €365 000 (€350 000 adjusted for inflation to 2017 values) will be assumed for major reformulations done by large companies, as assumed in the UK Annex XV restriction report, but it will be assumed that the cost of reformulations by the remaining companies in the industry (SMEs) is €42 000 per reformulation (this is the mid-point of the CE estimate for reformulations done by small companies, €40 000, adjusted to 2017 values).

There are two further factors that could influence the cost per reformulation. The first is that the costs mentioned above are per *successful* reformulation. Failed reformulations would increase costs. The Dossier Submitter has no specific information that would allow it to estimate what proportion of reformulations may fail. However, in the event of a restriction, the large number of reformulations required should create relevant knowledge and experience that ought to be applicable from one reformulation to another (whether within the same company or even between them, if information is shared), and thus would be expected to lower the average cost per reformulation. Again, the Dossier Submitter has

no specific information that would allow it to estimate how this would affect the cost per reformulation. In the absence of such specific information, it will be assumed that these two effects broadly cancel each other out.

C) Number of formulations containing D4, D5 and D6

The UK Annex XV restriction report applied an estimate that products based on D5 were estimated to account for around 20-30% by value of all cosmetics on the EU market. A similar calculation was performed for D4. The UK Annex XV restriction report acknowledged that other information (e.g. for the Canadian market) suggested the results of this approach may be a large overestimate. If the Dossier Submitter was to use the same approach for D4 and D5 (not even including D6) in the leave-on market, that would result in 57 600 to 86 400 formulations containing those substances. Cosmetics Europe have provided some calculations as well, based on a survey of their members and extrapolated to non-member companies, wherein they state that an estimate of 60 000 formulations could be realistic (CfE1#465).

Instead of using the above estimates, the Dossier Submitter has considered that more reliable data can be obtained from other sources which have information on products on the market today and include data on their ingredients. The best estimate will use data from a company called CosmEthics (CosmEthics, 2018), which gathers data on the ingredients contained in cosmetics products across the EU and provides a mobile application that allows consumers to scan products and inform themselves about their contents. The source of CosmEthics data is a combination of data provided by cosmetics companies themselves, data-gathering commissioned by the company, and product labels photographed by app users trying to scan products not yet on the database and transcribed at the company. Given the wide geographical spread of their data and the large number of products included, the Dossier Submitter considers it provides a good picture of the formulations available on the EEA market.

According to the data received from CosmEthics, 11% of formulations contain at least one of the ingredients D4, D5 and D6 above a concentration of 0.1% and would therefore need reformulation to be able to be kept on the market under the proposed restriction. By far the most common ingredient is D5, which is contained in 10% of formulations (either on its own, or in combination with one or both of the others).

The Dossier Submitter has triangulated these data with several other sources which are either more geographically narrow or include a smaller product base. As part of the ECHA market survey, researchers were commissioned to visit different kinds of retailers selling cosmetics in three EU Member States (France, Denmark and Lithuania). The researchers photographed all the products on the shelves in the relevant categories and identified whether they contained D4, D5 and D6 (COWI, 2018). The Dossier Submitter has also obtained data from consumer associations in France (Que Choisir, 2018) and Denmark (Danish Consumer Council THINK Chemicals, 2018) which have also developed cosmetics mobile apps. The characteristics of these data sources are summarised in Table 17.

According to those sources, the proportion of formulations containing at least one of the ingredients D4, D5 and D6 could be from 8% to 16%. The Dossier Submitter will use this figures as low and high estimates (keeping the 11% from CosmEthics as the best estimate, as mentioned).

Assuming, as discussed in Section 2.5.1.1, 430 000 formulations on the market, this results in approximately 34 400 to 68 800 formulations with D4, D5 and D6, with a best

estimate of 47 300.

Table 17: Characteristics of data sources at the disposal of the Dossier Submitter

	CosmEthics	**Que Choisir**	**Danish consumer council THINK**	**COWI survey**
Type	Online database	Online database	Online database	Market survey
Extraction date	28 September 2018	2 July 2018	August 2018	March 2018
Number of products in database at extraction date	95 764 products	86 883 products	ca. 10 000 products	1 557 products
Market	EU-wide. Most widely-used in Nordic countries & France	France	Denmark	France, Denmark, Lithuania
Period	Since 2013, with 78% of products since 2016	Since March 2018	Since 2015	Snapshot of early March 2018

Source: CosmEthics 2018; Que Choisir 2018; Danish consumer council THINK; ECHA market survey

Some of those formulations will belong to large companies, while some will belong to SMEs.

To estimate how many formulations belong to each group, the Dossier Submitter uses information provided by Cosmetics Europe based on the 2017 survey of their members mentioned above (CfE1#465). The survey sought to understand how many formulations they had containing D4, D5. They received responses from 75 companies, and consider that the bulk of uses of D4 and D5 are captured by that data. Only some of the companies that declared using D4, D5 in their products provided an estimate of the number of formulations, but by extrapolating the data to the rest of the companies declaring use of D4, D5 , Cosmetics Europe arrive at an estimate of approximately 12 000 formulations with D4, D5 belonging to their members. This number does not include formulations containing D6.

To account for formulations containing D6, the Dossier Submitter bases its estimates on CosmEthics data. The number of products containing only D6 as cyclohexasiloxane is 5.5% of products containing D4 and/or D5 (those listing as ingredients cyclotetrasiloxane and/or cyclopentasiloxane and/or cyclomethicone, which is a combination of D4, D5 and D6). The Dossier Submitter considers the latter category would correspond to 'formulations containing D4, D5'. Increasing 12 000 by 5.5% results in an estimate of 12 700 formulations with D4, D5 and D6 belonging to Cosmetics Europe members.

The Dossier Submitter uses this number of 12 700 as a proxy for the number of formulations with D4, D5 and D6 belonging to large companies (even though it is understood that some Cosmetics Europe members are SMEs), and assume the rest of the formulations (21 700 to 56 100, with a best estimate of 34 600) belong to SMEs.

D) Number of reformulations expected

The UK Annex XV restriction report uses the implicit assumption that every formulation containing the restricted ingredients would be reformulated because of the restriction. The Dossier Submitter thinks there are good reasons to believe this may not be the case.

In addition to containing information on ingredients, the detailed data sources, described in Table 17, characterise products as belonging to particular categories and subcategories. These subcategories provide a fairly good level of detail (e.g. Category: Make-up and

lipsticks; Sub-categories: eye shadow, blush/bronzer/contour, mascara, lipstick, etc.). The Dossier Submitter examined whether there were any subcategories where a very high proportion of products examined contained D4, D5 and D6, which could indicate a lack of alternatives that are D4, D5 and D6-free. Conversely, categories where only a small proportion of formulations contain D4, D5 and D6 could indicate plenty of alternatives.

The different data sources use different categories and subcategories, which makes them difficult to compare or combine. The Dossier Submitter has therefore relied on the CosmEthics database, due to their combination of wide geographical coverage and large number of products.

The data shows that for most subcategories, the products using D4, D5 and D6 are a minority. Out of 80 subcategories where products containing D4, D5 and D6 are present, in 75 categories (93% of them) products containing D4, D5 and D6 are less than 30% of the total products identified in their subcategory. In 49 categories (60% of them) these products are less than 10% of the total. In only one subcategory (serum/oil) they are over 50% (cf. Figure 2).

The proportion of products with D4, D5 and D6 for each subcategory is included in Annex A.

As a general approach, the Dossier Submitter will assume that the lower the proportion of products that contain D4, D5 and D6 within a subcategory, the lower the proportion of products within a subcategory that will actually be reformulated in the event of a restriction.

The reasoning for this assumption is that if there are many products within a category that do not contain D4, D5 and D6 then it is likely that these already offer comparable product performance to products that contain D4, D5 and D6. In this scenario companies (particularly large ones, which are also likely to produce alternative formulations within the same category) will accept that customers will switch to an existing alternative product rather than invest in reformulation. Where there are relatively few products within a subcategory that do not contain D4, D5 and D6 it is assumed that alternative products, not containing D4, D5 and D6, do not currently offer comparable product performance and that companies will, in this instance, prefer to reformulate existing products.

The rationale for comparable product performance is supported by information provided by the Nordic Swan Ecolabel, which reports that in Finland, Denmark and Sweden, there are 3 469[38] cosmetic products across various categories that fulfil the Nordic Swan Ecolabel criteria that 'D4, D5 and D6 must not be present in the product or raw material' (Nordic Swan Ecolabel, 2018). To obtain the Nordic Swan Ecolabel, products should pass 'efficiency testing' which, in cosmetics, consists of consumer acceptability tests. For sun-protection products, the Nordic Swan Ecolabel also requires that the performance of the product, as outlined in recommendation 2006/647/EG, also has demonstrated. Last but not least, products that have been granted an ecolabel certificate should demonstrate that the sales of the products are increasing or stable during three consecutive years – this is requested by the Nordic Swan Ecolabel organisation to document that the certified product is

[38] 3 469 cosmetics with the following repartition per category: Conditioner 184, deodorant 39, Facial cleanser 199, Hair care (mousse, wax, serum etc.) 195, Lip care 24, make up 23, Mouth wash 3, Nail polish remover 19, self-tanner 20, shampoo 394, Skin cream 732, soap 1058, Sun screen 310, Toothpaste 28, Wet wipe 222

accepted by the consumers for its primary function. The presence of Nordic Swan labelled products across cosmetic product categories can be considered to be evidence that alternatives offer acceptable product performance.

Despite the availability of alternatives, the Dossier Submitter understands that not all of these products will be exact substitutes in terms of performance, and the issue of performance loss is considered in section 2.5.1.3. However, the Dossier Submitter considers that this is a broadly suitable model of what is likely to take place.

The Dossier Submitter also notes that some alternatives might not be suitable for substitution due to environmental concerns, and are under regulatory scrutiny because of PBT concerns (e.g. linear siloxanes).

The specific assumptions used are as follows:

- For subcategories where products containing D4, D5 or D6 represent less than 30% of the market, the alternatives are expected to take over their market share and very few of these products are expected to be reformulated (assumed 5%).
- For subcategories where products containing D4, D5 or D6 represent between 30% and 70% of all products, it is assumed that half of these products would be reformulated. The remaining 50% of products are expected to be discontinued.
- For subcategories where products containing D4, D5 or D6 represent over 70% of all products, it would be assumed that 95% of those products would be reformulated. However, no subcategories in the data show such high prevalence of products containing D4, D5 or D6.

Using the data from CosmEthics, this approach results in an assumption that 19% of the formulations containing D4, D5 or D6 would actually be reformulated.

The total number of reformulations expected are therefore 6 500 to 13 00 (with a best estimate of 9 000). Of these, 2 400 are assumed to belong to large companies and 4 100 to 10 600 (with a best estimate of 6 600) to SMEs.

E) Coordination with baseline reformulations

The cosmetics industry is highly innovative and R&D/reformulations are undertaken regularly to ensure the product portfolios on the market respond to the latest market demands and advancements in the industry. The UK Annex XV restriction report assumed that, in normal circumstances, cosmetics formulations undergo major reformulations once every 20 years on average and minor reformulations once every 6-7 years (so, in effect, every year 5% of formulations undergo major reformulations and 15% undergo minor ones). The Dossier Submitter will use these assumptions as well.

The UK Annex XV restriction report further assumed that it would be possible to coordinate some of the reformulations required to remove D4, D5 with those that would already have happened in the baseline. The same approach is adopted, with the following assumptions:

(i) For products where the baseline major reformulation would have taken place during the transitional period (periods of 2 and 5 years analysed), they would be coordinated with removal of D4, D5 and therefore there would be no additional costs as a result of the restriction.

(ii) For products where the baseline major reformulation would have taken place during the 5 years after the end of the transitional period, that reformulation would be coordinated with removal of D4, D5 and done earlier, during the transition period. So

there would be only the costs of bringing those reformulations forward.

(iii) For products where the baseline major reformulation would have taken place six years or more after the end of the transitional period, no coordination would be possible, as it would be impossible to predict market demands that far in advance. For those products, there would be an additional major reformulation during the transition period (and the reformulations that would have taken 6+ years after the end of the transitional period would still take place). So for these products, the full cost of an additional reformulation would be incurred as a result of the restriction.

The UK Annex XV restriction report further assumed that the cost of the coordinated reformulations would not increase by incorporating the removal of D4, D5 (beyond the extra cost in (ii) of bringing them forward in time).

The Dossier Submitter intends to adopt this same broad approach, except that it will also incorporate assumptions about minor reformulations. It will be assumed that any minor reformulations that would have occurred during the transition period will now not happen separately and be 'saved', as they will be incorporated into the major reformulations to remove D4, D5 and D6. The schedule of minor reformulations would then continue as usual after the transitional period (this also contemplates the possibility that some of the formulations that have just undergone major reformulation may require some small adjustments after the transition period).

2.5.1.2. Raw material costs

There could be impacts on costs if products are reformulated and the alternative raw materials used to replace D4, D5 and D6 have a different price, or have to be used in different amounts.

The UK Annex XV restriction report used a price for D4, D5 of €4 000 per tonne, based on a report by AMEC (AMEC, 2013b). No further evidence on prices was provided by stakeholders. An examination of prices widely quoted on the internet (on online commerce sites, such as Alibaba.com) suggest that €4 000 per tonne is still an appropriate indicative price for D4, D5, and that it is a reasonable estimate for D6 as well.

The UK Annex XV restriction report presented an analysis of the alternatives available, and updated information on alternatives to D5 was provided by Cosmetics Europe (CfE1#465). Additional data on potential replacements to D4, D5 and D6 was found in the trade press (Woodruff, 2018), albeit including no information on the costs of the alternatives. More information on alternatives in presented in Appendix C.2.

The data provided by Cosmetics Europe was based on a survey of their members undertaken in 2017, and included information on how the unit prices of the alternatives compare with D5. No alternatives were identified with unit costs below that of D5. Some had similar prices, but the majority were more expensive, some substantially so.

Significant uncertainty still remains regarding which alternatives would be used, which makes it difficult to determine what the price differential may be. The Dossier Submitter will therefore follow the same approach as in the UK dossier, and assume the unit price for the alternative will be twice that of D4, D5 and D6.

Costs would also change if quantities required of the alternative and of D4, D5 and D6 were different, but little data is available on this topic, either. In the absence of evidence, the Dossier Submitter will again follow the approach in the UK Annex XV restriction report

and use a ratio of 1.0 (same amounts of the alternative as of D4, D5 and D6).

As described in the previous section, the analysis assumes that only a proportion (19%) of formulations containing D4, D5 and D6 will be reformulated. That means that the alternative ingredients referred to above would only be used for 19% of formulations. The Dossier Submitter has no data on how many tonnes of D4, D5 and D6 that represents, but in the absence of any other evidence, the 19% figure will be used as a proxy, and it will be assumed that only 19% of the tonnage of D4, D5 and D6 in cosmetics (not including the tonnage that is present as impurities, which may not be affected by the restriction; see section 2.7) will be replaced. The price premium would therefore only apply to that tonnage: 3 250 tpa.

For the remaining 81% of formulations the alternatives would be, in effect, products already on the market. In the best estimate, the Dossier Submitter will assume no net effect associated with their increased production, assuming that their presence on the market indicates they are profitable. The impacts of relaxing this assumption and assuming some additional raw material costs in the remaining 81% of formulations are analysed in Annex D.

2.5.1.3. Consumer costs associated with performance loss (and consumer valuation of environmental benefits)

The Dossier Submitter assumes in this dossier that not all formulations containing D4, D5 and D6 will be reformulated (some because the companies choose not to do so, some because reformulation attempts may fail). This could lead to the products available to consumers being of a different quality of those currently available and containing D4, D5 and D6. For instance, they may not feel as silky on the skin, may leave hair and skin less smooth, may leave a residue or may not dry as quickly.

It is also possible that formerly D4, D5 and D6-containing products that have been reformulated will have an improved quality and provide a performance gain to consumers, but in general, it could be expected that if those performance gains were possible, the substitution would have been undertaken already by industry in a previous reformulation cycle. In some cases, it is possible that either the substitutes were not known yet at the time, or that the costs in comparison to D4, D5 and D6 would have prevented the substitution. However, from the evidence available (including comments from industry about the identified potential alternatives) this does not seem a likely prospect (or at least not one that would affect a significant number of products).

The UK Annex XV restriction report included a specially-commissioned study that performed a so-called discrete choice experiment (Kanninen, 2007). A total of 829 UK respondents made choices between options that differed with regard to the levels of 3 attributes:

- Cosmetic quality (standard, superior)
- Accumulation of D4, D5 in the aquatic environment (low, high)
- Price (several different price levels)

This allowed the researchers to elicit:

- A willingness to pay value for the consumer loss connected to the functionality provided by D4 and D5 in cosmetics. This was estimated at €5/person/year.

- A value for willingness to pay to avoid the potential risks of accumulation of D4 and D5 in the aquatic environment. This was estimated at €46 /person/year for D4 and €40 /person/year for D5.

The scenarios in this study do not apply exactly to the current proposal (or to the UK dossier). The following points should be noted:

- The study covered both wash-off and leave-on products, so further calculations in the UK dossier had to adjust for the fact that the restriction proposal covered only wash-off. In that sense, the results would seem more easily applicable to the current proposal.
- The study covered only D4 and D5, while the current proposal covers D6 as well. D6 has a very similar use profile and produces similar properties to D5, so the Dossier Submitter may be able to assume the results for D6 could be similar to D5.
- The study asked participants to consider releases to the aquatic environment, but not releases to the air. That was suitable to the UK proposal as it covered only wash-off, but a high proportion of releases for the current proposal are to the air. This may mean the study results may be less applicable to the proposal, although it is uncertain in what direction this may change consumer valuations (they could be more or less concerned about atmospheric releases than about those to the aquatic environment).
- Further, the Dossier Submitter notes that SEAC expressed some reservation about the validity of the willingness-to-pay values derived from the study.

Considering the above points, the Dossier Submitter does not use the UK study to produce overall estimates of consumer loss or of consumer valuation of environmental benefits. Rather, the Dossier Submitter presents the study results as an indication that consumers place a value on both of these product characteristics and appear to be capable of trading them off against price increments, and that the value they place on the potential environmental benefits may compensate for some or all of the loss of consumer surplus suffered.

The Dossier Submitter also undertook work to consider whether some value for the consumer loss could be elicited through revealed preference, by analysing the variation in prices for products containing and not containing D4, D5 and D6. However, the analysis of the market survey data (the only source amongst those described in Table 17 that included price information) performed by an independent researcher (Alberini, 2018) revealed no statistically significant effect of the use of D4, D5 and D6 on the per-litre price. From that the Dossier Submitter concludes that the use of D4, D5 and D6 is not limited to specific products in a segment.

2.5.1.4. Other general assumptions

The following general assumptions have been applied to the calculation of the costs

- Entry into force of a restriction is the year 2020. This is when the transitional period starts to apply.
- The period of analysis is 20 years, to coincide with the cosmetics industry's baseline major reformulations cycle.
- A discount rate of 4% has been used.

- Costs are in 2017 prices, and so the Net Present Value (NPV) is presented to 2017.
- The reformulations undertaken as a result of the restriction take place throughout the transitional period, in equal numbers each year. The Dossier Submitter considers this is a more realistic assumption than all the reformulations taking place at the end of the transitional period, due to specialists who can undertake these reformulations being scarce resources.
- As a simplifying assumption, the Dossier Submitter has assumed that, although reformulations happen throughout the transitional period, reformulated products are only brought into the market immediately after the end of that period. Products that would be discontinued would also only be withdrawn from the market after the end of the transitional period. Reductions of releases therefore only start taking place at that point.

2.5.1.5. Summary of the costs

The Dossier Submitter's best estimate of the quantified costs associated with introducing a restriction on D4, D5 and D6, assuming a transitional period of 5 years, is a 20-year NPV of €703 million. This represents an average annual cost of €63 million. Of this, reformulation costs make up 85%, while the additional cost of alternative raw materials makes up the remaining 15%.

Under a shorter transitional period of 2 years, the 20-year NPV of total costs is estimated to be €929 million. This represents an average annual cost of €73 million, and the split between reformulation costs and the additional cost of alternative raw materials is broadly as above. The Dossier Submitter notes, however, that this estimate is based on the assumption that it is feasible to complete all the needed reformulations in 2 years. Evidence obtained in the consultation casts doubt on whether that would be possible to do at all, and if it is, whether the cost per reformulation would be the same (reformulating in only 2 years may require increasing resources to tackle in parallel reformulations which would otherwise have been done consecutively). The estimate for the cost of reformulations with a 2-year transitional period is therefore likely an underestimate, and it could be significantly higher. More details on the evidence received during consultation can be found in section 2.5.5 on the proposed transitional period.

Further analysis of the impact of different transitional periods is presented in Annex D.

The costs of the restriction are concentrated on a small number of broad product groups. The costs associated with Make-up and lipsticks and Skin care make up some $^4/_5$ of total average annual costs. More detailed analysis of the different broad product groups is presented in Section 2.5.4 (Proportionality).

2.5.2. Human health and environmental impact (effectiveness)

Human health impact

Not considered because a REACH Restriction proposal on cosmetic products can only address unacceptable risk to the environment.

Environmental impact

Significant emission reductions (ca. 93%) are envisaged from the Annex XV restriction proposal on the use of D4, D5 and D6. However, emissions will not be completely prevented as the use of silicone polymers (that may contain D4, D5 and D6 at

concentrations below the limit of 0.1% w/w) will continue (or even increase) after the restriction enters into force.

Although the proposed restriction is on the placing on the market of consumer/professional products it will also affect upstream supply chains i.e. formulation of cosmetic products, reducting releases from this life-cycle stage by approximately 75%. However, as it is assumed that the formulation of cosmetic products containing D4, D5 and D6 for direct export from the EU/EEA will continue, the releases arising from their formulation will not be prevented. These are estimated to be 0.05-0.34 tpa for the aquatic compartment and 1.15-1.98 tpa for all compartments, which is equivalent to 0.2-0.4 % of overall releases from cosmetic products to the aquatic compartment or 0.001-0.01% of releases to all compartments, respectively. This is based on the assumption that a proportion of cosmetics formulated in Europe (with D5 and D6) will keep on being formulated in the EEA and exported directly. This is a conservative assumption as products for export may also be reformulated to no longer contain D5 or D6 or be withdrawn from sale in the event of the restriction being adopted. It should also be noted that even if overestimated, these releases would represent a minor fraction of the remaining releases after the entry into force of the restriction.

In term of environmental releases, the impact of the restriction is summarised in Table 18.

Table 18: Environmental impact (cosmetics)

Use	Current use tonnage [tpa]	Current release to environment [tpa]		Expected effect of restriction on releases
		Aquatic only	All compartments	
Cosmetics formulation	21 400	0.22-1.45	4.93-8.46	Releases reduced by ca. 75% if the formulated tonnage decrease from 21 400 to 5 000[39]
Leave-on cosmetics (D4, D5 and D6)	17 000	7.62 – 50.31	16 399 -16 641	Reduced to 0
Wash-off cosmetics (D6)	200	12.17 – 20.96	55.56 – 114.51	Reduced to 0
Use of silicone polymers in cosmetics (leave-on and was-off)	637.5	6.52 – 12.44	567.75 – 595.02	Remain the same or slightly increase if D4, D5 and D6 are replaced by silicone polymers with impurity <0.1%

2.5.3. Other impacts

If a restriction on the intentional use of microplastics is adopted at a similar time as one on D4, D5 and D6, this would have an impact on reformulation costs in the cosmetics industry. A proportion of products will contain both microplastics and D4, D5 and D6, so

[39] It is assumed that a proportion of cosmetics formulated in Europe (with D5, D6) will be exported directly as of today, i.e. cosmetics containing 5 000 T of D5, D6. This is a conservative approach as products for export may also be reformulated to no longer contain D5 or D6 or be withdrawn from

at least some reformulations may be expected to be done just once to remove both types of substance. The costs per reformulation if the presence of D4, D5 and D6 and microplastics have to be addressed at the same time may be higher than assumed here and in the microplastics restriction dossier. However, it is expected that they would be lower than if they were performed independently. If the costs of reformulation are counted separately in each dossier, then this will likely represent double counting, at least for a proportion of the costs.

2.5.4. Proportionality

Using a 'business as usual' baseline, where cosmetics companies would continue to use D4, D5 and D6 at the same rates as they do now and would not seek to replace the substances voluntarily, and if the transitional period were 5 years, the central 'best estimate' of the 20-year NPV is €703 million for the cosmetics sector (with average annualised costs of approximately €63 million). The majority of those costs (some 85%) are related to the costs of reformulations.

In terms of cost-effectiveness, if the Dossier Submitter considers all releases, both to air and water (using the mid-point in the ranges estimated for each), this would result in €2.8 per kg of releases abated. If the Dossier Submitter was to consider only releases to water, the abatement costs would be higher: €1 030 per kg.

However, it is also possible to analyse cost-effectiveness using a measure based on the modelling of steady-state 'pollutant stock' remaining in the environment resulting from the total releases of D4, D5 and D6 to water and air, which is outlined in Section 1.5.4. Based on that modelling, the Dossier Submitter has calculated an estimate of the proportion of total releases that will remain in the environment (as they do not rapidly degrade) and therefore contribute to the steady-state stock. This fraction comprises a (relatively high) proportion of total releases to water and a (much smaller) proportion of total releases to air.

The proportion of total annual releases (water + air) that will remain in the environment is 2.6% of total releases of D4, 2.3% of total releases of D5 and 5.7% of total releases of D6. Applying these percentages to the estimates of total annual releases that would be abated due to the restriction results in an estimate of 450 tpa.

These 450 tpa are not a measure of stock. They represent a simplified approximation of the releases that will remain in the environment and would be prevented by the proposed restriction. When considering these releases that will remain in the environment as the basis for the cost effectiveness estimates, abatement costs would be €104 per kg per year.

Following on from section 2.4.2, using the releases that will remain in the environment, may be considered as a more suitable basis upon which to estimate cost-effectiveness, at least for these substances, when compared to using only releases to water or releases to water + air. Using only releases to water would effectively give a weighting of 0% to releases to air, while using releases to water + air would give releases to air a weighting of 100%. Considering the feedback from the PBT expert group (also described in section 2.4.2), neither of those extremes seem appropriate. Using instead the releases that will remain in the environment gives some weighting to releases to air, but not as much as releases to surface water.

Nevertheless, cost-effectiveness considering only releases to water and releases to water + air remain useful to establish the upper and lower extremes of cost-effectiveness. The

data also allows more granular analysis of cost-effectiveness by product group for these releases (see later in this section) which is why they are also presented in this dossier.

Cost-effectiveness measures based on the releases that will remain in the environment can be conceptually compared with those calculated for other restrictions on PBT and/or vPVB substances (based on releases to all compartments) where a very high proportion of overall releases were persistent, such as PFOA. To an extent, using this measure could also be considered as comparable with the restriction on D4 and D5 in wash-off cosmetics, as the releases to air prevented by that restriction were very low and a very high proportion of releases were to water, where they will remain in the environment.

For reference, below are cost-effectiveness figures for several recent restrictions.

Table 19: Cost effectiveness of recent REACH restrictions

Restriction under REACH	€/kg pa central value
Lead in shot in wetlands	9
Lead in PVC	308
D4 and D5 in wash-off cosmetics	415
DecaBDE	464
Phenylmercury compounds	649
PFOA-related substances	734
PFOA	1 649

For several variables in the cost and cost-effectiveness calculations, ranges were used to contemplate uncertainties.

Costs calculated using the low estimates for all the cost-related variables show a 20-year NPV of €649 million (with an average annualised cost of €58 million). Combining these costs with the upper end of the ranges for the release estimates results in a cost-effectiveness value of €2.6 per kg of releases to all compartments (air+water) abated, €607 per kg of releases to water abated, and €95 per kg per year of releases that will remain in the environment abated.

Costs calculated using the high estimates for all the cost-related variables show a 20-year NPV of €793 million (with an average annualised cost of €71 million). Combining these costs with the low ends of the ranges for the releases estimates results in a cost-effectiveness value of €3.2 per kg of releases to all compartments (air+water) abated, and €2 670 per kg of releases to water abated, and €119 per kg per year of releases that will remain in the environment abated.

As shown in Table 21 (at the end of this section), shortening the transitional period to two years from five years increases the NPV and average annualised costs, but also the quantity of releases prevented. On balance, such a change makes the cost-effectiveness estimates less favourable. The overall impact if such a change were made would be to increase the cost per kg of releases abated by approximately 10%. However, as noted in section 2.5.1.5, this estimate is based on the assumption that it is feasible to complete all the needed reformulations in 2 years. Evidence obtained in the consultation casts doubt on whether that would be possible to do at all, and if it is, whether the cost per reformulation would be the same (reformulating in only 2 years may require increasing resources to tackle reformulations in parallel, which would otherwise have been done consecutively). The estimate for the cost of reformulations with a 2-year transitional period is therefore likely an underestimate, and it could be significantly higher. More

details on the evidence received during consultation can be found in section 2.5.5 on the proposed transitional period.

The Dossier Submitter has also analysed whether costs and cost-effectiveness vary between different product groups, with as much detail as the data allowed. Separate calculations were possible for the following product groups in relation to (i) releases to water and (ii) releases to all compartments (air + water): deodorants and antiperspirants, make-up and lipsticks, skin care, sun/self-tanning, wash-off and hair styling and other.

Cost-effectiveness based on the releases that would remain in the environment is only currently possible to estimate for 'high-level' use categories e.g. uses in cosmetics vs other uses[40].

Table 20: Comparison between proportion of reformulations and proportion of releases for cosmetic product categories

Product group	Proportion of total reformulations expected	Proportion of total annual releases to water from cosmetics	Proportion of total annual releases (all compartments) from cosmetics
Deodorants and antiperspirants	3%	31%	45%
Hair styling ("LEAVE-ON") and other	1%	22%	31%
Make-up and lipstick	67%	3%	11%
Skin care	26%	7%	12%
Sun/self-tanning	1%	0%	0%
Wash-off	2%	36%	1%
Total	100%	100%	100%

Source: ECHA

Cost-effectiveness results vary substantially between product groups. The releases associated with sun/self-tanning products are comparatively very small (none to water, and 6 tpa to the air). As a result, while the number of reformulations expected for those products is small as well, costs per kg of releases prevented are still relatively high. Considering releases to all compartments (air+water), the cost per kg of releases avoided is €99 (no measures of cost-effectiveness were calculated for releases to water, as these are considered negligible).

The make-up and lipstick product group also stands out. Considering releases to all compartments, the cost per kg of releases avoided is €15, and considering just releases to water it is €21 500. This is because approximately 2/3 of all reformulations expected are within that product group, while only 3% of releases to water (and 11% of releases to air and water) are from make-up and lipsticks.

The situation is similar for the skin care product group. A quarter of reformulations expected are from that product group, while it makes up for 7% of releases to water (and 12% of releases to air and water). Costs per kg of releases avoided is €6 for releases to all compartments (air+water), and €3 500 for releases to water alone.

[40] Additional modelling on the basis of individual cosmetic product categories may be undertaken during the opinion-making phase of this restriction proposal, where considered appropriate and necessary.

The Dossier Submitter notes that there may be some ambiguities regarding whether certain products should be classified as make-up and lipstick or as skin care. The proportion of total formulations in each product group according to information provided from Cosmetics Europe and according to the broad product groups defined by the Dossier Submitter using CosmEthics data has been compared. For most product groups, the results are broadly consistent, but for make-up and lipstick and skin care, they differ, although for both subcategories added together, the results are broadly consistent. It appears likely that the Dossier Submitter must have considered certain products as skin care that Cosmetics Europe members considered as make-up and lipsticks, but it is difficult to identify which. As a result, it may be advisable to consider the two categories together. If this is done, the cost per kg of releases to water prevented is €8 600, and €10 for releases to water and air.

The Dossier Submitter has considered whether granting a longer transitional period for those product groups with greater costs per kg of releases prevented would improve proportionality. It does, but not substantially. For instance, increasing the transitional period to 8 years for make-up, lipsticks and skin care lowers the cost per kg of releases by 12%, to €7 600 for releases to water and to €9 for releases to water and air.

The Dossier Submitter has also considered what the results would look like for a restriction of all cosmetics with the exception of make-up, lipsticks and skin care. Such an option would avoid 90% of releases to water and just over three quarters of releases to air and water. The 20-year NPV of the costs is estimated to be €117 million (with average annualised costs of €10 million). As for measures of cost-effectiveness, the annual cost per kg of releases to water prevented would be €190, and €0.60 for releases to water and air.

The following figures show the different product groups and options graphically. They plot the tonnage of releases prevented against the cost per kg of doing so by the different product groups. Figure 8 does so for releases to water, while Figure 9 and Figure 10 do so for releases to air and water. The figures in brackets next to each product group name represent the transitional period used to calculate cost per kg of releases avoided. Note that Figure 8 does not include the Sun/Self-tanning product group, as releases to water are considered to be negligible.

Figure 8: Magnitude of releases to water and annual cost per kg of releases to water prevented, by product group

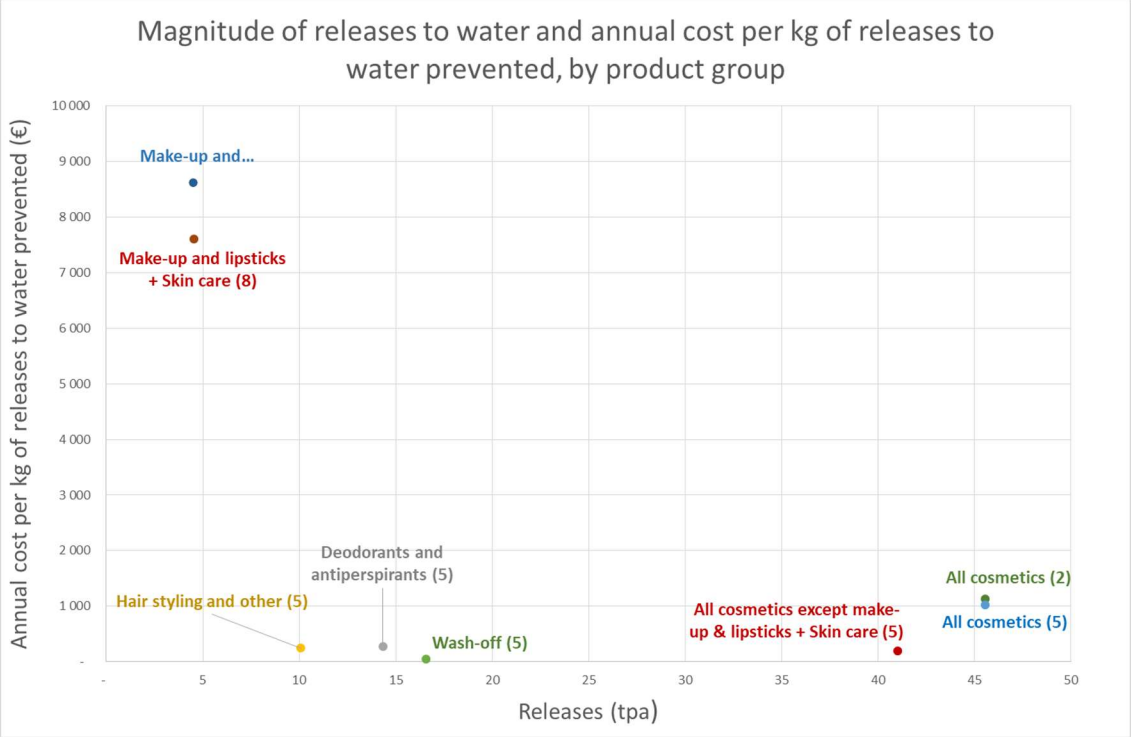
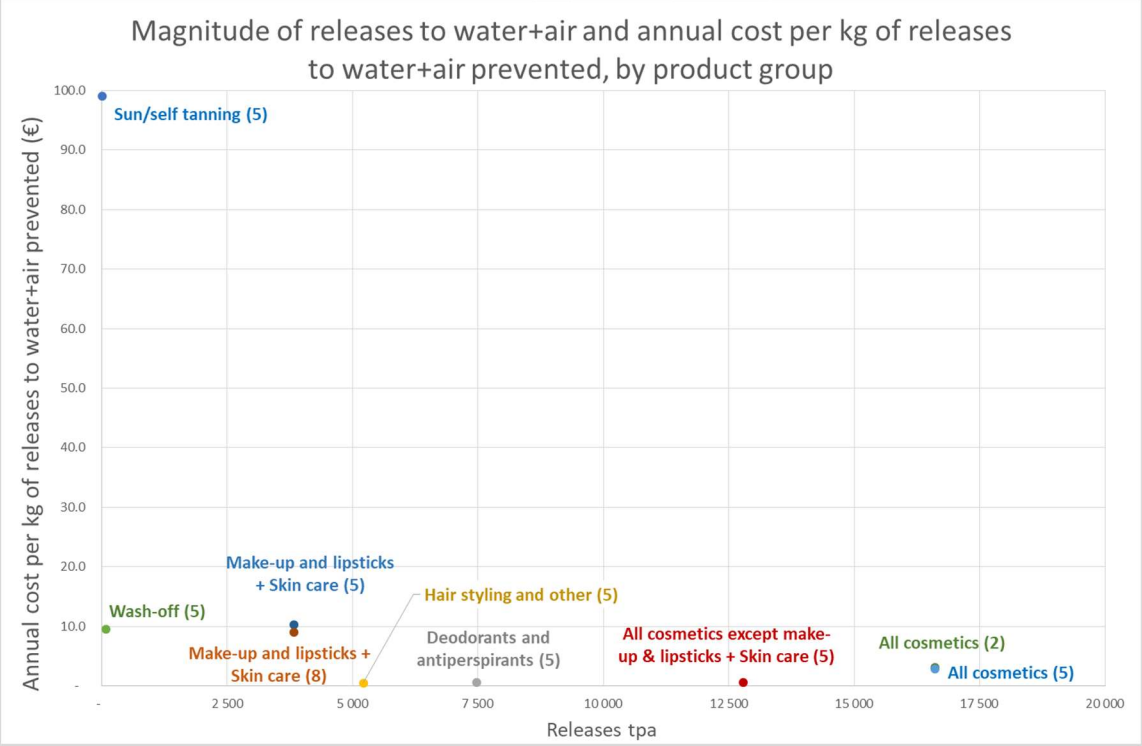
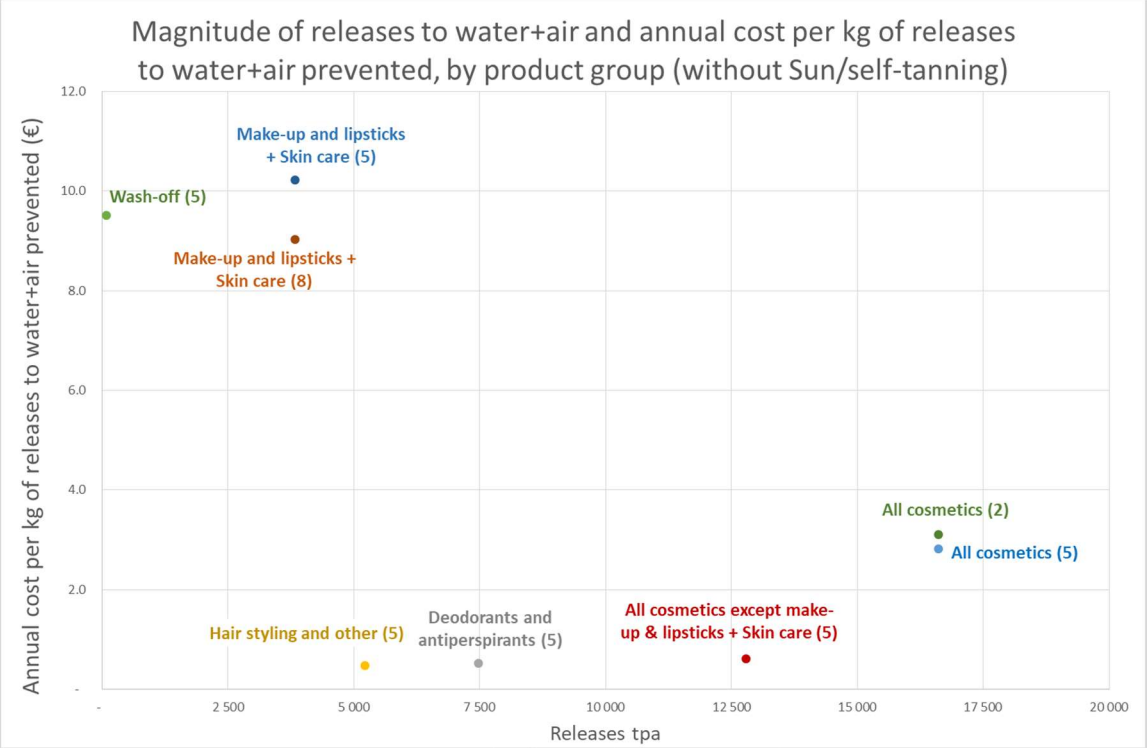


Figure 9: Magnitude of releases to water+air and annual cost per kg of releases to water+air prevented, by product group



It is difficult to distinguish the difference between most product groups in Figure 9, due to the presence of the sun/self-tanning product category, which has a comparatively high cost per kg of releases avoided. Figure 10 below shows the same figure, with the sun/self-tanning category excluded to improve the presentation of the differences between the remaining categories.

Figure 10: Magnitude of releases to water+air and annual cost per kg of releases to water+air prevented, by product group (without sun/self-tanning products).



The information on cost-effectiveness by product group can also be presented by showing how quantities of releases prevented and average annual cost per kg of releases prevented change as the restriction is made broader by another product group being added. In the following two figures, this information is presented assuming a 5-year transitional period.

It can be seen in Figure 11 that for releases to water alone, the annual cost/kg of releases prevented would be €49 if only wash-off products were included in the restriction and 17 tpa of releases (37% of the total) would be prevented. If the scope were expanded and products in the 'hair styling and other' product group were also included, the cost/kg of the restriction would increase to €166, and 27 tpa of releases (59% of the total) would be prevented. Expanding the scope and adding each of the other categories in turn would similarly increase the cost/kg and the tpa of releases prevented.

Figure 11: Evolution of average annual cost per kg of releases to water prevented as product groups added to the scope of the restriction

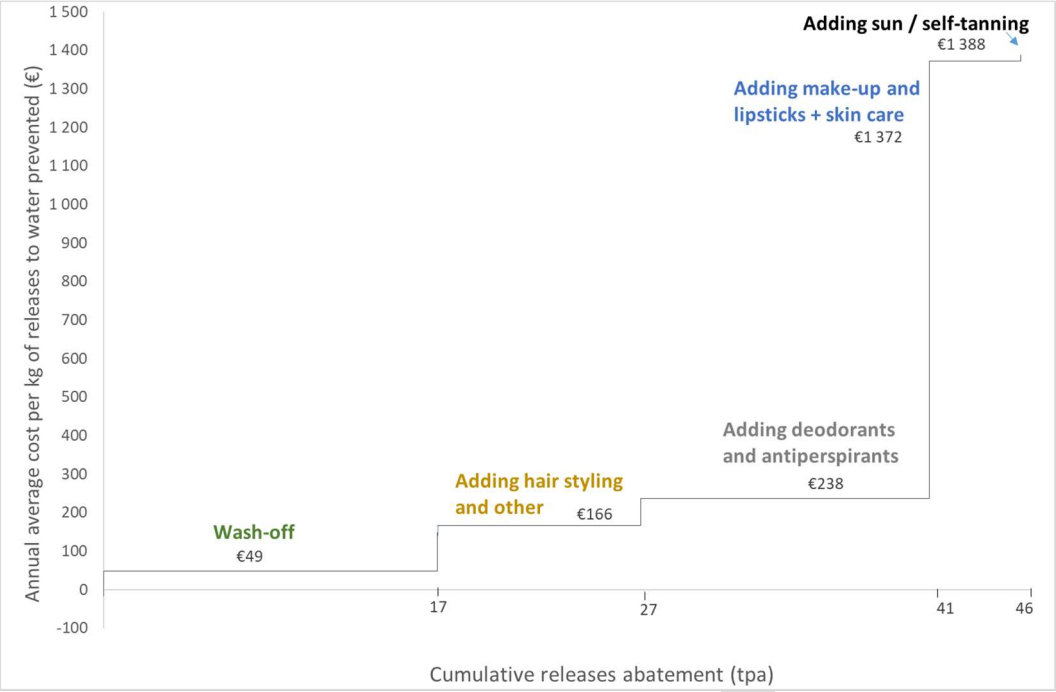


Figure 12 follows the same logic as Figure 11, but considers releases to water+air. The cost/kg of releases prevented would be €0.47 if only 'hair styling and other' products were included in the restriction and 5 200 tpa of releases (31% of the total) would be prevented. If the scope were expanded and deodorants and antiperspirants were also included, the cost/kg of the restriction would increase to €0.68, and 12 700 tpa of releases (76% of the total) would be prevented. Expanding the scope and adding other categories would similarly increase the cost/kg and the tpa of releases prevented.

Figure 12: Evolution of average annual cost per kg of releases to water+air prevented as product groups added to the scope of the restriction

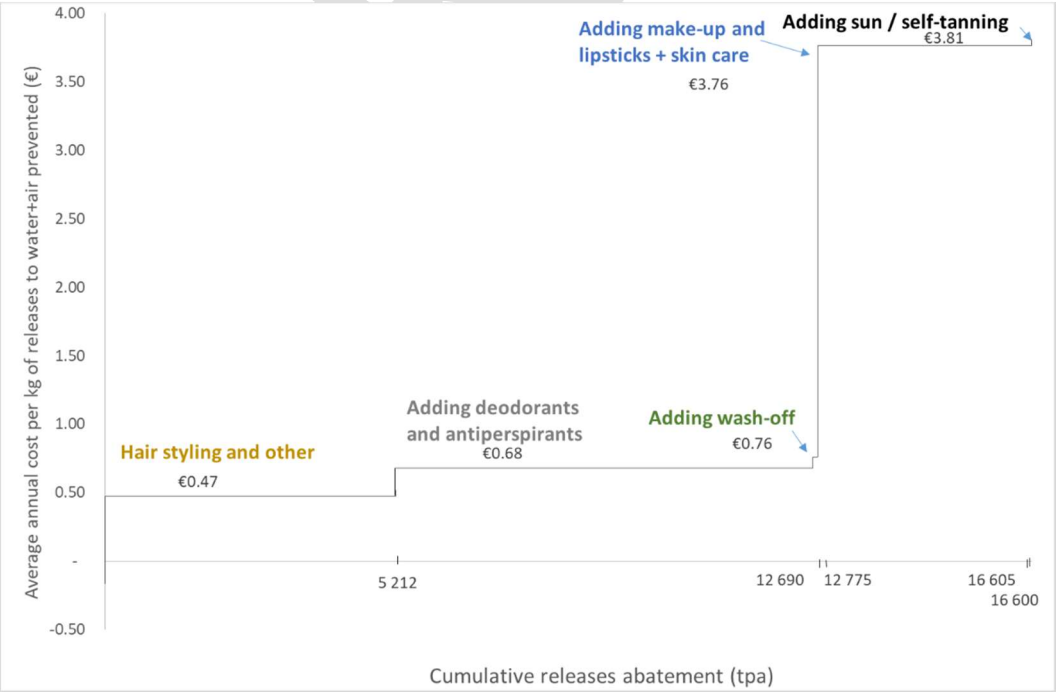


Table 21: Summary of proportionality assessment for cosmetics categories

Scope	Transition period	Cost-related estimates	Release estimates[41]	Average annual costs [€million]	Net Present Value (NPV)- 20 years [€million]	Releases to water prevented over 20 years (t)	Cost [€/kg] If releases to water only	Releases to water + air prevented over 20 years (t)	Cost [€/kg] If releases to all compartments	Cost [€/kg] If releases that will remain in the environment
All cosmetics	5 years	'Best'	Middle-value	63	703	683	1 029	251 338	2.8	104
All cosmetics	5 years	Low	Upper-value	58	649	1 069	607	251 338	2.6	95
All cosmetics	5 years	High	Lower-value	71	793	297	2 671	246 825	3.2	119
All cosmetics	2 years	'Best'	Middle-value	73	929	820	1 133	298 898	3.1	114
All cosmetics	2 years	Low	Upper-value	68	857	1 283	668	301 605	2.8	104
All cosmetics	2 years	High	Lower-value	83	1 048	356	2 942	296 190	3.5	131
Deodorants and antiperspirants	5 years	'Best'	Middle-value	5	59	215	275	112 176	0.5	N/A
Hair styling and other	5 years	'Best'	Middle-value	3	37	151	245	78 178	0.5	N/A
Make-up and lipsticks	5 years	'Best'	Middle-value	37	415	19	21 467	27 701	15.0	N/A
Skin care	5 years	'Best'	Middle-value	15	171	49	3 515	29 666	5.8	N/A
Sun/self tanning	5 years	'Best'	Middle-value	0.8	8.4	-	-	84.68	99.1	N/A
Wash-off	5 years	'Best'	Middle-value	1.1	12.1	249	49	1 275.93	9.5	N/A
Make-up and lipsticks + Skin care	5 years	'Best'	Middle-value	53	586	68	8 615	57 366.80	10.2	N/A
Make-up and lipsticks + Skin care	8 years	'Best'	Middle-value	44	414	54	7 611	45 893.44	9.0	N/A

[41] As the release estimates are expressed as a range (cf. section 1.5.3.2), some of the costs have been calculated with the lower and upper value of the release estimate range. 'Middle-range' means the average between the lower and upper value.

Scope	Transition period	Cost-related estimates	Release estimates[41]	Average annual costs [€million]	Net Present Value (NPV)- 20 years [€million]	Releases to water prevented over 20 years (t)	Cost [€/kg] If releases to water only	Releases to water + air prevented over 20 years (t)	Cost [€/kg] If releases to all compartments	Cost [€/kg] If releases that will remain in the environment
All cosmetics except make-up & lipsticks + Skin care	5 years	'Best'	Middle-value	10	117	615	190	191 715	0.6	N/A

Source: ECHA

2.5.5. Proposed transitional period

The analysis above has been done on the basis of a 5-year transitional period, based on information received during the Call for Evidence and the development of the dossier regarding what substitution would entail (for instance CfE#265, CfE#791). Respondents described substitution of the substances as being more difficult to achieve for leave-on products than for wash-off products (supported by initial assessment of alternatives undertaken by some cosmetics companies). Additionally, the Dossier Submitter's analysis found that many more products would be affected in the proposed restriction than in the restriction on D4 and D5 in wash-off cosmetic products, which could create bottlenecks in resources available (e.g. human resources with the expertise to work on reformulations) if the transitional period were short and required a large proportion of the needed reformulations to be done in parallel.

Information was received that supports a longer review period to deal with leave-on products during the consultation, and in most cases respondents argued that 5 years would not be enough (#2084, #2636, #2191, #2145, #2672, in addition to other responses claimed confidential). Several arguments were presented, such as unsatisfactory results of some early tests for alternatives, the potential need for fundamental research due to the lack of a drop-in substitute for (particularly) D5, the need to reformulate every product separately, without being able to simply apply alternatives found for one product to others without testing, and replacement of D5 and D6 in make-up being particularly challenging (a large proportion of the formulations containing D4, D5 and D6 are in that category).

On the other hand, information was also received during the consultation supporting a shorter transitional period. For instance, the Danish EPA (#2549) provided data from the database of The Danish Consumer Council's application 'Kemiluppen', showing that substitution of D4, D5 and D6 had already taken place in some products between 2015 and 2019. This indicates that efforts to substitute may already be taking place.

The Dossier Submitter therefore considers that 5 years is still the most appropriate transitional period for this restriction proposal.

2.6. Impact on other uses

As described in section 2.3 for all other uses except cosmetics the Dossier Submitter presents the information available for each use and provide qualitative assessments of the case for some type of derogation. It is done by considering the evidence against a set of criteria that could help decision-makers determine whether restriction is warranted for those uses.

The Dossier Submitter summarises the assessments by using a Red-Amber-Green rating system. **Green** signifies a good case for a restriction, with no derogation needed, while **Red** signifies a case that could be suitable for a derogation.

The following criteria are used:

- Whether functionality is maintained for users. This refers to the potential for significant consumer welfare loss to be avoided in the case of restriction. This encompasses whether the product can be reformulated to keep the benefits brought by D4, D5 and D6, whether alternatives without D4, D5 and D6 are available, and how comparable in terms of benefits to consumers those alternatives are. If consumers would likely lose significant functionality (if they end up with no alternatives or alternatives that were worse for their needs), it would be a **RED**. If the likely alternatives were somewhat worse for their needs, it would be an **AMBER**. If a restriction would not affect consumer welfare (or improve it), it would be a **GREEN**.
- The sustainability of alternatives. If the likely alternatives are more hazardous, it would be a **RED**. If similarly hazardous, an **AMBER**. If less hazardous, a **GREEN**.
- Magnitude of releases that would be prevented by a restriction. The Dossier Submitter has set up three ranges based on the figures in Table 7 and Figure 6 on relative contribution to different compartments. Contribution to total releases below 0.5% would be a **RED**. Contribution to total releases between 0.5% and 2% would be an **AMBER**. Contribution to total releases above 2% would be a **GREEN**.
- Proportion of expected releases from that use going into the atmospheric compartment (rather than into the aquatic compartment). The higher proportion of emissions going into the atmospheric compartment, the better the case for a derogation. Over 95% of emissions going into the atmospheric compartment would be a **RED**. Between 90% and 95% would be an **AMBER**. Below 90% would be a **GREEN**.

The available socio-economic evidence are also summarised, and it is considered whether releases could be further minimised using technical means or if they are already as low as they could be.

2.6.1. Dry cleaning (D5)

D5 is used as a solvent in dry cleaning. According to information received in the call for evidence (AMEC, 2013b), D5 carries detergent to clothes and rinses away suspended dirt and oils trapped by the detergent. Because D5 does not interact with textiles, it helps maintain the quality and colour of dry-cleaned clothes.

The technology used in the EU was popularised by GreenEarth Cleaning LLC, who submitted a response the Call for Evidence (CfE1#463). In it, they explain that the dry cleaning processes use a closed loop machine. The load of clothes is put into the machine

dry, washed in the dry cleaning liquid, and then dried as the dry cleaning fluid is reclaimed and recycled by being returned to the base tank of the dry cleaning machine. While all dry cleaning solvents use a similar washing machine, the level of cleaning achieved varies based upon the chemical characteristics of the solvent and the methods used to filter the solvent as it is recycled.

The 300 GreenEarth-associated dry cleaners in Europe purchase on average 126 kg of D5 per year each. In addition, GreenEarth estimates that there are approximately 100 further dry cleaners that also use D5 in the EU.

Tonnage used: 50 tpa of D5, according to the CSR in the registration dossier (2018). This is down from 100 tpa declared in 2017, also in the registration dossier.

Releases: D5 used in the dry cleaning process is contained during that process. Because the process is performed in a closed system (with solvent recycling), losses are limited to those that are seen in the filtration of the solvent and trace amount of solvent left on the clothes being cleaned. Releases to air occur when the dry cleaning cycle is concluded and the doors to the machine are opened.

Releases to surface water: 0 tpa. Releases to all compartments: 46 tpa. Relative contribution to overall emissions to all compartments: 0.25%-0.26%

Alternatives: Given that the process uses 100% D5, there would not be alternatives relying on lowering the concentration. The likely result of a restriction would be that dry cleaners currently using D5 either stop trading or switch to alternative dry cleaning solvents.

According to AMEC (AMEC, 2013b), the majority of dry cleaners in the EU (60% to 90%) use tetrachloroethylene (also known as perchloroethylene or 'PERC') as a solvent. It is followed in popularity by hydrocarbon/hydrocarbon blends (1% to 40%), professional wet cleaning (1% to 30%) and D5 (1% to 2%). There are also other alternatives that are much less common, such as Liquid CO2 and propylene glycol ethers and di(propylene glycol) tert-butyl ether (i.e. Rynex® Cleaning), but these have not been considered in detail in the material the Dossier Submitter has had access to.

- *Perchloroethylene (or PERC)*: According to AMEC (AMEC, 2013b) PERC performs at a similar level as D5, and would be a technically feasible alternative, although requiring, in most cases, changes to or replacement of dry cleaning machines. Its cost per litre has increased significantly over the last decades, although it is still less expensive than D5.

  PERC is classified under the CLP Regulation as a Carcinogenic category 2 substance, as well as Aquatic Chronic category 2. In addition to the human health concerns, this substance also poses a risk to the environment. Its use is already being phased out in some European countries such as France (where it will be totally banned by 2022) and California (by 2023). There is a general trend worldwide to move away from PERC in dry cleaning activities.

- *Hydrocarbon/hydrocarbon blends*: these consist of petroleum-based aliphatic hydrocarbons composed of a mixture of C9 to C13 isoparafins and/or cycloparafins, with some other minor ingredients such as preservatives.

According to AMEC (AMEC, 2013b) hydrocarbons perform at a similar level as D5, and would be a technically feasible alternative, although requiring, in most cases, changes to or replacement of dry cleaning machines.

Hydrocarbons were widely used in dry cleaning before PERC became the mostly used solvent. The reason they stopped being so widespread was the risk they posed due to their high flammability, which also meant that there were restrictions on where dry cleaners could operate and fire control measures were mandated. However, according to AMEC (AMEC, 2013b), lately new hydrocarbons have been developed with higher flashpoints, which may reduce some of those risks, but the high flash hydrocarbons have also the capacity to persist and bio-accumulate in the environment. They are also toxic to the aquatic environment (TURI, 2012a).

Hydrocarbons, in general, may also pose other risks to human health. The types used in dry cleaning contain little to no aromatic hydrocarbon content and very low concentrations of benzene, but high exposures can still cause neurotoxicity and irritation in the eyes, skin and respiratory tracts.

- *Professional wet cleaning (also known as Aqua Clean, Lagoon technology for example):* Professional wet cleaning involves both water and biodegradable detergents, and it uses computer-controlled washers and dryers that minimize the amount of detergent used. It uses the least amount of energy both in terms of electricity and natural gas. The EPA has concluded that the primary components of the detergents in wet cleaning do not have any expected health risks ((TURI, 2012a) and (TURI, 2012b)). However, the Dossier Submitter considers it possible that wet cleaning leads to the release of microplastics, and therefore also represents a risk to the environment.

The Dossier Submitter has considered which of the available alternatives are more likely to be used under a non-use scenario. PERC is still the most widely used in the dry cleaning market. However, the dry cleaners using D5 often do so because they consider it to be better for the environment (it is marketed as "green" and "eco-friendly", both by GreenEarth and by many of their associated dry-cleaners whose websites visited). The Dossier Submitter consider they would therefore be less likely to move to a substance like PERC. Additionally, evidence from which options were chosen by French dry cleaners who are substituting away from PERC provides useful data. According to the magazine Entretien Textile (Entretien textile, 2018), data provided by Cofreet (Comité français de l'étiquetage pour l'entretien des textiles) and FFPB (Fédération française des pressings et blanchisseries) indicated that 46% chose wet cleaning, 38% hydrocarbon/hydrocarbon blends and 16% other solvents (this includes D5). This suggests that wet cleaning could be becoming a more widely-used option than may be implied by the lower end of the range quantitative data regarding how widespread the option is in the market (1%-30%). However, it is not clear in the data what proportion of those who moved to wet cleaning moved to 'professional wet cleaning' (which is suitable for many types of garments) or to what's called "laundry wet cleaning" (which is suitable for fewer types of garments).

The Dossier Submitter will consider a switch to wet cleaning (whether the 'professional" or "laundry' version) to be the most likely non-use scenario, but assume some may also switch to hydrocarbons.

Socio-economic information available:

Within the EU there are 300 dry cleaners using this technology that are associated with GreenEarth Cleaning, and the company estimate that there are a further 100 that are not associated with them, a total of 400. There is also an estimate in AMEC (AMEC, 2013b) and EC Guidance on VOC substance and reduction (EC, 2009) that 2% of dry cleaners world-wide use D5, and that proportion would represent approximately 1200 businesses if applied to the EU. However, the 2% figure could mask a high variety of rates in different parts of the world, so the Dossier Submitter considers the estimate of 400 to be more reliable. Taking into account estimates provided for how many loads are undertaken per week by a typical D5-using dry cleaner and the length of the cycle, the Dossier Submitter would estimate an average of 1 machine per dry cleaner.

Switching to wet cleaning (or hydrocarbons/hydrocarbon blends) would require replacing the machinery, and running costs may be different. A 2012 report from the Toxics Use Reduction Institute of UMass Lowell ((TURI, 2012a) and (TURI, 2012b)), which analyses several dry cleaning alternatives, presents comparative costs as follows:

- D5-using equipment is estimated to cost $30 000 - $55 000. Wet cleaning equipment has a similar price ($36 000 - $61 000), whereas hydrocarbon-using equipment is more moderately more expensive ($38 000 - $75 000). It should be noted that the costs of replacing equipment are merely costs brought forward, as the D5-using equipment would need to be replaced at some point in the future as well.
- The report presents various running costs (cost of the chemicals, electricity usage, etc.), and summarises these in a 'typical cost per pound cleaned'. At an average of $1.71, D5 dry cleaning is more expensive than wet cleaning (average $1.10) and dry cleaning using hydrocarbons (average $0.88).

Additionally, dry cleaners using GreenEarth technology are required to pay a license to do so, which they would not have to do when using the alternatives.

Rating against the criteria:

Functionality maintained for users – Hydrocarbons are comparable in terms of performance to D5. For professional wet cleaning, evidence is more mixed, but latest evidence (Entretien textile, 2014) seems to indicate that more modern versions are substantially better than older ones. Wet cleaning may not be suitable for certain types of clothes (e.g. leather, sequins and other decorations), but on the other hand, it can be used for certain types of clothing for which using solvents is not appropriate. **GREEN**

Sustainability of alternatives – Hydrocarbons are more hazardous than D5 due to their flammability, which leads to safety concerns. This would be a RED. Wet cleaning could also be hazardous to the environment due to the potential release of microplastics. This would be an AMBER. Considered together, we're rating this an **AMBER**

Magnitude of releases that would be prevented by a restriction – Contribution to total releases is 0.25% - 0.26%. This is below 0.5%, so it would be a **RED**

Proportion of expected releases going into the atmospheric compartment – Almost 100% of expected releases go into the atmospheric compartment, so it would be a **RED**

Overall assessment of the potential for a derogation:

A potential derogation could be supported on the grounds that the potential alternative substances would not result in an overall reduction in risk (e.g. flammability, as well as

potential release of microplastics), tonnages used that are expected to be low, and with a low proportion of releases to water. Additionally, it is important to note that releases to air in this case could be further minimised. At the moment a high proportion of the tonnage used is released to the atmosphere, which could be improved by reducing evaporative losses at the end of the cycle (e.g. by waiting longer to open doors, etc.). This use therefore is not a clear-cut case for a restriction, or an obvious case for a derogation with no conditions. A longer transition period (e.g. of 10 years) followed by a derogation for placing on the market and use in closed systems which would also prevent the releases to the atmosphere could therefore be appropriate.

2.6.2. Cleaning of art and antiques (D4, D5)

During the market research exercise undertaken by ECHA, uses of D4 and D5 have been identified in the field of art (including contemporary and historic paintings) and antique cleaning / restoration.

Cleaning treatments for paintings are often based on aqueous solutions. Contemporary paint materials, like acrylics, but also older paintings, are particularly sensitive to water. Use of aqueous-based treatments to clean these materials can cause swelling, paint loss, surface disruption and leaching of components. According to some specialists in art restoration, D4 and D5 solve specific issues that could not be treated otherwise: e.g. cleaning of very sensitive and fragile materials (source: confidential emails with experts in the fields of restoration – Italy/US).

D4 and D5 (pure or in silicone-based gels containing up to 80% of D5) are primary used as a temporary 'masking/saturating' agent; that is, as a way of holding out water-based cleaning materials from penetrating into porous structures. D4 or D5 are applied as a protective layer before the cleaning with aqueous solutions (alkaline or acid) in order to create a water repellent layer on the material. It is important in restoration that materials that are not volatile by themselves be cleared or removed from these kinds of surfaces as efficiently as possible for their long term preservation. By temporarily 'holding out' and restricting cleaning materials to just the surface of fine art materials it makes their complete removal easier. Pre-loading of D5 into a water sensitive media (e.g. water-colour, gouache, distemper paints) also allows for the use of water based cleaning agents on or over otherwise water sensitive painted artefacts as well. D4 or D5 fill the pores of the material to be cleaned and prevent water, or other solvents, from penetrating beyond the surface of the material to be cleaned. The cleaning can then be done with the water-based solution until D4 or D5 evaporate. After cleaning, other types of work can be performed on the material such as consolidation work or repairs (source: confidential emails with experts in the fields of restoration – Italy/US).

Originally devised as a use of D4 in North America for the cleaning / restoration of acrylic paintings, this method became widespread in European countries for the treatment of contemporary and antique paintings, and for other works of art (on paper, on wood, on other sensitive support materials). The technique is taught in Europe via specific restoration workshops (Italy, France, Spain, Portugal, Ireland, Belgium, The Netherlands, Finland, Denmark, Norway, Austria, Croatia, Slovenia). Since 2014 about 250 conservators/restorers have been introduced to the use of cyclosiloxanes. In Europe, the use of D5 has been promoted, because of its lower toxicity to human as compared to D4. Nevertheless some important restoration activities have used D4 recently such as the Eugene Delacroix mural paints restoration at Saint Sulpice church in Paris (Utter, 2018), or restoration of Stone Figures at Penn Museum, Philadelphia (North, 2017).

Tonnage used: 0.1 tpa of D4, 0.2 tpa of D5

Releases: Releases to surface water: 0 tpa for D4 and D5. Releases to all compartments: 0.1 tpa for D4 and 0.2 tpa for D5. Relative contribution to overall emissions to all compartments: 0.002% for D4 and D5 together

Alternatives: Saturated hydrocarbons / low volatility aliphatic hydrocarbon solvents could be used in some instances for hydrophobisation of surfaces, which is what some conservators/restorers used to do before using cyclosiloxanes. The Dossier Submitter does not have information about which exact hydrocarbons these are, but in general, hydrocarbons have high flammability, and some can have higher health hazards. For contemporary paint media no other alternatives have been identified, as hydrocarbons would disrupt the paint layer.

Currently there are no alternatives to silicone-based gels or D4, D5 allowing the same degree of respect for the treated surface. Specialists indicate that if the use of D4, D5 were to be restricted in this field, they would probably go back to using aliphatic hydrocarbons for this purpose, or simply tolerate having residues of cleaning materials trapped in artefacts post-treatment, which would have a negative impact on the preservation of these materials, resulting in damage or loss of cultural property.

Socio-economic information available: Specialists contacted expressed no concern about potential costs implications of a restriction, but described a potential loss of function as explained above.

Rating against the criteria:

Functionality maintained for users: Due to likely actions of restorers, some of whom may not switch to the alternative due to health hazards, there is potential for damage or loss of cultural property. **AMBER**

Sustainability of alternatives: The alternatives have higher health hazards than D4 and D5. **RED**. The Dossier Submitter notes, however, that D5 would be an alternative to D4, and therefore for a restriction of only D4, this rating would change to a **GREEN**.

Magnitude of releases that would be prevented by a restriction: Contribution to total releases is 0.002% for both substances. This is below 0.5%, so it would be a **RED**

Proportion of expected releases going into the atmospheric compartment – All releases expected to go to air, so it would be a **RED**

Overall assessment of the potential for a derogation:

There is good case for a derogation for D5, justified on the grounds that use of typical alternatives would not result in an overall reduction of risk compared to D5, and without the use of these alternatives, there is potential for damage or loss of cultural property. Additionally, the tonnages used are estimated to be low, and with a low proportion of releases directly to the aquatic compartment.

This derogation is proposed for D5 but not for D4, because of its toxicity to humans. D5 also functions as an alternative to D4, which supports limiting the derogation to D5.

2.6.3. Detergents, household care and vehicle maintenance products (D5, D6)

Due to a very low response rate to the call for evidence for this specific sector, ECHA carried out a market study of this sector, contacting more than 40 stakeholders

representing downstream user associations, formulators, distributors, Contract Manufacturing Organisations (CMOs) (15% of the market), brand owners (65% of the market), big companies and SMEs, as well as representatives of the Nordic Swan Ecolabel, to better understand the uses of D4, D5 and D6, and the availability and functionality of alternatives.

No use of D4 was identified in these sectors. This was also confirmed by A.I.S.E., the International Association for Soaps, Detergents and Maintenance Products, who indicated that there is no use of D4 in detergents, household care, and maintenance products.

The use of D5 in products used by professionals or the general public is also limited to specific product types: two companies were identified as using D5, one producing air freshener (only a single product was identified on the market that contained a very high percentage of D5, with a solvent function), and one producing car care products (reporting the use of 30 tpa).

A.C.E.A., the European automobile manufacturers association indicated that D5 may still be found with variable content in automotive care and maintenance products such as car wax, polishes, and some industrial & professional car shampoos & wash detergents. D5 is reported to improve the drying performance (drying speed) of products, notably in automatic car wash installations with air circulation systems.

Quite a number of D5 C&L notifications were submitted in 2010, including by companies working in the field of leather care for horse riding equipment. However, there is no confirmation that this is a use of D5, rather a use of silicone polymers that containing D5 as an impurity.

Although a registered use, no use of D6 was identified in these sectors. This is supported by information from one of the main actors in the provision of cyclosiloxanes, who report that they do not provide any D6 for this use (CfE2#792).

Overall, it seems that the uses of D5 and D6 in detergent, household care and maintenance product are rather infrequent, and perhaps are limited to D5 only. CES indicated that based on the input received by downstream user associations they might reassess the reported use of D5 and D6 in this sector and, if warranted, even remove the identified uses and related exposure scenarios in the CSRs (CES, 2017c).

Tonnage used: According to the registration dossiers, there are a total of 60 tpa of D5 used (40 tpa in washing and cleaning products, 20 tpa in polishes and waxes). As mentioned above, only about half of that use (30 tpa) has been identified, and it is expected the amounts reported in the registration dossiers may be overestimates.

For D6, there is still some reported use in the registration dossiers, a total of 30 tpa (20 tpa in washing and cleaning products, 10 tpa in polishes and waxes). As with D5, this is expected to be an overestimate, as no uses have been identified in the ECHA market research.

Releases: In spite of the tonnage used likely being an overestimate, the reported numbers were used to calculate the following releases. Releases to surface water: 3-6 tpa. Releases to all compartments: 50-66 tpa. Relative contribution to overall emissions to all compartments: 0.28%-0.36%.

Alternatives: For consumers, there exist many alternatives on the market for air

fresheners and also for car care products. Many of these have the Nordic Swan Ecolabel[42], and that includes performance testing to ensure no loss of function.

The company producing an air freshener using D5 are investigating potential alternative solvents, although with no results so far. They have noted that some of the alternatives considered have a worse hazard profile than D5 and are more expensive.

For the company producing car care products, D5 is used in 19 out of a large range of products made by the company. The company has reported it considers replacement of D5 in about half of the products to be straightforward, but it may be more difficult in the rest. The alternatives they are considering are a combination of hydrocarbons with short linear silicones.

Socio-economic information available:

The company producing air freshener has estimated it would take 2 years to put an alternative on the market and that it would require investment in R&D. Also, as mentioned, potential alternatives have so far been substantially more expensive. However, that particular air freshener constitutes approximately 1% of their turnover, so the impact of discontinuing that line if no alternatives are found may be moderate.

For the company producing car care products, the alternatives being considered are several times more expensive than D5. In case of a 1-to-1 substitution of D5 with the linear silicones, the numbers provided suggest that the increase in the cost of raw materials could be of approximately €1 million.

The overall economic impact of a restriction on this sector is likely to be small. However, it could be focused on a very small number of actors and could therefore be significant to them.

Rating against the criteria:

Functionality maintained for users – hydrocarbons are comparable in terms of performance to D5. Plenty of alternatives exist on the market on both air freshener and car care products. Information from Nordic swan indicates that the quality is comparable. **GREEN**

Sustainability of alternatives – As mentioned, there are lots of alternatives existing with Nordic Swan ecolabel, which would be less hazardous for the environment. That would imply a GREEN. However, if short linear siloxanes are used, as one of the companies reports it is considering, these could have the same properties as D5 (and in fact, one of the linear siloxanes mentioned is currently being investigated due to concerns that it could be a vPvB/PBT substance). Overall, however, it would be a **GREEN**.

Magnitude of releases that would be prevented by a restriction – Contribution to total releases is below 0.5%, so it would be a **RED**.

Proportion of expected releases going into the atmospheric compartment – Out of all releases associated with these products, 86% go to air, so it is a **GREEN**.

Overall assessment of the potential for a derogation:

There is not a strong case for a derogation for these uses. The magnitude of releases is

[42] Car and boat care product with a Nordic Swan Ecolabel "must not contain D4, D5 and D6". 562 products in the category car and boat care have the Nordic Swan Ecolabel (Nordic Swan Ecolabel, 2018).

comparatively small, but there are plenty of alternatives that are sustainable, and there is a substantial proportion of releases going to water. Additionally, further minimisation of releases would not be possible, as there is no containment possible in the uses described, so introducing conditions for use would not be a viable restriction option.

2.6.4. Pharmaceutical products and medical devices for human use (D5, D6)

The definitions of 'pharmaceutical products' and 'medical devices' overlap and a clear distinction is not always possible. In addition, national regulations for pharmaceuticals and medical devices may differ considerably (for medical devices this may change in the future due to the replacement of Directive 93/42/EEC with Regulation 2017/745). Thus, it is, especially for mixtures used in topical applications, often up to the formulator to decide if the mixture is registered as a pharmaceutical product or as a medical device under the medical devices or pharmaceutical products legislations. The registration type for a same mixture/brand might also differ from one Member State to another depending on national regulations. For example, the same product (or type of product) might be classified in different Member States as either a medical device[43], or a registered medicine medicine (i.e. prescription or non-prescription medicinal product as set in Directive 2001/83/EC). Head lice treatments are an example of this (cf. example in Table 22).

In the common language, medical devices and non-prescription medicinal products are often refered as "OTC" (over the counter) because they are sold 'over the counter' without any prescription.

No use of D4 has been reported for medical devices or pharmaceutical products.

Use of D5 and D6 has only been reported in a limited number of applications, essentially for topical uses as indicated in Table 22. Apart from their biocompatibility, D5, D6 are used in pharmaceutical products and medical devices for various functions that are indicated in Table 22.

Based on tonnage ratio between use in pharmaceuticals and medical devices, which is provided by formulators and in REACH registrations (e.g. CSRs and CfE2#788), it could be assumed that 90% of the uses occur in medical devices, and the rest in pharmaceutical products.

[43] The new Medical Device Regulation MDR (EU 2017/745) recognises the existence of (substance-based) medical devices: according to the classification rule 21, set in Annex VIII to the MDR, (substance-based) medical devices (SB-MD) can be defined as 'medical devices that are composed of substances or combinations of substances that are to be introduced into the human body through a natural orifice or applied to the skin and that are absorbed by or locally dispersed in the human body'.

Table 22: Use of D5 and D6 in pharmaceutical products and medical devices

Type	Range of identified concentration of D5 (% w/w)	Range of identified concentration of D6 (% w/w)	Main function and regulatory status
Head lice treatments	50% to 96%	N.A.	Function: occlusive (head lice cannot excrete and their gut ruptures resulting in mortality) Registered as a medicine in UK and as medical device in other Member States
Lubricants and massage gels	95% to 97%	N.A.	Function: emollient, silky feel, solvent (diffusion of active substance) Class IIa or IIb medical device (rule 21) [1]
Skin disease (e.g. dermatitis, eczema, psoriasis, ichtyosis aka skin dryness…) topical treatment	Up to 13% reported (#2109)	Up to 13% reported (#2109)	Function: emollient, silky feel, solvent (diffusion of active substance) OTC (over the counter): Class IIa or IIb medical device (rule 21) [1], but could also be registered as a medicine in some member states (not confirmed)
Other topical treatment (confidential)	Confidential	Confidential	Function: emollient, silky feel, solvent (diffusion of active substance) Registered as a medicine (not yet registered)
scar/wound treatment or wound prevention (gel or sheet)	5 to 60%	N.A.	Function: viscoelastic behaviour allows contacting biological tissues by minimizing the risk of trauma at the interface Class IIa or IIb medical device (rule 21 or 4) [1]
Stoma care products (Spray and wipe-based product)	5 to 50 %	N.A.	Function: adhesive remover, barrier forming liquid to prevent irritation from spills and leaks Class IIa or IIb medical device (rule 21) [1]

Source: ECHA market study, call for evidence, and consultation

Note:

[1]: the medical device class has been assigned by ECHA based on the interpretation of the device class definition specified in the medical device regulation EU 2017/745 – Annex VIII (EU, 2017)*. This is provided only as an illustrative example. It should be noted that with the entry into force of the medical device regulation EU 2017/745, (substance-based), medical devices applied on the skin (or cavities) have to be classified according to classification rule 21, and can no longer be classified as a Class I MD (low risk MD).*

As a summary, there is a small number of types of pharmaceutical products/medical devices where D5 and D6 are used (there is no reported use of D4). Some are used in a similar way as leave-on cosmetics, while others as wash-off cosmetics. Concentration levels can be seen in Table 22:

- Head lice treatments: some are leave-on, some are wash-off (the same product can have different use instructions in different countries). Kills lice by occluding their digestive system.
- Lubricants and massage gels: leave-on or wipe-off

- Topical treatments (treatment of skin disease or dryness essentially, and confidential use): leave-on. Topical treatment aims at hydrating and improving the condition of dry/damaged skins.
- Scar/wound treatment and wound prevention (gel or sheet): leave-on. Those for scar/wound treatment helps heal scars and wounds. Often used for high-risk wounds and for treatment of keloid or hypertrophic scars, where silicone-based treatments are considered best practice ((Monstrey et al., 2014) and (Gold et Al., 2014)). Those for wound prevention are used for preventing conditions such as pressure ulcers and incontinence-associated dermatitis (IAD).
- Stoma care products[44] (spray and wipe-based products): leave-on. The function of the products that have been identified are adhesive remover and barrier-forming liquid to prevent irritation from spills and leaks.

Tonnage used: There are 250 tpa of D5 used in pharmaceuticals and medical devices. Of these, 70% are used in leave-on products and the remainder in wash-off products.

For D6, the total amount used is 100 tpa. The split is the same between leave-on products (70%) and wash-off (30%).

The Dossier Submitter is not able to disaggregate the tonnages per each of the categories above. However, given the nature of the uses (their expected concentration of D5, D6, the quantity in which they might be expected to be applied during normal use and the number of people that could be expected to use each of them), it would be expected the bulk of the tonnage used to be in head lice treatments.

Releases: Releases to surface water: 6.5-11.9 tpa. Releases to all compartments: 274-305 tpa. Relative contribution to overall emissions to all compartments: 1.5% - 1.7%.

As mentioned above for tonnage used, the Dossier Submitter could expect the majority of releases to be associated with head lice treatments.

Alternatives:

For **head lice treatments**, treatment alternatives include neurotoxic insecticide products, physical removal, and treatments with a physical (coating) action. The treatments using D5 fall in the latter category.

Although they can be effective, Burgess (Burgess, 2016) warns that there are potential severe resistance issues with many insecticide products, particularly pyrethroid and malathion insecticide-based products.

Another alternative is the physical removal of lice (e.g. by wet combing with conditioner), but the effectiveness of this method is far from 100%.

Treatments with a physical action are becoming more common, and they can be based on many different substances. Options based on silicones, mineral oils, lipid esters, surfactants, oil-surfactant co-polymers (which aim to make oils more washable), or essential oils are available.

Regarding effectiveness, Combescot-Lang et al (Combescot-Lang et al., 2015) performed

[44] In this context, a stoma is an opening in front of the abdomen which is made using surgery. It allows faeces or urine to be collected in a pouch (bag) on the outside of the body.

ex vivo effectiveness tests of French over-the-counter products against head lice. Amongst products found to have 100% pediculicidal activity and 100% ovicidal activity were products not containing D5 or D6. However, it should be noted that ex vivo testing (Combescot-Lang et al collected head lice and their eggs from children and tested the products in a laboratory) may not fully reflect 'real world' effectiveness, as ease of correct application seems to be very important for head lice treatments. Burgess (Burgess, 2016) identifies the lack of published efficacy evidence as a problem, and refers to only two products for which there are published clinical investigations (Heukelbach et al., 2008) showing high effectiveness. Both contain dimeticone (a silicone polymer with residual amounts of D4, D5 and D6), but while one contains D5 as an excipient, the other does not use D4, D5 and D6 as ingredient.

For **lubricants , massage gels**, **and topical treatments** plenty of alternative products exist on the market that are free from D5 and D6. These products being similar to some cosmetic product in term of formulation and D5, D6 function. Reformulation is not expected to be an issue if sufficient time is granted for the reformulation to happen.

For **scar/wound treatment, wound prevention** and **stoma care products**, the information received in the call for evidence raises doubts that the alternatives to D5 and D6 that could be suitable for cosmetics would be appropriate for medical devices. For some (those vegetable oil-based) performance could be affected due to lack of suitable properties, while for others (the alternative silicones with suitable properties), there is generally a greatly increased flammability risk.

Socio-economic information available:

Information on costs was obtained from a single company producing D5-based **head lice treatments**. They estimated the cost of reformulations to replace D5 would be approximately €230 000, and if reformulation efforts were not successful, lost revenue would amount to approximately €15 million per annum. The Dossier Submitter is not aware of the total number of head lice treatment products on the market using D5 (or D6).

Other impacts depend on the effectiveness of alternative head lice treatments. The Dossier Submitter understands that alternatives are available, and can perform at the same level. In that case, there would be no further impacts. However, if the alternatives were less effective, head lice infestations would be expected to become more prevalent and long-lasting, with the associated time and financial costs of treatment. According to the US Centers for Disease Control[45], head lice are not known to transmit any disease and therefore are not considered a health hazard. However, the itching sensation is uncomfortable and can result in sores caused by scratching, which can sometimes become infected with bacteria normally found on a person's skin. As head lice are most common in children, these effects would be mostly felt by them.

No socio-economic information was received for **lubricants, massage gels, and topical treatments**.

Some additional information was also received in the consultation for other pharmaceutical products and medical devices (see #2109, #2134, #2722, #2643 for the non-confidential responses) for which derogations were sought.

[45] https://www.cdc.gov/parasites/lice/head/disease.html

General socio-economic information was received for **scar/wound treatment, wound prevention** and **stoma care products**. Potential reformulations are estimated to have substantial costs and take at least 2 years. Stakeholders also identify costs associated with getting products approved / re-validated. According to the Medical Device Regulation (2017/745), these products are required to be designed and assessed using stringent processes by the legal manufacturer and the products must be thoroughly assessed for risks to patients, healthcare professionals and the environment. Medical devices are subject to a risk assessment to consider both their beneficial effect and the suitability of their design, including composition for the intended use. For substance-based medical devices as part of the design and approval process the substances chosen must be assessed for both patient safety, suitability for the indication and their mode of action.

Other impacts depend on the effectiveness of alternatives. If alternatives were not as effective, there could potentially be negative health effects, which could be concentrated on vulnerable patients such as the old and patients with burns. All this suggests relatively high costs for moving to alternatives.

Rating against the criteria:

Functionality maintained for users – For head lice treatments, evidence indicates that effective alternatives exist. For lubricants, massage gels, and topical treatments no evidence was received indicating a potential loss of functionality associated with alternatives. For these, it would be a **GREEN**. For medical devices for scar/wound treatment, wound prevention and stoma care products evidence seems to indicate that it is possible some functionality could be lost, and that this would affect particularly vulnerable users. This would be a **RED**.

Sustainability of alternatives –For head lice treatment, since the most commonly alternatives are not insecticides, this would be a **GREEN**. For the other categories, no information was received about potential alternatives. For the sake of precaution, it will be rated an **AMBER**.

Magnitude of releases that would be prevented by a restriction – In total, it contribution to total releases is 1.50% - 1.59% Being above 0.5% but under 2%, it would be an **AMBER** for the category as a whole. As mentioned above when describing tonnage used, the Dossier Submitter does not have specific data for each of the uses described in this section, but there are good reasons to expect most of the tonnage to be concentrated in head lice treatments and potentially lubricants and massage gels, and this is supported by information received in the consultation regarding the tonnage The Dossier Submitter will therefore assume that the rating for medical devices for scar/wound treatment or wound prevention and stoma care products would be a **RED**.

Proportion of expected releases going into the atmospheric compartment – Approximately 97% of releases are expected to go into the atmospheric compartment, so it would be a **RED**.

Overall assessment of the potential for a derogation:

There is no evidence supporting the need for a derogation for **head lice treatments**, **lubricants and massage gels, and topical treatments**. Functionality seems likely to be maintained, with sustainable alternatives, and there are substantial tonnages used, albeit with a low proportion of releases to water.

However, derogations for **medical devices for scar/wound treatment or wound**

prevention and **stoma care products** could be warranted. There is a risk that functionality could be lost, and that this would affect vulnerable patients such as the old, the bed-ridden and patients with burns. Additionally the tonnages used are expected to be low, and with a low proportion of releases to water.

As mentioned, additional information was also received in the consultation for other pharmaceutical products and medical devices (see #2109, #2134, #2722, #2643 for the non-confidential responses) for which derogations were sought. Not enough information was provided for those uses to warrant a derogation.

However, the information provided did provide useful evidence regarding substitution of D5 and D6 in these uses. Those pharmaceutical products and medical devices would have to be reformulated, and information was provided regarding the time this could take. Particularly, in addition to the time taken to find and implement technically feasible alternatives to D5 and D6, there may be regulatory requirements that need to be fulfilled before a product is placed on the market after an ingredient is changed. After considering the evidence provided, the Dossier Submitter considers that given what reformulation of these products would entail, the transitional period for uses of D5 and D6 in medical devices should be consistent with that for uses in leave-on cosmetics. A transitional period of 5 years is therefore proposed for this use.

2.6.5. Summary of the qualitative impact assessment

Table 23 provides a summary of the qualitative impact assessment performed for uses other than cosmetics.

Table 23: Summary of the outcomes of the qualitative assessments for other uses

Section	Use	Functionality maintained for users	Sustainability of alternatives	Magnitude of releases that would be prevented by a restriction	Proportion of expected releases going into the atmospheric compartment	Recommendation
2.6.1	Dry cleaning (D5)					Process-limited derogation proposed
2.6.2	Cleaning of art and antiques (D4)					No derogation
2.6.2	Cleaning of art and antiques (D5)					Derogation proposed
2.6.3	Detergents, household care and vehicle maintenance products (D5, D6)					No derogation
2.6.4	Pharmaceutical products and medical devices for human use (D5, D6) - head lice					No derogation
2.6.4	Pharmaceutical products and medical devices for human use (D5, D6) - lubricants and massage gels and other topical treatments					No derogation TP as for leave- on cosmetics.
2.6.4	Pharmaceutical products and medical devices for human use (D5, D6) - Medical devices for scar/wound treatment or wound prevention					Derogation proposed

It should be noted that each of the criteria could be weighted differently, so the overall assessment is not simply a straight average of them.

Derogations are proposed for:

- **Medical devices for scar/wound treatment, wound prevention and the care of stoma**, on the grounds that there is a risk that alternatives would not provide the required technical function, and that this would affect vulnerable populations, such as the old and infirm (particularly patients with burns). Additionally, the tonnages for this use are estimated to be relatively low, with a low proportion of releases directly to the aquatic compartment.
- **Use of D5 in the cleaning or restoration of art and antiques**: on the grounds that use of typical alternatives would not result in an overall reduction of risk compared to D5, and without the use of these alternatives, there is potential for damage or loss of cultural property. Additionally, the tonnages used are estimated to be low, and with a low proportion of releases directly to the aquatic

compartment. D5 functions as an alternative to D4, and therefore the derogation proposed for this use is limited to D5.

- **Dry cleaning activities (process-limited)**: This derogation is associated with a longer transition period. It is justified on the grounds that some of the likely alternative substances would not result in an overall reduction in risk (e.g. flammability), and that tonnages used are expected to be low, and with a low proportion of releases to water. Use beyond the transitional period would only be permitted when strict operational conditions and risk management measures are adopted (e.g. use of closed systems).

For the other uses analysed in this section, the Dossier Submitter does not consider a derogation would be justified. Nevertheless a transition period similar to the one proposed for leave-on cosmetics is proposed for the (substance-based) medical devices and pharmaceutical products, in order to allow these sector to reformulate the products if needed.

2.7. Impact on uses of silicone polymers

As described in section 1.4.4, D4, D5 and D6 are key monomers used to produce silicone polymers, and it not technically possible to produce silicone polymers with 'zero content of D4, D5 and D6' using conventional production techniques. In addition, under certain conditions (high temperatures, presence of certain types of fillers), silicone polymers can break down, resulting in low concentrations of D4, D5 and D6.

As a result, some products containing silicone polymers can contain D4, D5 and D6 as impurities. For many products, the concentration will be below 0.1%, so a restriction based on such a concentration level would not impact them. This would mean that the products could remain on the market and there would be no costs to producers, but also that the releases of D4, D5 and D6 associated with them would continue.

In some cases there is some evidence that concentration levels may be above 0.1% w/w. According to CES, 'The feasibility of reducing residual levels of D4/D5 in polymers or in formulated products - as they leave the factory gate of the silicone manufacturers - is dependent on the manufacturing process, on the chemical nature of the formulations and additives, and on the formulation process and the energy input during this formulation process' (CES, 2018a). This would apply to D6 as well. CES indicate that the lower the volatility, the more technically difficult it is to remove the substance, and D6 is less volatile than D5, which is, in turn, less volatile than D4. Additionally, a specific question was asked about this topic in the consultation, requesting that respondents provide information about uses of silicone polymers where concentrations of D4, D5 or D6 may be above 0.1% w/w. Information was received about a several uses, and these have been incorporated into this Background Document.

Sections 2.7.1 to 2.7.7 below present the evidence available about the uses of silicone polymers in the different sectors shown in Figure 3: Split of EU silicone polymer uses between sectors, including where concentration levels of D4, D5 and D6 may be above 0.1% and where it may be difficult to bring them below that concentration level.

It should be noted, however, that significant uncertainty remains on this issue due to the quality of the evidence available. In some key cases, different sources diverge on whether they would expect concentration levels to be above or below 0.1%. For some products there is evidence regarding the concentration levels of D4, D5 and D6 in the silicone

polymers that go into the products, but not about what the concentration levels would be after formulation (the silicone polymers delivered by silicone producers may be further processed to give them a specific shape or function, or formulated with other ingredients –both of these could reduce the concentration level of D4, D5 and D6 impurities). And even if the Dossier Submitter was to accept that some kinds of products currently on the market will contain impurities of D4, D5 and D6 above 0.1%, it is unknown in what proportion of them this is the case. For these reasons, it has not been possible to produce an overall estimate of the cost of the restriction for these products.

Tonnage used: 1 445 tpa of D4, D5 and D6, of which 640 tpa are used in cosmetics and 805 in other silicone mixtures and articles. This tonnage used is approximately 40% D4, 40% D5 and 20% D6, both for cosmetics and for other silicone mixtures.

This section does not include an analysis of the use of silicone polymers in articles and cured silicone mixtures (see Section 1 for an explanation of why these have been excluded from the scope).

Releases: For silicone polymers used in cosmetics, releases to surface water: 7-12 tpa. Releases to all compartments: 567-595 tpa. Relative contribution to overall emissions to all compartments: 3.15%-3.22%

For silicone polymers used in other mixtures, releases to surface water: 27-47 tpa. Releases to all compartments: 586-681 tpa. Relative contribution to overall emissions to all compartments: 3.25%-3.68%

Further disaggregation of tonnages used and releases have not been possible with the information available. In a few cases, information on tonnage of D4, D5 and D6 has been provided for a particular use of silicone polymers, and the Dossier Submitter includes that, but it is not available across the board. Where available, the Dossier Submitter has also included information on tonnage of silicone polymers used within the relevant subsection, but the tonnage of D4, D5 and D6 within those silicone polymers is uncertain.

2.7.1. Use of silicone polymers in household, detergent and motor vehicle maintenance products

In this sector, silicone polymers (essentially silicone fluids and cured elastomers) may be used in the formulation of granular and liquid detergents, wood/surface care products, shoe care products, tyre and car care products, insecticides and air fresheners.

The main functions of silicone polymers in these products are the following:

1. Anti-foaming: foam control in washing detergent and fabric softener – both during the formulation and then the use by consumer and professional users
2. Dewatering (to accelerate the drying of clothes, fabrics but also cars and vehicles)
3. Anti-wrinkling (and ease of ironing)
4. Perfume release agent (silicone fluids and cured elastomers[46])

The sector estimates it uses between 500 and 5 000 tpa of silicone polymers/products; it represents less than 1% of the sold quantities of silicone polymers in Europe according to

[46] This use is consistent with ECHA's working definition of a 'microplastic' and is being assessed as part of the Annex XV investigation into intentional uses of microplastics in consumer and professional products of any kind.

a Global Silicones Council report (AMEC, 2016)). Silicone polymers purchased by the formulators contain typically < 0.1% D4 and D5, and < 0.2% D6 (CfE1#467, CES, 2017b, CSRs). After formulation, the residual amount of D4, D5 and D6 is usually below 0.1%. However, in shoe care products, the residual level of D4 could be up to 0.5%, and in some car care products up to 1% (ECHA market survey).

The Market research undertaken by ECHA identified a very small number of companies whose final products may contain D4, D5 and D6 in concentrations above 0.1%. In 2 cases, this was D4 in car shampoos. This was also confirmed by AISE and ACEA.

Alternatives: From contacts with companies made during the ECHA market survey, the overall view was that it does not seem problematic to replace and find alternatives to D4, D5 and D6, silicones with impurities above 0.1%. A number of companies contacted had already been able to substitute the silicone polymers to achieve this without any problems. One of the examples given was substitution with 'cosmetic grade of the same silicone', at a small (3-6%) increase in price, and another was substitution with 'vegetal oils'. The latter were found to be more expensive, but the company considered that this had given them a competitive advantage (including a positive impact on their sales), due to them being able to be certified by an eco-label and using the eco-friendliness as a marketing argument.

2.7.2. Use of silicone polymers in cosmetics

According to CES (Silicons Europe, 2018), about half of all make-up, hair, skin-care and antiperspirant products used in Europe contain D4, D5 and D6 residues due to the use of silicone polymers in cosmetics formulations.

Based on several sources of information, it is estimated that the cosmetics sector uses between 20 and 30% of the silicone polymers sold in Europe (AMEC, 2016).

A wide range of silicone fluids, blends, elastomer dispersion and resins are used, conferring attributes such as good spreading (for example in sun care products), film-forming, wash-off resistance, pleasant skin feel, rapid drying (volatility) and permeability.

According to CES (CfE1#467), and the information provided in the CSRs, silicone polymers purchased by the cosmetics formulators contain typically < 0.1% D4 and D5. In certain silicone polymers, especially in emulsion polymers, the residual amount of D5 might reach 1 to 2%. This information could not be confirmed by Cosmetics Europe.

However, this concentration refers to the silicone polymers themselves. After formulation, the residual amount of D4, D5 and D6 in the final product used by professional and consumers is expected to be below 0.1%.

There is some data regarding the presence of D4 and D5 as impurities in wash-off cosmetics. For those products, the registrants have estimated 40 tpa both for D4 and D5. This tonnage corresponds to the use of silicone polymers containing less than 0.1% residue of D4, D5 once the restriction on wash-off products is implemented.

The evidence available therefore suggests that a restriction with a concentration limit of 0.1% would have no impact on the use of silicone polymers in cosmetics.

2.7.3. Use of silicone polymers in medicines and medical devices (healthcare)

D4, D5 and D6 are present in medicines and medical devices as residues of silicone polymers. Total quantities are uncertain, but D6 in pharmaceuticals and medical devices (excluding long term implants) is estimated as 7 tonnes by MedTech (CfE2#796).

In pharmaceutical products, silicone polymers are used as:

1. Antifoaming agents (e.g. Simethicone) in the coating of tablets, or in the formulation of anti-flatulence drugs (where they are considered as API[47])
2. Excipients for topical use due to its emollient, spreading and odourless properties

In medical devices, silicone polymers are used in a wide range of healthcare applications such as prosthetic limbs, orthopaedics, catheters, drains and shunts, components in kidney dialysis, long term implants, mould-making, topical products, artificial skin for burn treatment, adhesives etc.

D6 average residual amounts in silicone polymers used in medical devices (articles) have been reported to be below 0.1% by some silicone polymers suppliers (CfE2#787), and around 0.2% by CES (CfE2#788).

Regarding particular products where D4, D5 and D6 are present as impurities, information is not complete regarding whether they are above or below 0.1%, but data on a number of products was provided in the consultation. The following is what has been reported so far:

- Products where D4, D5 and D6 have been reported as impurities under 0.1%: IVD assays/mixtures, according to MedTech Europe (CfE2#796)
- Products where D4, D5 and D6 have been reported as impurities but concentration levels are unknown but estimated to be under 0.1%: antifoam, excipients for topical use, elastomers, silicone rubbers.
- Products where D4, D5 and D6 have been reported as impurities potentially over 0.1%, but no further information about concentrations has been provided: gel for wounds, artificial skin for burn treatments.
- Products where D4, D5 and D6 have been reported as impurities over 0.1%, and information about concentrations has been provided:
    - medical bonding adhesives: 0.2% w/w for D4, D5 or D6
    - dental imprints and functional polymers for dental impression moulds: 0.2% w/w for D5 and 1% w/w for D6
    - (substance-based) medical devices for topical use: 0.2% w/w for D4, D5 or D6

Overall assessment of the potential for a derogation: Derogations are needed for this use, as the data available indicates that the residual concentration of D4, D5 and D6 is above 0.1 % w/w in some of the mixtures placed on the market for consumer or

[47] API: active substance ingredient

professional use. The Dossier Submitter proposes an increase in the concentration limit for the specific uses of silicone polymers for which data is available (medical bonding adhesives, dental imprints and functional polymers for dental impression moulds and medical devices for topical use). The concentration limit for these uses should be only high enough to allow the use of silicone polymers to continue, so the Dossier Submitter proposes the values noted in the previous paragraph.

The Dossier Submitter notes that it is possible that there may be other uses of silicone polymers where the concentration of D4, D5 and D6 is above 0.1%. However, sufficient information has not been received to determine the need for a derogation and what the new concentration limit should be for those uses. Information has been requested by the Dossier Submitter from trade associations during the preparation of the report, and, as mentioned, in the Consultation, but limited information has been received.

2.7.4. Use of silicone polymers in vehicles (automotive / aviation / aerospace / marine)

Silicones polymers, particularly silicone rubbers, are used in a wide variety of applications in vehicles.

According to ACEA, the use of silicone polymers in car manufacturing seems to be limited to the production of complex articles, such as air bags, body components, chassis, electrical components, fuel systems and the power train. Some of these articles are of special importance for electric vehicles and lithium ion batteries, for which there is currently no substitutes available. On average, a car contains approximately 3 kg of silicone polymers.

Silicone polymers are also used in marine vessel manufacturing as well as in the aviation and aerospace sector, also in the production of complex articles. Applications include door and window seals, aileron flap seals and safety devices that require short term resistance to very high temperatures in the event of a fire.

Based on this information, a restriction on the use of D4, D5 and D6 in mixtures would not have an impact on these sectors.

2.7.5. Use of silicone polymers in construction

Construction represents the largest market segment for silicone polymers. According to a recent Global Silicones Council report (AMEC, 2016). The sector is estimated to use approximately 50% of the silicone polymers in Europe.

Silicone polymers uses in construction includes, for example:

1. silicone sealants (including caulking) and adhesives
2. polyurethane foam for building insulation

They are usually available for consumers and professionals in various forms such as dough-like material, or adhesive.

The evidence available during the dossier development was mixed regarding the level of D4, D5 and D6 as impurities in these products. According to CES, residual D4, and D5 levels in construction sealants are, on average, 0.2%. On the other hand, in the call for evidence, the European sealant and adhesives industry association (FEICA) and the European Federation for Construction Chemicals (EFCC) indicated that silicone sealant

manufacturers target D4, D5 impurity levels below 0.1% (CfE1#455 and 461). As for D6, the average concentration of D6 in silicone sealants products is reported to be 0.1-1% (CfE2#788 and 792).The ECHA market survey also received information from one company, which reported that their adhesives contain a residual amount of D4, D5 between 0.1 and 3%.

Further information was received during the consultation. Several stakeholders FEICA (##2089), Bostik GmbH (#2342), and EFCC (#2484) indicated that, in view of the usual criteria for environmental labels (SVHC < 0.1%) such as green building schemes (Nordic Swan, Basta, LEED, DGNB, Blue Angel, etc. and company policies), formulators of silicone sealants expect silicone polymers to have a concentration of D4, D5 andD6 below 0.1% as soon as possible. However, the information provided implied that this is not the case at the moment (especially for D6). Cefic - CES Silicones Europe (#2177) confirmed that there is a demand from downstream users for silicone polymer manufacturers to supply products with a lower level of impurities. They also provided data on D4, D5 and D6 concentration in silicone polymers in adhesives and sealants used in construction (#2469). This was reported to be 0.1%-3% w/w, with a concentration limit of 1% w/w being considered sufficient to exclude the majority. This information was consistent with that contained in several other (confidential) responses.

Additionally, based on information provided during the consultation, the Dossier Submitter proposes a concentration limit of 0.3% w/w for D4 for protective coatings (e.g. buildings).

Alternatives: According to CES (CES, 2018b), using devolatilisation techniques (see the end of this section) to reduce the concentration of impurities of D4, D5 and D6 in the silicone polymers that are currently used may not be applicable to this category of products, as they would lose their expected performance. This seems to be particularly the case with D6.

Several potential alternatives have been identified for joint sealants. Their prices tend to be lower, but the technical performance is generally considered to be poorer (AMEC, 2013a).

Overall assessment of the potential for a derogation: A derogation is needed for this use, as the data available indicates that the residual concentration of D4, D5 and D6 is above 0.1 % w/w in some of the mixtures placed on the market for consumer or professional use. The Dossier Submitter proposes an increase in the specific concentration limit for mixtures for use as adhesives or sealants that cure in situ, as this is considered to cover uses in construction but also in other sectors. The concentration limit for this use should be only high enough to allow the use of silicone polymers to continue, so the Dossier Submitter proposes 1% for this use.

The Dossier Submitter notes that it is possible that there may be other uses of silicone polymers in this sector where the concentration of D4, D5 and D6 is above 0.1%. However, sufficient information has not been received to determine the need for a derogation and what the new concentration limit should be for those uses.

2.7.6. Use of silicone polymers in electronics

Essentially gels, rubbers and sealants types of silicone polymers are used in this market segment. They keep moisture away from the electronic components, and are resistant to low and high temperatures. They are used in chips, semi-conductors, LED devices, ICT equipment manufacturing for example. Approximately 2% of silicone polymers are used

in this sector.

The Dossier Submitter does not have information on typical impurity concentrations or potential for release to the environment in this sector. However, no specific information has been received indicating that levels of impurities of D4, D5 and D6 would be an issue in this sector. The Dossier Submitter will therefore assume the proposed restriction would not have an impact on this sector.

2.7.7. Use of silicone polymers in 'special systems'

By special systems, it is meant applications in the textile and clothing industry, in adhesive and coating (other than construction) and in agrochemicals (AMEC, 2016). This use makes up ~20% of silicone polymer usage.

Within this sector, information was received during the consultation for adhesives and sealants. The Dossier Submitter proposes a concentration limit of 1% w/w for D4, or D5 or D6 for adhesives or sealants that cure *in situ*. This proposal covers uses in construction and in other sectors, including this one.

Information was also received in the consultation regarding emulsion concentrates used for protective coatings for e.g. building. The Dossier Submitter proposes a concentration limit of 0.3% w/w for D4 for emulsion concentrates for use as protective coatings.

The Dossier Submitter does not have information on typical impurity concentrations or potential for release to the environment for any other uses in this sector.

2.7.8. Other uses

Based on confidential information received during the consultation, the Dossier Submitter proposes the following concentration limit for the applications listed below:

- rapid prototyping and mould making: 1% w/w for D5 and 3% w/w for D6
- high performance uses stabilised by quartz filler: 1% w/w for D5 and 3% w/w for D6

2.7.9. Overall conclusion for silicone polymers

Socio-economic information available on the impact of a restriction on uses of silicone polymers:

For producers of products with D4, D5 and D6 as impurities above a 0.1% concentration level, one option would be requiring silicone producers to supply them with silicone polymers with lower concentrations of these impurities. CES consider that to be able to achieve that, silicone producers would need to install additional devolatilisation equipment or to slow down the production process (to allow further evaporation of D4 and D5).

CES have provided an estimate for the scale of the costs of installing additional devolatilisation equipment for D4 and D5 in all the markets where they identify the presence of impurities potentially above 0.1% (joint sealants, silicone rubber in cars, antifoaming in pulp and paper manufacturing, detergents and oil drilling, medical applications, personal care products, household products and additives for PU foam). This cost is estimated to be around €600 million. The expected lifetime of this equipment is not certain. CES estimate that some of the equipment to be used for devolatilisation has an expected lifetime of 10-15 years, while chemical apparatuses where processes are run also required in the process might have a lifetime of 20 to 30 years. The Dossier Submitter

is therefore not able to calculate an annualised cost figure. Most of these silicone polymer producers are based outside of the EU; however, it would be expected that at least a proportion of the costs of additional investments would be passed onto their EU customers.

It should be noted that CES claim that even if a restriction with 0.1% concentration limit applied to only some of these markets (e.g. if it were found that the concentration limits were below 0.1% for some markets, or if some benefitted from derogations), they would still expect most of this estimated cost to be incurred. This is because each producer of silicone polymers supplies several different markets (so, equally, the silicone polymers for a particular market come from several different silicone producers). If a particular market is affected by the concentration limit of the restriction, all the silicone polymer producers supplying to it would need to invest in the devolatilisation equipment if they wanted to continue to sell to that particular market. This claim does not take into account the possibility that supply relationships may be rearranged, with a small number of silicone polymer producers concentrating the production of silicone polymers with very low concentrations of D4, D5 and D6 and impurities.

No information was provided regarding the costs or potential effectiveness of slowing down the production process. Additionally, there may be energy implications from building and running devolatilisation plants, which would need to be considered. However, no information was provided on this topic either.

Devolatilisation or process slowdown may be enough to provide silicone polymers that would result in concentrations of D4, D5 and D6 below 0.1% in some markets. However, CES have identified certain consumer/professional mixtures for which it is expected that achieving such a concentration level may be difficult, and potentially not feasible. The products identified are the following (CES, 2018c)[48]:

- Sealants
- Mould-making and prototyping applications
- Dental imprints
- Gel for wound treatment
- Artificial skin for burn treatment

CES expect that the most heavily impacted product group would be sealants. According to FEICA, the European market turnover in 2015 for sealant type products is approx. €2 440 million per annum and silicone-based products have an approximate 40% share. Approximately 200 000 tpa of silicone polymers are produced for the manufacture of sealants (AMEC, 2016) (CfE1#467). It is unknown, however, what proportion of these sealants would be affected by a restriction with concentration limit of 0.1%.

The industry expect that they will probably not be able to reduce the content of D4, D5 and in particular D6 in the sealant mixtures placed on the market to below 0.1% across the range of sealants. If that is the case, then those silicone sealant products would be withdrawn from the market. This would represent a significant impact in lost profits both for the silicone-producing industry and the sealants industry. Additionally, there could be major impacts associated with loss of performance in construction. Silicone sealants are

[48] The list is only indicative as no additional information regarding other applications has been received

important products in the construction and structural glazing industries, as their technical performance and durability are reported to be much better than that of alternative products. Industry report that these sealants allow the construction of water- and air-tight structures, and of specific structures such as very tall buildings.

Summary of the overall assessment of the potential for a derogation:

Based on the considerations above, a derogation would not appear to be needed for most uses of silicone polymers as the residual concentration of D4, D5 and D6 would be below 0.1 % w/w in the mixtures placed on the market for consumer or professional use.

However, specific higher concentration limits are proposed for uses of silicone polymers which information received by the Dossier Submitter indicates would be inadvertently affected by a concentration limit of 0.1% w/w. These are:

- Mixtures that contain D4 or D5 or D6 in a concentration equal to or less than 1% w/w, for use as adhesives or sealants that cure *in situ*
- Mixtures that contain D5 in a concentration equal to or less than 0.2% w/w or D6 in a concentration equal to or less than 1% w/w, for use as medical devices (as defined in Regulation 2017/745) for dental impression.
- Emulsion concentrates that contain D4 in a concentration equal to or less than 0.3% w/w, for use as protective coatings.
- Mixtures that contain D5 in a concentration equal to or less than 1% w/w or D6 in a concentration equal to or less than 3% w/w, for (i) rapid prototyping and mould making, and (ii) high performance uses stabilised by quartz filler.
- Mixtures that contain D4 or D5 or D6 in a concentration equal to or less than 0.2% w/w, for use as medical devices as defined in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745.

It is possible that other uses of silicone polymers may also be inadvertently affected. However, the Dossier Submitter does not have sufficient information to suggest derogations for other uses. If sufficient information is received during the consultation on the draft SEAC opinion, similar derogations may be proposed for other uses.

2.8. Practicality

2.8.1. Implementability and manageability

Alternatives to D4, D5 and D6 are available and economically feasible (cf. Annex C for alternatives on cosmetics, and the relevant sections in 2.6 for the other uses). In addition, the reformulation or transition to alternatives is feasible if sufficient transition time is given.

For certain category of cosmetics and mixtures used in other sectors, there are already alternatives available on the market that are free from D4, D5 and D6.

Therefore the proposed restriction is considered implementable.

2.8.2. Enforceability

The scope of the proposed restriction is clear and unambiguous: it covers the uses of D4, D5 and D6 as a substance or in mixtures used by consumers and professionals. Industrial uses and articles are out of scope.

Standardised laboratory methods for measuring D4, D5 and D6 in cosmetic products (and

environmental samples) have been developed in response to the restriction proposal in wash-off products, suggesting that the restriction is practical and monitorable both for cosmetic products and other uses of D4, D5 and D6 in mixtures. One of these laboratory methods is Gas Chromatography, which enables accurate measurement of D4, D5 and D6 down to 0.1% w/w in mixtures such as cosmetic products. Recent publication in 2017 (Brothers et al., 2017) have indeed demonstrated the accuracy and reliability of such simple analytical methods when combined with a proper preparation of the analysed sample (i.e. emulsion break, liquid–liquid extraction to isolate the non-polar phase from the emulsion break, and silylation sample preparation to abate potential in situ formation of cyclics during the course of GC-FID analysis). Brothers et al. have also demonstrated the potential for generation of false positives when an inappropriate sample approach is applied to detect the presence of D4, D5 and D6: for example QuEChERS[49] sample preparation procedure commonly used for analysis of pesticide residues in food and agricultural products is not recommended.

In addition, for cosmetic products, a simple preliminary check can already be done by reading the INCI ingredients list on cosmetics packaging: even if this information is (i) not 100% reliable (especially if the brand owner does not respect the EU Regulation in this matter), and (ii) does not indicate the concentration in the product; this quick check can nevertheless give an indication of the presence of D4, D5 and D6 in the product. D4, D5 and D6 can be recognised with the following names on the cosmetics ingredient list:

- Cyclotetrasiloxane for D4
- Cyclopentasiloxane for D5
- Cyclohexasiloxane for D6
- Cyclomethicone for a blend of D4, D5 and D6

Nevertheless, this label reading should not replace a laboratory testing for the reasons indicated above.

2.9. Monitorability

Voluntary Industry programmes on WWTP monitoring on D4, D5 could be expanded with D6. CES, and Cosmetics Europe confirmed indeed (#2177 and #2191) that the sampling and measurement of D4 and D5 in municipal WWTP inffluents are feasible to monitor the effectiveness of the restriction on D4 and D5 in wash-off products. The sampling and measurement of D6 in municipal WWTP influents was also confirmed by CES (#2469).

The presence of cosmetics on the market containing D4, D5 and D6 could be monitored using the databases or the applications such as the ones that were used as sources for this Annex XV report (see Table 17). Mystery shopping campaigns could also be used for the same purposes.

[49] QuEChERS refers to the 'Quick, Easy, Cheap, Effective, Rugged and Safe'

3. Assumptions, uncertainties and sensitivities

Exposure assessment:

A number of assumptions have been made in the releases estimations due to the limited information provided in the CSR and in the replies to the calls for evidence, for example:

Tonnages and uses:

- Use of D4, D5 and D6 in washing, cleaning and maintenance products is uncertain and might be overestimated.
- Residual amounts of D4, D5 and D6 in the silicone polymers is uncertain and might vary from one product type to another. An average value is considered for each sector of use based on information provided by stakeholders.
- Use of silicone polymers tonnages and splits between residual amount in mixtures and in articles is uncertain.
- Assumptions have been made with regard to the proportion of discarded packaging containing remaining D4, D5 and D6. The current proportions could be more important in the future due to circular economy initiatives that would increase the recycling, and therefore the proportion of packaging washed-off prior to the recycling itself. The effect of recycling has been explored with a simple sensitivity analysis. It has been concluded by the Dossier Submitter that the proportion of discarded packaging containing remaining D4, D5 and D6 is a sensitive parameter for the calculation of the releases to surface water for the relevant uses (cosmetics, pharmaceuticals, medical devices, waxes and polishes). On the other hand, the effect on the estimated overall releases (air+water) is negligible.

Release factor to air and waste water:

- Differences between the release factors applied by the registrants and the one agreed by RAC in the previous Annex XV restriction proposal for D4, D5.
- Release factor for articles is uncertain, for the atmospheric and water releases, default ERC release factors have been used. Leading to potential overestimates.

Environmental stock modelling:

- The model used to simulate the environment stock of D4, D5 and D6 was not parameterised to predict environmental concentrations but rather provide an indicative assessment of the proportion of D4, D5 and D6 that would remain 'undegraded' in the environment after release. However, comparison of the predicted regional concentrations for air and fresh water with the limited available environmental monitoring data (from the D4 REACH Registration dossier) has been undertaken. By doing so, the appropriateness of the selected model parameters, key assumptions made and the order of magnitude of the emission calculations have been tested. The comparison shows that predicted and measured values are in the same order of magnitude, and that the model is currently under predicting concentrations compared to measured value. It might therefore be assumed that the environmental stock predicted by the model is realistic.

WWTP efficiency and connection rate:

- Connection rate: based on latest EUROSTAT information, a WWTP connection rate of 90% has been taken into account instead of 80% (standard REACH value). A 10% increase for WWTP connection rate, has a significant impact on the emissions to surface water (ca. 40%).
- WWTP modelling: SimpleTreat v4.0 Model has been used to calculate the efficiency rate of the WWTP. In comparison to SimpleTreat v3.1, the WWTP efficiency have improved and has an impact on the emissions to surface water (ca. 20% reduction).

The sensitivities analysis are further described in Annex D, and are summarised in the Table 24 where the arrows indicate the impact of the uncertainity on the release estimates (↑ the assumption increases the estimates / ↓ the assumption lowers the estimates / negligeable).

Table 24: Summary of sensitivities analysis (exposure assessment)

Uncertainty	Impact on release estimates (low scenario - water only)	Impact on release estimates (high scenario – all compartments)
Tonnage and uses		
Use and tonnage of D4, D5 and D6 in washing, cleaning and maintenance products might be overestimated	Negligible	Negligible
Use and tonnage of silicone polymers and splits between residual amount in mixtures and in articles might be overestimated	↑	Negligible
The proportion of discarded packaging containing remaining D4, D5 and D6 might be underestimated	↓	Negligible
Release factor to air and waste water		
Release factors applied by the registrants and the one agreed by RAC in the previous Annex XV restriction proposal for D4, D5	Ranges have been provided taken into account the variability in the release factors	
Release factor for articles is uncertain, for the atmospheric and water releases, default ERC release factors have been used	↑	Negligible
WWTP efficiency and connection rate		
Connection rate of 90% has been taken into account instead of 80% (standard REACH value)	↓	Negligible
SimpleTreat v4.0 Model has been used to calculate the efficiency rate of the WWTP	↓	Negligible

Socio-economic analysis:

Appendix D1 in the Annex document presents sensitivity analysis related to variables identified as key. A summary of the results is presented below:

Effect of different transitional periods (Appendix D.2.1): A longer transitional period would decrease the costs associated with the restrictions, as it would allow more coordination with baseline reformulations. However, the shorter the transitional period, the more releases would be prevented over the 20-year study period. On balance, increasing the transitional period improves cost-effectiveness (by 3% for every year added).

Effect of assuming voluntary substitution of D4, D5 and D6 in by the cosmetics industry (Appendix D.2.2): If under the "no restriction" baseline, the cosmetics industry were moving away from the use of D4, D5 and D6, this would affect both the costs that could be attributed to the restriction (making them lower), but also the amount of releases prevented directly as a result of the restriction (making them lower as well).

Without concrete information about the proportion of products voluntary substitution could affect, or about how quickly it may happen, the Dossier Submitter has calculated a maximalist scenario where industry would move away from D4, D5 and D6 fully in 10 years. This could, on balance, make the restriction substantially less cost-effective (cost per kg would approximately triple). However, as mentioned, this is a maximalist scenario, and the reality is likely to be somewhere in between the best estimates presented earlier in this report and the maximalist scenario.

Effect of different prices of raw materials used in place of D4, D5 and D6 (Appendix D.2.3a): There still remains much uncertainty regarding which substances will be used to replace D4, D5 and D6 in reformulated products, and therefore little is known about their price, beyond some data presenting indicating that most alternatives that are being considered will be more expensive. However, because additional costs of raw material represent a small proportion of the total cost of the restriction, the total costs (and cost-effectiveness measures) are not very sensitive to the price of the alternatives. For instance, the best estimate assumes costs that are double those of D4, D5 and D6, but even if it was assumed that the costs are triple instead, the total cost of the restriction woud increase by only 14%.

Effect of variations in the price of raw materials used in D4, D5 and D6-free products (Appendix D.2.3a): Increased demand for D4, D5 and D6-free products could increase the cost of the raw material used in those products. The proportion of products containing D4, D5 and D6 is low (estimated at 8%-16% of all products), so this effect is not expected to be very large. Each 5% increase in the unit cost of the raw material used in alternative products is estimated to lead to an increase of 17% in the average annual additional cost of raw materials. However, the effect on total costs of the restriction is much smaller: a 5% increase in unit cost of the raw material leads to a 2.5% increase in the total costs of the restriction.

Effect of using different assumptions regarding what proportion of formulations containing D4, D5 and D6 would be reformulated (Appendix D.2.4): Only a proportion of the formulations containing D4, D5 and D6 are assumed to actually be reformulated. It is assumed under the best estimate that this proportion is approximately 20%. Both cost and cost-effectiveness estimates are very sensitive to this assumption, being directly proportional.

Under the maximum scenario, where it is assumed that all products with D4, D5 and D6 would be reformulated, the NPV of total costs would be €3 700 million, compared to €703 million under the best estimate. The annual cost per kg of releases to water prevented would be almost €5 500, and of relases to water + air prevented would be €15.

The Dossier Submitter considers this is one of the key areas of uncertainty of this analysis.

Effect of assuming different proportions of formulations containing D4, D5 and D6 belong to large companies and SMEs: It is assumed that approximately a quarter of reformulations are undertaken by large companies (at a higher cost per reformulation) and the rest of SMEs. Sensitivity analysis shows that for every 10% increase in the proportion of reformulations assumed to be undertaken by large companies, total costs increase by 6%.

Effect of assuming different costs per reformulation: The Dossier Submitter has assumed costs per major reformulation of €365 000 for those undertaken by large companies and €42 000 for those done by SMEs, with minor reformulations assumed to have costs a tenth of major ones. Each 10% increase in costs per reformulation leads to an 8.5% increase in total costs of the restriction and cost/kg of releases abated.

4. Conclusions

D4, D5 and D6 are substances with PBT and/or vPvB properties. PBT/vPvB substances give rise to specific concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are difficult to reverse even when releases cease. Therefore, the risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way e.g. by derivation of risk characterisation ratios. Emissions and subsequent exposure, in the case of a PBT/vPvB substance, are therefore a proxy for risk.

D4, D5 and, to a lesser extent, D6, are high tonnage substances. They are used as monomers for the production of silicone polymers, but also used as substances on their own or in the formulation of various mixtures that are subsequently used by consumers and professionals. The total releases to the environment have been estimated to be approximately 18 000 tpa. The Dossier Submitter has also estimated that the steady-state stock of D4, D5 and D6 that remains in the environment associated with these releases is approximately 500 t.

Despite the already existing restriction on D4, D5 in wash-off cosmetics, the wide-dispersive use of D4, D5 and D6 in cosmetic products remains the main source of releases. Other uses such as in dry-cleaning, household detergents and car care, pharmaceuticals and medical devices, cleaning of art and antiques contribute to overall releases, but are relatively much less significant. D4, D5 and D6 can also be present as residues in silicone polymers. The uses of silicone polymers have also been analysed by the Dossier Submitter to understand the potential impact of the restriction on them.

Alternatives to D4, D5 and D6 exist for the majority of the identified uses. In addition, the reformulation or transition to alternatives is considered to be feasible if sufficient transition time is given. For a number of consumer and professional uses, there are already alternative mixtures available on the market that do not use D4, D5 and D6.

When the use of alternatives would not result in an overall reduction in risk, or where the restriction would appear to be disproportionate from society's perspective, the Dossier Submitter has proposed derogations from the proposed restriction. This is the case for (i) the use of D5 in the cleaning of art and antiques, and (ii) for the use of D4, D5 and D6 in medical devices used for scar and wound treatment and stoma care, and (iii) dry cleaning systems where the washing liquid is recycled or incinerated, and with no release to air.

The Dossier Submitter has identified several uses of silicone polymers in mixtures that potentially contain relatively high concentrations of D4, D5 and D6 as impurities (mixtures containing silicone polymers used as medical devices and as sealants used in the construction sectors). Information was submitted during the consultation to allow for the proposal of dedicated concentration limits for some of these uses to ensure they are not affected by the restriction. Information on what would be a suitable concentration limit to avoid these impacts is still lacking for some others. For those uses, the Dossier Submitter considers therefore that the need for a different concentration limit could be further considered if additional information is submitted during the consultation on SEAC's draft opinion to justify it.

The proposed restriction is estimated to cost in total some €700 million[50] for cosmetic products, assuming a 5-year transitional period. Best estimates of the cost per kg of releases prevented are €3 for all releases (to air and water) and €1 000 for releases to water alone. The cost per kg of preventing releases that will remain in the environment, which is considered by the Dossier Submitter to be the most appropriate measure for these substances, is estimated to be €104 per kg.

Although significant emission reductions (ca. 90%) could be envisaged through the Annex XV restriction proposal on the use of D4, D5 and D6, emissions will not be totally prevented as releases will remain from uses of silicone polymers where the concentration of D4, D5 and D6 is below the limit proposed in the restriction.

Overall, the proposed restriction is considered to be a balanced, justified and cost-effective measure. The proposed restriction is also practical and monitorable measure for industry and enforcement authorities.

In conclusion, this Annex XV report demonstrates that an action is required on a Union-wide level and the proposed restriction is the most appropriate measure.

[50] 20-year NPV value

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Annexes

Annex A: Manufacture and uses

A.1. Uses of D4, D5 and D6 and silicones in cosmetics

Annex B: Information on hazard and risk

B.1. Identity of the substance(s) and physical and chemical properties

B.2. Manufacture and uses

B.3. Classification and labelling

B.4. Environmental fate properties and behaviour

B.5. Human health hazard assessment

B.6. Human health hazard assessment of physicochemical properties

B.7. Environmental hazard assessment

B.8. PBT and vPvB assessment

B.9. Exposure assessment

B.10. Risk characterisation

Annex C: Impact Assessment

C.1. Risk Management Options

C.2. Alternatives

Appendix C.1. Differenciation between uses at industrial sites and uses by professional workers

Annex D: Assumptions, uncertainties and sensitivities

D.1. Exposure assessment: sensitivity analysis

D.2. Socio-economic analysis: sensitivity analysis

Annex E: Stakeholder information

E.1. ECHA's calls for evidence

E.2. Market study

E.3. Consultation of Member State Competent Authorities