ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

Annexes

SUBSTANCE NAME(S):	**Octamethylcyclotetrasiloxane (D4)**
	Decamethylcyclopentasiloxane (D5)
	Dodecamethylcyclohexasiloxane (D6)
EC NUMBER(S):	**209-136-7, 208-764-9, 208-762-8**
CAS NUMBER(S):	**556-67-2, 541-02-6, 540-97-6**

CONTACT DETAILS OF THE DOSSIER SUBMITTER:

European Chemicals Agency

Annankatu 18, PO BOX 400, FI-00121, Helsinki, Finland

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Annex A: Manufacture and uses

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

A.1.1. A historical perspective

Cyclosiloxanes (D4, D5 and D6), linear siloxanes, organo-functional polydimethylsiloxanes (PDMS), silicone elastomer dispersions and resins are widely used in cosmetics formulation. All these substances are often referred to as silicones.

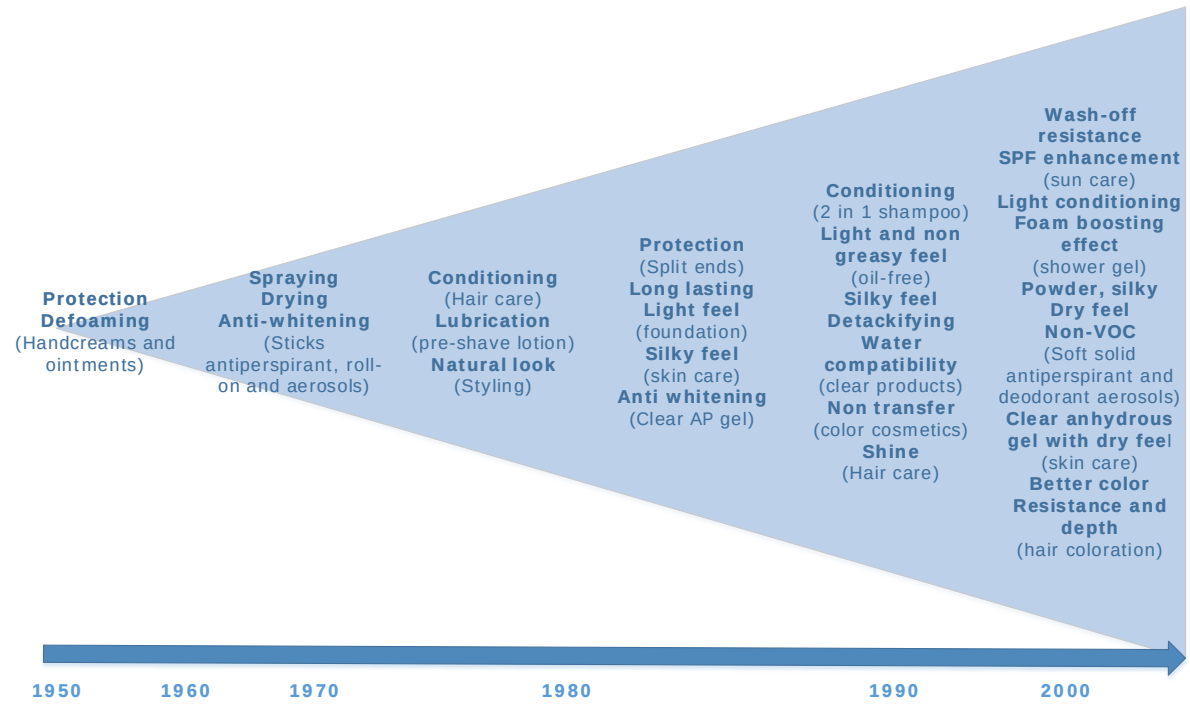
The first use of silicones in cosmetics dates from the late 1940s when the American company Revlon launched 'Silicare skin lotion', a formulation containing dimethicone, which, according to the company, was providing a 'protective, breathable barrier on the skin and was reducing the whitening or "soaping" effect typically encountered during rub-in of the lotion' (Gruber James V., 1999).

It was in 1973 that the first deodorant stick product containing cyclomethicones was launched, and in 1978 'Dry Idea' launched in the US a faster drying roll-on, containing 75% cyclomethicone, which was also reported to feel drier during application (Gruber James V., 1999). Following this product introduction, cyclomethicones became the major component in most non-aerosol antiperspirant and deodorant formulations.

Since then the use of silicones in cosmetics has continued to increase. Figure 1 depicts in a simplified manner the history of D4, D5, D6 and silicones uses in cosmetics.

Today, silicones (including D4, D5 and and D6) are used in many cosmetics products placed on the market. PDMS are the most frequent silicone used.

Figure 1: History of silicone uses in cosmetics



Source: Silicones in personal care application (Andriot et al., 2007)

A.1.2. Presence of D4, D5 and D6 in cosmetics

Table 1: Proportion of products containing D4 or D5 or D6 in cosmetics

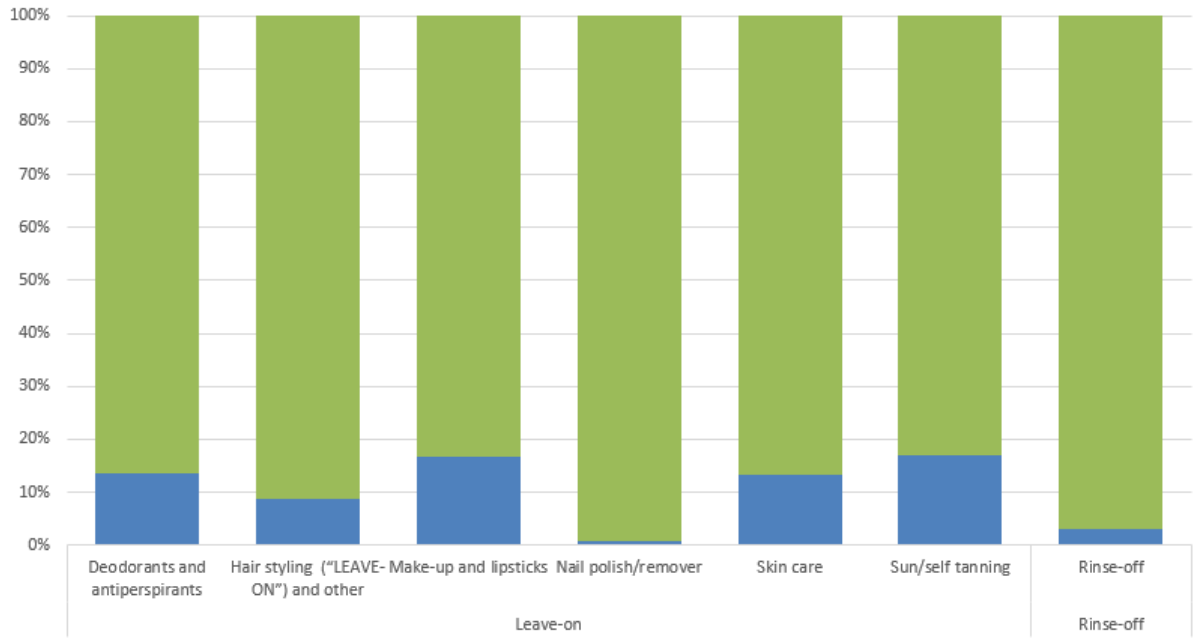
Cosmetic	Cosmetic type	Product category	Proportion containing D4 or D5 or D6 [%]
Serum/oil	Leave-on	Skin care	60%
Foundation/BB Cream	Leave-on	Make-up and lipsticks	43%
Concealer	Leave-on	Make-up and lipsticks	35%
Treatments	Leave-on	Skin care	34%
Lip liner, pen	Leave-on	Make-up and lipsticks	31%
Eyebrow pen/gel/powder	Leave-on	Make-up and lipsticks	29%
Deodorant	Leave-on	Deodorants and antiperspirants	25%
Body butter	Leave-on	Skin care	21%
After sun moisturiser	Leave-on	Sun/self tanning	21%
Anti-age cream	Leave-on	Skin care	19%
Styling cream	Leave-on	Hair styling ('LEAVE-ON') and other	19%
Eyeliner liquid/gel	Leave-on	Make-up and lipsticks	18%
Sunscreen	Leave-on	Sun/self tanning	18%
Self-tanner	Leave-on	Sun/self tanning	18%
Highlighter	Leave-on	Make-up and lipsticks	17%
Serums and treatments	Leave-on	Skin care	17%
Moisturisers/Face cream	Leave-on	Skin care	16%
Foot lotion	Leave-on	Skin care	16%
After sun	Leave-on	Sun/self-tanning	16%
Eye moisturiser	Leave-on	Skin care	16%
Anti-cellulite	Leave-on	Skin care	16%
Make up remover	Rinse-off	Rinse-off	15%
Facial moisturizers	Leave-on	Skin care	14%
Conditioner	Rinse-off	Rinse-off	13%
Body lotion	Leave-on	Skin care	12%
Creams and lotions	Leave-on	Skin care	12%
Body lotion/Balm/Cream/Gel	Leave-on	Skin care	12%
After shave	Leave-on	Skin care	11%
Eyeliner, pen	Leave-on	Make-up and lipsticks	11%
Hair spray	Leave-on	Hair styling ('LEAVE-ON') and other	11%
Foot cream	Leave-on	Skin care	10%
Eye gel	Leave-on	Skin care	10%
Eye shadow	Leave-on	Make-up and lipsticks	10%
After sun gel	Leave-on	Sun/self-tanning	9%
Other nail or cuticle products	Leave-on	Nail polish/remover	8%
Masks	Leave-on	Skin care	7%

Cosmetic	Cosmetic type	Product category	Proportion containing D4 or D5 or D6 [%]
Blush/Bronzer/Contour	Leave-on	Make-up and lipsticks	6%
Thickening product	Leave-on	Hair styling ('LEAVE-ON') and other	6%
Facial care	Leave-on	Skin care	6%
Body oil	Leave-on	Skin care	6%
Lipstick	Leave-on	Make-up and lipsticks	6%
Mascara	Leave-on	Make-up and lipsticks	6%
Dry shampoo	Leave-on	Hair styling ('LEAVE-ON') and other	5%
Self-tanner face	Leave-on	Sun/self-tanning	5%
Lip gloss	Leave-on	Make-up and lipsticks	4%
Hair gel	Leave-on	Hair styling ('LEAVE-ON') and other	4%
Hair wax	Leave-on	Hair styling ('LEAVE-ON') and other	4%
Holding or styling foam or mousse	Leave-on	Hair styling ('LEAVE-ON') and other	4%
Pressed powder	Leave-on	Make-up and lipsticks	4%
Hair styling	Leave-on	Hair styling ('LEAVE-ON') and other	3%
Powder	Leave-on	Make-up and lipsticks	3%
Hair color	Rinse-off	Rinse-off	3%
Wipes	Leave-on	Skin care	3%
Cream	Leave-on	Skin care	3%
Cleansers	Rinse-off	Rinse-off	3%
Intimate care	Rinse-off	Rinse-off	3%
Foot wash/bath	Rinse-off	Rinse-off	3%
Scalp Care	Leave-on	Hair styling ('LEAVE-ON') and other	3%
Hair removal	Rinse-off	Rinse-off	2%
Other baby products	Leave-on	Hair styling ('LEAVE-ON') and other	2%
Massage oil	Leave-on	Skin care	2%
Exfoliators/Body scrub	Rinse-off	Rinse-off	2%
Loose powder	Leave-on	Make-up and lipsticks	2%
Exfoliators	Rinse-off	Rinse-off	2%
Antiseptic	Leave-on	Skin care	2%
Lotion	Leave-on	Skin care	2%
Toners and mists	Leave-on	Skin care	2%
Shaving foam	Rinse-off	Rinse-off	1%
Foot scrubs	Rinse-off	Rinse-off	1%
Lip balm	Leave-on	Make-up and lipsticks	1%
Shampoo	Rinse-off	Rinse-off	1%
Hand sanitizer	Leave-on	Skin care	1%
Baby Oil	Leave-on	Skin care	1%
Perfume/Parfum/Eau de Parfum	Leave-on	Deodorants and antiperspirants	1%
Cleansers/Scrubs	Rinse-off	Rinse-off	1%

Cosmetic	Cosmetic type	Product category	Proportion containing D4 or D5 or D6 [%]
Shaving gel	Rinse-off	Rinse-off	0%
Soaps	Rinse-off	Rinse-off	0%
Body wash	Rinse-off	Rinse-off	0%
Hand wash	Rinse-off	Rinse-off	0%
Nail polish	Leave-on	Nail polish/remover	0%
Baby wash	Rinse-off	Rinse-off	0%
Bath foam/oil/salt/	Rinse-off	Rinse-off	0%
Butter	Leave-on	Skin care	0%
Diaper Ointment	Leave-on	Skin care	0%
Eau de Parfum	Leave-on	Deodorants and antiperspirants	0%
Eau de Toilette	Leave-on	Deodorants and antiperspirants	0%
Hands and Nails	Leave-on	Skin care	0%
Mouthwash	Rinse-off	Rinse-off	0%
Nail polish remover	Leave-on	Nail polish/remover	0%
Shower gel	Rinse-off	Rinse-off	0%
Soap	Rinse-off	Rinse-off	0%
Tinted lip balm	Leave-on	Make-up and lipsticks	0%
Toothpaste	Rinse-off	Rinse-off	0%
			11%

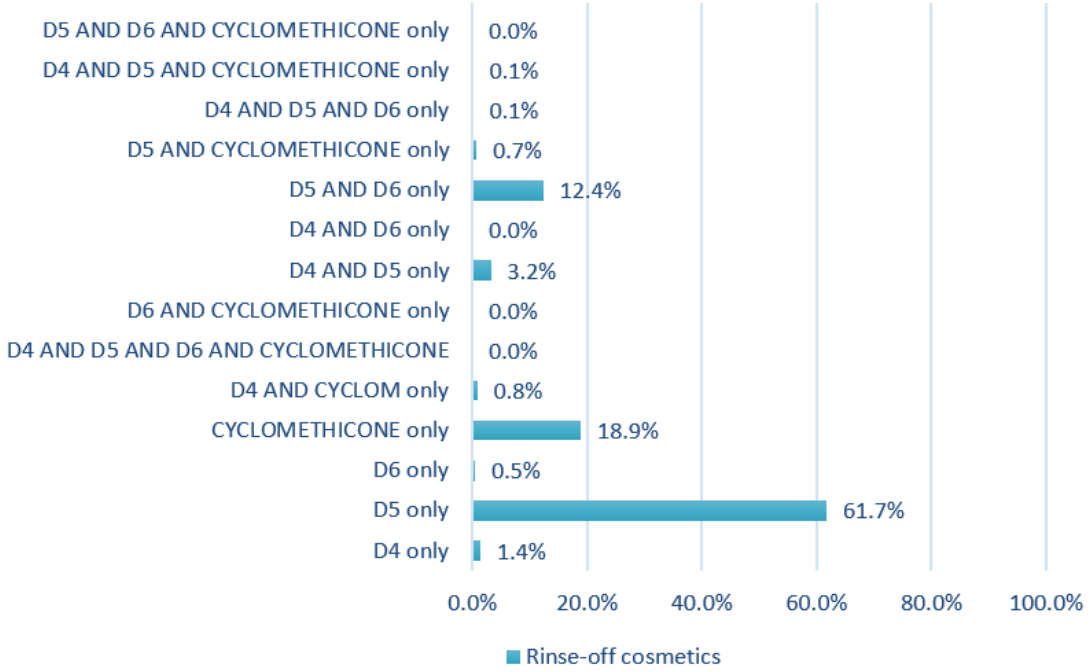
Source: ECHA market survey (CosmEthics, 2018)

Figure 2: Proportion of products containing D4 or D5 or D6 per product category (blue portion of the bar)



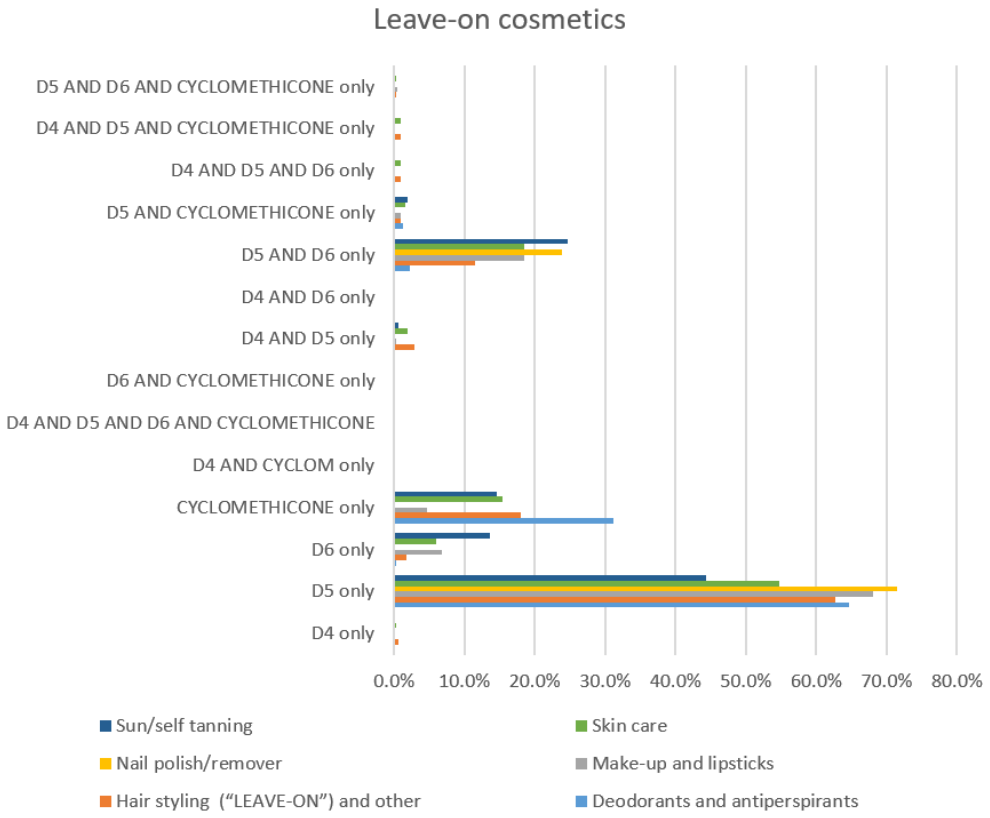
Source: ECHA market survey (CosmEthics, 2018)

Figure 3: Composition of rinse-off cosmetics containing cyclosiloxanes (percent)



Source: ECHA market survey (CosmEthics, 2018)

Figure 4: Composition of leave-on cosmetics containing cyclosiloxanes (percent)



Source: ECHA market survey (CosmEthics, 2018)

Annex B: Information on hazard and risk

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

B.1.1. Name and other identifiers of D4, D5 and D6 in cosmetics

Ingredients[1] 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. 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

Cyclomethicone (CAS: 69430-24-6) is further described in the European COSING database (COSING) as 'a mixture of low molecular weight volatile cyclic siloxanes, the principal ingredients of which are octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6), in varying proportions'.

According to the 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 both D4 and Cyclomethicone on the labelling of cosmetics placed on the market in Europe. When Cyclomethicone is indicated on the label, it remains unclear what are the components of this mixture, and it is not possible to conclude if D4 is or is not part of the blend.

B.2. Manufacture and uses

Already covered in the Annex XV report

B.3. Classification and labelling

Already covered in the Annex XV report

[1] '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.

B.4. Environmental fate properties and behaviour

B.4.1. Environmental fate modelling

B.4.1.1. Summary

The following section will detail the key assumptions and input parameters used in the multi-media modelling of the fate and environmental distribution *('environmental stock modelling'*) of D4, D5 and D6 undertaken to support the Annex XV restriction report preparation. Relevant results from a modelling exercise will also be presented.

B.4.1.2. Key assumptions and fate input parameters

A spreadsheet format of the multimedia fate model SimpleBox, version 4.01 (Hollander et al., 2016) was used, due to its simplicity, transparency and reproducibility; as well as its previous use in different European regulatory contexts. The SimpleBox regional environment was used as the primary model environment, with the scenario name (referring to the compartmental dimensions and set-up) selected as 'EUSES settings' and the case name (referring to the number of compartments) being 'default' (Hollander et al., 2016).

Environmental emissions for the EU (continental scale) have been estimated based on the use of D4, D5 and D6 in various applications, e.g. cleaning, polishing, detergents, leave-on cosmetics and other products, as well as due to their presence as impurities in different cosmetics, other product types and mixtures. The emission estimation, including lower and upper emission ranges, has been described elsewhere in this Annex XV restriction proposal report.

The upper range of these estimates were used as inputs to the air and fresh water model compartments (cf. Table 2). Regional emissions were assumed to one tenth (10%) of the total continental emission burden. Two scenarios were, subsequently, tested for each of the three substances, namely one scenario assuming emissions to both air and fresh water and one assuming emissions only to water. In this way, the influence of the additional atmospheric input to the fate, distribution and overall residence time of cyclic methyl siloxanes could be investigated.

Table 2: Summary of D4, D5 and D6 emissions used as model inputs

Chemical	D4	D5	D6
Continental environmental emissions (tpa)	522	15369	2353
% of total emissions to air	96%	99%	98.0%
% of total emissions to water	4%	1%	2.0%
% regional emission of total	10%	10%	10%
Regional emissions to air (tpa)	50.1	1521.5	230.6
Regional emissions to water (tpa)	2.1	15.4	4.7

Physical-chemical and other fate properties: Table 3 summarises the key physical-chemical and fate input to the model, with most of these parameters extracted from the three Substance of Very High Concern (SHVC) Dossiers submitted to ECHA during 2017 and 2018 (ECHA, 2018a).

Regarding solids partitioning, the use of experimentally-derived carbon-water partition coefficient (K_{OC}) values was favoured over estimated values for octanol-water partition coefficients (K_{OW}), by use of the Karickhoff equation (Mackay, D, 2001).

Regarding degradation via reactions with OH^- radicals, rates corresponding to atmospheric half-lives of 8-11 days have been used, obtained from either the ECHA dissemination site (ECHA, 2018b) or the SHVC identification dossiers (ECHA, 2018a).

Table 3: Key physico-chemical and other fate input

	D4	D5	D6
Molecular weight (g/mol)	297	371	445
Melting point (ºC)	18	-38	-3
Vapour pressure (Pa)	132	33.2	4.7
Water solubility (mg/L)	0.056	0.017	0.0051
Log K_{OC}	4.22	5.17	5.9
Degradation rate in air (s^{-1})	8.4E-08	1.2E-07	1.2E-07

B.4.1.3. Model simulations – compartmental distribution in the regional environment

Table 4 summarises the predicted environmental distribution of D4, D5 and D6 in the main model compartments for the regional environment derived from the two different emission scenarios (emissions to air and water: a+w and emissions only to water: w).

Table 4: Regional compartmental distribution of D4, D5 and D6 predicted by SimpleBox 4.01

Chemical	D4_a+w	D4_w	D5_a+w	D5_w	D6_a+w	D6_w
% Air	30.3%	1.5%	21.9%	0.2%	4.1%	0.1%
% Fresh water	14.1%	20.0%	2.7%	3.4%	1.0%	1.1%
% Fresh water sediment	52.5%	74.2%	72.1%	92.2%	90.2%	94.0%
% Rest	3.1%	4.3%	3.3%	4.2%	4.7%	4.8%

As can be seen from Table 4, a higher atmospheric percentage is derived for D4, reflecting its slower atmospheric degradation compared to D5 and D6. This percentage in air is as high as 30.3% for D4, falling to 4.1% for D6, when assuming emissions to both air and fresh water. The respective percentage in air drops markedly in simulations where atmospheric emissions are not considered.

Regarding freshwater, the compartmental distribution is decreasing from D4 to D6, reflecting the higher sorption capacity and, thus, shifting of partitioning to freshwater sediments. As expected, considering emissions only to water increases the chemical stock to this compartment, especially for D4. Again, the increase in freshwater distribution for D5 and D6 is counteracted by the increased solids portioning and fast chemical transfer to sediments.

B.4.1.4. Model simulations – 'unreacted' chemical stocks in regional and continental environment

Table 5 summarises the model output referring to the estimated regional compartmental

chemical stock, after all loss processes (advection, reactions, deposition processes, etc.) having taken place. For D4, approximately 82 kg are predicted to still reside in the model atmospheric compartment at any given time, assuming state-state conditions, corresponding to 0.16% of the total amount emitted to air. The corresponding atmospheric stocks for D5 and D6 are simulated to be 2.4 tonnes and 364 kg. It can, thus, be inferred that, though small considering the total amount released, still measurable traces of these chemicals, especially, D5 will be present in the regional atmosphere.

Table 5: D4, D5 and D6 chemical stock predictions for the regional environment

	D4	D5	D6
Emission in air (tpa)	50.1	1521.5	230.6
Emission in water (tpa)	2.1	15.4	4.7
Atmospheric 'stock' (tpa)	0.1	2.4	0.4
Remaining in air of total emitted in air	0.16%	0.16%	0.16%
Freshwater 'stock' (tpa)	0.04	0.29	0.09
Remaining in water of total emitted in water	1.8%	1.9%	1.9%
Regional 'stock' (tpa)	**0.27**	**10.9**	**8.8**
Remaining in regional environment of total emitted	0.5%	0.7%	3.7%
Remaining in regional over all other environments	1.1%	2.3%	9.9%

Regarding freshwater, the respective stocks at steady-state are much smaller (38-290 kg), accounting for approximately 1.9% of the amounts directly emitted to fresh water. It needs to be noted that the amount predicted to reside in water (regional scale) is likely to also be influenced by deposition inputs from air.

Two additional parameters were modelled, namely the total chemical stock at any given time as a percentage of the total amount emitted in the regional environment (0.5-3.7%), as well as the percentage chemical residing in the regional environment as opposed to the respective amount that is advective transported to the other SimpleBox 4.01 environments (continental, moderate, arctic, etc.). This percentage is 1.1% - 9.9%, with D6 showing the highest 'affinity' for the regional environment.

As can be seen by these estimations, the fact that only a small percentage of the initially emitted chemical resides in the air and freshwater regional compartments may be outweighed by the much higher chemical presence in the other model environments. Thus, an additional scenario was tested, namely the respective 'stocks' and compartmental distributions for the continental scale, assuming only emissions in the regional scale. It is acknowledged that this assumption introduces differences to the compartmental distribution and concentrations (especially of the freshwater continental compartment) if continental emissions were also introduced. Table 6 summarises the key findings.

Table 6: D4, D5 and D6 chemical stock predictions for the continental environment, assuming emissions to the regional-scale only

Chemical	D4	D5	D6
Emission in air (tpa)	50.1	1521.5	230.6
Emission in water (tpa)	2.1	15.4	4.7
Atmospheric 'stock' (tpa)	1.6	40.9	6.2
Remaining in air of total emitted in air	3.2%	2.7%	2.7%
Freshwater 'stock' (tpa)	0.00	0.00	0.00

Chemical	D4	D5	D6
Remaining in water of total emitted in water	0.0%	0.0%	0.0%
Continental 'stock' (tpa)	**1.8**	**43.2**	**7.7**
Remaining in continental of total emitted	3.4%	2.8%	3.3%
Remaining in continental over all other environments	7.1%	8.9%	8.7%

As expected, the residing atmospheric stock, both as an amount and as a percentage, is increased when the continental scale is considered. For example, from 0.16% of the amount emitted to 2.7-3.2%. The respective stock for water is negligible. The respective overall amount remaining in the continental scale has also increased for D4 and D5. For the same substances, the higher importance of the continental environment as a 'sink' was also highlighted by the model calculations.

It is also possible to estimate the total 'unreacted' stock residing in the regional and continental scales after regional releases (Table 7). The resulting estimates of the percentage of release that remain unreacted in the environment after fate and degradation processes will form the starting basis for the cost-effectiveness calculations that will be presented in the Annex XV report.

Table 7: Regional and continental stock of D4, D5 and D6

Chemical	D4	D5	D6
Regional release (tpa)	52.2	1 536.9	235.3
Regional stock (tpa)	0.27	10.9	8.8
Continental stock (tpa)	1.8	43.2	7.7
Total stock (tpa)	2.07	54.1	16.5
Percent of regional release (%)	**4.0**	**3.5**	**7.0**

B.4.1.5. Model simulations – chemical concentrations

Despite the fact that the model was not parameterised with the objective of predicting environmental concentrations, an additional investigation involving the comparison of predicted regional concentrations for air and fresh water with limited existing monitoring data (from the D4 REACH Registration dossier) can be undertaken. By doing so, the appropriateness of the selected model parameters, key assumptions made and the order of magnitude of the emission calculations can be tested (Table 8). Modelled concentrations are comparable to those reported for ambient fresh water levels, whilst air concentrations may be somewhat under-predicted by the model.

Table 8: Predicted and measured concentrations in air and fresh water

Chemical	D4	D5	D6
Predicted regional concentration in air (ng/m3)	2.0	5.9	9
Measured regional concentration in air (ng/m3)	10-100	20-200	
Predicted regional concentration in fresh water (ng/L)	10.6	80.9	25.0
Measured regional concentration in water (ng/L)	<30	<10; 59	

B.5. Human health hazard assessment

Not relevant

B.6. Human health hazard assessment of physicochemical properties

Not relevant

B.7. Environmental hazard assessment

Not relevant – cf next section on PBT vPvB assessment

B.8. PBT and vPvB assessment

D4 has been identified as a PBT/vPvB substance (ECHA MSC, 2018d) . D5 and D6 have been 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:

- For D4: https://echa.europa.eu/documents/10162/680ea46d-b626-1606-814e-62f843fe2750
- For D5: https://echa.europa.eu/documents/10162/1b116de3-d5f9-40a2-d681-2e00d3953a7b
- For D6: https://echa.europa.eu/documents/10162/81c323a0-f0ce-8375-5091-b08d44f35553

B.9. Exposure assessment

B.9.1. General discussion on releases and exposure

B.9.1.1. Summary of the existing legal requirements

D4 and D5 are restricted under REACH Annex XVII entry 70 (REACH, 2018) with the following conditions:

- D4 and D5 Shall not be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0,1 % by weight of either substance, after 31 January 2020
- For the purposes of this entry, 'wash-off cosmetic products' means cosmetic products as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009 that, under normal conditions of use, are washed off with water after application.

B.9.1.2. Summary of the effectiveness of the implemented operational conditions and risk management measures

Due to the intrinsic properties of D4, D5, and D6 (e.g. evaporation) and the way the mixtures containing D4, D5 and D6 are used (e.g. wide dispersive uses by consumers and professional, disposal down the drain), the releases of D4 and D5 from wash-off cosmetics could not be further reduced by risk management measures, therefore a restriction was the only option to reduce the releases to the environment.

Despite the existing restriction, wide dispersive uses remains and should be further reduced.

B.9.2. General assumptions for the release calculations

Releases to the environment (essentially aquatic) for D4, D5 and D6 were estimated in previous UK RAR (2009) and in the Annex XV restriction proposal for use of D4 and D5 in wash-off products. Following the publication of the restriction on wash-off products, industry have carried out new measurement campaigns and updated their CSRs. The information on tonnages, and releases (release factors) provided in the most recent CSRs is different (although only modestly different) from the release factors proposed by RAC during the opinion-making phase of the Annex XV restriction proposal for wash-off products.

This section aims to summarise the assumptions made by the Dossier Submitter to calculate the emissions of D4, D5 and D6 to both the aquatic and atmospheric environment.

B.9.2.1. Tonnages

B.9.2.1.1. Identification of relevant exposure scenarios

The starting point for the exposure assessment is a review of the latest[2] submitted CSRs by the registrants, to identify the relevant exposure scenarios.

Based on the further details gathered during the calls for evidence and the ECHA market study, additional exposure scenarios have been added to the initial list provided by the registrants.

The list of selected exposure scenarios is depicted in Table 9 below; the exposure scenarios covered by the registrants in their CSRs are identified with their exposure scenario number ES#. The ones not covered by the registrants in their CSRs are identified with a tick ✓. The column 'emission to air' indicates that the main release to the environment is to Air, while the column 'emission to water', implies that the main release is towards the aquatic environment. The main target for emission is indicated with a +.

[2] D4 joint CSR submitted by the lead on 18 July 2018, on 6 July 2018 for D5, and on 19 June 2018 for D6.

Table 9: Exposure scenarios of interest for the Annex XV restriction proposal

Exposure scenario	D4 relevant (CSR#)	D5 relevant (CSR#)	D6 relevant (CSR#)	Release to air	Release to water	Comment
Formulations of mixtures containing D4, D5 and D6						
Formulation of cosmetics products	-	ES7	ES5			Formulation is an industrial use, and is per se out of scope of the Annex XV restriction proposal ; but if a restriction is adopted, it will impact the upstream supply chain
Formulation of household and maintenance products	-	ES9	ES9			
Formulation of pharmaceuticals and medical devices	-	ES14	ES13			
Uses of D4, D5 and D6						
Detergent, household care and vehicle maintenance products	-	ES10 /11/ 12	ES10 /11/ 12	+ (ES12)	+	ES10 and 11: household care, washing and cleaning products ES12: waxes and polishes
Dry cleaning	-	ES13	-	+		
Rigid PU foam	-	ES17	-	+		
Leave-on cosmetics	-	ES18	ES6/ 8	+		
Wash-off cosmetics	-	-	ES7		+	
Pharmaceuticals products and medical devices	-	✓	ES14 to 16	+		
Cleaning of art and antiques	✓	✓	-	+		
Use of silicone polymers (containing D4, D5 and D6 impurities)						
Presence of impurities in silicone polymers used in cosmetics	✓	✓	✓		+	In the CSR, only a generic ES has been provided.
Presence of impurities in silicone polymers used in other sectors	✓	✓	✓	+	+	

B.9.2.1.2. Tonnages

Table 10 gives an overview of the considered annual EU tonnage across the various ES. This summary is based on the UK Annex XV restriction report on D4 and D5, the call for evidence for the current restriction proposal, registration data and the market research exercise undertaken by ECHA. In the absence of further information (e.g. on the uses of silicone polymers: volume of silicone polymers and silicone types, residual amounts of D4, D5 and D6), assumptions have been taken based on the best available information at the time of the Annex XV restriction proposal preparation. The assumptions are indicated below Table 10.

Table 10: Overview of annual EU tonnage splits between uses

Sector / Uses	D4 - Annual EU tonnage[1] [tpa]	D5 - Annual EU tonnage[1] [tpa]	D6 - Annual EU tonnage[1] [tpa]
Formulations of mixtures containing D4, D5 and D6	**-**	**20 300** [2]	**1 530**
Formulation of cosmetics products	-	20 000	1 400
Formulation of household and maintenance products	-	50	30
Formulation of pharmaceuticals and medical devices	-	250[3]	100 [4]
Uses of D4, D5 and D6	**0.1**	**15 366** [2]	**1 530**
Detergent, household care and vehicle maintenance products	-	60 [5]	30 [5]
Dry cleaning	-	50	-
Rigid PU foam	-	6	-
Leave-on cosmetics	-	15 000	2 000 [6]
Wash-off cosmetics	-	-	200 [7]
Pharmaceuticals products and medical devices	-	250 [3]	100 [4]
Cleaning of art and antiques	0.1 [8]	0.2 [8]	-
Use of silicone polymers (containing D4, D5 and D6 impurities) [9]	**900**	**900**	**450**
Use of silicone polymers in cosmetics	255[10]	255[10]	127.5[10]
Use of silicone polymers in other sectors	645	645	323

Source: Dossier Submitter assumptions based on best available information

Assumptions on tonnages:

[1]: Annual EU tonnage as reported in the Registration/CSR dossiers, unless specified otherwise.

[2]: A part of the formulation is exported outside Europe, this is why the formulated and used tonnages are different

[3]: Consolidated tonnage information provided during the call for evidence (CfE1#467) by relevant down-stream sectors. This information was not available in the registration dossiers.

In addition, it is assumed that ca. 70% of the tonnage is used in leave-on pharmaceuticals and medical devices. This is based on information provided by the registrants for D6 – the same proportion is assumed for D5.

[4]: The tonnage differs between the registration data and the information provided in the CfE (CfE2#788) by the down-stream user association. The Dossier Submitter has therefore decided to use the highest available reliable information rounded up.

In addition, it is assumed that ca. 70% of the tonnage is used in leave-on pharmaceuticals and medical devices. This is based on information provided by the registrants.

[5]: The annual tonnage includes both the professional and consumer use of waxes and polishes (ES12), of washing and cleaning products (ES11), as well as the use of household care products by workers in industrial settings (ES10). The later includes laundry products used in automatic processes and vehicle cleaning products used in semi-automatic processes (source CSR D5 and D6).

According to the CSRs, it is estimated that 2/3 of the tonnages is used down-the-drain,

and 1/3 used in waxes and polishes with essentially a release to air.

[6]: The annual tonnage has been provided after the second call for evidence (October 2018) by the relevant industry sector – it is based on a survey of 29 companies formulating in the cosmetics sector. The survey might not be representative of the industry sector, but this value is already 30% higher than the value reported by the registrants. The Dossier Submitter has therefore decided to use the highest available reliable information, which is the tonnage indicated in the call for evidence, and round it up.

[7]: A lower tonnage has been provided after the second call for evidence (October 208). The Dossier Submitter has therefore decided to use the highest available reliable information, which is the tonnage indicated by the registrants, and round it up.

[8]: Additional information provided during the market research. Estimations are based on information provided by experts in art cleaning and restoration on previous sales.

[9]: Estimates of the uses of silicone polymers are the best estimates that could be made based on the available information:

According to the registrants and CES (CfE1#467), it is assumed that a total of ca. 450 000 tpa of basic silicone polymers (excluding silanes and industrial sector uses) are used in products traded in on the EU market. This figure is in line with the 2013 European data on silicones supply chain sales in key sectors (AMEC, 2016).

It is assumed that the basic silicone polymers could contain residual D4, D5 and D6.

There is a lack of precise data for D4, D5 and D6 residues in silicone polymers. However, the registrants and CES have indicated an average residual level of 0.2% for D4 (CES, 2017a) and D5 (CES, 2017b), and 0.1 % for D6 in polymers to calculate the quantity of D4, D5 and D6 emitted to the environment from the silicone polymers. These values, which correspond to a worst case scenario, have been considered for the calculation of the annual emissions from silicone polymers: i.e. a total of 900 tpa of D4 residues, 900 tpa of D5 residues and 450 tpa of D6 residues emitted from silicone polymers.

It is also assumed that the sector distribution for the uses of silicone polymers has not evolved much since 2013, and the data on sectoral distribution available (AMEC, 2016) is still broadly valid. The following tonnage distribution has therefore been used to estimate the quantity of silicone polymers per sector:

- Use of silicone polymers in cosmetics: between 20 and 30 % of the total silicones uses, i.e. 255 tpa emissions for D4 and D5, and ca. 130 tpa emissions for D6. The D4 assumed tonnage is close to the upper bound estimate indicated by Cosmetics Europe (CE, 2018a).
- The rest of silicone polymers is assumed to be shared equally between silicone mixtures and silicone articles as no information was specifically available regarding the split between uses of silicone polymers in mixture or in article.

[10]: Estimates from the registrants: 40 tpa in wash-off, the rest in leave-on – considering that the first restriction of D4, D5 in wash-off products is implemented. For D6, the Dossier Submitter has used the same proportion to split the emissions from silicone polymers from cosmetics between leave-on and wash-off.

B.9.2.2. Consumer behaviour

Consumer behaviours and habits in term of (i) removal of substance, mixtures after use (essentially cosmetics, and leave-on medical devices), but also in terms of (ii) disposal of

unused/outdated products, or product packaging after use, have been considered to identify the different type and level of releases for the various uses.

Removal of cosmetics and other products applied on the skin/body

Leave-on products (in cosmetics, but also in Medical Devices applications) are intended to stay for a certain period of time in contact with the skin, the hair or the mucous membranes. Leave-on products include a broad range of different products: in cosmetics for example they include lipstick, face-care products, body-cream, nail-care products, etc. Depending on the type of products, consumers use different techniques to remove the products from their body, skin, or mucous membranes. The removal methods impact directly the releases of D4, D5 and D6 to the environment (main route, and release factor).

A survey (CE, 2018c) has been conducted by Cosmetics Europe in 2018 with the participation of 8 000 consumers located in 8 European countries (UK, France, Germany, Italy, Netherlands, Poland, Spain and Sweden) in order to better understand consumer habits in term of make-up removal. Although the results of the survey were submitted in the frame of the Annex XV restriction preparation on intentionally added microplastics, the Dossier Submitter has considered the information relevant also for the D4, D5 and D6 restriction dossier preparation. Consumer habits per cosmetics category are summarised in the table below.

Table 11: Consumer habits for the removal of leave-on cosmetics

Leave-on category	**% of product removed with a cotton or wipe disposed in bin**	**% of products washed off (or removed with a cotton pad or wipe disposed in toilets)**
Skin care products	24.20%	75.80%
Make up and make up removing products	72.25%	27.75%
Deodorants and antiperspirants	10.36%	89.64%
Hair styling and hair Care Products ('LEAVE-ON')	8.52%	91.48%
Products intended for application to the lips	72.25%	27.75%
Sun protection product	13.22%	86.78%
Products for tanning without sun	13.22%	86.78%
Nail varnish/remover products	81.96%	18.04%
Other personal care products (i.e. remaining leave-on)	24.20%	75.80%

Source: Cosmetics Europe (CE, 2018c)

Disposal of cosmetics, pharmaceuticals, medical devices or waxes/polishes packaging:

Sometimes cosmetics, pharmaceuticals, medical devices or waxes/polishes are not fully used before their expiry date and/or the empty packaging that is disposed of includes a residual amount of the product. The Dossier Submitter has estimated that 5% of the tonnage associated with the use would be discarded on this basis. No evidence was available to support this assumption, but 5% was used based on expert judgement as a realistic and plausible estimate.

It is also assumed that a small proportion of this cosmetic product packaging would be

cleaned with water by the consumer before placing it in the bin, or that uncleaned packaging would be recycled with one of the first steps of the recycling being the shredding/washing of the materials. The Dossier Submitter has assumed that 10% of the discarded packaging would be recycled or washed prior to disposal. This leads to the assumption that for certain type of uses (e.g. cosmetics, pharmaceuticals and medical devices, waxes and polishes) 0.5% of the tonnage of D4, D5 and D6 intended to be used would be released to wastewater. This percentage can be considered as the proportion of D4, D5 and D6 that is disposed down the drain without having been used.

Discarded cosmetic product packaging that is not recycled will be either incinerated or disposed in landfill.

Table 12: Assumptions on the disposal of packaging

% of D4, D5 and D6 tonnage disposed by consumer:	5%
% recycled and/or washed-off:	10%
% of D4, D5 and D6 going down the drain without having been used:	**0.5%**

B.9.2.3. Release factors to air and wastewater

Information on the releases of D4, D5 and D6 to wastewater and air during the uses are limited. In addition, the available data are often limited to very specific types of uses (e.g. deodorants and antiperspirants), and also representing a very limited amount of samples (ECHA, 2016).

Release factors have therefore been reviewed by the Dossier Submitter based on the data available in the CSRs, the release factors for wash-off and leave-on products from the RAC and SEAC opinion on the UK Annex XV restriction proposal on wash-off cosmetic products aka 'RAC proposed release factors' (ECHA, 2016), and also monitoring values from waste water treatment plant received during the call for evidence (some are claimed as confidential). In the absence of further information on release factors, estimates have been made based on the best available information at the time of the Annex XV restriction proposal preparation. This is particularly true for the release factors from articles where no information has been received during the calls for evidence.

For the sake of clarity, the release factors adopted/agreed by RAC, during the opinion-making phase of the Annex XV restriction proposal for wash-off products containing D4, D5, are summarised in Table 13.

Table 13: RAC D4, D5 release factors for cosmetics end-uses

	RAC release factors to waste water [%]	**RAC release factors to air [%]**
Wash-off cosmetics	54 – 93%	7 – 46 %
Leave-on cosmetics	0.1 – 2.6 %	97.4 – 99.9%

Source: (ECHA, 2016)

Due to the uncertainties, the release factors, and then the associated emissions estimates will be provided within a lower, and higher band.

The release estimates to surface water and air will be provided for different assumptions (low, and high ranges) allowing for comparison between them.

B.9.2.4. Release factors for municipal solid waste

According to the ECHA guidance on environmental release estimation for the waste life stage (ECHA, 2012), the following release factors should be applied to municipal solid waste.

Table 14: Typical release factor for municipal solid waste

Landfill
Release factor to water [via leachate] : 3.2%
Release factor to air [via wind] : 96.8%
Incineration
Release factor to water [via scrubbing]: 0.01%
Release factor to air [release to air]: 0.01%

Source: (ECHA, 2012)

In addition, according to EU-wide statistics on treatment of municipal solid waste, when recycling is omitted, 40% of solid waste is incinerated, and the remaining 60% is landfilled. The following release factors will therefore be applied for the municipal solid waste:

Table 15: Release factors applied to municipal solid waste

Release factor to water	1.9 %
Release factor to air	58.1%

B.9.2.5. WWTP efficiency and connection rate

<u>WWTP efficiency for D4, D5 and D6:</u>

Based on the values identified in the Annex XV report for the vapour pressure (Vp), and the mean Koc (Soil Organic Carbon-Water Partitioning Coefficient), and noting that the substances are not readily biodegradable, the overall removal in a typical WWTP has been calculated using SimpleTreat v.4.0 model for each substances, and is summarised in Table 16 below.

Table 16: WWTP efficiency

	D4	**D5**	**D6**
Efficiency of the WWTP (i.e. removal of substance) (%)	97%	98%	98%
Release directed to air at the WWTP (%)	49%	23%	9%
Release directed to sludge at the WWTP (%)	48%	75%	89%

Source: calculation made with SimpleTreat v.4.0

It should be noted that the WWTP efficiency used by the Dossier Submitter differs from (i) the one used in the previous Annex XV dossier proposal for restriction of D4, D5 in wash-off cosmetics, and (ii) from the one used by the registrants in their CSRs. In both cases, an earlier version of the SimpleTreat model was used, which estimated lower removal efficiency.

A simple sensitivity analysis has been performed and is available in Annex D.

<u>WWTP connection rate:</u>

The REACH default connection rate is 80% (ECHA, 2016), but based on the most-up-to date data on the percent of EU population (28 member states) connected to urban wastewater treatment with at least secondary treatment, connection to WWTP has been

assumed to be 90%. This connection rate is also in line with the eighth and ninth report on the implementation of the Urban Waste Water Treatment Directive which states that between 88.7% and 92% of the waste waters in the EU received secondary treatment in compliance with the provisions of the UWWTD, 10 percentage points up from the previous Report (European Commission, 2017).

In addition, with regard to the releases associated to municipal solid waste, 100% connection rate to municipal WWTP is assumed: meaning that the release to water from landfill (via leachate) and incineration (via scrubbing), will be treated and not go directly to surface water.

B.9.2.6. Release calculation

For each path emission, the release calculation is made with the following formulas:

Release to waste water (WW):

[Release to WW] = [tonnage] x [release factor to WW]

Release to surface water:

Although the WWTP efficiency is very high for D4, D5 and D6, a small portion of the influent is likely to remain in the effluent. In some cases (cf. WWTP connection rate), the waste water might not be treated in a WWTP and released therefore directly to surface water. The formula below depicts the release to surface water:

[Release to surface water] =

[Release to WW] x (1 – ([WWTP connection rate] x [WWTP efficiency])[3]

Release to air:

D4, D5 and D6 are volatile substances (cf. Henry's law constants values) and are released to air during the use itself. A small proportion is released to air at the WWTP during the aeration steps for example. This is taken into account in the below formula.

[Release to air] =

([tonnage] x [release factor to AIR]) + [Release to WW] x [Release directed to air at the WWTP]

B.9.3. Overall environmental exposure assessment

B.9.3.1. Cosmetics

Tonnage: use in leave-on cosmetics estimated at 15 000 tpa for D5, and 2 000 tpa for D6. Use in wash-off cosmetics estimated at 200 tpa for D6.

Sources of releases and pathways:

For leave-on cosmetics, applying a release factor to waste water of 2.6%, which corresponds to the upper release factor agreed by RAC, to all leave-on products does not seem realistic. Confidential information submitted during the call for evidence seems to indicate that the release to waste water treatment plants could be half the upper boundary agreed by RAC. Nevertheless, the results provided were based on limited data both in

[3] [Release to surface water] = ([Release to WW] x [WWTP connection rate] x (1 – (WWTP efficiency rate)) + ([Release to WW] x (1 – [WWTP connection rate])

terms of geographical area and number of samples, so a general conclusion cannot be reached based on this. However, based on a study on consumer habits (CE, 2018c), complemented by a report on D5 temporal analysis of consumer habits (CE, 2018d), the Dossier Submitter has assumed that certain types of leave-on products (e.g. make up) are essentially removed first with a wipe or cotton and disposed of in a bin, and acknowledges that for these products, the release to water is less important, as most of the products on the skin have already been removed before showering or washing the skin.

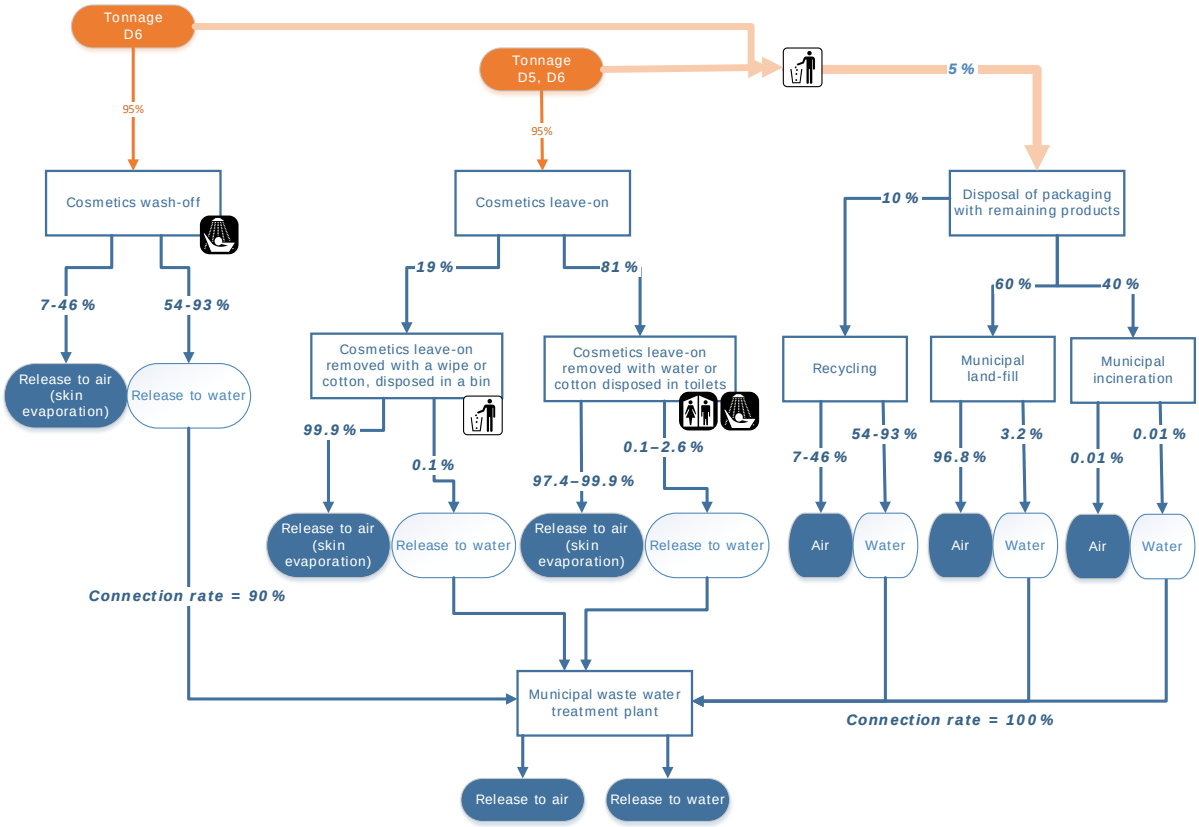
Based on the outcome of the consumer habits (cf. chapter B.9.2.2) the following release factors to waste water have been applied:

- 0.1 % to the leave-on products disposed in the bin (ca. 19 % of the EU tonnage)
- 0.1 - 2.6% to the leave-on products disposed down the drain (81% of the EU tonnage)

The tonnage proportions have been calculated based on aggregated tonnage information per type of products submitted by Cosmetics Europe, and the analysis of the consumer behaviour.

For wash-off cosmetics, the registrants have indicated in their CSRs, release factors to air and wastewater that are very close to the lower RAC agreed release factor to wastewater for wash-off cosmetics. The release factor value set by the registrants is based on (Montemayor et al., 2013). The results of this study were already discussed by the RAC during the opinion-making of the D4 and D5 restriction in wash-off products, and it was concluded that 'even though reliable, the study presents some methodological limitations'. At that time, RAC decided to set an upper and lower value for the releases to wastewater of 93% and 54%, respectively. As the call for evidence has not brought forward any new conclusive information on releases, the Dossier Submitter has therefore considered that the lower and upper release factors for wash-off cosmetics agreed by RAC could also be used for the down-the-drain detergent, household care and maintenance products.

Figure 5: Conceptual release pathways for cosmetics



Emissions estimates:

Table 17: Leave-on cosmetics that are then removed with a wipe or cotton pad and disposed of in a bin

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	0.1%	0.1%	0	0	99.9%	99.9%	0	0	**0**	**0**
D5	2 650			0	0			2647	2647	**2648**	**2648**
D6	353			0	0			353	353	**353**	**353**

Table 18: Leave-on cosmetics that are then washed-off or removed with a wipe or cotton pad and disposed in the toilet

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	0.1%	2.6%	0	0	97.4%	99.9%	0	0	**0**	**0**
D5	11 600			1	36			11368	11592	**11404**	**11593**
D6	1 547			0	5			1510	1545	**1515**	**1546**

Table 19: Wash-off cosmetic products

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	54.0%	93.0%	0	0	7.0%	46.0%	0	0	**0.00**	**0.00**
D5	0			0	0			0	0	**0.00**	**0.00**
D6	190			12.1068	20.8506			29.203	96.634	**50.05**	**108.74**

Table 20: Total emissions (including disposal behaviour)

Use	Substance	Tonnage	Lower release to surface water (tpa)	Upper release to surface water (tpa)	Lower total release to air (tpa)	Upper total release to air (tpa)	Lower total emissions (tpa)	Upper total emissions (tpa)
Leave-on cosmetics	D4	-	0	0	0	0	0	0
Leave-on cosmetics	D5	15 000	7	44	14432	14678	14476	14685
Leave-on cosmetics	D6	2 000	1	6	1917	1956	1923	1957
Wash-off cosmetics	D4	-	0	0	0	0	0	0
Wash-off cosmetics	D5	-	0	0	0	0	0	0
Wash-off cosmetics	D6	200	12	21	35	102	56	115

B.9.3.2. Pharmaceutical products and medical devices

Tonnage: use in leave-on pharmaceuticals and medical devices is estimated at 175 tpa for D5, and 70 tpa for D6. Use in wash-off pharmaceuticals and medical devices is estimated at 75 tpa for D5 and 30 tpa for D6.(cf. Table 10)

Sources of releases and pathways:

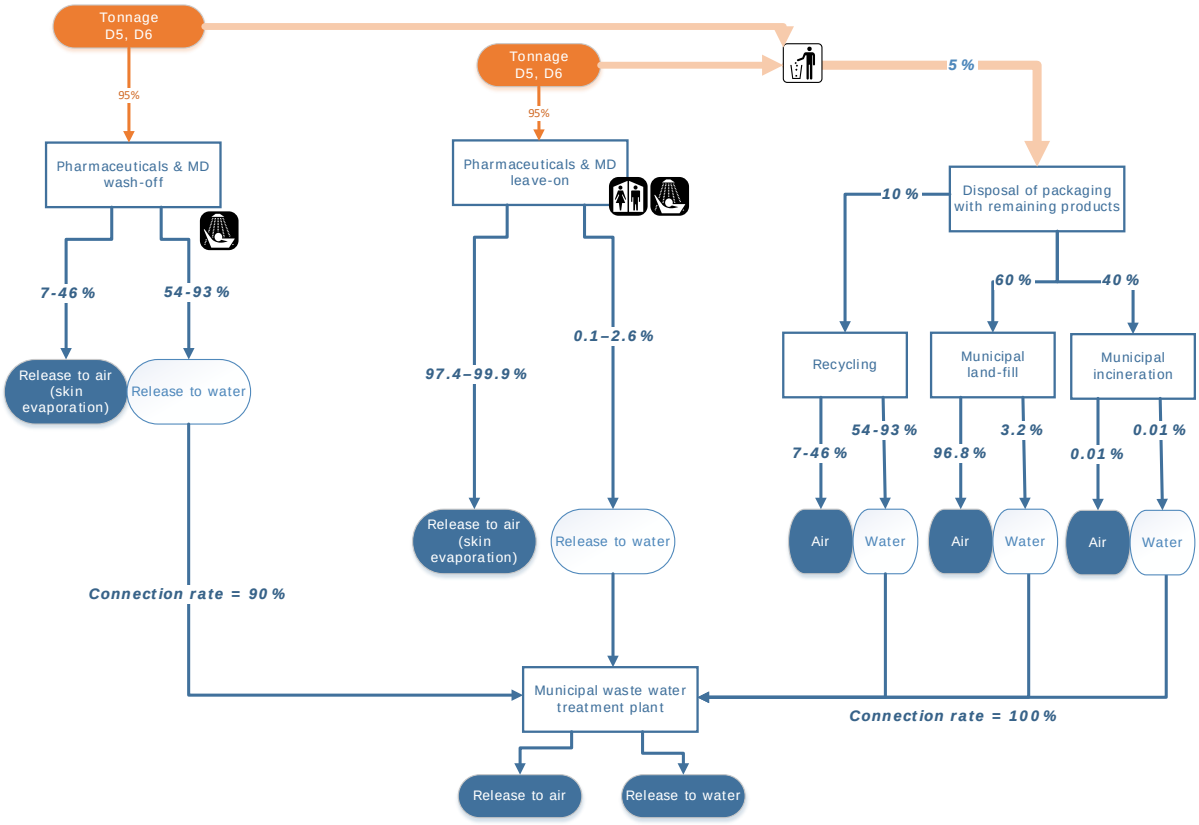
No information has been submitted during the call for evidence on consumer habits with regards to medical devices and pharmaceuticals containing D4, D5 and D6. The Dossier Submitter has therefore considered that:

- For leave-on pharmaceuticals and medical devices: the release pattern is similar to the one of leave-on cosmetics that are disposed of down the drain, hence the same release factors are used.
- For wash-off pharmaceuticals and medical devices: the release pattern is similar to the one of wash-off, hence the same release factors are used.

In addition, the Dossier Submitter has assumed that a minor part of pharmaceuticals and medical devices (both wash-off and leave-on) remains in the packaging that are disposed of by consumers (this proportion could correspond as well to a proportion of unused products which is not collected by take-back schemes but directly disposed of by consumers). Assumptions set in the section B.9.2.2 on Consumer behaviour have therefore been used, and release estimates from this path have been considered as well.

The emission pathways are depicted in Figure 6 below.

Figure 6: Conceptual release pathways for pharmaceuticals and medical devices



Emissions estimates:

Table 21: Leave-on pharmaceuticals and medical devices

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	0.1%	2.6%	0	0	97.4%	99.9%	0	0	**0.00**	**0.00**
D5	166.25			0.0196175	0.510055			162.921675	166.1219875	**163.43**	**166.14**
D6	66.5			0.007847	0.204022			64.92661	66.439485	**65.13**	**66.45**

Table 22: Wash-off pharmaceuticals and medical devices

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	54.0%	93.0%	0	0	7.0%	46.0%	0	0	**0.00**	**0.00**
D5	71.25			4.54005	7.818975			20.227875	41.62425	**28.05**	**46.16**
D6	28.5			1.81602	3.12759			4.38045	14.4951	**7.51**	**16.31**

Table 23: Total emissions (including disposal behaviour)

Use	Substance	Tonnage	Lower release to surface water (tpa)	Upper release to surface water (tpa)	Lower total release to air (tpa)	Upper total release to air (tpa)	Lower total emissions (tpa)	Upper total emissions (tpa)
Pharmaceutical products and medical devices	D4	-	0	0	0	0	0	0
Pharmaceutical products and medical devices	D5	250	5	8	190	215	199	220
Pharmaceutical products and medical devices	D6	100	2	3	72	84	75	86

B.9.3.3. Detergent, household care and vehicle maintenance products

Tonnage: down the drain uses estimated at 40 tpa for D5, and 20 tpa for D6. Use in waxes and polishes estimated at 20 tpa for D5 and 10 tpa for D6. (cf. Table 10)

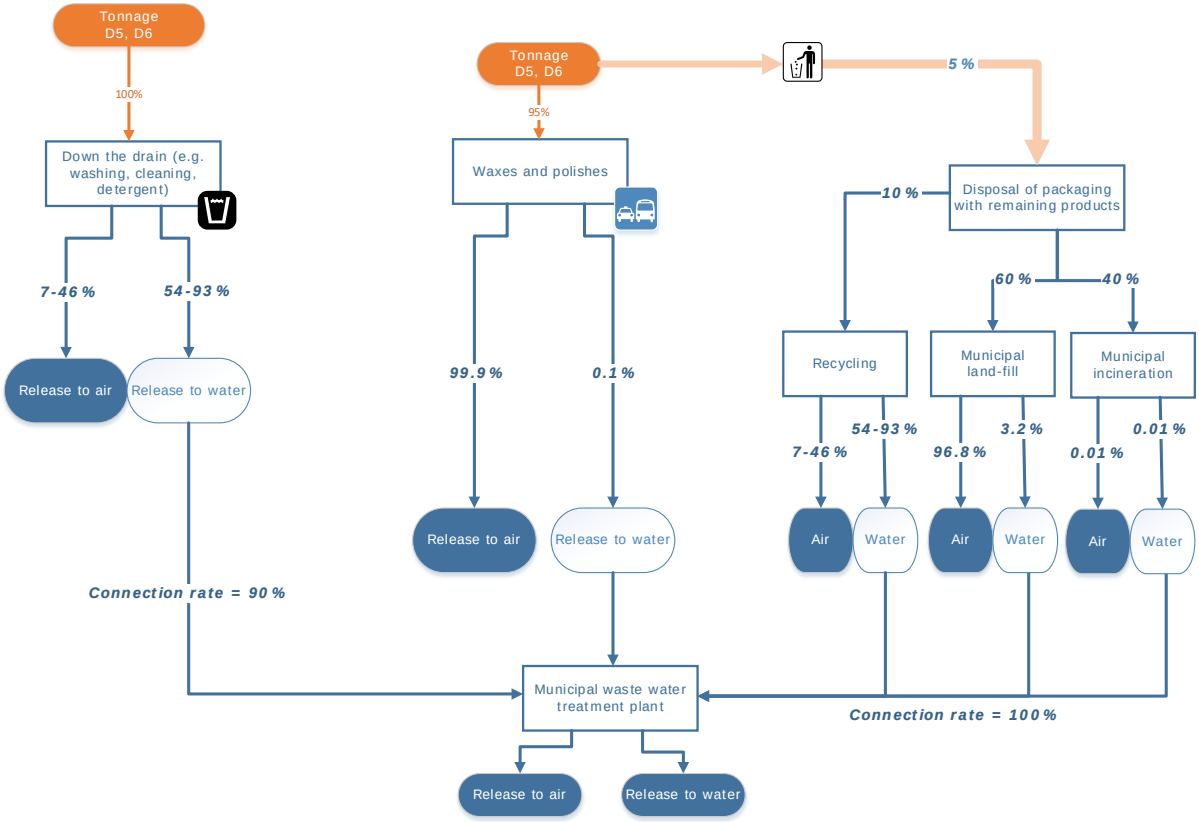
Sources of releases and pathways:

Down the drain uses are assumed to be similar to wash-off cosmetic uses both by the registrants and the Dossier Submitter. The registrants have indicated in their CSRs, release factors to air and wastewater that are very close to the lower RAC-agreed release factor to wastewater for wash-off cosmetics. The Dossier Submitter has therefore considered that the lower and upper RAC agreed release factors for wash-off cosmetics could be used for the down the drain detergent, care and maintenance products.

On the other hand, waxes and polishes are assumed to be similar to leave-on cosmetic uses that would remain for a longer period on the skin. The registrants have indicated in their CSRs, release factors to air and wastewater that correspond to the lower RAC agreed release factor to wastewater for leave-off cosmetics. The Dossier Submitter has not received any information that would justify to deviate from the registrants assumptions, and therefore has applied the agreed RAC release factor to wastewater for leave-off cosmetic for the emissions calculations.

In addition, due to the physical properties, and viscosity of such products, the Dossier Submitter, has assumed that a minor part of waxes and polishes remains in the packaging that are disposed of by consumers. Assumptions set in the section B.9.2.2 on Consumer behaviour have therefore been used, and release estimates from this path have been considered as well.

Figure 7: Conceptual release pathways for detergent, household care and vehicle maintenance products



Emissions estimates:

Table 24: Down the drain products

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	54.0%	93.0%	0	0	7.0%	46.0%	0	0	**0.00**	**0.00**
D5	40			2.5488	4.3896			11.356	23.368	**15.75**	**25.92**
D6	20			1.2744	2.1948			3.074	10.172	**5.27**	**11.45**

Table 25: Waxes and polishes

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	0.1%	0.1%	0	0	99.9%	99.9%	0	0	**0.00**	**0.00**
D5	19			0.002242	0.002242			18.98537	18.98537	**18.99**	**18.99**
D6	9.5			0.001121	0.001121			9.491355	9.491355	**9.49**	**9.49**

Table 26: Total emissions (including disposal behaviours)

Use	Substance	Tonnage	Lower release to surface water (tpa)	Upper release to surface water (tpa)	Lower total release to air (tpa)	Upper total release to air (tpa)	Lower total emissions (tpa)	Upper total emissions (tpa)
Detergents, household care and vehicle maintenance products	D4	-	0	0	0	0	0	0
Detergents, household care and vehicle maintenance products	D5	60	3	4	31	43	35	45
Detergents, household care and vehicle maintenance products	D6	30	1	2	13	20	15	21

B.9.3.4. Dry cleaning

Tonnage: 50 tpa for D5 (cf. Table 10)

Sources of releases and pathways:

In the dry cleaning process, D5 circulates in a closed loop system. The registrants and GreenEarth (CfE1#463) have indicated that most releases of D5 occurs to air, and that some minor release of D5 can occur to waste water when condensed water from the process is , as a worst case, sent to drain. In addition, some losses of D5 happen during the filtration of the solvent (via activated clay, or cardbridge filter for example). After the dry cleaning process has taken place, waste, which is in powder form, is disposed of. This explains why release factors to air and waste water do not add up to 100%.

The Dossier Submitter did not see a reason to deviate from the registrants and the technology owner assumptions. Therefore the release factors indicated by the registrants have been considered for the emissions calculations.

Emissions estimates:

Table 27: Dry cleaning

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	0.00001%	0.00001%	0	0	92.0%	92.0%	0	0	**0.00**	**0.00**
D5	50			5.664E-07	5.664E-07			46.0000011	46.0000011	**46.00**	**46.00**
D6	0			0	0			0	0	**0.00**	**0.00**

B.9.3.5. PU foam

Tonnage: 6 tpa for D5 (cf. Table 10)

Sources of releases and pathways:

The registrants have indicated that from modelling studies and measurements with sealants, the entire residue of D5 in the rigid PU foam would be lost to the air. Therefore a 100% release factor to air has been assumed.

Emissions estimates:

Table 28: PU foam

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	0.0%	0.0%	0	0	100.0%	100.0%	0	0	**0.00**	**0.00**
D5	6			0	0			6	6	**6.00**	**6.00**
D6	0			0	0			0	0	**0.00**	**0.00**

B.9.3.6. Cleaning of art and antiques

Tonnage: < 1 tpa for D4 and D5 (cf. Table 10)

Sources of releases and pathways:

D4 and D5 are applied on art and antiques, in a similar way as a leave-on cosmetic product would be applied on the skin.

The releases are therefore considered similar to one for leave-on, and the RAC-agreed release factors for leave-on have been used by the Dossier Submitter. This is considered to be the most plausible assumption.

Emissions estimates:

Table 29: Cleaning of art and antiques

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0.1	0.1%	2.6%	0.0000127	0.0003302	97.4%	99.9%	0.098674	0.099949	**0.10**	**0.10**
D5	0.2			0.0000236	0.0006136			0.195996	0.199846	**0.20**	**0.20**
D6	0			0	0			0	0	**0.00**	**0.00**

B.9.3.7. Formulations

Tonnage: 20 300 tpa for D5 and 1 530 tpa for D6. With a very large proportion assigned to formulation of cosmetics (cf. Table 10)

Sources of releases and pathways:

For the release factor to waste water, the Dossier Submitter has assumed:

- For pharmaceutical formulations: such formulation sites are assumed to be well-controlled, therefore the emission factor of 0.009% will be applied for the lower and upper boundaries.
- For cosmetics and household sector: industry indicated in the CSR that the formulation sites are well-controlled; on the other hand, RAC assumed in the previous restriction proposal on D4, D5 in wash-off cosmetics that 40% of formulation sites are assumed to be well-controlled. This statement was not challenged during the public consultation process. It is therefore proposed to apply

an emission factor in the range of 0.009% and 0.0576% for that type of formulation sites. It is the same range that was applied in the previous restriction dossier proposal on D4 and D5.

For this industrial uses, the Dossier Submitter has also assumed that 100% of the wastewater releases would be treated by a WWTP.

Emissions estimates:

Table 30: Formulation of cosmetics

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	0.009%	0.058%	0	0	0.020%	0.020%	0	0	**0**	**0**
D5	20000			0.2124	1.35936			4.414	6.6496	**4.63**	**8.01**
D6	1400			0.014868	0.0951552			0.29134	0.352576	**0.31**	**0.45**

Table 31: Formulation of detergent, household care and vehicle maintenance products

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	0.009%	0.058%	0	0	1.000%	1.000%	0	0	**0**	**0**
D5	50			0.000531	0.0033984			0.011035	0.016624	**0.01**	**0.02**
D6	30			0.0003186	0.00203904			0.006243	0.0075552	**0.01**	**0.01**

Table 32: Formulation of pharmaceuticals and medical devices

		Emissions to water				Emissions to air					
	EU tpa	Lower release factor to waste water(%)	Upper release factor to waste water(%)	Lower release to surface water (tonnes/year)	Upper release to surface water (tonnes/year)	Lower release factor to air (%)	Upper release factor to air (%)	Lower total release to air (tonnes/year)	Upper total release to air (tonnes/year)	Lower total emissions (tonnes/year)	Upper total emissions (tonnes/year)
D4	0	0.009%	0.058%	0	0	0.020%	0.020%	0	0	**0**	**0**
D5	250			0.002655	0.016992			0.055175	0.08312	**0.06**	**0.10**
D6	100			0.001062	0.0067968			0.02081	0.025184	**0.02**	**0.03**

B.9.3.8. Presence of impurities in silicone polymers used in cosmetics

Tonnage: 255 tpa for D4 and D5 and 127.5 tpa for D6. It is assumed that 15% of these tonnages are used in wash-off cosmetics (cf. Table 10)

Sources of releases and pathways:

With regard to cosmetics products, the same release factors and assumptions have been considered both for the use of D4, D5 and D6 and the use of silicone polymers containing residual amounts of D4, D5 and D6.

Emissions estimates:

Table 33: Impurities in silicone polymers used in cosmetics

Use	Substance	Tonnage	Lower release to surface water (tpa)	Upper release to surface water (tpa)	Lower total release to air (tpa)	Upper total release to air (tpa)	Lower total emissions (tpa)	Upper total emissions (tpa)
Presence of impurities in silicone polymers used in cosmetics	D4	255	3	5	229	239	235	242
Presence of impurities in silicone polymers used in cosmetics	D5	255	3	5	219	234	224	236
Presence of impurities in silicone polymers used in cosmetics	D6	128	1	2	107	115	109	117

B.9.3.9. Presence of impurities in silicone polymers

Tonnage: 645 tpa for D4 and D5 and 323 tpa for D6. It is assumed that 50% of these tonnages are used in mixtures, the other half in articles or cured mixtures (cf. Table 10)

Sources of releases and pathways:

No information has been received during the call for evidence. The Dossier Submitter has therefore made the following assumptions:

- Use of silicone polymers in mixture: it is assumed that 50% of the silicones will be used down the drain (the release factor for wash-off cosmetics will be applied), and 50% as oil/lubricants (the release factor for leave-on cosmetics will be applied). This gives a release factor range for wastewater between 27.1% and 47.8%, and between 52.2 and 73% for air.
- Use of silicone polymers in articles and cured mixtures: the dossier submitter has decided to use the default ERC11a (widespread use of articles with low release (indoor)) and ERC10a (widespread use of articles with low release (outdoor)). This gives a release factor range for WW between 0.05% and 3.2%, and between 0.05 and 3.3% for air.

Emissions estimates:

Table 34: Impurity in other silicone polymers

Use	Substance	Tonnage	Lower release to surface water (tpa)	Upper release to surface water (tpa)	Lower total release to air (tpa)	Upper total release to air (tpa)	Lower total emissions (tpa)	Upper total emissions (tpa)
Presence of impurities in silicone polymers	D4	645	11	21	249	289	270	300
Presence of impurities in silicone polymers	D5	645	10	19	206	266	226	276
Presence of impurities in silicone polymers	D6	322.5	5	10	92	127	101	132

B.10. Risk characterisation

Not relevant

Annex C: Impact Assessment

C.1. Risk Management Options

C.1.1. Discarded restriction options

A number of restriction options were identified and analysed prior to the Dossier Submitter selecting a preferred option. This section sets out the reasons for discarding the other restriction options which were assessed against the main criteria for proposing a restriction identified in Annex XV of REACH: effectiveness, practicality and monitorability.

Option 1: A restriction on the placing on the market of all products intended for consumer and professional use containing D4 and/or D5 and/or D6 - i.e. a 'blanket approach' restriction without derogations (except for industrial uses) or concentration limit.

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

These options are considered together.

The main rationale for restricting the placing on the market and use of all 'products' containing D4, D5 and D6 is to reduce emissions into the environment as quickly as possible. Only exemptions for industrial uses (to maintain the scope set out in the Commission request) would be included. The emission reduction (a proxy for risk) would be greater than the proposed restriction, although most of the additional uses captured by these options will have significantly less emissions than the uses specifically captured in the scope of the proposed restriction.

For option 2, this could encourage further efforts to reduce the concentration of D4, D5 and D6 in silicone polymers which are further used as substances as such, in mixtures and/or as substances in articles.

Due to the increased number of products in scope, and the lack of time to develop and transition to alternatives, this would mean increased costs for companies to comply with the restriction. The benefits may also be increased but this would be unlikely to be in proportion to the increased costs, so the proportionality of this option would be decreased relative to the preferred option.

In term of enforceability, the limit of the detection of analytical methods are typically reported to be 0.1 ppm, which is far below the proposed concentration limit for the restriction (0.1% = 1 000 ppm; 0.01% = 100 ppm), hence the detection limit might not be an issue. Nevertheless, the detection methods would not allow to distinguish the presence of D4, D5 and D6 due to the presence of the substance itself or due to the presence of a silicone polymers: having no limit or a very low limit would be more likely to inadvertently capture uses of silicone polymers, that contain low concentrations of D4, D5, and D6 as impurities (and without any function) in silicone polymers. Further reduction of D4, D5 and D6 in silicone polymers cannot, in some cases, be achieved without losing the intended functionalities of the silicone polymers or the article. A restriction on the use of silicone polymers (including articles) was also not the intention of the Commission's request.

The practicality (implementability, enforceability, manageability) of this option was considered to be lower than the proposed option by the Dossier Submitter due to the lack of transitional periods and the increased scope when considered against the uncertain increase of any benefits. Companies could not plan for their implementation of the

restriction, products would have to be removed from the shelves and enforcement would be more complicated. Monitorability of the restriction would also be less straightforward than the proposed option.

Therefore, this option was discarded as it would be less net beneficial to society than the proposed restriction.

Option 3: A restriction on the placing on the market and use of non-solid substances and mixtures intended for consumer and professional use containing D4 and/or D5 and/or D6 - i.e. articles, and post cured mixtures would be out of scope.

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).

Option 4: A restriction on the placing on the market and use of specifically identified mixtures for consumer and professional use containing D4 and/or D5 and/or D6 (≥ 0.1 % w/w) (with derogations)

Such a restriction would be a 'use by use' restriction compared to the 'blanket' approach proposal.

The Dossier Submitter has undertaken an extensive investigation into possible uses of D4, D5 and D6, including the uses of silicone polymers containing residues of D4, D5 and D6. Therefore, on the basis of the uses assessed, the Dossier Submitter considers that the scope of the proposed restriction is justified, despite its inclusive scope. However, if the proposal were to capture uses in addition to those that were assessed, then the Dossier Submitter estimates that the impact would be limited.

This wide scope is also important to prevent the new uses of D4, D5 and D6 in consumer and professional applications as well as uses of silicone polymers containing high residues of D4, D5 and D6.

Option 5: Labelling of all mixtures and articles for consumer and professional use containing D4 and/or D5 and/or D6 (≥ 0.1 % w/w) with a phrase such as 'contains PBT/vPvB substance > 0.1%', with a requirement for user instructions to minimise releases to wastewater e.g. dispose to municipal waste)

The main rationale for this restriction option is to rely on the informed choices of consumers and professionals to change their purchasing habits and avoid buying products containing PBT/vPvB substances. However, there is currently no evidence that labelling would be an effective RMM for the uses considered in this dossier. This is because it is not clear if consumers and professionals would change their habits based on such a label and also that, given the volatile properties of D4, D5 and D6, specifying specific conditions of use that could effectively reduce the potential for releases is not possible.

The direct costs to duty holders would be minimal if a transition period was given to align labelling changes with normal re-labelling cycles. However, if a significant number of consumers changed their buying habits then the profits of the relevant companies would be reduced or they would have to change their formulations. This could lead to more significant costs for industry if companies do not have time to transition to alternatives, potentially greater than the costs estimated for the proposed restriction. Overall, however, the benefits (in terms of reduced releases to the environment) are likely to be lower than the proposed restriction, and the costs could be equivalent or greater, so the proportionality of this option would be decreased relative to the preferred option.

The practicality (implementability, enforceability, manageability) of this option was

considered similar to the proposed option as with the transitional period, companies could plan for their implementation of the restriction, and organise the products removal from the shelves.

Monitorability of the restriction is expected to be similar to the proposed restriction.

This option was overall discarded as it would be less net beneficial to society than the proposed restriction.

C.1.2. Other Union-wide risk management options than restriction

As a first step, the possibility to address the risks posed by the use of D4, D5 and D6 under other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined. Whilst it was recognised that some existing or proposed EU legislation or other measures could have an impact on the risk management of certain sectors, these were assessed as inappropriate to address *all* of the sectors and products contributing to risk.

Possible Union-wide risk management measures other than a restriction are outlined in Table 35 below. However, it is concluded that none of these are realistic, effective and balanced means of solving the problem. As such, none of these other risk management options have been analysed further.

Table 35: Possible other Union-wide options discarded (other than restriction)

Option	Reasons for discarding this option
Non-legislative measures	
Voluntary industry agreement to restrict the use of D4, D5 and D6 in professional and consumer products.	D4, D5 and D6 have been identified as SVHC substances, and this might imply a voluntary move away from these substances by the formulators. In general, SVHC listing seems to make 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, as well as some stakeholders from other sectors contacted during the ECHA market survey, have indicated 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 yet. Consumers, consumers association and NGOs awareness-raising activities can also lead to a 'voluntary' move away from substances listed as SVHCs, as they can often be included in 'negative lists', that recommend to retailers and consumers, for example via phone apps, 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 professional and consumer 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. On the other hand, some of the stakeholders are challenging the identification of D4, D5, and D6 as PBT/vPvB. In that context, and similarly to what was concluded in the UK Annex XV restriction report, the Dossier Submitter considers that the results of potential voluntary measures are uncertain both on the efficiency and timing aspects, and conditioned to the acknowledgement of the PBT/vPvB status by industry.

Option	Reasons for discarding this option
Voluntary agreement for industry to label mixtures containing D4, D5 and D6.	Possible labelling options include: - 'Contains PBT/vPvB substance > 0. 1%'. The agreement to use this label would be a voluntary measure similar to the rejected restriction option. - 'Dispose appropriately' (exact measures to be determined by industry). The agreement to use this label would be a voluntary measure similar to that proposed for some industry sectors in the proposal. This RMO will also share many of the disadvantages of the voluntary agreement to restrict substances such as enforcement and coverage (as above). The option to label would also share the issues with the relevant rejected restriction. In the case of labelling 'dispose appropriately' conditions of use as a risk management measure, a label would not be relevant for uses where the majority of releases would be to the atmosphere via the evaporation of the product. As such, it would not result in effective risk reduction.
Information campaign to consumers to avoid buying 'products' containing D4, D5 and D6.	This RMO does not seem to be sufficiently effective. For the consumer, it will be difficult to identify the mixtures containing D4, D5 and D6.
Legislation other than REACH	
Control of emissions under the IED and/or Water Framework Directive and waste legislation	Mixtures containing D4, D5 and D6 have wide dispersive use by consumers and professional users. Exposure to the environment via emissions occurs mainly during the use phase, not the production phase. Therefore, measures aimed at point sources, including WWTWs, would not effectively address the source of exposure and, as safe thresholds for PBT/vPvB substances in the environment cannot be derived (REACH Annex I) the derivation and implementation of EQS values for the aquatic environment would not be an effective risk management measure. These measures would also not address releases of the substance to the environment via the atmosphere.
Taxation on D4, D5 and D6 content	Taxation in general is not a harmonised measure across the EU. Therefore, whilst it might be effective in encouraging substitution, it is not likely that all Member States would introduce relevant taxes and thereby, not all EU citizens will be protected. This is likely to lead to a non-harmonised situation where different Member States apply different tax rates (if at all).
Sector-specific legislation	Uses within the scope of the proposal are varied and widely dispersed. It would be resource intensive to address the risks via a large number of sector specific legislation, which also does not exist for all relevant sectors. In addition, surveys have revealed that REACH restrictions are a convenient way to communicate all-encompassing regulatory measures related to chemicals. However, efforts have been made to derogate mixtures in the restriction proposal which are adequately covered by existing sector specific EU legislations (e.g., medicines, medical devices, etc.) to avoid unnecessary overlap of regulatory actions and improve clarify for stakeholders. *Medicines Regulations: Directive 2001/82/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004* The Union legislation for veterinary and human medicines are set out in Directive 2001/82/EC and Directive 2001/83/EC respectively. They provide the legal framework for the authorisation, manufacture and distribution of medicines in the EU. The centralised authorisation procedure for human and veterinary medicines is based on Regulation (EC) No 726/2004, which

Option	Reasons for discarding this option
	established the European Medicines Agency (EMA). All medicines must be authorised before they can be marketed and made available to patients. In the EU, there are two main routes for authorising medicines: a centralised route and a national route. Under the centralised authorisation procedure, pharmaceutical companies submit a single marketing-authorisation application to EMA. This allows the marketing-authorisation holder to market the medicine and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorisation. EMA's Committee for Medicinal products for Human Use (CHMP) or Committee for Medicinal products for Veterinary Use (CVMP) carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not. For veterinary medicinal products, an ERA (Environmental Risk Assessment) is required and mandatory for all types of marketing authorisation applications, including for new medicinal products, generics, variations and extensions. The ERA is taken into account in the risk-benefit analysis in view of the authorisation. With regard to human health medicinal products, since October 2005, an ERA is required for new products to be placed on the market, but the ERA results in this specific case cannot lead to denying a market authorisation, even if some Risk Mitigation Measures (RMM) can be required when considered necessary. In its current state, the ERA could therefore not be used to deal with the concerns from D4, D5 and D6 and ensure that D4, D5 and D6 are not present in the medicines in concentration above 0.1%.
	The Detergents Regulation (EC) No. 648/2004 This regulation covers the manufacturing, placing and making available on the market and use of detergents. The Regulation harmonises the rules for the placing on the market of detergents and of surfactants for detergents; the biodegradability of surfactants in detergents; restrictions or bans on surfactants on the grounds of limited biodegradability; the additional labelling of detergents, including fragrance allergens; the information that manufacturers must hold at the disposal of Member State competent authorities and medical personnel; limitations on the content of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents. However, it does not cover the presence of PBT/vPvB substances and therefore could not currently regulate the risks from the use of D4, D5 and D6 in these products.
	Construction Products Regulation: Under this Regulation the information on the content of hazardous substances in the construction products should be included in the declaration of performance to reach all potential users. As D4, D5 and D6 are not classified as hazardous (except for D4), but rather as PBT/vPvB, it is not evident if this legislation would apply, or if it would be an effective tool for reducing releases to the environment.
	Medical Device Directives: Directive 90/385/EEC regarding active implantable medical devices (AIMD); Directive 93/42/EEC regarding medical devices (MDD); Directive 98/79/EC regarding in vitro diagnostic medical devices (IVDD) Three Directives deal directly with medical devices, either as the medical devices themselves, or as implantable medical devices or as *in vitro* diagnostics. According to these Directives, medical devices must be designed and manufactured taking into account the toxicity of materials used and minimising the risk for substances to leak out of the device. Environmental issues are not dealt with by these Directives.

Option	Reasons for discarding this option
	These directives will soon be repealed and replaced by EU Regulations (EU) 2017/745 on Medical Devices (aka MDR), and (EU) 2017/746 on *in vitro* diagnostic medical devices (aka IVDR) that will come into force respectively on 26 May 2020, and 26 May 2022. The MDR and IVDR bring significant changes in term of Vigilance, Post-market Surveillance and communication on safe use (for humans and the environment).
	Cosmetics Regulation (EC) 1223/2009 The Cosmetics Regulation only applies to the human health hazards of cosmetics and not the environmental issues.
General Product Safety Directive 2001/95/EC	This Directive addresses risks to consumers (termed health and safety of consumers) related to specific products and not risks related to a cumulated exposure from different products, or to risks posed to the environment. In certain circumstances, it can be used to restrict products but this needs annual renewal (similar to the old decision on phthalates in toys that was eventually converted into a REACH restriction).
Persistent Organic Pollutants Regulation (POP) 850/2004	In general, the identification of a substance as a POP is complex and might not be agreed easily nor reach promptly a consensus. The process is underway for D4, but this substance is of a less priority with regard to other POPs (e.g. halogenated pesticides, dioxins etc.), and intense discussions and negotiations would be required with non-EU countries especially with regard to the socio-economic aspects. D5 and D6 cannot be listed as POP as they are not identified as 'Toxic'.
Other REACH processes	
Update of registration dossiers	Since D4, D5 and D6 have been identified by ECHA's Member State Committee as SVHC substances with PBT/vPvB properties, registrants should therefore in theory reflect the PBT/vPvB status of D4, D5, and D6 in their dossiers and recommend risk management measures to minimise emissions, potentially they could chose as well to not support any more certain uses (i.e. uses advised against). The Dossier Submitted recognises that this risk management option can potentially reduce environmental emissions, nevertheless this does not give any guarantees that the downstream users would stop using D4, D5 and D6 in their formulations in case the uses are not supported anymore by the registrants (e.g. they could prepare and submit to ECHA a downstream user report according to REACH article 38). In addition, registrants are only legally obliged to consider the tonnage they supply individually, not collectively.
REACH Authorisation process	D4, D5 and D6 have been identified by ECHA's Member State Committee as SVHC substances and could therefore be further prioritised for inclusion on Annex XIV to REACH (list of substances subject to Authorisation). The Dossier Submitter notes that a targeted restriction on the use of D4, D5 and D6 was proposed and adopted to Annex XVII of REACH in preference to the Authorisation process. As such, further risk management is appropriate under the restriction regime, rather than Authorisation.

C.2. Alternatives

The evidence on alternatives to D4, D5 and D6 available for uses other than cosmetics are presented in the main body of the report, sections 2.6 and 2.7. This section presents information only on alternatives to D4, D5 and D6 in cosmetics.

C.2.1. Evidence available

Annex C in the UK Annex XV restriction report proposing a restriction on wash-off personal care products presented a detailed assessment on alternatives to D4 and D5, based on information provided by Cosmetics Europe (AMEC, 2013h). The data used was based on stakeholder consultation, which identified approximately thirty substances, and included data on alternatives that could be used to substitute D4 and D5 in leave-on products as well as in wash-off products.

The UK Dossier Submitter concluded that there were no general drop-in one-for-one replacements for D4 and D5 in wash-off Personal Care Products, but that several potential alternatives had been identified. Many appeared to be more costly than D4 or D5, and to be less available, but not all. In terms of the risks associated with them, the analysis concentrated on environmental risks, as it was considered that the EU Cosmetics legislation constrains the use of substances in cosmetics with particular human health-related hazardous properties. The identified alternatives varied in regards to their relative environmental risks. For some there were also concerns about PBT properties, but there were others that appeared less risky than D4 and D5.

As part of the Call for Evidence for the preparation of this Dossier, Cosmetics Europe provided updated information on alternatives (AMEC, 2017). This was based on a survey of a large number of their members, and while they were asked about both D4 and D5, the information provided was about D5, as D4 is currently hardly used in cosmetics. The survey did not enquire about D6, as it was undertaken before D6 was added to the scope of this Dossier and thus not part of that call for evidence. However, the Dossier Submitter assumes that many of the alternatives identified for D5 are likely to be potential alternatives for D6 as well.

Some 25 alternatives to D5 were identified by over 30 respondents to the survey, who provided information on the alternatives' technical performance, environmental and human health implications, availability and costs. Most of the alternatives identified related to make-up, lipsticks and skin care products, and very little information was provided relating to alternatives to deodorants/antiperspirants and sun protection/tanning products. Very few substances had been identified as definitely suitable, but quite a few more were identified as 'maybe suitable', with research still pending. Additionally, several potential alternatives had been analysed and rejected as unsuitable.

A confidential annex is provided containing a detailed assessment of each of the identified alternatives, including their technical performance as compared to D5, their environmental, health and safety implications, their availability and any cost implications. The general conclusions confirm those in (AMEC, 2013h). No drop-in, one-to one alternatives have been identified. It's expected even suitable alternatives would likely require adaptations to the formula. The picture regarding environmental, health and safety risks is varied. For several of the alternatives no concerns were identified, while for others potential environmental and/or health concerns were identified (the latter not to users of cosmetics but to workers, due to the substances having lower flash points than D5, and

thus being highly flammable). Availability of the identified alternatives did not seem to be an issue, but in general, the price tended to be higher. No alternatives were identified with unit costs below that of D5. Some had similar prices, but the majority were more expensive, some substantially so. However, the report authors state that the differences in raw material prices are not likely to be a significant cost driver, compared to the cost of reformulation.

The issue of alternatives to D4, D5 and D6 seems to be on that is live in the trade press. As an example, a recent article in the periodical SPC soap perfumery & cosmetics summarised a raft of potential alternatives. These include silicones, silicone hybrids, and also several plant-based alternatives. However, the article presents no information beyond the identification of the substance and some key characteristics, so it has not been possible to compare the alternatives identified there with those in (AMEC, 2017) with regards to price, availability and technical feasibility.

Finally, evidence about the technical and economic feasibility of alternatives in a particular product group, wash-off products containing D6, can be read across from the experience of the UK Annex XV restriction report. There has been substantial activity in that area, with companies looking into replacing other silicones from wash-off products (Woodruff, 2018).

C.2.2. Conclusions

Based on the information available, no one-for-one, drop-in alternatives to D4, D5 and D6 appear to be available. Replacing D4, D5 and D6 would require the products to be reformulated. A range of substances that could function as potential alternatives in reformulations have been identified and have either already been deemed suitable (a minority) or are being subjected to further testing (the majority). More alternatives have already been identified for some product groups (e.g. make-up, lipsticks, skin-care products), than for others (e.g. deodorants/antiperspirants, sun protection/tanning products).

The alternatives have different profiles with regards to environmental risks, with some having potentially similar environmental concerns as D4, D5 and D6. As for health and safety risks, some appear to pose safety concerns to workers due to being highly flammable. However, many of the alternatives appear to have no health and safety concerns and are of less environmental concern than D4, D5 and D6.

In general, availability of the identified alternatives did not appear to be an issue. Most of them, however, seem to be more expensive than D4, D5 and D6. Some were reported to have similar prices, but more were reported to be more expensive. It should be noted, however, that for those alternatives that end up being used, an increased volume produced may allow for economies of scale and thus lower costs. Any costs associated with increased raw material prices also appear to be considered minor in comparison to reformulation costs.

A wide range of price differentials were reported, and without a better understanding of which alternatives will actually be used (and different ones would be expected to be used for different products), the Dossier Submitter is not able to reliably estimate the likely average price differential for the alternatives. A conservative assumption that the alternatives will be twice as expensive as D4, D5 and D6 has been used as a central estimate in the analysis, and sensitivity analysis regarding this assumption is presented in Annex D.

The evidence available suggests that substitution of D4, D5 and D6 with alternatives is both technically and economically feasible for many cosmetics, although it is possible that it would not be viable for some specific products. Efforts seem to be underway already. This conclusion, as well as the assumptions made in this Dossier regarding price differentials, should be subject to revision during the opinion-making phase of the proposal, if more detailed information becomes available as cosmetics producers and producers of alternatives progress further with their research.

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

The information below is extracted from the ECHA Guidance R.12 on Use description (ECHA, 2015).

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. However, no detail is given on the difference between the two and clarification is needed to support companies in this decision.

The terminology 'industrial' and 'professional' is used in two different contexts:

- To differentiate between life cycle stages
- To define the level of occupational health and safety management systems applied in companies[4]

It is recommended to understand the concept 'professional' as a characteristic to distinguish between use: i) at industrial sites and ii) uses outside industrial sites (but not consumers or general public). This will lead to different life cycle stages in terms of use description.

The following table provides a non-exhaustive list of characteristics associated with industrial sites and professional activities outside industrial sites, and can be used in a weight of evidence approach to determine whether a use is considered: as 'use at industrial site' or as a 'widespread use by professional workers'.

Table 36: Characteristics helping in differentiating between industrial sites and professional activities outside industrial sites and relation with the life cycle stages

	Use at industrial site	**Widespread use by professional workers**
REACH Legal text	Industrial use (activity)	Professional use (activity)
Number of places where substance is used (at EU level)	Low to high	High
Number of persons potentially in contact (at EU level)	Low to high	High
Type of enterprises, type of business, examples	Production sites Large construction sites Large maintenance/repair and service sites	Services (mobile or stationary micro sites), administration, education, small building and construction works
Number of users/enterprises proportional to size of municipality by inhabitants	No	Yes
Activity requiring a permit according to the Industrial Emissions Directive (IED)	Often yes	Usually not
Availability of capital intensive equipment for automation and engineering controls	Often yes	Usually not, but can be
Amount of processed chemicals per single enterprise/actor	Low to high	Low

[4] This is called industrial/professional 'settings' in ECETOC TRA

	Use at industrial site	**Widespread use by professional workers**
Connection to public sewer	Often yes, sometimes not	Yes
Tonnage reference for local environmental standard assessment	Tonnage for one representative industrial site per use (industrial point source)	Tonnage per use proportional to 10,000 inhabitants (municipal point source)

Examples:

The following list includes typical examples for business involving chemicals which would be considered as 'widespread use by professional workers':

- Building and construction business with broad variety of activities (mostly micro companies)
- Maintenance services for office/household equipment
- Indoor cleaning services for all kind of buildings
- Facade cleaning services
- Car wash and other car care services
- Hairdressing and other beauty services
- Health care services

Typical examples for business involving chemicals which would be considered as 'uses at industrial site' are:

- Production of cars and other vehicles
- Production of paper
- Textile dyeing and finishing
- Production of semiconductors

There are also cases which are considered 'borderline' i.e. it is more difficult to conclude on their Life cycle stage. Some examples have been listed below including some possible approaches:

- **Industrial cleaning services carried out by small or large, well-trained or less trained service providers**. This can include tank-cleaning, boiler cleaning, cleaning of machinery, etc. at industrial sites. This case should be regarded as a 'use at industrial site' regardless if the actual work is carried out by employees of the site or by external service providers. The resulting releases will be from the site where the cleaning operation takes place;
- **Workshops for car repair and finishing**. The sites may be small but could be also large. The predominant characteristic of the business is the huge number of small enterprises and the correlation to the municipal infrastructure (population density) so they should be reported as 'widespread use by professional workers'. In some cases, the workers' protection standards under which these businesses operate are similar to those of the car industry. This can be reflected when performing the human health exposure assessment by e.g. selecting the conditions of uses corresponding to 'industrial' settings;
- **Consumer textile cleaning with solvents and other heavy duty or specialised chemicals in micro-workshops**. The predominant characteristic of the business are the small size of the enterprises and the correlation to the municipal infrastructure so they should be considered as 'widespread use by

professional workers', even though a high level of engineering control may be applied;

- **Large sites for water based washing/cleaning of textiles used in industry (cleaning wipes and work wear)**. These should be considered as 'uses at industrial sites'. The number does not correspond to the size of the municipality as few large sites normally serve a bigger region. Extensive and site-specific treatment infrastructure for wastewater and waste are normally present;
- **Large sites for maintenance and repair related to public transport infrastructure (trains, airports/harbours)**. These cases should be considered as 'uses at industrial sites'. The structure of the service for trains, ships and planes does not correlate with the municipal infrastructure. Sites for maintenance of buses and trams are more closely related to the municipal infrastructure. Nevertheless usually their size is sufficiently big to treat them as an industrial site.

With regards to the use of the terms 'industrial' and 'professional' in the context of human health exposure assessment, they flag the occupational conditions under which the workers use a substance or product. In general, it is assumed that 'industrial' conditions are associated with training of workers, proper work instructions and supervision. The use of exposure assessment models can result in different exposure estimates depending on the type of conditions selected (industrial or professional) e.g industrial conditions may assume a higher level of effectiveness for RMM.

Actually, a use can take place 'at industrial site', but for workers exposure assessment a lower effectiveness of RMM may be assumed ('professional setting'), as for example when workers from a contractor cleaning machinery between shifts in an industrial site. There may also be uses where the opposite is the case, well trained, instructed and equipped mobile services with chemicals (e.g. biocides).

The table below illustrates the two aspects and how they relate to each other in different examples.

Table 37: Illustration of life cycle versus operational health and safety management systems

Life cycle stage	Occupational health and safety management system	Example
Use at industrial site	Advanced ('industrial conditions' or similar)	Use of substance as intermediate in manufacturing process
	Basic ('professional conditions')	Contractors working in an industrial site on cleaning tasks
Widespread use by professional workers	Advanced ('industrial conditions' or similar)	Application of biocidal products by specialised companies
	Basic ('professional conditions')	Self-employed painter painting in private households

Annex D: Assumptions, uncertainties and sensitivities

D.1. Exposure assessment: sensitivity analysis

This section explores the sensitivity of key input parameters to the calculation of the releases estimates. The sensitivity has been explored by the Dossier Submitter with a simple quantitative manner.

D.1.1. Effect of the WWTP connection rate

As explained in section B.4.2.5, the Dossier Submitter has used the latest information available regarding the connection rate to waste water treatment plants (WWTP) in Europe, i.e. 90% connection rate instead of 80%.

A 10% improvement in the connection rate is leading to ca. 45 % reduction in surface water emissions, and less than 1 % reduction in overall emission (water+air) as shown in Table 38.

Table 38: Sensitivity analysis - effect of the WWTP connection rate

		80 % WWTP connection rate		90 % WWTP connection rate	
Use	Tonnage	*Low scenario* *(Emissions to water only) [tpa]*	*High scenario* *(Emissions to all compartments) [tpa]*	Low scenario (Emissions to water only) [tpa]	High scenario (Emissions to all compartments) [tpa]
Leave-on cosmetics	17000	*13 - 91*	*16440 - 16647*	7 - 50	16399 - 16641
Pharmaceutical products and medical devices	350	*11 - 21*	*283 - 310*	6 - 11	273 - 305
Wash-off cosmetics	200	*22 - 38*	*72 - 124*	12 - 20	55 - 114
Detergents, household care and vehicle maintenance products	90	*7 - 12*	*55 - 69*	3 - 6	50 - 66
Dry cleaning	50	*0 - 0*	*46 - 46*	0 - 0	46 - 46
PU Foam	6	*0 - 0*	*6 - 6*	0 - 0	6 - 6
Cleaning of art and antiques	0.3	*0 - 0*	*0 - 0*	0 - 0	0 - 0
Formulations	-	*0 - 2*	*5 - 9*	0 - 1	5 - 8
Presence of impurities in silicone polymers	1612.5	*47 - 90*	*637 - 729*	26 - 50	597 - 707
Presence of impurities in silicone polymers used in cosmetics	637.5	*11 - 22*	*577 - 600*	6 - 12	567 - 595
All uses (including silicone polymers)	**19946.3**	***114 - 279***	***18125 - 18544***	**63 - 153**	**18000 - 18491**

In conclusion, the WWTP connection rate is a sensitive parameter for the calculation of the releases to surface water. On the other hand, the effect on the estimated overall releases (air+water) is negligeable.

D.1.2. Effect of the WWTP efficiency

As explained in section B.9.2.5, the Dossier Submitter has used the latest version of SimpleTreat (RIVM, 2015) in order to assess the fate of D4, D5 and D6 in waste water treatment plants, and estimate the emissions from waste water treatment plants (WWTP)

and the exposure in surface water. The version 4.0 of SimpleTreat is a revision of SimpleTreat 3.1 which supported the chemical act 25 years ago in the Netherlands and later in the European Union (EU). According to RIVM, 'the revision was necessary to account for recent scientific insights with respect to behaviour of the chemical in domestic sewage and activated sludge'.

As shown in Table 39, the WWTP efficiency rate has improved between the two versions by 1 % for D4, 3% for D5 and 5% for D6.

Table 39: Sensitivity analysis - comparison between SimpleTreat v3.1 and v4.0

	SimpleTreat v3.1			SimpleTreat v4.0		
	D4	*D5*	*D6*	D4	D5	D6
Efficiency of the WWTP (i.e. removal of substance)	*96%*	*95%*	*93%*	97%	98%	98%
Release directed to air at the WWTP	*48%*	*22%*	*8%*	49%	23%	9%
Release directed to sludge at the WWTP	*48%*	*73%*	*85%*	48%	75%	89%

Source: calculation made with SimpleTreat v.3.1 and SimpleTreat v.4.0

The impact on the emissions is depicted in Table 40. An improvement of a few percentage points in the efficiency of the WWTP is leading to ca. 20 % reduction in surface water emissions, and less than 0.1 % reduction in overall emission (water+air).

Table 40: Sensitivity analysis- effect of the WWTP efficiency

		SimpleTreat v3.1		SimpleTreat v4.0	
Use	Tonnage	*Low scenario* *(Emissions to water only) [tpa]*	*High scenario* *(Emissions to all compartments) [tpa]*	Low scenario (Emissions to water only) [tpa]	High scenario (Emissions to all compartments) [tpa]
Leave-on cosmetics	17000	*9 - 63*	*16407 - 16642*	7 - 50	16399 - 16641
Pharmaceutical products and medical devices	350	*8 - 15*	*276 - 306*	6 - 11	273 - 305
Wash-off cosmetics	200	*16 - 28*	*61 - 118*	12 - 20	55 - 114
Detergents, household care and vehicle maintenance products	90	*4 - 8*	*51 - 67*	3 - 6	50 - 66
Dry cleaning	50	*0 - 0*	*46 - 46*	0 - 0	46 - 46
PU Foam	6	*0 - 0*	*6 - 6*	0 - 0	6 - 6
Cleaning of art and antiques	0.3	*0 - 0*	*0 - 0*	0 - 0	0 - 0
Formulations	-	*0 - 1*	*5 - 8*	0 - 1	5 - 8
Presence of impurities in silicone polymers	1612.5	*31 - 59*	*602 - 710*	26 - 50	597 - 707
Presence of impurities in silicone polymers used in cosmetics	637.5	*7 - 14*	*568 - 595*	6 - 12	567 - 595
All uses (including silicone polymers)	**19946.3**	***79 - 191***	***18025 - 18502***	**63 - 153**	**18000 - 18491**

In conclusion, the WWTP efficiency is a sensitive parameter for the calculation of the releases to surface water. On the other hand, the effect on the estimated overall releases (air+water) is negligeable.

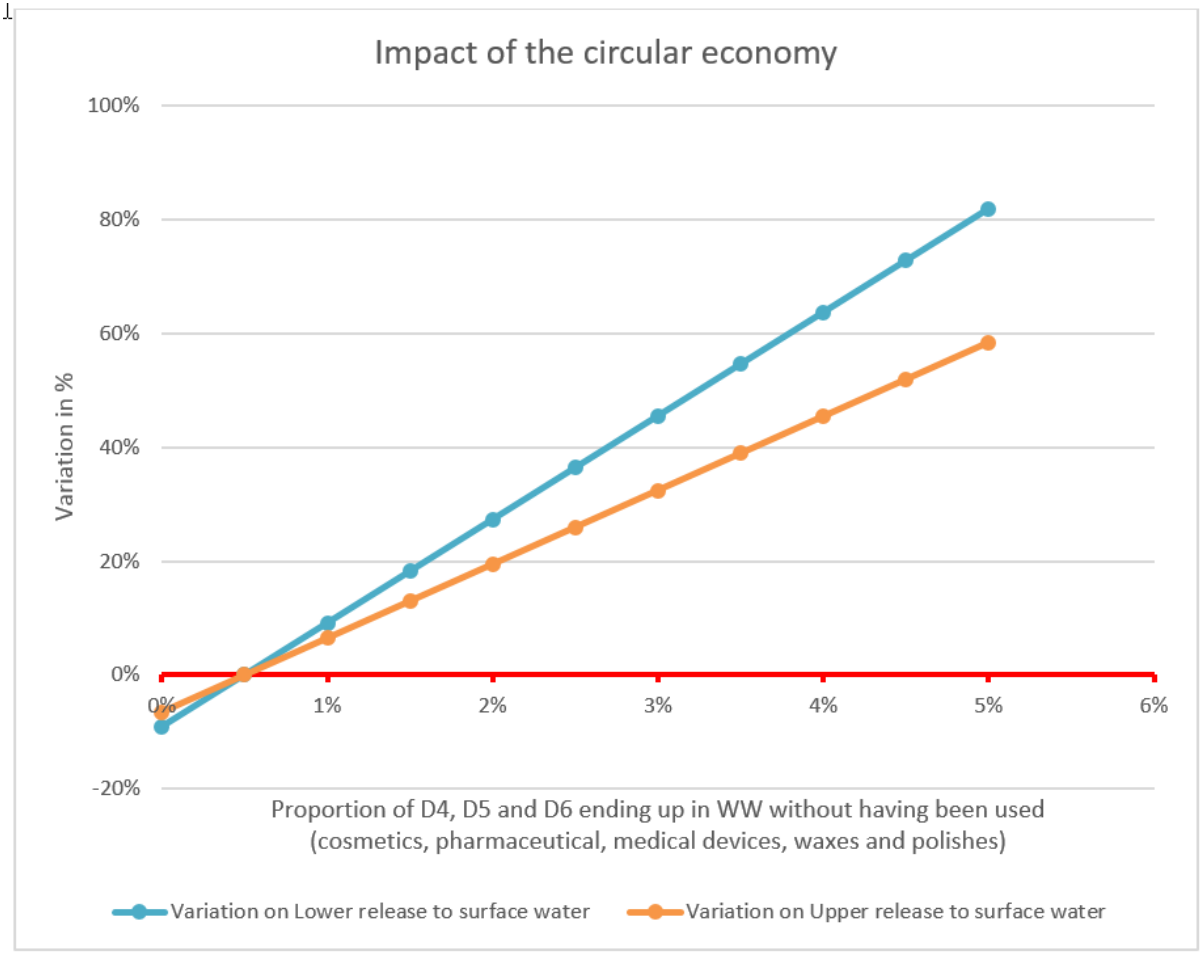
D.1.3. Effect of the proportion of discarded packaging containing remaining D4, D5 and D6

As explained in section B.9.2.2, the Dossier Submitter has assumed that 5% of the use's tonnage would be discarded by the consumers, and that 10% of this discarded tonnage would be cleaned down the drain before disposal by the consumer, or recycled (which involves a washing pre-step of the packaging). This leads to the assumption that for certain type of uses (e.g. cosmetics, pharmaceuticals and medical devices, waxes and polishes) 0.5% of the tonnage of D4, D5 and D6 intended to be used would go down-the drain before having been used.

European society in general is more and more moving towards initiative to improve the circular economy. Therefore the impact of the recycling has been looked at in a simple sensitivity analysis.

The results are visible in the Figure 8 below.

Figure 8: Sensitivity analysis – effect of the proportion going down the drain without being used



In conclusion, 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.

D.2. Socio-economic analysis: sensitivity analysis

This section explores the sensitivity of key outcomes of the socio-economic analysis (such as the average annualised costs of a restriction and its cost-effectiveness) to potential variations in key input variables.

It should be noted that as this analysis concerns PBT/vPvB substances and it has not been possible to quantify the environmental impact, the Dossier Submitter was not able to quantify (or monetise) benefits of the restriction proposal. This sensitivity analysis thus does not attempt to identify 'switching values'[5] for the different assumptions it analyses.

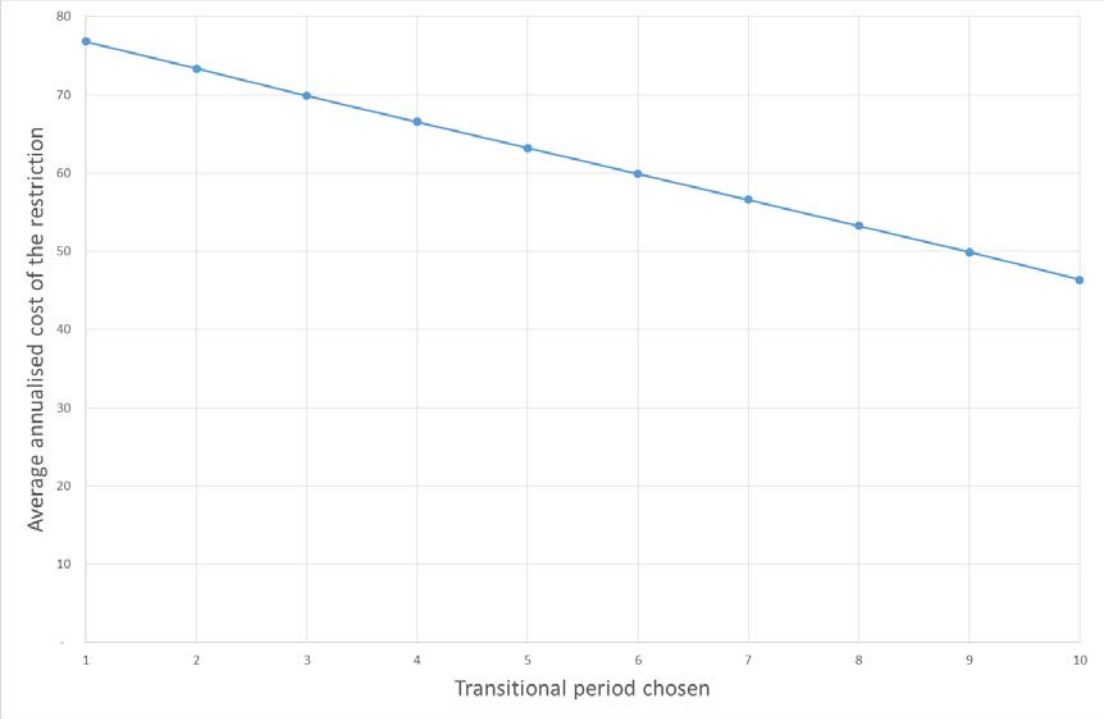
D.2.1. Effect of different transitional periods

The socio-economic analysis assumes, in line with the UK Annex XV restriction report, that a degree of coordination is possible between the reformulations required to remove D4, D5 with those that would already have happened in the baseline. The longer the transitional period, the larger the share of the reformulations induced by the restriction that could be coordinated with reformulations that would have happened anyway. A longer transitional period would thus lead to lower costs.

For this analysis, the Dossier Submitter has considered all cosmetics, and taken the central/best estimate for all other assumptions. Figure 9 shows the sensitivity of the average annualised cost of the restriction to the transitional period chosen. The relationship is not quite linear, but close.

[5] A 'switching value' is the value an assumption would have to take for a proposed intervention option to switch from a being recommended to not.

Figure 9: Sensitivity of the average annualised cost of the restriction to the transitional period chosen



The average annualised cost is of €77 million if a transitional period of only 1 year is selected. For every year added to the transitional period, the average annualised cost of the restriction decreases by an average of €3.4 million, which is approximately 4.5% of the cost with a 1-year transitional period. Moving from a 1-year transitional period to a 10-year one lowers the costs of the restriction by 40% (to €46 million).

D.2.2. Effect of assuming voluntary substitution of D4, D5 and D6 in cosmetics

As explained in Section 4 of the Annex XV report, there are reasons to believe that there could be some voluntary move away from using D4, D5 and D6 in cosmetics even in the absence of a restriction. 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.

To understand how assuming a baseline with voluntary substitution could affect the costs of the restriction and its cost-effectiveness, the Dossier Submitter has modelled a relatively maximalist best-case scenario to provide comparison.

The comparison is made with the best estimates scenario for a 5 year transitional period calculated in the Annex XV report, which used best estimates for the costs and the midpoint of the ranges for estimates of releases (heretofore called the 'Best-5' scenario). These assumptions are maintained in the scenario calculated for this section and the only change is in the baseline (which, in the Best-5 scenario, was assumed to be 'business as usual').

In the new scenario ('Full Voluntary Substitution' scenario):

- All products containing D4, D5 and D6 would be voluntarily withdrawn from the market;
- This withdrawal would take place throughout 10 years, starting from the date of Entry into Force of the restriction (assumed to be 2022);
- There is a 5 year transitional period;
- Best estimates for the costs and the midpoint of the ranges for estimates of releases are used; and
- The proportions of products that would be reformulated and withdrawn from the market are the same as assumed in Section 5.4.1.1.D of the Annex XV report.

The costs of the restriction under the Full Voluntary Substitution scenario (€18 million average annualised costs and €199 million 20-year NPV) are substantially lower than under the Best-5 scenario (€63 million average annualised costs and €703 million 20-year NPV). This is because under the Full Voluntary Substitution scenario, all costs of reformulation and additional costs of more expensive raw material would have been incurred anyway; the effect of the restriction is only to accelerate the process and have it be completed by 2027, rather than by 2032, as would have occurred under the baseline.

However, it is important to note that assuming voluntary withdrawal of D4, D5 and D6 in cosmetics also impacts how much of the releases prevention can be attributed to the restriction. This affects the cost-effectiveness estimates.

Under the baseline in the Full Voluntary Withdrawal scenario, all releases of D4, D5 and D6 would be stopped voluntarily, eventually. The impact of the restriction would be on the timing: releases would stop completely by 2027, rather than by 2032, as would have occurred under the baseline. This leads to fewer total releases over the 20-year study period:

- Total releases to water over the 20-year study period are estimated at 478 tonnes under the baseline, and 410 tonnes if a restriction is implemented.
- Total releases to water + air over the 20-year study period are estimated at 175 000 tonnes under the baseline, and 150 000 tonnes if a restriction is implemented.

It is important to highlight that these releases have different time profiles under the baseline and in the case a restriction is implemented. However, the issue of explicitly discounting physical quantities (as opposed to doing so implicitly, as when monetised values based on physical quantities are discounted) is one that is not settled[6]. For the sake of transparency and consistency with previous restriction proposals, the Dossier Submitter has opted to present the undiscounted releases here (in other sections and in the Annex XV report the analysis is done on an annualised basis, which obviates the issue).

Because of the consideration of releases over the entire 20-year study period, measures of cost-effectiveness are not directly comparable to those in other sections of this appendix

[6] There are arguments for and against discounting physical effects that occur at different moments in time. On one hand, it can be argued that for cost-effectiveness to be a meaningful measure of regulatory impact it should not be affected by the time when the impact occurs as otherwise regulatory rollout should always be postponed (the so-called Keeler-Cretin paradox). On the other hand, these impacts are meant to take place at each moment in time, thus discounting physical quantities may be misleadingly suggest smaller aggregate impacts than expected.

and in the Annex XV report, and will not be reported here in absolute values. The more relevant result is how the 20-year cost per kg of releases compares between the Full Voluntary Withdrawal scenario and the Best-5 scenario (with cost-effectiveness calculated using the same methodology). Assuming Full Voluntary Withdrawal of D4, D5 and D6 lowers the 20-year cost per kg of releases to water by 11%, and that of releases to air+water by 5%[7].

The Dossier Submitter therefore concludes that introducing an element of voluntary withdrawal of D4, D5 and D6-containing products into the assessment does not have a substantive effect on the overall cost-effectiveness of the restriction proposed, although it does reduce the costs that could be attributed to it. As mentioned earlier, Full Voluntary Withdrawal is considered to be a maximalist scenario, and the Dossier Submitter expects that the real situation would be somewhere between that scenario and Best-5.

D.2.3. Effect of different prices of alternative raw materials

The main estimates presented in the Annex XV report are based on two key assumptions regarding the prices of alternative raw material:

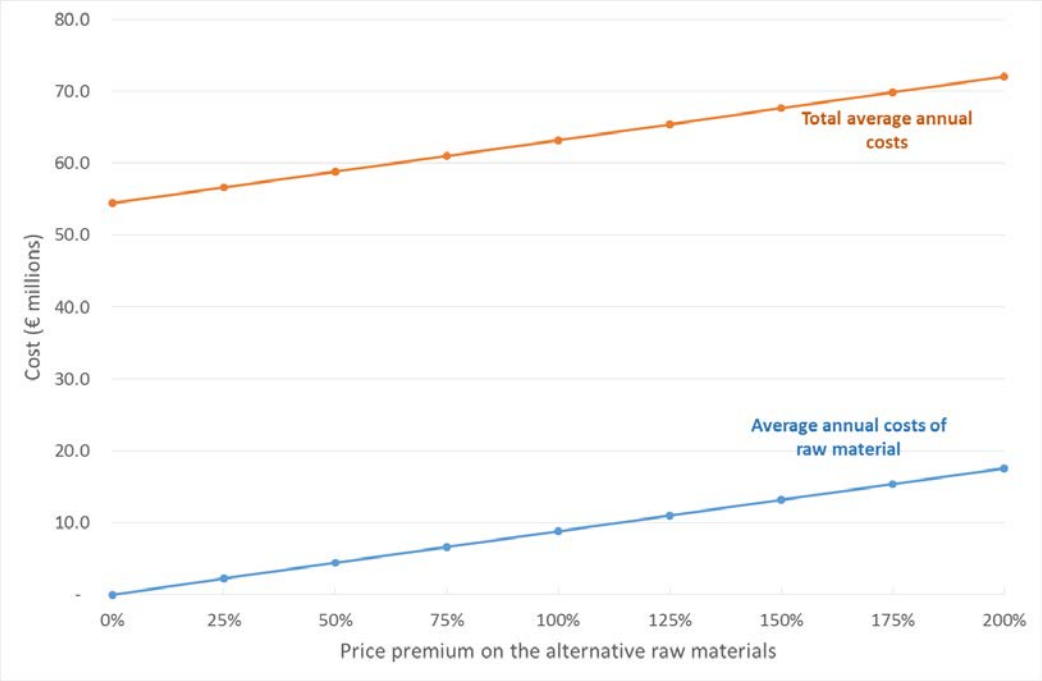
a) For those formulations which are actually reformulated, the cost of the alternative raw material(s) used in place of D4, D5 and D6 is double the cost of D4, D5 and D6.
b) In the case of the formulations that are withdrawn from the market, with consumers switching to already existing D4, D5 and D6-free products, there are no consequences on the profitability of those products (i.e. they can be produced at higher volumes without the unit cost of their raw material being affected).

a) Effect of different prices of raw materials used in place of D4, D5 and D6

The relationship between the price premium commanded by the raw materials used in place of D4, D5 and D6 and total costs (both total additional costs of raw material and total costs of the restriction) is linear, as can be seen in Figure 10.

[7] The methodology used here does not allow the calculation of a cost-effectiveness measure relating to abatement of pollutant steady-state stock.

Figure 10: Change in total additional cost of raw material and total costs of the restrictions due to changes in the price premium commanded by alternative raw materials



However, because the additional costs of raw material are a small proportion of total costs (approximately 10%), changes in the price premium result in moderate increases in the total estimated cost of the restriction. For instance, if instead of twice as expensive (100% price premium), it is assumed that the alternative raw materials are three times as expensive (200% price premium), the average additional annual cost of raw materials doubles (from €9 million to €18 million), but the average annual total cost of the restriction increases by only 14% (from €63 million to €72 million), and the measures of cost-effectiveness change by the same rate.

In conclusion, while there is much uncertainty regarding the potential cost of alternative raw materials that could replace D4, D5 and D6 in cosmetics, the total cost of the restriction (and its cost-effectiveness) are only moderately sensitive to even large changes in the price premium assumed.

b) Effect of variations in the price of raw materials used in D4, D5 and D6-free products

As explained in section 5.4.1.1.C of the Annex XV report, the evidence available suggests that only a minority of total formulations on the market contain D4, D5 and D6 (between 8% and 16%). Of those some will be replaced by reformulated alternatives, and the rest are assumed to switch to already-existing products that are D4, D5 and D6. It is therefore likely that any effect on the unit cost of the raw material used in those alternative products would be small.

The Dossier Submitter has modelled the effect of increases in the unit cost of the raw material used in alternative products by assuming those raw materials have the same unit price as D4, D5 and D6 (in the absence of any other information) and applying a price premium over that price to the tonnage of D4, D5 and D6 currently used and expected not to be reformulated (just over 80% of the total tonnage currently used).

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. The effect is the same on the measures of cost-effectiveness.

In conclusion, if a switch of consumers to existing products that are D4, D5 and D6-free had an effect on the price of their raw materials, the effect on the estimated costs of the restriction and its cost-effectiveness are expected to be small.

D.2.4. Effect of using different assumptions regarding what proportion of formulations containing D4, D5 and D6 would be reformulated

As described in Section 5.4.1.1.D of the Annex XV report, in the best estimates presented, only a proportion of the formulations containing D4, D5 and D6 are assumed to actually be reformulated. It is assumed that if there are many D4, D5 and D6-free alternatives in a particular subcategory, companies (particularly large ones, which likely also own some of those alternative formulations) will choose to have their customers switch to other products in their lines rather than invest in reformulation.

The specific assumptions used were as follows:

- For subcategories where products containing D4, D5 and 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 and 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 and 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 and D6.

The Dossier Submitter has considered how changes in these assumptions would affect the cost of the restriction and its cost-effectiveness. The different scenarios are compared to the best estimates scenario for a 5 year transitional period calculated in the Annex XV report, which used best estimates for the costs and the midpoint of the ranges for estimates of releases (heretofore called the 'Best-5' scenario).

Costs and measures of cost-effectiveness are directly proportional to what proportion of formulations with D4, D5 and D6 are assumed to be reformulated. If the proportion assumed in the Best-5 scenario (19%) is doubled, then so are costs (total costs of the restriction and costs per kg of releases or pollutant stock abated).

The most extreme scenario would be that all formulations containing D4, D5 and D6 would be reformulated. If that were the case, approximately 5 times more reformulations would be expected, and costs would be 5 times higher as well (average annual costs would be €335 million). Measures of cost-effectiveness would increase in the same proportion, with the annual cost per kg of releases prevented increasing to €7 350 if only releases to water were considered, and to €20 if releases to air and water were considered. If considering D4, D5 and D6 steady-state stock, abatement costs would be €450 per kg per annum.

In conclusion, the results of the analysis are quite sensitive to the assumptions made about how many formulations with D4, D5 and D6 are reformulated, which is a key area of uncertainty in the analysis.

Annex E: Stakeholder information

During the preparation of this Annex XV restriction proposal, the Dossier Submitter has maintained an open and interactive dialogue with relevant stakeholders: industry associations and companies at different level of the supply chains, but also consumer associations and Member States Competent Authorities (MSCA).

The consultation of the stakeholders has been made using various means such as written consultation via calls for evidence, market study, but also through targeted calls and emails on specific issues.

E.1. ECHA's calls for evidence

A first call for evidence to support the preparation of this Annex XV dossier was open on the ECHA website from 03/05/2017 to 03/08/2017. It was focusing on specific topics such as:

- Information to support the socio economic analysis of a potential restriction on leave-on cosmetics
- Identification of the uses of D4, D5 in consumer and professional products, and concentration of D4, D5 in these products
- Information on silicone polymers containing residual amount of D4, D5, and their use
- Emission rates from consumer and professional products containing D4, D5

After the European Commission requested ECHA to include D6 within the scope of their ongoing Annex XV report, a supplementary call for evidence was organised between 02/05/2018 and 18/06/2018. The purpose of this second call for evidence was to gather:

- Information on the uses of D6 in consumer and professional products
- Request some specific information in relation to the uses of D4 and D5

The background notes[8] for the calls for evidence give more details on the specific questions that were asked to the stakeholders.

In total, 18 comments were received during the first call for evidence, and 11 during the second one. As depicted in Table 41, comments were essentially submitted by industry associations representing all actors and relevant sectors in the supply chain: producer of D4, D5 and D6, downstream users, and consumer associations. MSCA and individual companies from various sectors including cosmetics, dry-cleaning, medical devices, painting and aerospace, provided information as well.

Table 41: Replies received to the calls for evidence

Stakeholder type	Call for evidence #1	Call for evidence #2
Industry association	9	5
Company	7	2
MSCA	2	2
NGO/Consumer association	0	1
Individual	0	1

[8] https://echa.europa.eu/documents/10162/64df6d1b-de83-0f72-bcbb-e23fc509edd3

and https://echa.europa.eu/documents/10162/2c1909df-96db-0134-7c43-a9399a456099

The comments provided during the calls for evidence have been considered by the Dossier Submitter. In some cases, some follow-up exchanges have been organised by email, phone or meeting in order to clarify some information.

E.2. Market study

In parallel to the call for evidence, the Dossier Submitter has undertaken a market study that included:

- a 'mystery shopping' pilot exercise on French cosmetic web retailer
- a 'mystery shopping' exercise (COWI, 2018)
- a market research exercise where more than 100 stakeholders were contacted – essentially actors in the D4, D5 and D6 supply chains such as suppliers, formulators (own-brand and contract manufacturing organisations), retailers.

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).

This market study has proven to be crucial in identifying new uses, and clarifying certain issues on alternatives for example. The information collected during the market study have been used in the preparation of this dossier.

E.3. Consultation of Member State Competent Authorities

Given the relative magnitude of releases to each of these environmental compartments, the choice of which releases to include in cost-effectiveness estimates would have a significant effect of the overall cost-effectiveness of any proposed restriction. Therefore the ECHA PBT expert group was consulted during the 18th PBT expert group meeting, and later by written procedure in May 2018 about their views on the type of releases to be considered (aquatic only vs atmospheric+aquatic) for the cost-effectiveness calculation of the D4, D5 and D6 restriction dossier preparation.

The outcome of the written consultation was presented during the plenary session of the 19th PBT expert group meeting. No clear consensus on the most appropriate releases to consider emerged from the discussions or the written consultation, but in general the experts considered that in case of PBT/vPvB substances 'no compartment should be excluded' *a priori*, and that an assessment could progress via a tiered approach, where necessary. Some experts indicated nevertheless that the SEA ought to take into account the lower persistence of D4, D5 and D6 in the atmospheric compartment. Some ideas were suggested that have been considered by the dossier submitter (e.g. stock modelling).

Figure 11 gives a snapshot of the support document that was used for this written consultation.

Figure 11: Support document used for the PBT expert group consultation (4 pages)

05 May 2018

Relevant fate properties of PBT/vPvB substances in socio-economic analysis – cyclic siloxanes (D4, D5, D6) case study

Purpose

ECHA's committee for socio-economic analysis (SEAC) has published a paper on how it evaluates the socio-economic impacts of restrictions and applications for authorisation for PBT/vPvB substances[1]. Various potential impacts (and their associated value) are considered useful but, based on the difficulties in valuing the environmental impacts of chemicals, emission reduction and associated compliance costs are typically the starting point of any analysis.

The paper acknowledges that the range of environmental compartments affected by a particular PBT/vPvB substance is important to consider in a socio-economic analysis, but does not develop this concept further i.e. 'what is an affected compartment?'. However, the paper notes that the most appropriate way to address this, and various other aspects relating to the impact of a PBT/vPvB substance, would be on a case-by-case basis.

Noting that the ECHA Secretariat is currently developing a restriction proposal for the cyclic siloxanes D4, D5 and D6 in consumer and professional products, this paper invites ECHA's PBT expert group to more explicitly consider how the specific fate and behaviour properties of PBT/vPvB substances (e.g. half-life in different compartments) could be appropriately reflected during socio-economic analysis, with specific reference to the environmental fate and behaviour of D4, D5 and D6. Feedback from the PBT expert group will assist the ECHA secretariat as they continue to develop their Annex XV restriction analysis for consumer and professional uses of D4, D5 and D6.

Background

The REACH regulation recognises that the hazard and exposure assessment of PBT/vPvB substances (those substances that fulfil REACH Annex XIII criteria) cannot be carried out with sufficient reliability for a quantitative characterisation of risks. Therefore, REACH registrants of PBT/vPvB substances shall 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) have applied a similar semi-quantitative approach when justifying that uses pose an unacceptable risk on an EU-wide basis.

The quantification of impacts arising from the release of PBT/vPvB substances to the environment is challenging. Noting that it is not currently possible to weight the damage potential/impacts of different PBT/vPvB substances, SEAC currently advocates a 'cost-effectiveness' approach as a key element of their evaluation of restriction proposals or applications for authorisation for PBT/vPvB substances[1]. This 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). The PBT expert group contributed to the development of this first approach in 2015 in particular by identifying factors which

[1] https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf - this paper was developed based on input from ECHA's PBT expert group.

potentially could have influence on the socio-economic analysis (see Annex I of the approach).

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 the non-threshold nature of the hazard, an unacceptable risk is considered to arise in any compartment that a PBT/vPvB substance is released to. However, as discussed in the PBT expert group, and reflected in the current approach, PBT/vPvB substances may have significantly different fate and behaviour in different environmental compartments. This raises the possibility that releases to and exposure in certain environmental compartment(s) could be taken specifically into account in the socio-economic analysis when considering the proportionality of any measure. For example, it may be appropriate to exclude the releases to one or more environmental compartments from cost-effectiveness calculations if releases to those particular compartment are not associated with 'impacts/damage' *per se*.

For example, the UK's proposal for a restriction on the use of D4 and D5 in wash-off cosmetic products was underpinned with a cost-effectiveness analysis limited to releases to the aquatic compartment only.

Cyclic volatile siloxanes as a case study

As a follow-up to the restriction on the placing on the market of D4 and D5 in 'wash-off' cosmetic products proposed by the UK in 2015[2], and adopted by the Commission in 2018, the ECHA Secretariat is currently considering the socio-economic implications of a restriction on the use of several cyclic siloxanes (D4, D5 and D6) in a range of additional consumer and professional products[3], notably 'leave-on' cosmetic products (e.g. hair conditioners, make-up) and household cleaning products (e.g. autocare). As a result of their high volatility (D4>D5>D6), the majority of releases arising from these uses are expected to be directly to the atmospheric compartment, rather than to the aquatic compartment (see Annex).

The Secretariat is currently considering if the cost-effectiveness of any proposed restriction should be estimated based on the releases to the aquatic compartment in line with the original UK proposal or, alternatively, be underpinned by the releases to all environmental compartments, i.e. including releases to the atmospheric compartment. Given the relative magnitude of releases to each of these environmental compartments (see Annex) the choice of which releases to include in cost-effectiveness estimates will have a significant effect of the overall cost-effectiveness of any proposed restriction.

The ECHA Secretariat welcomes the view of the PBT Expert group on this issue and any advice or feedback that wishes to share with the ECHA secretariat.

Options for discussion

1. Estimate the cost-effectiveness of any proposed restriction on the use of D4/D5/D6 in consumer and professional products based on releases to all environmental compartments.

2. Underpinned by current information on the fate and behaviour of D4/D5/D6 in the atmospheric compartment, estimate cost-effectiveness based on releases to the aquatic compartment only (i.e. exclude releases to the atmosphere / soil).

[2] https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/9444/term
[3] https://echa.europa.eu/current-activites-on-restrictions

Annex

Fate and behaviour of cyclic siloxanes in the atmospheric compartment

REACH Registration dossiers (and the Background Document for the UK restriction proposal on D4/D5) conclude that releases of D4, D5 or D6 to the atmosphere are unlikely to result in significant deposition to surface media, despite their relatively long atmospheric half-lives. Based predominantly on modelling data the substances are currently understood to remain in the atmospheric compartment until they are degraded (behaving as 'flyers'). This conclusion has been challenged to a certain extent by a study that described deposition of D4, D5 and D6 via snow scavenging during the arctic winter and subsequent bioaccumulation in plants and animals (Sanchís et al., 2015).

Although RAC considered that, without additional evidence, the Sanchís et al. (2015) study was insufficient to prove that deposition was occurring, its opinion noted that on the basis of the large volumes of these substances released to the atmospheric compartment only low rates of deposition would be necessary to result in a concern. It should be noted that the available environmental monitoring data for D4, D5 and D6 in pristine aquatic environments in the EU do not report the presence of D4/D5/D6.

Estimated releases of cyclic siloxanes to different environmental compartments during use

The consolidated RAC and SEAC opinion on the proposed restriction on the use of D4 and D5 in 'wash-off' cosmetics products reviewed the available empirical studies on releases and considered upper and lower bound release factors to wastewater of between 54% and 93% for wash-off cosmetic products and between 0.1% and 2.6% for leave on products. **The remainder or releases will occur directly to air.** Additional releases to air also occur after release to wastewater during wastewater treatment. Although these estimates will be revised by the Secretariat based on updated tonnage information provided by industry they provide useful 'order of magnitude' information on the relative size of releases to wastewater and air from leave-on and wash-off cosmetics. As can be readily seen from Tables 1 and 2, the relative tonnage of D4 and D5 in leave on products is much greater than the tonnage in wash-off products. Although they are associated with lower releases to water, use in leave-on products will result in releases to air.

Table 1. Emissions to wastewater estimated by RAC for direct uses of D5 in PCPs

D5	EU tonnages/a	RAC scenario "lower boundary"		RAC scenario "upper boundary"	
		Release factor	Emission tonnages/a	Release factor	Emission tonnages/a
Direct use in wash-off PCPs	750	54%	405	93%	697.5
Direct use in leave-on PCPs	14250	0.1%	14.3	2.6%	370.5

Table 2. Emission to wastewater estimated by RAC for direct uses of D4 in PCPs

D4	EU tonnages/a	RAC scenario "lower boundary"		RAC scenario "upper boundary"	
		Release factor	Emission tonnages/a	Release factor	Emission tonnages/a
Direct use in wash-off PCPs	11	54%	6.1	93%	10.5
Direct use in leave-on PCPs	214	0.1%	0.2	2.6%	5.6

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