EUROPEAN CHEMICALS AGENCY

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background Document

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

ECHA/RAC/RES-O-0000001412-86-97/D
ECHA/SEAC/RES-O-0000001412-86-109/F

EC Number	CAS Number
D4: 209-136-7	556-67-2
D5: 208-764-9	541-02-6

9 June 2016

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List of Acronyms

ACP	Arctic contamination potential
BAT	Best available techniques
BREF	BAT reference
CAS No	Chemical Abstract Service registry number
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
CSR	Chemical Safety Report
cVMS	Cyclic volatile methyl siloxanes, a generic term for D4, D5, D6, etc.
D3	Hexamethylcyclotrisiloxane
D4	Octamethylcyclotetrasiloxane
D5	Decamethylcyclopentasiloxane
D6	Dodecamethylcyclohexasiloxane
DEHP	Di(2-ethylhexyl) phthalate
DNEL	Derived No Effect Level
dw	Dry weight
ECHA	European Chemicals Agency
EC No	European Inventory number
EEA	European Economic Area
EQC	Equilibrium Criterion
EQS	Environmental Quality Standard
ESD	Emission Scenario Document
EUROSTAT	Statistical Office of the European Communities
FELS	Fish early life stage
FS	Fluorosiloxanes
IPPC	Integrated Pollution Prevention and Control
LoD	Limit of analytical detection
LoQ	Limit of quantification
Log K_{OC}	Organic carbon-water partition coefficient
Log K_{OW}	Octanol water partition coefficient
MF/RO	Microfiltration/reverse osmosis
MSC	Member State Committee
NOEC	No-observed effect concentration
OECD	Organisation for Economic Co-operation and Development
PAH	Polycyclic aromatic hydrocarbon
PBDE	Polybromodiphenyl ether
PBT	Persistent, bioaccumulative and toxic
PCP	Personal care product
PDMS	Polydimethylsiloxane
PEC	Predicted Environment Concentration
PHS	Priority Hazardous Substance
PNEC	Predicted No Effect Concentration
POP	Persistent Organic Pollutant
PS	Priority Substance
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measures
SCCS	Scientific Committee on Consumer Safety
SEA	Socio economic analysis
SME	Small and Medium Enterprises
STP	Sewage treatment plant
SVHC	Substance of Very High Concern
TE	Transfer Efficiency
vB	very bioaccumulative
VOC	Volatile organic compound
vP	Very persistent
vPvB	Very persistent very bioaccumulative
UKIR	UK Water Industry’s Research Body
w/w	Weight per weight
WFD	Water Framework Directive

WTP	Willingness to pay
WWTP	Waste Water Treatment Plant

PROPOSAL FOR A RESTRICTION

About this report

In November 2012 the PBT Expert Group agreed with the dossier submitter that octamethylcyclotetrasiloxane (D4) meets the Annex XIII criteria for identification as a persistent, bioaccumulative and toxic (PBT) and very persistent very bioaccumulative (vPvB) substance and decamethylcyclopentasiloxane (D5) meets the criteria for a vPvB substance. Information published in the scientific literature since November 2012 supports the conclusions reached by the PBT Expert Group. As a contribution to this restriction proposal, the Member State Committee (MSC) confirmed that both substances meet the Annex XIII vPvB criteria in an opinion issued in May 2015 at the request of the Executive Director of ECHA, pursuant to Article 77(3)(c) of the REACH Regulation.[1]

Experience with PBT/vPvB substances has shown that they give rise to specific concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are difficult to reverse (even when emissions cease). Therefore, the risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way (e.g. by derivation of risk characterisation ratios) and a qualitative risk assessment should be carried out (see Annex I/6.5 of the REACH Regulation). Emissions and subsequent exposure, in the case of a PBT/vPvB substance, can be considered as a proxy for unacceptable risk.[2]

Both D4 and D5 are high tonnage substances; D4 has been registered in the 100,000 to 1,000,000 tonne band and D5 in the 10,000 to 100,000 tonne band. They are mainly used as monomers for silicone polymers, but also have a direct use in personal care products (PCPs), cleaning products and a range of other uses detailed in Section B.9.3.
Their presence as intentional constituents or impurities in a very wide variety of consumer products means that they have significant potential for environmental release.

A review of the evidence, covered in Section B.4, shows that emissions of D4 and D5 to air are unlikely to result in significant redeposition to surface waters or the terrestrial environment. Therefore, whilst releases to air can be significant and result in long-range transport to remote regions, they are unlikely to provide a significant route of exposure for biota. The key concerns for D4 and D5 relate to their persistence and accumulation in the aquatic environment, and so the aim of this restriction is to reduce releases to surface waters.

The exposure scenarios in the REACH Chemical Safety Reports (CSRs) were assessed to identify those with waste water releases. Updated estimates of EU emissions of D4 and D5 in the EU were then collated from stakeholders (including the REACH Registrants and Cosmetics Europe[3]). The relative contributions of the different applications to the total EU emissions were evaluated, so that risk management could be focussed on those applications that lead to the greatest risk to surface waters. Wash-off PCPs account for the majority of the D5 emitted to waste water at this scale. Releases of D4 from wash-off PCPs are much smaller, but D4 is included in this restriction as a contribution to its emission reduction and to prevent substitution of D5 with D4.

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[1] http://echa.europa.eu/about-us/who-we-are/member-state-committee/opinions-of-the-msc-adopted-under-specific-echa-s-executive-director-requests

[2] This dossier only considers measures to protect the environment and does not consider measures to protect human health. D4 and D5 do not meet the criteria for identification as substances of very high concern (SVHC) on human health grounds and a review of other human health risks has not been performed for this report.

[3] The main European trade body for the PCP industry.

This proposal builds on a UK national assessment (EA, 2009a&b), a formal dossier submitted to ECHA under the REACH transitional measures (EA, 2013a&b), and a Canadian assessment (Government of Canada, 2008a&b; BoR, 2011) for each substance. For readability, the report is concise, with full details provided in Appendices (or the MSC opinion and its supporting documents) where relevant. Since the dossier discusses data for two different substances, the text for each is distinguished by different colours for clarity (purple for D4 and blue for D5).

Note: In this report, “EU-wide” or “the EU” also covers the European Economic Area (EEA), unless stated otherwise.

A. Proposal

A.1 Proposed restriction(s)

A.1.1 The identity of the substance(s)

Substance Name:	**Octamethylcyclotetrasiloxane**
IUPAC Name:	2,2,4,4,6,6,8,8- octamethylcyclotetrasiloxane
EC Number:	209-136-7
CAS Number:	556-67-2
Molecular Formula:	$C_8H_{24}O_4Si_4$

Substance Name:	**Decamethylcyclopentasiloxane**
IUPAC Name:	2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane
EC Number:	208-764-9
CAS Number:	541-02-6
Molecular Formula:	$C_{10}H_{30}O_5Si_5$

A.1.2 Scope and conditions of restriction(s)

This is the proposed wording of the restriction.

Designation of the substances, of the group of substances or of the mixture	Conditions of the restriction
a) Octamethylcyclotetrasiloxane EC Number: 209-136-7 CAS Number: 556-67-2 **b) Decamethylcyclopentasiloxane** EC Number: 208-764-9 CAS Number: 541-02-6	1. Shall not be placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products that are washed off in normal use conditions. 2. Personal care products shall be taken to mean any substance or mixture intended to be placed in contact with the various external parts of the human body (epidermis, hair, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition. 3. Normal use may be determined by packaging instructions, indicating the purpose of the product and how it is to be used. 4. This restriction shall come into force on DD/MM/YY [at least 2 years after publication in the Official Journal]. 5. By DD/MM/YY [ten years after entry into force] the Commission shall carry out a review of the other sources of these substances to investigate whether any further emission reduction measures are necessary. On the basis of this review, the Commission shall, if appropriate, present a legislative proposal to extend the restrictions in paragraph 1.

This proposal covers personal care products that are intended to be washed off the hair or body with water within a few minutes of application, with the rinsate discharged to waste water. It is not intended to cover therapeutic shampoos since they are normally left on overnight.

A.2 Targeting

The proposal is based on the risks posed by the PBT/vPvB properties of D4 and D5, taking account of their environmental partitioning behaviour which results in a large fraction of emissions residing in the atmosphere, where effects on biota are unlikely.

The exposure assessment comprises a summary of relevant waste water emissions, partitioning behaviour in wastewater treatment plant (WWTP) and monitoring data. Predicted No Effect Concentrations (PNECs) have not been calculated, as the risks of PBT/vPvB substances cannot, in general, be assessed quantitatively.

A.3 Summary of the justification

A.3.1 Identified hazard and risk

The hazards and risks of the use of D4 and D5 are summarised as follows:

- D4 meets the definition of a PBT and a vPvB substance and D5 meets the definition of a vPvB substance in accordance with Annex XIII of the REACH Regulation.
- As set out in Section B.9.3.7, relevant uses result in total EU releases to waste waters of around <20 tonnes/year of D4 and <1,000 tonnes/year of D5.

A.3.2 Justification that action is required on a Union-wide basis

The primary reason to act on a Union-wide basis is to effectively reduce aquatic environmental exposure to D4 and D5 across all EU Member States. European-wide measures to minimise emissions are appropriate because products containing D4 or D5 produced in one Member State may be transported to and used in other Member States. In addition, one EU Member State may receive D4 or D5 emissions arising from other Member States. This means that it is appropriate to consider EU-wide measures for risk reduction. This offers the most effective way to implement controls efficiently and uniformly within the EU.

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

A.3.3 Justification that the proposed restriction is the most appropriate Union-wide measure

Effectiveness in reducing the identified risks

The REACH Registrants have not identified D4 or D5 as meeting the PBT/vPvB criteria due to their interpretation of the available bioaccumulation data, and therefore have not identified any specific risk management measures (RMMs) to take account of these properties in their CSRs. Failure to recommend appropriate RMMs means that there is no intention to reduce current environmental emissions (and therefore risks).

The proposed restriction is predicted to reduce surface water emissions of D4 and D5 by around 78 per cent and 97 per cent, respectively, compared to the baseline. During public consultation additional tonnage data was submitted, using this data the predicted reductions of surface water emissions are broadly supportive of these estimates. Surface water concentrations are likely to decline rapidly as a result (to levels close to the current limits of analytical detection).

Proportionality to the risks

The proposed restriction is likely to affect both production decisions for the manufacturers of wash-off PCPs containing D4/D5 (through its impact on costs and revenues) and consumption decisions for consumers (through its impact on costs and revenues). Assuming that reformulation is completely successful in replacing the wash-off PCPs containing D4/D5, the aggregate cost of reformulation ranges from €7.6-42 million and €23-61 million per year under a 5- or 2-year compliance period, respectively. If reformulation was only partly (50%) successful, the costs range from €53-87 million and €68-106 million per year under a 5- or 2-year compliance period, respectively. Environmental (and other) benefits arise from the reduction in potential risks associated with accumulation of D4/D5 in the aquatic environment. The aggregate environmental benefits to the EU population from reductions in the accumulation of wash-off PCP's containing D4/D5 are conservatively estimated at around €0.65 billion. Comparing benefits and costs, it is clear that the benefits of the restriction significantly outweigh the costs. Moreover, the proposed restriction appears to be relatively cheap, when the cost-effectiveness is compared with previous measures to control similar substances under REACH. It is also clear that when considered in terms of the affordability of the proposed restriction to consumers of wash-off PCPs, the impact would be minor.

Practicality, including enforceability

Although no single substance appears to be capable of providing all of the benefits of D4 and D5 in wash-off PCPs, around 64% of wash-off PCPs (by sales volume) do not contain D4 or D5. Data provided by industry also suggests that most new wash-off PCP formulations will not contain D4 or D5. It is therefore clear that substitution is technically and economically feasible in general for this product type, although the efficacy of PCPs containing D4/D5 compared to those that do not is unknown.

A concentration limit of 0.1 per cent w/w is proposed to enhance the enforceability of the restriction. Analytical methods to verify this concentration are well established, although an EU-standardised method is not available.

Monitorability

Monitoring of the proposed restriction will be carried out through regular enforcement activities for PCPs. Existing mechanisms, such as the labelling requirements of the Cosmetics Regulation, should help to identify relevant PCPs for targeted analysis.

Environmental monitoring of the receiving environment (including WWTP influent and effluent) would provide further evidence about whether the restriction is having the desired effect.

A.4 Uncertainties

Environmental concentrations: The exposure assessment is based on several assumptions, in particular:

- An estimate of the amount of D4 and D5 used in wash-off and leave-on PCPs based on the results of a survey for the CSR; it is possible that some minor downstream users were missed.
- The level of release of the substances from wash-off PCPs to waste water.
- The assumption that air emissions are less important than aquatic emissions.
- The removal efficiency in WWTP.
- The general level of WWTP connectivity across Europe.

The predicted concentrations of D4 and D5 in surface waters are reasonably consistent with the measured concentrations reported in the limited number of available monitoring studies (i.e. they lie within the same range), which suggests that the emission scenarios developed to describe the baseline emission scenario are sufficiently reliable.

Cost estimates: Costs were estimated based on uncertain assumptions regarding the number of PCPs affected, the costs of reformulation, and the baseline levels of reformulation that would be undertaken in the absence of the restriction.

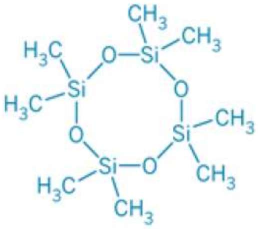
Benefit estimates: The main component of the benefits estimate (associated with environmental improvements from the reduction in emissions of D4 and D5) is based on a novel and original valuation study based on “Willingness to Pay”. Although the results of this study are uncertain in a number of respects, they provide order of magnitude indications of the size of such benefits.

B. Information on hazard and risk

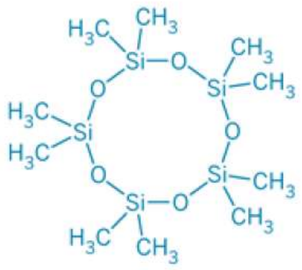
B.1 Identity of the substance(s) and physical and chemical properties

Commercial mixtures are available that intentionally contain both substances along with others, and they may also be present as impurities in cyclic and linear siloxane substances as well as polymers. Given this complexity, the restriction focuses on their presence in final products at a particular concentration limit, regardless of source.

B.1.1 Name and other identifiers of the substance(s)

Name:	**Octamethylcyclotetrasiloxane**
EC Number:	209-136-7
CAS Number:	556-67-2
IUPAC Name:	2,2,4,4,6,6,8,8-octamethylcyclotetrasiloxane
Molecular Formula:	$C_8H_{24}O_4Si_4$
Structural Formula:	
Molecular Weight:	296.62 g/mole
Synonyms (and registered trade names):	Cyclic dimethylsiloxane tetramer, Cyclen D4/OMCTS, Cyclen D4/OMCTS WN, Cyclomethicone, Cyclotetrasiloxane, octamethyl-, Cyclotetrasiloxane, D4, Dow Corning 244, KF 994, DC 344, DC 244, Dow Corning 344, NUC silicone VS 7207, Oel Z020, OMCTS, SF 1173, Tetramere D4/OMCTS, Tetramere D4/OMCTS Silbione, TSF 404, Volasil 244 and VS 7207.

The abbreviation D4 is used for the substance throughout this dossier.

Name:	**Decamethylcyclopentasiloxane**
EC Number:	208-764-9
CAS Number:	541-02-6
IUPAC Name:	2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane
Molecular Formula:	$C_{10}H_{30}O_5Si_5$
Structural Formula:	
Molecular Weight:	370.77 g/mol
Synonyms (and registered trade names):	2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentaoxapentasilecane, 2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentoxapentasilecane, 30535_FLUKA, 4-04-00-04128 (Beilstein Handbook Reference), 444278_ALDRICH, 541-02-6, BRN 1800166, C10H30O5Si5, CCRIS 1328, Cyclic dimethylsiloxane pentamer, Cyclopentasiloxane, decamethyl-, Decamethyl-cyclopentasiloxane, DECAMETHYLCYCLOPENTASILOXANE, Dimethyl-siloxane pentamer, Dow Corning 245, Dow Corning 245 fluid, EINECS 208-764-9, HSDB 5683, KF 995, LS-58254, NCGC00163981-01, NUC silicone VS 7158, Polydimethylsiloxane, SF 1202, Silicon SF 1202, Union Carbide 7158 silicone fluid and VS 7158

The abbreviation D5 is used for the substance throughout this dossier.

B.1.2 Composition of the substance(s)

D4 is a monoconstituent substance. Octamethylcyclotetrasiloxane is the main constituent, typically present at concentrations ≥80% w/w. Small amounts of impurities can include other cyclic siloxanes, including D5.

D5 is a monoconstituent substance. Decamethylcyclopentasiloxane is the main constituent, typically present at concentrations ≥80% w/w. Small amounts of impurities can include other cyclic siloxanes, including D4.

B.1.3 Physicochemical properties

Data in Table 1 were obtained from the public registration information on the ECHA dissemination website[4] (date of access 9 September 2014). An assessment of these data was included in the MSC opinion.

Table 1 Summary of physicochemical properties for D4 and D5

Property	Value		Comments
	D4	**D5**	
Physical state at 20 °C and 101.3 kPa	Liquid	Liquid	-
Vapour pressure	132 Pa at 25 °C	33.2 Pa at 25 °C	Derived from a temperature-vapour pressure correlation using critically evaluated data (see EA (2009a&b) for further discussion).
Water solubility	0.056 mg/L at 23 °C	0.017 mg/L at 23 °C	Varaprath *et al.* (1996) (slow-stirring method)
n-Octanol/water partition coefficient (K_{OW})	6.49 ($\log_{10}$ value) at 25 °C	8.02 ($\log_{10}$ value) at 25 °C	OECD Test Guideline 123 (slow-stirring method) Original report not reviewed by the dossier submitter; considered 'reliable without restriction' by the Registrants. EA (2009a&b) discussed the preliminary findings from this study and found them to be consistent with other data.
Henry's Law constant	12 atm.m^3/mol at 21.7 °C [1.21 × 10^6 Pa.m^3/mol]	33 atm.m^3/mol at 24.6 °C [3.34 × 10^6 Pa.m^3/mol]	Non-standard syringe method for simultaneous measurement of K_{OW}, K_{OA} and K_{AW}. Original report not reviewed by the dossier submitter; considered 'reliable with restrictions' by the Registrants as it was not conducted to GLP. EA (2009a&b) discussed the preliminary findings from this study and found them to be consistent with other data.
n-Octanol/air partition coefficient (K_{OA})	4.22 ($\log_{10}$ value) at 24 °C cited in CSRs (no data on public website) [4.34 ($\log_{10}$ value) at 25 °C cited in EA (2009a)]	4.96 ($\log_{10}$ value) at 24 °C cited in CSRs (no data on public website) [5.07 ($\log_{10}$ value) at 25 °C as cited in EA (2009b)]	
Air/water partition coefficient (K_{AW})	2.69±0.13 ($\log_{10}$ value) at 21.7 °C	3.13±0.13 ($\log_{10}$ value) at 24.6 °C	

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[4] http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

B.2 Manufacture and uses

B.2.1 Manufacture, import and export

According to the ECHA dissemination website, the registered tonnage band for D4 is 100,000 – 1,000,000 tonnes/year, and there are eight Registrants (with ten registration numbers). The registered tonnage band for D5 is 10,000 – 100,000 tonnes/year, and there are seven Registrants (with nine registration numbers). The actual quantity produced or supplied by each company is confidential. The Registrants are listed in Table 2.

Table 2 REACH Registrants

Company	Location	D4	D5
Bluestar Silicones France S.A.S	France	✓	✓
Chemical Inspection & Regulation Service Limited	Ireland	✓	×
Dow Corning Europe S.A.	Belgium	✓	✓
Dow Corning Limited	United Kingdom	✓	✓
KCC Europe GmbH	Germany	✓	✓
Momentive Performance Materials GmbH	Germany	✓	✓
Shin-Etsu Silicones Europe BV	Netherlands	✓	✓
Wacker Chemie AG	Germany	✓	✓

Source: ECHA dissemination website, accessed on 08/04/2015

The production process has been described by EA (2009a&b). D4 and D5 are prepared commercially by the hydrolysis of dichlorodimethylsilane. This process forms a mixture of linear oligomeric siloxanediols and cyclosiloxanes (commonly called “cyclics”). The hydrolysate is split by flash distillation to separate the more volatile cyclics. These cyclics contain around 70 – 80% D4 and 15 – 20% D5, together with smaller amounts of hexamethylcyclotrisiloxane (D3), dodecamethylcyclohexasiloxane (D6) and higher homologues. The cyclics mixture is then fractionally distilled. D3 is removed as a volatile component and D4 and D5 of very high purity are then isolated as the main cut.

The “hydrolysate” produced is always a mixture of cyclic and linear siloxanes and the distribution between the two classes of material may not reflect commercial needs. Techniques have, therefore, been developed to convert linear siloxanes to cyclics and vice versa. D4 and D5 produced by this method are often of higher purity than that obtained directly by hydrolysis of dichlorodimethylsilane, which can in turn be used to prepare higher purity polymers.

B.2.2 Uses

The REACH Registrants identify a wide variety of uses in their CSRs, as indicated in Tables 3-5.

Table 3 Registered uses for both substances

Exposure Scenario	**Comment**
Use as a monomer in the production of silicone polymers, resins and other organosilicon substances*	On either the manufacturing site or by downstream users
Use in electronics applications	Potting agents, sealants and adhesives on electronic substrate
Use in coatings	Paints and resins as a solvent
Use of personal care products (PCPs)	-
Use of household care products in industrial settings$^+$	Cleaning products such as detergents, waxes and polishes (e.g. car cleaning products)
Use as a laboratory agent	Intermediate in the synthesis of silicone based chemicals
Formulation and use of lubricants and release agents	Lubricant oils and mould release agents

Note: * Emission scenarios combined as 'chemical intermediate off-site'
$^+$ Emission scenarios combined as 'household products use by general public'

Table 4 Registered uses for D4 only

Exposure Scenario	**Comment**
Use in non-metal surface treatment	Production of surface treated silica

Table 5 Registered uses for D5 only

Exposure Scenario	**Comment**
Dry cleaning	Used as a replacement for perchloroethylene in dry cleaning processes
Formulation of medical adhesives and pharmaceuticals	-
Processing aid in the pulp manufacturing industry	-

The major use of these substances is as a feedstock for the production of silicone polymers. These silicone fluids, elastomers, gels and resins in turn have a very wide range of uses, including as rubber; elastomers for coatings and sealants; antifoams; flow and/or gloss improvers in alkyd paints and varnishes; softening, waterproofing and wetting agents in textile manufacturing; components of polishes and other surface treatment formulations; lubricants, greases, anti-adhesion coatings and mould release agents; paper coatings; hydraulic, dielectric and heat transfer fluids; and consumer products such as personal, household, and automotive care products (Ashford, 1994; Chandra, 1997). The polymers may also be modified with additional functional groups, with a myriad of other applications. Onsite intermediate and polymerisation uses the vast majority of D4, with less than 5% being used in PCPs. The use of D5 in PCPs is approximately a quarter of the total volume manufactured, most of the remainder is used as an intermediate and in polymerisation, with the remaining uses being much smaller (Reconsile Consortium, 2014 a&b).

The total worldwide production of silicone polymers is above 1,000,000 tonnes/year (EA, 2009a&b).

The focus of this restriction is on the direct use of D4 and D5 in personal care products (PCPs). The Cosmetic Toiletry and Perfumery Association (CTPA) have indicated that the cyclic siloxanes perform three main functions in PCPs – as hair-conditioning agents, as skin-conditioning agents (emollient), and as solvents (EA 2009a&b).

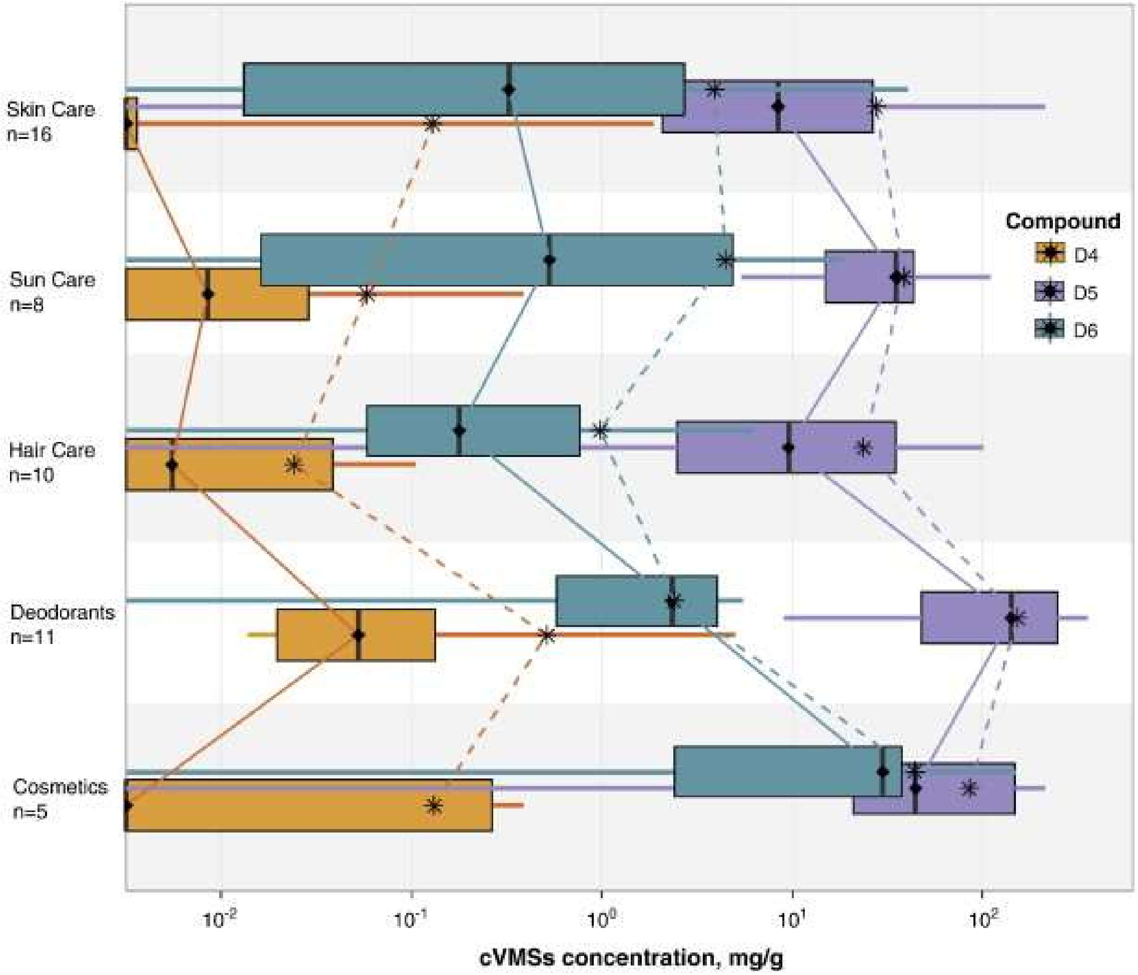
D4 and D5 are used in two distinct types of PCP that lead to very different emissions to the aquatic environment:

- Leave-on products, such as
    a. Skin care products (e.g. leave-on moisturiser);
    b. Products intended for application to the lips;
    c. Foundation;
    d. Make-up products for the face and eyes;
    e. Make-up removing products for the eyes (impregnated wipes or applied with cotton wool/tissue);
    f. Deodorants and antiperspirants;
    g. Sun protection products;
    h. Products for tanning without the sun;
    i. Hair care products (e.g. leave-in conditioner, mousse and gel); and
    j. Other PCPs including sub-categories of nail products and manicure preparations, cleaning wipes, baby wipes.

- Wash-off products, such as
    a. Skin care products (e.g. oils for use in the bath or shower);
    b. Make-up removing products (e.g. facial cleanser, scrub and mud masks);
    c. Hair care products (e.g. shampoo and wash-off hair conditioner);
    d. Shower gels; and
    e. Other PCPs including shaving foam, glide gel and lubricant.

Figure 1 shows the typical concentrations of D4 and D5 in a range of personal care products from an EU survey carried out in 2011 (Dudzina *et al*., 2014). The sample numbers are small, so their representativeness is unknown.

Figure 1 Concentrations of D4 and D5 in personal care products in the EU (from Dudzina *et al*., 2014)



Note The boxes in the plot represent the interquartile range. The right and left edges of the box indicate the 75th and 25th percentile of the data set, respectively. The ends of the horizontal lines indicate the maximum and minimum values observed. Solid and dashed coloured lines link the medians and means of the individual substance concentrations found in different product categories, respectively. D5 has the highest mean and median concentrations in every category. Indicative maximum concentrations of D5 in EU cosmetic and personal care products are given in Appendix B.4.

B.2.3 Uses advised against by the Registrants

No uses are advised against by the Registrants.

B.3 Classification and labelling

B.3.1 Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Only D4 has a harmonised classification as described in Table 6.

Table 6 Harmonised hazard classification of D4

Index no.	International Chemical Identification	Classification	
		Hazard Class & Category Code(s)	**Hazard statement code(s)**
014-018-00-1	Octamethylcyclotetrasiloxane (D4)	Repr. 2 Aquatic Chronic 4	H361f: Suspected of damaging fertility H413: May cause long lasting harmful effects to aquatic life

The harmonised classification is based on a water solubility below 1 mg/L and a lack of ready biodegradation and log K_{OW} >3. The 2nd ATP to the CLP Regulation should result in a more stringent environmental classification since the lowest reliable aquatic chronic NOEC is around 4.4 µg/L (equivalent to Aquatic Chronic 1 (H410)). The M-factor would be 10.

Self-classifications have also been notified to ECHA for D4 as follows:

Not classified (2 notifiers)
Flammable 3 (1,535 notifiers)
Aquatic Chronic 1 (13 notifiers)
Aquatic Chronic 2 (43 notifiers)
Acute Toxicity 1 (1 notifier)
Acute Toxicity 3 (1 notifier)
Acute Toxicity 4 (1 notifier)

Self-classifications have also been notified to ECHA for D5 as follows:

Not classified (2,211 notifiers)
Aquatic Chronic 4 (106 notifiers)
Acute Toxicity 3 (46 notifiers)
Eye Irritant 2 (31 notifiers)
Skin Irritant 2 (26 notifiers)
STOT SE 3 (2 notifiers)

The reasons for these differences have not been investigated by the dossier submitter. Information contained in the CLP Inventory is not necessarily accurate, complete or up to date and has not been reviewed or verified by ECHA or any other regulatory authority. The database is refreshed every two weeks with new or updated CLP notifications from manufacturers and importers.

B.4 Environmental fate properties

The key environmental fate characteristics relevant to this restriction proposal are behaviour in water (especially consideration of removal in wastewater treatment plant (WWTP)) and behaviour in the atmosphere (especially consideration of the potential for D4 and D5 to redeposit to surface water and land following release to air). Only a brief summary of the degradation and bioaccumulation properties is given in this section as they have already been confirmed at EU level in the MSC opinion and supporting documents[5].

B.4.1 Degradation

Table 7 provides a summary of key degradation information for D4 and D5 as presented in the CSRs (see EA, 2009a&b and EA, 2013a&b for further details).

Table 7 Summary of measured degradation half-life data for D4 and D5

Compartment	Degradation half-life		Comment
	D4	**D5**	
Air	ca. 14 days	ca. 10.4 days	Both substances react with atmospheric hydroxyl radicals[6]. Reactions with other atmospheric photo-oxidants are likely to be negligible, although might be enhanced in the presence of mineral aerosols and ozone.
Water	Hydrolysis: • 16.7 days at pH 7 and 12 °C • 2.9 days at pH 8 and 9 °C	Hydrolysis: • 315 days at pH 7 and 12 °C • 64 days at pH 8 and 9 °C	The cited values are extrapolated from the measured data in EA (2009a&b). The conditions are considered to represent typical freshwater and marine environments, respectively. The substances are poorly soluble in water, and hydrolysis might be attenuated by adsorption to dissolved organic matter and particulates. Neither substance is readily biodegradable.
Sediment	242 days at 24 °C in aerobic sediment (longer in anaerobic sediment)	>1,200 days at 24 °C in aerobic sediment (longer in anaerobic sediment)	Depends on sediment organic carbon content and pH. Much longer half-lives are predicted using multi-media models and from monitoring.
Soil	Estimated to be around 4.1 – 5.3 days for temperate soils at a relative humidity of 50 to 90 per cent	Estimated to be around 0.08 days for temperate soils at a relative humidity of 32 per cent	A standard simulation study is not available. Degradation is inhibited by increasing moisture content, with no degradation expected at 100 per cent relative humidity. Degradation may therefore be rapid in some situations, but much slower in others.

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[5] http://echa.europa.eu/about-us/who-we-are/member-state-committee/opinions-of-the-msc-adopted-under-specific-echa-s-executive-director-requests

[6] The calculation assumes an average atmospheric hydroxyl radical concentration of 5×10^5 molecule/cm^3 and a measured rate constant of 1.55×10^{-12} cm^3/molecule/s.

D4 and D5 are both poorly soluble in water, volatile and adsorb strongly to organic carbon (see Sections B.1.3 & B.4.2.1). These are important properties for assessing overall environmental persistence, as examined in various modelling studies (for example, Whelan (2009a,b,c&d)). The modelling is limited by a lack of sensitivity analysis, but in general terms, it predicts a relatively short persistence in the water column (due to volatilisation and hydrolysis (the latter being more important for D4)), which depends on temperature. Loss processes may be attenuated by adsorption to organic carbon and a significant proportion is expected to distribute to sediment where persistence may be much higher (depending on a number of site-specific factors including pH, water depth, temperature, sediment deposition rate, concentration of particulate and dissolved organic carbon, rate of sediment burial and re-suspension, etc.).

Reaction products in all compartments are expected to be silanols (e.g. dimethylsilanediol). These are more hydrophilic than the parent substances, and will therefore be removed from the atmosphere by wet deposition (either adsorbed onto particulates or dissolved), and undergo further degradation in the environment to ultimately form carbon dioxide and silicic acid and/or silica.

B.4.2 Environmental distribution

B.4.2.1 Adsorption potential

A reliable experimental study is available for both substances over a range of conditions for three different soils. The mean log K_{oc} (organic carbon-water partition coefficient) from the adsorption isotherm experiments was 4.22 for D4 (Miller, 2007) and 5.17 for D5 (Durham, 2007). This is equivalent to a K_{oc} of 1.7×10^4 L/kg for D4 and 1.5×10^5 L/kg for D5. A lower log K_{oc} value (mean: 3.86) was measured for D4 using activated sludge samples. A higher log K_{oc} value (mean: 6.16, range: 5.8-6.33) was measured for D5 with filtered river water samples. No effect of ageing has been found on adsorption in tests with soils and sediments.

It is therefore likely that D4 and D5 will adsorb strongly to organic matter in sewage sludge, sediment and soil. The very low water solubility and high volatility also indicate that leaching from soil is not expected to be a significant process in the environment.

B.4.2.2 Behaviour in wastewater treatment plant (WWTP)

Based on the values for vapour pressure and mean K_{OC} summarised in Section B.1.3 and B.4.2.1, respectively, and assuming that the substances are not readily biodegradable[7], the overall removal in a ‘typical’ WWTP predicted using SimpleTreat modelling within EUSES 2.0.3 is around 96 per cent (i.e. about 48% to air and 48% to sludge) for D4 and around 95 per cent (i.e. about 22% to air and 73% to sludge) for D5.

These predictions are similar to the removal of the substances in a pilot-scale municipal activated sludge wastewater treatment plant measured by Parker *et al*. (1999), i.e. 86 and 96 per cent removal for D4 and D5, respectively (summarised in EA, 2009a&b). The overall mass balance in the experiment was generally low so the results are somewhat uncertain.

The predicted degree of removal is consistent with WWTP monitoring studies for D5 (summarised in Appendix B.1). The range of removal efficiency at 31 WWTP[8] with discrete concentrations reported for both influent and effluent above the limit of analytical

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[7] Some studies suggest that anaerobic biodegradation could occur in the WWTP (e.g. Xu *et al*., 2013).

[8] One further WWTP had higher effluent levels than influent, so has been ignored in this analysis.

detection was 28.9–99.7 per cent, with seven WWTP achieving less than 90 per cent removal. The median removal efficiency was 95.8 per cent, which is comparable to the SimpleTreat prediction. The arithmetic mean removal efficiency was 90.4 per cent.

The data set for D4 includes a larger number of censored values so it is more difficult to draw reliable conclusions. The range of removal efficiency at eleven WWTP with discrete concentrations reported for both influent and effluent above the limit of analytical detection was 13.3 – 99.7 per cent, with three WWTP achieving less than 96 per cent removal. The median removal efficiency was 97.4 per cent, which is slightly higher than the SimpleTreat prediction. The arithmetic mean removal efficiency was 82.8 per cent.

The initial influent concentration and treatment type both have a major effect on the final WWTP effluent concentration, with the lowest removal efficiencies observed at WWTPs that only perform primary treatment[9]. The vast majority of studies have only considered the concentrations in the WWTP influent and effluent, so the relative importance of volatilisation and sludge adsorption cannot be established. However, as no significant differences are observed in the removal efficiencies of secondary and tertiary treatment, volatilisation during the aeration stages of wastewater treatment appears to be an important WWTP removal process for these substances.

Based on this information, all of the modelling in this dossier assumes that the release of D4 and D5 to surface water from a municipal WWTP is 4 per cent and 5 per cent, respectively, of the influent concentration (i.e. the overall level of removal is assumed to be slightly higher for D4 than D5, at 96 and 95 per cent, respectively). Although removal rates might be lower or higher at individual WWTPs, these values are considered to be broadly representative. They are the same as those assumed in the REACH CSRs for a ‘standard’ WWTP involving surface aeration (Reconsile Consortium, 2014a&b), although the CSRs also take into account a higher removal rate of 98.6 per cent for WWTP that use bubbling.

B.4.2.3 Atmospheric behaviour

Both substances are very volatile (with a Henry’s Law constant of 1.21×10^6 Pa.m^3/mol at 21.7 °C for D4 and 3.34×10^6 Pa.m^3/mol at 24.6 °C for D5, respectively; see Section B.1.3). They can therefore volatilise rapidly from water and soil. For example, the volatilisation half-life from water is estimated to be 2 hours for D5 in a model river (assuming a river depth of 1 m, a current velocity of 1 m/s, and a wind velocity of 5 m/s) and 183 hours in a shallow lake (assuming that the lake has a depth of 1 m, a current velocity of 0.05 m/s, and a wind velocity of 0.5 m/s), using the USEPA EPI estimation program. Volatilisation half-lives for D5 are estimated to be one day for agricultural soil and half a day for grassland soil using the methods outlined in the REACH Guidance. The corresponding half-lives for D4 are slightly shorter.

D4 and D5 also have relatively long atmospheric half-lives (see Section B.4.1), and combined with their volatility, this means that the major portion of the environmental burden will reside in the air. For example, Kim & Kozerski (2011) carried out distribution modelling for D5 using the Equilibrium Criterion (EQC) multimedia fugacity level III (steady state dynamic) model[10]. A scenario that involved a standard release rate of 950 kg/hour to air, 5 kg/hour to water and 45 kg/hour to soil was considered to be realistic. Most of the total mass of D5 in the system was distributed between air (73.5 per cent of the total steady state mass) and sediment (23.9 per cent of the total steady state mass).

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[9] For example, in Canada, the removal efficiency was up to 98% for higher tier (e.g., secondary) waste water treatment processes, but as low as 90% in a lagoon in the winter time (Wang *et al*., 2013a).

[10] The modelling assumed a temperature of 25 °C, a vapour pressure of 33.2 Pa, a Henry’s Law constant of 33 atm.m^3/mol, a log K_{OW} of 5.17, a K_{OC} of 1.48×10^5 L/kg and a BCF of 13,300 L/kg. The degradation half-lives were assumed to be 166 hours in air, 1,691 hours in water, 302 hours in soil and 74,400 hours in sediment.

The sensitivity analysis indicated that the K_{OC} was the dominant factor controlling the total variability associated with the mass distribution and advection time, and half-life in air was the dominant factor controlling the total variability associated with reaction loss. The emission rate to water was also identified as an important parameter affecting the predicted fate, distribution and transport of D5.

Due to their propensity to reside in the air compartment and their long atmospheric half-lives, D4 and D5 also have the potential to undergo long-range transport to remote regions via the atmosphere. Several modelling studies have been performed (summarised in EA, 2009a&b and EA, 2013a&b), which suggest that the travel distance is high (several thousand kilometres). Monitoring data in locations truly remote from human activity are very sparse, but the available data tend to support the predictions. For example, Genualdi *et al.* (2011) detected D5 in air at concentrations in the range 0.14 – 4.0 ng/m^3 at five Arctic locations (Ny-Ålesund, Norway; Storhofdi, Iceland; Barrow, United States; Alert, Canada; and Little Fox Lake, Canada). Krogseth *et al.* (2013) detected mean D5 concentrations (± standard deviation) in Arctic air of 0.73±0.31 ng/m^3 in late summer and 2.94±0.46 ng/m^3 in early winter, at Svalbard[11]. The results were broadly in line with modelling predictions which suggest that concentrations in the Arctic are higher during winter (when the duration and intensity of sunlight exposure is low), with variation in levels explained by the seasonality of hydroxyl radical concentrations. D4 concentrations in the samples were up to 0.95 ng/m^3 in late summer and up to 2.13 ng/m^3 in early winter, although the reliability of these findings is uncertain as they were similar to levels found in storage control samples. Follow-up studies at the Zeppelin Observatory, Svalbard during 2013 and 2014 reported similar results (NILU, 2014 & 2015).

An important aspect of the atmospheric behaviour of these substances is that due to their high Henry's Law constants, they have a low potential for subsequent deposition to surface media in remote regions. Public comments submitted by CES-Silicones Europe in response to this restriction proposal (comment #1416) include a paper specifically addressing atmospheric deposition (CES, 2015) including a summary of a Japanese expert workshop on long range transport potential (Xu, 2014, in CES, 2015) and a related poster presented to SETAC (Xu, 2015 [ABST]). Key information is summarised below – the focus of most of the studies is on D5 but similar conclusions can be drawn for D4 (which is more volatile and less adsorptive).

- Whelan *et al*. (2004) assessed the atmospheric fate of D4 and its degradation products using a simple equilibrium-partitioning model to investigate the relative rates of removal by reaction with hydroxyl radicals and atmospheric deposition. Although the model included several gross simplifications, making it unsuitable for giving accurate absolute predictions of concentrations, the findings suggest that the parent siloxane occurs mainly in the vapour phase, with relatively small amounts associated with the water and particulate phases. The findings of the paper are equally applicable to D5.

- Whelan (2009d) used the CoZMo-POP model set up with environmental parameters consistent with the Baltic Proper to investigate the fate of D5 in a freshwater–marine continuum. A net deposition of D5 from air to the open sea was predicted during the winter period (between September and April) which was dependent on the assumed emission distribution to air, water and soil. However, the total predicted net deposition was very low (of the order of 0.004 per cent of the total emission).

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[11] The site's altitude means that most of the time it is above the local inversion layer, limiting the influence of local sources (such as from nearby Ny-Ålesund).

- Xu & Wania (2013) analyzed the global environmental fate, latitudinal distribution, and long range transport of D4 and D5 using two multimedia chemical fate models (the OECD P_{OV} and LRTP Screening Tool, version 2.1.2 and the GloboPOP model) using the best available physicochemical properties as inputs and known persistent organic pollutants (POPs) and highly persistent volatile organic chemicals ("fliers") as references. Transfer Efficiency (TE) indicates the efficiency of transfer from a source region to a remote region. Both D4 and D5 had a TE (1.6×10^{-2}% and 6.8×10^{-3}%, respectively) well below the reference value (≥2.25%) used to define the chemical domain for "POP-like" substances. In addition, the Arctic contamination potential (ACP) values after 10 years of continuous emission (under both a realistic release scenario and 100% emission to air) was in the range of 5×10^{-6} to 5×10^{-5}%, which is very small (4–5 orders of magnitude lower than those of the three reference POPs under the same release scenario). The conclusion was that although D4 and D5 can travel a substantial distance in the atmosphere, they have little potential for deposition to surface media in remote regions.

  Expanding on this theme, CES (2015) highlighted that the TE values of D4 and D5 are much smaller than those of acetone and methanol using the OECD Screening Tool under both uniform and urban scenarios. The values were lower under the urban release scenario, where release rates are proportional to the population density of the urban centre (which is a better scenario for substances with a significant use in consumer products). CES (2015) also report calculations performed by Xu (2014) using the OECD GloboPOP model which indicate that D4 and D5 can reach steady state within one year of release, and that air concentrations decrease significantly from the source to remote regions for D4 and D5.

- CES (2015) indicate that for a model environment in which air in the troposphere (6,000 m) is in equilibrium with soil, the ratio between the mass distribution in soil (M_S) and air (M_A) can be calculated using the following equation, valid at any environmentally relevant temperatures:

  $$M_S/M_A = \rho_s \times f_{OC} \times (V_S/V_A)(K_{OC}/K_{AW})$$

  where V_S = soil volume, cm^3
  V_A = air volume, cm^3
  ρ_s = soil density (1.3 g/cm^3)
  f_{OC} = fraction of organic carbon (2%)

  The percentage soil distribution for D5 (i.e. mass in soil divided by the total mass in the soil and air compartments in the remote region) was estimated as follows (the fractions are lower for D4):

Air temperature (°C)	Soil depth	
	5 cm	25 cm
-10	0.07%	0.37%
0	0.03%	0.15%
10	0.01%	0.07%
20	0.01%	0.03%
30	0%	0.02%

Based on monitored air concentrations in the Arctic, the estimated soil concentration arising from deposition from air would not be detectable using current analytical methods. This highlights the importance of the high K_{AW} and relatively low K_{OA} (i.e. K_{OC}/K_{AW} ratio) values of these substances.

- Xu (2015) [ABST] presented the results of further modelling analyses. This suggests that in Arctic air-plant-soil systems, the fraction of D5 deposited to surface media will be in the order of 0.05% at 25 ºC and 0.1% at 0 ºC. For an Arctic air-aquatic system, the deposition is predicted to be in the order of 0.1% at 25 ºC and 1% at 0 ºC.

- McLachlan *et al*. (2010) compared measured D5 concentrations in ambient air at a rural site in Sweden (collected daily between January and June 2009) with predicted concentrations using an atmospheric circulation model (Danish Eulerian Hemispheric Model) parameterized using emissions estimates and physical chemical properties determined in laboratory experiments. The good agreement between the measured and modeled concentrations suggests that D5 is effectively removed from the atmosphere via phototransformation and that atmospheric deposition has little influence on the atmospheric fate. Similar conclusions were drawn by MacLeod *et al*. (2011) using the BETR Global 2.0 model.

- The possibility of deposition of D5 from the atmosphere was considered at an expert panel workshop (Global Silicones Counsel, 2009). Vapour condensation was considered to be irrelevant as this can occur only when the concentration in air exceeds the concentration corresponding to the saturated vapour pressure at any given temperature, and the concentrations of D5 predicted in Arctic air are many orders of magnitude lower that the saturated vapour pressure. Similarly, wet gaseous deposition at temperatures above 0 °C was not considered to be a significant process due to the high air-water partition coefficient for D5. Wet and dry deposition via organic and mineral aerosols was also thought to be insignificant as, although D5 has a high log K_{oc} so may be expected to partition to such aerosols, the aerosol/air partition coefficients for D5 are not sufficiently large to offset the low concentrations of such aerosols in the atmosphere (i.e. a significant flux of D5 to surface media would not be expected). In addition, some mineral aerosols are known to catalyse transformation.

  The potential for deposition of D5 at or below 0 °C adsorbed onto the surface of snow crystals was also considered. It was concluded that the snow-air partition coefficient for D5 is relatively small, so the maximum concentration of D5 adsorbed by snow would be around 1 per cent of the total amount in the air compartment (assuming a very high snow area index[12]; for more compacted snow, the concentration of D5 was predicted to fall). It is important to note that the D5 deposited in snow is only temporarily stored in the deposited snow. As

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[12] Snow area index is the vertically integrated surface area of snow crystals.

the snow melts, the majority of D5 will volatilise.

Overall, the expert panel workshop concluded that the ultimate deposition of D5 from the atmosphere to surface media is unlikely to be significant. A similar conclusion is justified for D4.

The Arctic climate is highly variable but characterized by long, cold winters and short, cool summers. Winter temperatures range from about −40 to 0 °C (with an average of around −34 °C), and winter temperatures can drop below −50 °C over large areas. Summer temperatures range from about −10 to +10 °C (with an average of around +3 to +12 °C), with some land areas occasionally exceeding 30 °C. The available information therefore does not permit a detailed consideration of deposition in the Arctic because the focus is on temperatures towards the higher end of those experienced.

- Biota monitoring studies provide indirect evidence that atmospheric deposition is unlikely to lead to significant food chain exposure. For example:

  - D5 levels in one species of fish were below the limit of quantification (LoQ) of 0.6 ng/g wet weight (ww) in Swedish lakes that only receive input from the atmosphere, in contrast to fish sampled from lakes with WWTP effluent input (Kierkegaard *et al*., 2013; this study did not investigate D4 levels).

  - Very low D5 concentrations (<1 ng/g ww) were also reported for another fish species from remote Swedish lakes (Kierkegaard *et al*., 2010).

  - Borgå *et al.* (2013a&b) collected seven samples of two fish species from a remote Norwegian lake. D4 concentrations were below the LoQ in all samples analysed (<10 or <40 ng/g lipid depending on species). D5 was present below the LoQ in the single sample of one fish species (< 20 ng/g lipid), but was detected in five out of six samples of the other at a mean concentration (±standard error) of 39±14 ng/g lipid. Wet weight concentrations will be lower.

  - Campbell (2010)[13] measured concentrations of D5 in various species sampled in 2008 and 2009 from areas around Bjørnøya (Svalbard) in the Arctic. The most remote site was considered to be Liefdefjorden (~79°34'N 12°44'E), which has no human settlements but does receive frequent visits from cruise ships during the summer months. D5 was not detected in zooplankton (n≤9; limit of detection (LoD): 0.68-1.77 ng/g ww), the bivalve *Chlamys islandies* (n=4; LoD: 1.83-2.36 ng/g ww), the bivalve *Mya truncata* (n=2; LoD: 2.18-2.46 ng/g ww) or the bivalve *Serripes groenlandica* (n=2; LoD: 1.98-2.12 ng/g ww). It was detected at 3.26 ng/g ww in one of two shrimp (*Latin name not stated*) samples (LoD: 1.9 ng/g ww) and in 8 out of 18 samples (though this may refer to subsamples of a smaller number of actual samples) of fish liver (Sculpin *Latin name not stated*) in the range 0.72 – 2.9 ng/g ww (LoD: 0.68-1.77 ng/g ww). The detected concentrations were close to the LoD.

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[13] Similar (or the same) results are reported by Warner *et al*. (2010).

Samples were also collected from areas with human settlements (Kongsfjorden[14], ~78°55'N 11°54'E and Adventfjorden, ~78°13'N 15°40'E; there is a waste water outfall in Adventfjorden). D5 was not detected in 15 marine sediment samples from Kongsfjorden but was detected in 9 out of 15 marine sediment samples (range: 0.57 – 3.91 ng/g ww) at Adventfjorden (LoD: 0.47 – 2.36 ng/g ww), confirming a local emission source there. D5 was detected in all samples of Sculpin liver from Adventfjorden, in the range 6.9 – 345 ng/g ww (n≤16). In addition, it was detected in all samples of Atlantic Cod (*Gadus morhua*) liver, in the range 13 – 110 ng/g ww (n≤11).

- Evenset *et al.* (2009) investigated D5 concentrations in Polar Cod (*Boreogadus saida*) from remote regions around Svalbard (Liefdefjorden, Billefjorden and close to Moffen). D5 was detected in all liver samples in the range 6.9 – 19.1 ng/g ww [18 – 55 ng/g lipid] (n=6), and 4 out of 5 whole fish samples in the range <2.5 – 5.1 ng/g ww [<74 – 128 ng/g lipid].

- Kaj *et al*. (2005b) included several "background" locations[15] as part of a monitoring campaign in six Nordic countries during 2004/2005. The exact nature of the sites is not described. D4 or D5 were not detected in surface water or sediment at any of these sites (LoDs for D5 were below 0.1 µg/L for water and in the range 0.1-10 ng/g dw for sediment (exact limits are not provided)). In contrast, D5 was detected at approximately 2.5 µg/m^3 in air at Sepstrup Sande, Denmark (value read from a graph). It is not clear whether seabird eggs (Fulmar, Black Guillemot and Herring Gull) from Sweden and the Faroe Islands were all sampled from background sites, but D4 and D5 were not detected. D4 was not detected in any fish liver sample. D5 was not detected in fish livers from the two freshwater[16] background sites or from four of six marine[17] background sites (the LoD was around 0.5 ng/g ww). At the other two marine sites the D5 concentration was in the range 10 – 40 ng/g ww.

- Sanchís *et al*. (2015a) reported detection of D4 and D5 in samples of soil (n=11), vegetation (lichen, moss, grass) (n=17), phytoplankton (n=11) and krill *Euphausia superba* (n=11) collected in the Antarctic during 2009. Mean D5 concentrations were 33.0 (range: <LoD – 110) ng/g dw for soil, 18.5 (range: <LoD – 55.4) ng/g dw for vegetation, 3.24 (range: 0.30 – 27) ng/g dw for phytoplankton and 36.6 (range: 21.3 – 63.1) ng/g dw for krill. Soil concentrations directly correlated with the fraction of soil organic carbon. The study authors suggested that snow scavenging from the atmosphere could be a significant process in the Antarctic.

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[14] The report also provides information for biota samples from Kongsfjorden or Liefdefjorden, without stating which. Given this uncertainty these data are not provided here.

[15] The background sites specifically identified in the report are: Denmark - air - Sepstrup Sande, surface water and sediment – Kattegat, biota - marine fish from two areas of the Wadden Sea and the North Sea; Norway - surface water and sediment - Lake Bergsjøen, Lake Røgden, and Færder in the Outer slofjord, biota - marine fish from Farsund near Lista on the Norwegian South coast; Sweden: sediment - Baltic Sea (Ö Gotlandsdjupet, Ö Landsorts djupet), biota - eggs from herring gull (*Larus argentatus*) – location not stated; Faroe Islands - biota - freshwater fish from lake á Mýranar; marine fish from Mýlingsgrunnurin and Kaldbaksfjord (although the text states that this fjord is known to be influenced to some degree by pollution).

[16] Arctic Char and Brown Trout.

[17] The species are not specified, but include Eelpout, Flounder, Cod, Sculpin and Dab.

However, the validity of the study methodology and the credibility of the conclusions have been questioned by other researchers (Warner *et al*., 2015; Mackay *et al*., 2015), based on:

- The unexpected nature of the findings. Siloxanes are mostly (>95%) released in the Northern Hemisphere[18]. Soil concentrations (e.g. up to 110 ng/g dw for D5) were similar to or greater than those from agricultural soil in Canada and Spain with known histories of biosolid amendment. Biota concentrations (e.g. up to 63 ng/g dw for D5) were similar to those found in European water bodies directly impacted by waste water effluent. The surface media concentrations correspond to estimated atmospheric concentrations that significantly exceed those in urban environments in North America.
- The possibility of sample contamination. For example, the apparently long time between sampling and analysis (possibly several years) could have resulted in contamination during storage or sample handling for other studies. In addition, limitations were identified in sample collection, processing and quality control, including a suggested lack of appropriate field blanks/spikes, inappropriate laboratory matrix blanks, and possible exposure of samples to contaminated laboratory air.
- Uncertainties in data processing, e.g. inappropriate statistical techniques and inconsistencies between the paper and supporting information.

In response, Sanchís *et al*. (2015b) provided some clarifications about sampling methodology, indicating that samples had been sealed at the point of collection (with the exception of phytoplankton, which had lower concentrations in any case), and had not been used for other studies. They point out that the sampled soils are very different from temperate soils, with poor structure and an organic fraction containing lichen, animal residues and penguin faeces. Indeed, it is suggested that penguin faeces could be a major source of the substances in the soils with the highest concentrations. The authors concluded that future work should focus on the field determination of D4/D5 concentrations in snow, depositional fluxes, and their snow scavenging ratios. The dossier submitter agrees, and considers that the findings should be confirmed by a further study before they can be considered reliable.

It should be noted that the number of samples is small (e.g. only three fish from each lake in the Kierkegaard *et al*. (2013) study), so the representativeness of the findings is unknown. In addition, some of the lakes are not far from rural habitation, so there is a possibility for some local contamination (e.g. from swimming or other outdoor activity). Biota concentrations in remote areas of Svalbard are likely to be due to atmospheric deposition, although some local contamination from visiting cruise ships cannot be completely ruled out (the substances may be present in textile surface coatings as well as silicone greases used in engines). N.B. Concentrations in biota arising solely from air emissions are related to all uses of the substances, not just PCPs.

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[18] CES (2015) report calculations performed by Xu (2014) using the OECD GloboPOP model that indicates that a fraction of D4 and D5 released in the Northern Hemisphere can reach the Arctic atmosphere, but not the Antarctic atmosphere due to limited mixing.

- The lead REACH Registrant (CSR Section 10.20.3.1: Factors affecting regional PEC values) indicates that the amount of release to air has a negligible effect on concentrations in water or sediment.

Environmental risks from exposure via air are likely to be low:

- Bioaccumulation potential in air-breathing organisms is a function of both K_{OW} and K_{OA} (Kelly *et al.*, 2004). Physiologically-based pharmacokinetic modelling based on a comprehensive experimental data set (e.g. Andersen, 2005) shows that metabolism and exhalation are important mechanisms for elimination, and that the rapid clearance by these two routes means that D4 and D5 are unlikely to accumulate significantly in mammals following inhalation exposure. No information is available for plants, birds, reptiles, amphibians or air-breathing invertebrates.

- In terms of direct risks, the CSRs use a DNEL of 13 and 17.3 mg/m^3 for long-term inhalation exposure for D4 and D5, respectively, to show that risks to humans in occupational and consumer settings are likely to be low (RCRs << 1). On the other hand, a draft opinion from the SCCS (2015) considers that the aggregate human exposure to D5 via both oral and inhalation routes from the use of cosmetic products is not safe due to the contribution of body lotion and hair styling aerosols containing high concentrations. This has been challenged by industry stakeholders, and is not yet a final conclusion. Even so, air concentrations in the environment will be much lower than those in the immediate vicinity of a user of cosmetics.

  On this basis, non-human organisms in the environment are unlikely to experience direct effects following inhalation exposure.

- Abiotic effects are also unlikely. For example, degradation of D4 and D5 in the atmosphere does not lead to the formation of ground-level ozone (EA, 2009a&b).

B.4.2.4 Overall summary

D4 and D5 are poorly soluble in water, volatile and adsorb strongly to organic matter in WWTP, sediment and soil. They are not rapidly degraded, and have long environmental half-lives in sediment in particular. WWTP are usually efficient at removing them from waste water (especially if there is an aeration step, when a significant portion of the removal will be to air). Once in the atmosphere, they can be transported long distances, and have been detected in remote regions. However, they are expected to remain in the atmosphere until degraded, and their potential for deposition to surface water and land is generally very low.

For this reason, the dossier submitter considers that emissions to atmosphere are less relevant to the risk management of these substances than aquatic emissions. This is an important element of this restriction proposal, although it should be noted that air emissions are substantial (e.g. EA (2009b) estimated that 14,814 tonnes/year of D5 may be emitted to air from the use of PCPs alone).

Although the typical removal efficiency in WWTP is very high, a small percentage of the influent concentration is likely to remain in effluent, and in some cases waste water might not be treated in a WWTP. The magnitude of the surface water emissions is estimated in Section B.9.3.

B.4.3 Long range transport

As noted in Section B.4.2.3, there is potential for both D4 and D5 to be transported long distances in the atmosphere. However, surface re-deposition potential is believed to be of relatively low significance. Long-range transport through the marine environment is likely to be less relevant given these substances' overall volatility, hydrolytic instability at normal pH values of the marine environment and removal to sediment.

B.4.4 Bioaccumulation and transformation

A summary of key bioaccumulation data for D4 and D5 is presented in Table 8.

Table 8 Summary of bioaccumulation data for D4 and D5

End point	D4	D5	Comment
Fish bioconcentration factor	≥11,495 L/kg	>10,000 L/kg	These are the highest reliable BCFs reported (for parent substance).
Fish dietary biomagnification factor	0.5 – 4.6	0.6 – 3.9	The actual value depends on the treatment of the data. The highest values take account of fish growth, lipid normalisation and kinetic approaches.
Trophic magnification factor	Most studies indicate trophic dilution, but BMFs are above 1 in some food webs or feeding relationships	Trophic magnification may occur in some food webs whereas trophic dilution occurs in others. BMFs are above 1 for some feeding relationships.	Several field studies are available. The findings should be treated with caution as they are complicated by a range of factors (such as migratory behaviour of the species sampled, difficulties in establishing trophic position and feeding relationships, concentration gradients in water and/or sediment, and measurement limitations, etc.).

In laboratory dietary experiments, fish achieved D4 concentrations of up to 100 mg/kg ww, and D5 concentrations of up to 111 mg/kg ww. Field studies show that both substances can be found in aquatic food webs at many locations, including top predatory fish, birds and mammals, with the highest levels close to sources of emission. Concentrations of D4 are generally relatively low with many non-detects (which may be a consequence of its relatively minor use in emissive applications), but some samples contain up to a few tens of microgram per kilogram ww, and concentrations in the range 0.1 – 0.9 mg/kg ww have been reported in tissues of some fish species. For D5, concentrations have been reported up to 1-3 mg/kg ww.

The bioaccumulation potential for D4 and D5 in mammals appears to be much lower than may be expected based on their fish BCF or log K_{OW} alone, particularly in relation to inhalation exposure. This relates to the more rapid elimination kinetics (via respired air given the high K_{AW} value) and more rapid metabolism in rodents compared with fish. The pharmacokinetic behaviour of D4 and D5 in mammals exposed via oral routes is complex and does not appear to be as well understood as the inhalation and dermal routes. Although it is likely that rapid metabolism and/or excretion does occur, both substances are expected to be available for storage in lipid compartments.

B.5 Human health hazard assessment

Human health considerations for the constituents of rinse-off PCPs are regulated under EU cosmetics legislation, which limits the consumer use of substances with particular human health-related hazardous properties.

The following information is relevant for the T criterion of the PBT assessment, which has not been assessed by the MSC. Derived No Effect Levels (DNELs) are not relevant for the purposes of this restriction proposal. The text is taken from two previous regulatory reviews by the dossier submitter (EA, 2009a&b), and does not take account of new toxicological studies that may have been performed since then.

B.5.1 Human health hazards of D4

As mentioned in Section B.3, D4 has a harmonised human health classification under Regulation (EC) No. 1272/2008, as follows:

- Hazard class and category: Repr. 2.
- Hazard statement: H361f: Suspected of damaging fertility.

The classification arises from mammalian studies via inhalation exposure, and a summary of relevant data is provided below for information (and comparison with D5).

The effects of D4 on fertility were examined in two range-finding studies, male and/or female cross-over studies, and ‘phased female’ studies, as well as in a two-generation study (Holson *et al*., 1995, 1996, 1997a, 1997b; Stump *et al*., 1997, 1998, 1999, 2001). In these studies, male and/or female Sprague Dawley rats were exposed by whole-body vapour inhalation to D4 at concentrations that ranged from 70 to 700 ppm for six hours per day, seven days per week. The general protocol for each study was similar and included exposure for at least 28 or 70 days prior to mating, and exposure to females continued in some studies throughout gestation and lactation.

The major findings in females exposed to 500 ppm or more were statistically significant treatment-related decreases in the number of corpora lutea, number of uterine implantation sites, total number of pups born, and mean live litter size (Holson *et al*., 1995, 1996, 1997a; Stump *et al*., 1998, 2001). These effects are likely to be inter-related.

The mean live litter size in the 700 ppm exposure group was consistently 60–70 per cent of the control values. At 500 ppm, litter size was around 80–90 per cent of control values and at 300 ppm in the two-generation study the litter size was 89.5 per cent of control in the F1 generation and 92 per cent of control in the F2 generation (Stump *et al*., 2001). Although the mean live litter size was reduced, the number of live births as a percentage of the total number of pups born compares with control values in each case.

No effects on the number of uterine implantation sites, the litter size, or the mean live litter size occurred in male cross-over studies in which males were mated to unexposed females (Holson *et al*., 1997b; Stump *et al*., 1997). Exposure to D4 did not affect sperm production, motility, or morphology, nor did it result in either weight or histopathological changes of male reproductive or accessory sex organs. It is therefore concluded that the effects on litter size are not male mediated.

In addition to the studies described above in which animals were exposed to D4 throughout pre-mating, mating, gestation, and lactation, studies in which female rats were exposed during selected phases of the reproductive cycle (Stump *et al*., 1998, 1999) were conducted. These were designed to identify the critical portions of the reproductive cycle in female Sprague Dawley rats during which exposure to D4 must occur for the litter size to be affected.

The first of these studies involved exposure of separate groups beginning (Stump *et al*., 1998):

- at least 28 days prior to mating and continuing through to gestation day 19 (overall phase);
- 31 days prior to mating and stopping three days prior to mating (ovarian phase);
- three days prior to mating and continuing to gestation day three (fertilisation phase) or between gestation days two and five (implantation phase).

In both the overall phase and the fertilisation phase the numbers of corpora lutea, uterine implantation sites, and foetuses were reduced, along with an increase in pre- and post-implantation loss. There was no effect on fertility parameters in females exposed during the ovarian or implantation phases, which suggest that the key events occur during the three days before and after mating.

This critical period was confirmed in the subsequent study in which groups of females were exposed to 700 ppm D4 six hours per day for single days or groups of days that covered a period from four days before mating to gestation day three (Stump *et al*., 1999). Only in the group exposed for six days before and three days after mating were the numbers of corpora lutea and implantation sites reduced. Also, the number of small implantation sites in this group substantially increased. Numbers of corpora lutea were not affected in rats exposed once on days four, three, two, or one before mating. However, there was a treatment-related reduction in pregnancy rate in females exposed on day one prior to mating. The ovaries from this group had a normal complement of corpora lutea, but only 65 per cent of females with evidence for mating became gravid compared to 90 per cent or more in all other groups.

That no effect in females exposed to D4 prior to, but not during, the critical window surrounding mating is observed indicates that it is reversible. In September 2006 specialised experts discussed the mechanism and relevance for human health of these findings in the context of classification and labelling. These experts were of the opinion that the mechanism behind the reproductive effects of D4 could be relevant to human health.

The NOAEL for this effect is 300 ppm, on the basis of a two-generation study that showed a reduction in live litter size at is around 10 per cent or less compared to controls (the reduction was 10–20 per cent at the next concentration, 500 ppm).

This the key reproductive effect of D4. The effects of D4 on fertility via oral or dermal routes have not been studied.

Other potentially relevant effects

This information is included for comparison with the data set for D5. Full details are provided in EA (2009a).

The effects of repeated exposure to D4 have been studied by all relevant routes. Inhalation of D4 causes respiratory tract irritation in rats. The key systemic effect is liver enlargement and associated hypertrophy caused by phenobarbital-type enzyme induction. Liver enlargement occurs after both oral and inhalation exposures in rats. As increases in liver weight greater than 10 per cent lie just outside the range of normal human variation, any such increases are considered adverse to health. Furthermore, very large increases in liver size can compress other abdominal organs, and enzyme induction can alter the normal response to other xenobiotics. An inhalation NOAEL of 5 ppm (60 mg/m^3) is identified on the basis of a 90-day study that shows a 14 per cent increase in liver weights at 10 ppm (121 mg/m^3). An oral NOAEL of 25 mg/kg/day is identified on the basis of a 17 per cent increase in liver weight at 100 mg/kg/day in a 14-day gavage study in rats. The relevance of the liver effects for wildlife population sustainability is unclear.

No adverse effects are reported in rabbits given dermal doses of up to 96 mg/kg/day for three weeks – this is the highest dose tested.

D4 does not have mutagenic potential either *in vitro* or *in vivo*.

EA (2009a) discusses a carcinogenicity study for D4 in which F344 rats were exposed to 10, 30, 150, or 700 ppm, six hours per day, five days per week for up to two years (Battelle Toxicology Northwest, 2004). The only neoplastic finding associated with exposure to D4 is uterine endometrial adenoma and adenocarcinoma. Uterine adenomas were found in 11 per cent (4 in 35) of females at 700 ppm. The adenomas were accompanied by an increased incidence of endometrial epithelial hyperplasia that affected 80 per cent (28 in 35) rats compared to 19 per cent (11 in 58) in controls. One endometrial adenocarcinoma also arose in a female rat exposed to 150 ppm for 12 months with a recovery period of 12 months, as did one endometrial adenoma in a female rat exposed to 30 ppm for 12 months and allowed the same recovery period. Endometrial epithelial hyperplasia also occurred in this group, but there was no clear dose relationship. No uterine adenomas were reported in animals culled after 12 months of exposure or in concurrent control groups. It seems inconsistent that treatment-related tumours can occur at 30 ppm and 150 ppm in animals exposed for 12 months and allowed a 12-month recovery period, and yet no tumours occurred in animals exposed to this regime at 700 ppm and none in those exposed to 30 ppm or 150 ppm for 24 months. Equally, it is difficult to dismiss the tumours since they are of the same type as the treatment-related ones that occurred at 700 ppm. On this basis it is assumed that these tumours are treatment-related.

Mechanistic studies indicate that the endometrial tumours arise because D4 acts as a dopamine agonist (CES, 2005). By maintaining dopaminergic inhibition of prolactin secretion, female reproductive senescence is delayed, which leads to prolonged stimulation of the endometrium and eventually to tumours. Differences in the reproductive ageing process between humans and rodents render this mechanism irrelevant to humans (CES, 2005). It is not clear whether tumours that occur after D4 exposure are relevant to other species exposed via the food chain. However, because the carcinogenic effect occurs late in life, it is not an effect that influences the sustainability of a population. It is therefore not necessary to take the carcinogenicity of D4 into account for PBT assessment.

Developmental toxicity studies by the inhalation (up to 700 ppm) and oral (up to 1,000 mg/kg/day) routes have been conducted in rats. In each study there was evidence for maternal toxicity at the upper end of the dose range, but no evidence for any adverse developmental effects caused by D4.

[No relevant data are available for birds.]

B.5.2 Human health hazards of D5

As mentioned in Section B.3, D5 is not classified for human health effects under Regulation (EC) No. 1272/2008 on the basis of carcinogenicity, mutagenicity, reproductive toxicity or specific target organ toxicity.

The dossier submitter notes that a draft opinion has been issued by the Scientific Committee on Consumer Safety (SCCS, 2015), which concludes that the use of D5 in cosmetic products is safe for human health, with the exception of use in body lotion and hair styling formulations, and in those product forms that can give rise to lung exposure of the consumer through inhalation (e.g. aerosols, pressurised sprays, powders, etc.). This is based on maximum concentrations in the finished products. Such products are not subject to this restriction proposal, but any further controls arising under the Cosmetics Regulation will help to reduce environmental emissions. In addition, SCCS (2015) recommends that the purity of D5 in cosmetic products put on the market should be > 99% (due to health concerns about D4).

Other potentially relevant effects

This information is included for comparison with the data set for D4. Full details are provided in EA (2009b).

Inhalation of D5 causes respiratory tract irritation in rats at 75 ppm and above in repeat dose studies. A NOAEL of 25 ppm for this effect was identified in a 90-day study. No adverse effects are reported in repeated dermal dosing studies at concentrations of up to 1,600 mg/kg/day, the highest dose tested in any study. In relation to systemic effects, the main concern is liver enlargement and associated hypertrophy caused by phenobarbital-type enzyme induction. A NOAEL of 28 ppm (435 mg/m^3) was identified for the inhalation route from a 90-day study in rats and a LOAEL of 25 mg/kg/day was identified for the oral route from a 14-day study in rats, based on a 13 per cent increase in liver weight. Although a consistent NOAEL could not be identified for liver enlargement after oral exposure, the inhalation NOAEL of 28 ppm equates to an extrapolated oral NOAEL of 19 mg/kg/day, which is below the oral LOAEL of 25 mg/kg/day. Although this NOAEL is very close to the LOAEL, it is an appropriate endpoint as the adverse effects seen at the LOAEL are marginal. No functional or histopathological changes appear to accompany the liver weight change, and as for D4, the relevance of the liver effect on wildlife population sustainability is unclear.

D5 is not considered to have mutagenic potential either *in vitro* or *in vivo*.

D5 appears to have caused uterine tumours in F344 rats following repeated daily inhalation exposure. The mode of action appears to be not relevant to humans; it might be relevant to other vertebrate species but further information is lacking. As these tumours appeared late in life, such an effect, even if it were to occur in the environment, would not be expected to influence population sustainability.

No adverse effects on fertility were seen in the two reproductive toxicity studies conducted for D5 via the inhalation route up to 160 ppm (2,496 mg/m^3), the maximum concentrations achievable. This concentration is lower than the NOAEL for fertility effects identified for D4 and, given the structural similarities between D4 and D5, it is possible that positive findings might be obtained for D5 if higher systemic doses could be achieved (e.g. following oral dosing). However, it should be noted that administration of D5 by the oral route results in a different kinetic profile than administration by inhalation, with more D5 being bound and not available for interaction with tissues. On this basis, reproductive toxicity is of concern but a conclusion cannot be drawn on the basis of the available data. The highest dose tested of 160 ppm can be adopted as a surrogate for a NOAEL (equivalent to an extrapolated oral NOAEL of 105 mg/kg/day).

[Although the following study is not relevant for human health, it is for wildlife, and so is mentioned here. The CSR indicates that D5 did not cause treatment-related effects in an OECD TG 206 reproduction test using Japanese Quail (*Coturnix coturnix japonica*) at concentrations up to 1,000 mg/kg feed. (The dossier submitter has not evaluated the original test report.)]

B.6 Human health hazard assessment of physico-chemical properties

Not relevant since the dossier concerns environmental rather than human health risks.

B.7 Environmental hazard assessment

The following information is relevant for the T criterion of the PBT assessment, which has not been assessed by the MSC. Detailed study summaries are only provided for the key studies.

N.B. PNEC derivation is not relevant for PBT/vPvB substances (see Section B.8), since risk management is based on the premise that it is not possible to reliably identify a safe level of emission.

B.7.1 Environmental hazards of D4

Many of the available studies were carried out using modified test systems (e.g. with no headspace) to address the inherent problems of testing D4 (low water solubility, high volatility).

D4 is not toxic to fish when they are exposed for short durations (e.g. up to 96 hours) at concentrations up to the solubility limit in the test media. However, it causes toxicity in fish over longer exposure durations. Sousa *et al*. (1995) performed several experiments with Rainbow Trout (*Oncorhynchus mykiss*):

- In a prolonged acute toxicity test, 20 per cent mortality was observed at an exposure concentration of 6.9 µg/L, and the 14-day NOEC was 4.4 µg/L. Additional studies indicated that smaller fish appear to be more sensitive to D4 than larger fish.
- In contrast, a NOEC of ≥4.4 µg/L was obtained from a long-term (93-day) fish early life stage toxicity study (this was the highest concentration tested and no adverse effects were observed). It cannot be ruled out that effects might have been observed at higher concentrations (as suggested by the prolonged acute test).

Generally, a longer-term test with early life stages is preferable to a prolonged acute test for the purposes of chronic toxicity assessment. However, the two studies did not overlap in test concentration, so the true level of toxicity to fish over the long-term is unclear. Overall, the long-term NOEC for fish is assumed to be around 4 – 6 µg/L, although there is some uncertainty in the actual value and the reasons for the differences between the two studies. It is noted that this substance causes effects on mammalian fertility (see Section B.5.1), and no data are available to determine whether it affects fish reproduction.

D4 is not toxic to aquatic invertebrates when they are exposed for short durations at concentrations up to the solubility limit in the test media. Following longer exposure, D4 does cause toxicity. The key study is:

- Sousa *et al*. (1995) carried out a 21-day reproduction study with *Daphnia magna* using a flow-through system with no head space (to minimise loss of D4 through volatilisation). The D4 tested was >99 per cent pure and stock solutions of the substance were prepared by slow-stirring dilution water with a floating layer (approximately 6 mm thick) of D4. This method of stock-solution preparation gives reproducible results and can achieve a maximum concentration of ca. 15 µg/L in hard freshwater. Five exposure concentrations were used (measured concentrations were 1.7, 1.8, 4.2, 7.9, and 15 µg/L).

  This study showed a statistically significant ($p = 0.05$) reduction in the survival at the highest concentration tested (survival in the 15 µg/L was

77 per cent) compared with the control population (survival was 93 per cent) after 21 days. The 21-day $NOEC_{survival}$ was therefore 7.9 µg/L.

For the reproduction endpoint, the mean cumulative number of offspring per female daphnid was 111 in the control, 107, 92, 123, 151, and 167 in the 1.7, 1.8, 4.2, 7.9 and 15 µg/L treatment groups, respectively. There were no statistically significant ($p = 0.05$) differences between the control response and the treatment response in the 1.7, 1.8, and 4.2 µg/L groups, but the mean cumulative number of offspring per female was significantly higher in the 7.9 µg/L treatment group than in the control groups (the data for the 15 µg/L treatment group were not included in the statistical analysis as a reduction in daphnid survival occurred in this group). Therefore it is concluded that concentrations of D4 ≤7.9 µg/L do not adversely affect the reproduction of *D. magna*.

No reliable laboratory data are available on the toxicity of D4 to algae but consideration of QSAR data in EA (2009a) suggests that algae should not be more sensitive to D4 than fish or invertebrates.

Long-term sediment toxicity studies are available for three species (*Chironomus riparius*, *Ch. tentans* and *Lumbriculus variegatus*). The lowest NOEC is <0.73 mg/kg dry weight, obtained in a 28-day study with *Lumbriculus variegatus* (Krueger *et al*., 2009) (although a higher NOEC of 13 mg/kg dry weight was found for this species in a second study (Picard, 2009))[19]. If the results are normalised to a standard organic carbon content of 5 per cent, the $NOEC_{standard}$ is <1.5 mg/kg dry weight. For comparison with pelagic organisms (assuming that the effects occur due to exposure via pore water), the equivalent pore water concentration is estimated to be around <2 µg/L using the methods outlined in the REACH Guidance. This value is well below the solubility limit of the substance in pure water.

No terrestrial organism toxicity test data are available for D4. The Registrants use a category approach to fill the data gaps but this has not been reviewed for the purposes of this report.

B.7.2 Environmental hazards of D5

D5 is not acutely toxic to fish at concentrations up to its solubility limit in test media. Two standard guideline fish early life stage (FELS) studies have been performed:

- Lee (2009) performed an OECD TG 210 toxicity test using Rainbow Trout (*Oncorhynchus mykiss*) with an overall duration of 90 days (30 days to hatch and 60 days post-hatch). The D5 used had a purity of 99.16 per cent and stock solutions were prepared in dimethylformamide. The test was carried out using a flow-through system. The flow rate provided 7.7 aquarium volumes per day (90 per cent replacement time) up to day 75. On day 75 it was found that the exposure concentrations were lower than expected (possibly owing to the increased biomass present in the aquarium by this time point) and so the flow rate was increased to provide around 15 aquarium volumes per day (90 per cent replacement time of 4 hours) for the remainder of the study. The dilution water used was well water with hardness in the range 38 to 60 mg/L as $CaCO_3$ and a pH in the range 6.3 to 7.3. The test was carried out at a temperature of 12 °C ± 2 °C and the dissolved oxygen concentration was found to be in the range 6.6 to 11 mg/L throughout the test.

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[19] Original test reports have been reviewed by Environment Canada but not the dossier submitter.

A total of five test concentrations (nominally 17, 8.5, 4.3, 2.1 and 1.1 µg/L) were tested along with a control and solvent control (containing 0.034 mL/L of dimethylformamide). Four replicates were used for each treatment and control group. At the start of the test, each replicate consisted of 30 fertilized eggs (the eggs were approximately 1.25 hours old (post-fertilization) at the start of the test). The fertility of the exposed eggs was assessed on day 19 of the study and the percentage hatch was determined on day 30 of the study (at this time no more than 10 per cent unhatched viable embryos remained in any replicate). The post-hatch phase of the study was carried out using 15 embryos/larvae (these were selected on day 19 of the study in order to assure unbiased thinning of the larvae at the completion of hatch). The larvae were fed three times daily from day 9 post-hatch. The test was terminated at 60 days post-hatch. At this time point the percentage larval survival was determined, along with mean larval weight and length.

During the course of the test, samples of water were collected and analysed for the concentration of D5 present. The mean (±standard deviation) concentrations of D5 determined in the five exposure groups were 14±2.3, 7.8±1.3, 4.0±0.67, 2.0±0.35 and 0.92±0.16 µg/L, which represented 82 to 95 per cent of the nominal concentrations.

No statistically significant difference (95 per cent level of certainty) was found between the control response and solvent control response for any endpoint considered, and so the responses from the treatment groups were compared with the pooled control group.

The mean embryo viability determined on day 19 of the test was in the range 68 to 81 per cent, which was consistent with the laboratory's expectation and historical performance. The mean per cent hatch determined on day 30 of the study was found to be 82 per cent in the control and 89 per cent in the solvent control (pooled control was 86 per cent). The mean per cent hatch in the D5 treatment groups was in the range 83 per cent to 94 per cent and these values were not statistically significantly different from the pooled control. Therefore no treatment-related effects on hatching success were evident in this study.

The mean per cent normal larvae in the control and solvent control at the end of the hatching period (day 30) were both 98 per cent. The mean per cent normal larvae in the D5 treatment groups was in the range 93 to 99 per cent. No statistically significant differences were evident between the treatment groups and the pooled control groups. Therefore no treatment-related effects on the per cent normal larvae were evident.

At the end of the test (60 days post-hatch), the mean larval survival in the control group and solvent control group was 92 per cent and 90 per cent respectively (the pooled control was 91 per cent). The mean larval survival in the treatment groups was in the range 90 per cent to 92 per cent, which were not statistically significantly different from the pooled control group. Therefore no treatment-related effects on larval survival were evident.

The mean total length of larvae on day 60 post-hatch was 52.5 mm in the control group and 52.1 mm in the solvent control group (the pooled control group was reported to be 52.1 mm[20]). The mean total lengths of larvae in the treatment groups were in the range 51.2 mm to 52.0 mm, which were not statistically significantly different from the pooled control group. Similarly no

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[20] This value appears to be an error. Based on the raw data given in the test report, the mean larval length in the pooled control group should be 52.3 mm; this does not affect the conclusions of the study. This has subsequently been confirmed by CES (2010).

statistically significant differences were found in the mean dried weight at day 60 post hatch of the treatment groups compared with the pooled control group. The mean dried weight of the larvae was 0.239 g in the control group and 0.238 g in the solvent control group (pooled control 0.239 g). The mean dried in the treatment groups was in the range 0.236 g to 0.246 g.

Overall, this study is of good quality (valid without restrictions). The overall 90-d NOEC is ≥14 µg/L, the highest concentration tested.

- Parrott *et al*. (2010) performed a FELS test with the egg to embryo-larval stages of Fathead Minnow (*Pimephales promelas*), over a total exposure period of 65 days (approximately five days in the egg stage and 60 days in the larval to juvenile stages). A total of five nominal D5 concentrations were used in the test (1.25, 2.64, 5.59, 11.8 and 25.0 µg/L). The test system was a flow-through system and a solvent (dimethyl sulphoxide) was used to prepare the stock solutions. The concentration of solvent in the exposure tank was 20 µL/L. A control and solvent control were run in each case.[21]

  Four replicates were used for each exposure level, with thirty eggs in each replicate at the start of the test. The key time points during the study were at day 28 post hatch, where the fish were thinned to 18 per replicate, and day 48 post hatch, where the fish were thinned to 12 per tank.

  The concentration of D5 in the water was determined analytically at intervals during the study. The concentrations measured were found to be consistent over the entire exposure period, and the mean concentrations measured were 0.253, 0.815, 1.68, 3.63 and 8.66 µg/L at the five treatment levels.

  No significant adverse effects were found between any of the treatment groups and the control groups for any of the endpoints monitored in the study (egg survival, percentage hatch, and survival, length weight and condition factor of the fish at days 28, 48 and 60 post hatch). There was a statistically significant increase in the condition factor in the two highest exposure groups compared to the control groups by day 60 post hatch but this was not considered to be an adverse effect.

  Overall the study is considered to be of good quality (valid without restriction). The 60-d NOEC is ≥8.66 µg/L, the highest concentration tested.

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[21] The first trial was carried out using nominal concentrations between 2.5 and 50 µg/L but was terminated at days 18 and 19 post-hatch owing to poor control survival (thought to result largely from the use of some inferior eggs in the experiment). A second trial using the same nominal exposure concentrations was also terminated early (on days 11 and 13 post-hatch) when a malfunction in the water filtration system resulted in a large number of larval deaths. The concentration of solvent in the exposure tank was 40 µL/L for both trials.

It is therefore concluded that D5 is not toxic to fish early life stages. No data are available to determine whether it affects fish reproduction.

D5 is not toxic to *Daphnia magna* in either short-term studies or a 21-day reproduction study:

- A reliable unpublished chronic *Daphnia* reproduction study (full details of which are reported in the CSRs) was carried out under static renewal conditions (the test solution was renewed every 24 hours) using sealed vials with no headspace to minimise loss of D5 from volatilisation. The substance tested was ^{14}C-labelled D5 with a radiochemical purity of 100 per cent. A total of five exposure concentrations were tested (the time-weighted mean measured concentrations were determined as 1.0, 1.7, 3.5, 7.2, and 15 µg/L). A control and solvent control (acetone at a concentration of 0.1 mL/L) were also used. No significant (p = 0.05) differences were seen in the response of the two control groups, and no significant differences were seen between any of the treatment groups and control groups for parent survival (95 per cent the pooled controls; 100 per cent in all treatment groups), mean cumulative number of offspring released per female (146 in the pooled controls, 138–150 in the treatment groups), or growth of the parent [as measured by both mean body length (4.99 mm in the pooled controls, 4.99–5.05 in the treatment groups) and dry weight (1.12 mg in the pooled controls, 1.15–1.20 in the treatment groups)].

  Therefore the 21-day NOEC from this study is ≥15 µg/L, the highest concentration tested.

D5 is not toxic to algae:

- A reliable unpublished OECD TG 201 algal toxicity study with *Pseudokirchneriella subcapitata* is summarised in the CSRs (a second study is of uncertain reliability because the actual exposure concentrations are unclear, and the test system appears to have been an open static system, which means loss by volatilisation may have occurred). The test was carried out using sealed containers with no headspace (sodium bicarbonate was added to the test medium to ensure sufficient algal growth; the control response was satisfactory). A single test concentration of D5 was used (the initial mean measured concentration was 12 µg/L) and the test substance was added to the medium as a solution in acetone. No effects were seen on either growth rate or biomass. The 72-hour NOEC was therefore determined as ≥12 µg/L. This result is based on the initial measured concentration of D5 in the test. No information on concentrations of D5 at other time points during the test was given.[22] It is assumed that this concentration was effectively the solubility limit in the test media).

Long-term sediment toxicity studies are available for four species (*Hyalella azteca*, *Chironomus riparius*, *Caenorhabditis elegans* and *Lumbriculus variegatus*), although the test for one of the species (*Ca. elegans*) is of questionable validity. The lowest NOECs from these studies are 70 mg/kg dry weight for *Ch. riparius* (Krueger *et al*., 2008) and 62 mg/kg dry weight for *H. azteca* (Norwood *et al*., 2010). If the results are normalised to a standard organic carbon content of 5 per cent, the lowest $\text{NOEC}_{\text{standard}}$ is 109 mg/kg dry weight for *Ch. riparius*. For comparison with pelagic organisms (assuming that the effects occur due to exposure via pore water), the equivalent pore water concentration is estimated to be around 0.014 mg/L using the methods outlined in the REACH Guidance. This value is close to the solubility limit for D5 in pure water (0.017 mg/L at 23 °C).

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[22] Environment Canada (2008) indicates that the concentration had fallen to ca. 2 µg/L at the end of the test. This would give a mean exposure concentration over the 96-hour period of 7 µg/L.

D5 has been shown to cause effects in long-term toxicity tests on two plant species (barley *Hordeum vulgare* and durum wheat *Triticum durum*), springtails *Folsomia candida* and earthworms *Eisenia andrei*. The affected plants are monocots; no significant effects were noted with two dicot species (red clover *Trifolium pretense* and radish *Raphanus sativus*) (Soil Toxicology Laboratory, 2010; Velicogna *et al*., 2012). The lowest reported IC_{50} was 209 mg/kg dry weight (dw) for barley (individual dry mass of barley roots after 14 days; other effects were noted at higher concentrations on shoot and root length). The organic carbon content of the soil used in the test was not given and so it is not possible to normalise the reported effect concentrations to a standard organic carbon content of 2 per cent, nor is it possible to estimate the equivalent pore water concentration at these exposure levels.

The results are based on the initial concentration of D5 in soil. Significant loss through volatilisation would be expected in the test system used and so the actual exposure concentrations (and hence effect concentrations) may be significantly lower than those based on the initial concentration.

B.8 PBT and vPvB assessment

In May 2015 the MSC unanimously agreed that both D4 and D5 are very persistent and very bioaccumulative (vPvB) substances[23]. The MSC was not asked to consider the T criterion.

Persistence: *A substance is considered to be persistent (P) if it has a degradation half-life >60 days in marine water or >40 days in fresh or estuarine water, or >180 days in marine sediment or >120 days in freshwater or estuarine sediment or soil. A substance is considered to be very persistent (vP) if it has a half-life >60 days in marine, fresh or estuarine water, or >180 days in marine, freshwater or estuarine sediment, or soil.*

Bioaccumulation: *A substance is considered to be bioaccumulative (B) if it has a bioconcentration factor (BCF) >2,000 L/kg or very bioaccumulative (vB) if it has a BCF >5,000 L/kg. REACH Annex XIII also allows a weight of evidence approach.*

Toxicity: *A substance fulfils the toxicity criterion (T) when:*

- *the long term no observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01 mg/L (10 µg/L); or*
- *the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B) or toxic for reproduction (category 1A, 1B or 2); or*
- *there is other evidence of chronic toxicity, as defined by the classifications STOT (repeated exposure), category 1 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) or category 2 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume, according to Regulation (EC) No 1272/2008.*

B.8.1 PBT/vPvB assessment of D4

Persistence

D4 is not readily biodegradable. Although it can hydrolyse in pure water with a relatively short half-life (e.g. 16.7 days at pH 7 and 12 °C), it is highly adsorptive to organic matter in suspended solids, sediment and soils, and this adsorption may limit the rate of hydrolysis in natural waters. A conclusion about overall persistence in natural waters cannot be drawn in the absence of definitive data.

In freshwater sediment, D4 has a degradation half-life of the order of 242 – 365 days at 24 °C, expected to be longer at lower temperatures. Persistence in sediment is also supported by the sediment core data from Lake Pepin, USA.

The available data do not allow a reliable soil degradation half-life to be derived.

It is therefore concluded that D4 meets the Annex XIII criteria for both a persistent (P) and a very persistent (vP) substance in sediment (a decision cannot be made for water or soil).

Bioaccumulation

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[23] http://echa.europa.eu/about-us/who-we-are/member-state-committee/opinions-of-the-msc-adopted-under-specific-echa-s-executive-director-requests

The key data for D4 are a measured fish BCF >10,000 L/kg, which clearly meets the Annex XIII criteria for B and vB.

In addition, a BMF above one (up to 4.6) has been reported in fish dietary studies, leading to significant whole body concentrations (up to 100 mg/kg ww).

Field studies typically show that trophic dilution is occurring in many aquatic food webs. However, there may be biomagnification between some parts of the food web, and there is unequivocal evidence that D4 can be found in a wide range of organisms (particularly fish and aquatic invertebrates but also birds and mammals) throughout aquatic food chains, including top predators. Concentrations in both field and laboratory studies are comparable to levels of other substances that are considered to meet the vB criteria. Although accumulation in air-breathing mammals is expected to be lower than in other aquatic organisms, the top predator in some food chains may not be air breathing (e.g. sharks, which have not been sampled).

Overall, D4 meets the Annex XIII criteria for both a bioaccumulative (B) and very bioaccumulative (vB) substance based on the fish BCF, supported by the other available data.

Toxicity

D4 has a long-term fish NOEC of around 4 – 6 µg/L (although there is some uncertainty in this value) and a long-term $NOEC_{survival}$ of 7.9 µg/L for *Daphnia magna*. Significant toxicity to invertebrates is also apparent in sediment organism studies. In addition, it is classified as toxic to reproduction category 2. Therefore it can therefore be concluded that D4 meets the Annex XIII criteria for toxicity (T) based on both aquatic and mammalian end points.

Conclusion

D4 meets the REACH Annex XIII criteria for both a PBT and vPvB substance.

D4 is also a vPvB containing substance, as D5 may be present as an impurity above 0.1 per cent w/w (see Section B.8.2).

B.8.2 PBT/vPvB assessment of D5

Persistence

D5 has a hydrolysis half-life of 365 days at pH 7 and 12 °C (freshwater), and 64 days at pH 8 and 9 °C (marine water), and is not readily biodegradable. It has a degradation half-life in freshwater sediment of the order of 800-3,100 days at 24 °C, expected to be longer at lower temperatures.

The available data do not allow a reliable soil degradation half-life to be derived.

It is therefore concluded that D5 meets the Annex XIII criteria for both a persistent (P) and a very persistent (vP) substance in water and sediment (a decision cannot be made for soil).

Bioaccumulation

The key data for D5 are a measured fish BCF >10,000 L/kg, which clearly meets the Annex XIII criteria for B and vB.

In addition, a BMF above one (up to 3.9) has been reported in fish dietary studies, leading to significant whole body concentrations (up to 111 mg/kg ww).

Field studies provide a mixed picture of the bioaccumulation behaviour of D5. It appears that trophic magnification is possible for some pelagic food webs, and BMFs are above one for some fish feeding relationships. There is unequivocal evidence that D5 can be found in a wide range of organisms (particularly fish and aquatic invertebrates but also birds and mammals) throughout aquatic food chains, including top predators. Concentrations in both field and laboratory studies are comparable to levels of other substances that are considered to meet the vB criteria.

Although accumulation in air-breathing mammals is expected to be lower than in other aquatic organisms, the top predator in some food chains may not be air breathing (e.g. sharks, which have not been sampled).

Overall, D5 meets the Annex XIII criteria for both a bioaccumulative (B) and very bioaccumulative (vB) substance based on the fish BCF, supported by the other available data.

Toxicity

The available aquatic toxicity data for fish, invertebrates and algae show that D5 does not cause toxic effects in either short- or long-term studies at concentrations up to (or close to) its water solubility limit. Therefore it can be concluded that D5 does not meet the Annex XIII T criteria based on the available data on its toxicity to pelagic organisms.
D5 is toxic to sediment and soil organisms. The calculated pore water concentration in the sediment tests corresponding to the lowest NOEC is around 0.014 mg/L (close to the water solubility limit of the substance), so the sediment data are consistent with the substance not meeting the Annex XIII criteria. It is not possible to carry out the calculation for the available soil toxicity data.

D5 is not classified for human health hazards relevant to the Annex XIII T criteria. No adverse effects have been observed in an avian reproduction test. Other toxic effects (e.g. liver enlargement, increased incidence of uterine endometrial adenomas and adenocarcinomas) may be relevant for wildlife, but are not considered sufficiently adverse to trigger the criteria. There may be a data gap for reproductive effects in mammals following oral exposure.

Overall, D5 is not considered to meet the T criteria on the basis of the available evidence.

Conclusion

D5 meets the REACH Annex XIII criteria for a vPvB substance.

D5 is also a PBT/vPvB containing substance, as D4 may be present as an impurity above 0.1 per cent w/w (see Section B.8.1).

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

As described in Section B.4, D4 and D5 partition significantly to air, and re-deposition appears to be a relatively insignificant process. Consequently, air emissions have not been considered, and the exposure assessment is focussed instead on releases to waste water (which are also linked to emissions to land via sewage sludge spreading) and surface water. It is important to note that both D4 and D5 are efficiently removed by many types of WWTP, especially if they have an aeration step (see Section B.4.2.2). Removal efficiency is typically above 95 per cent, and so it is most appropriate to consider surface water (and sediment) concentrations when considering relative levels of risk from different applications (N.B. these substances do not appear to persist in soils).

By far the most significant use of these substances is as chemical intermediates (monomers) in the production of various types of silicone polymers, in which they can remain as residual impurities. These polymers have a very wide range of uses. There is also a relatively small direct use in PCPs and household cleaning products.

The starting point for the exposure assessment was a review of the REACH Registrants' CSRs (as updated in 2014) to identify exposure scenarios with relevant emissions to waste water (Table 9).

Table 9 D4 and D5 exposure scenarios (ES) and emissions to air and waste water (Reconsile Consortium 2014a&b)

Exposure Scenario	D4 CSR ES no.	D5 CSR ES no.	Emission to Air	Emission to waste water
Production and use as a chemical intermediate at the same site	1	1	✓	✓ (negligible)
Use as a monomer*	2	2	✓	✓ (negligible)
Use as a chemical intermediate*	3	3	✓	✓ (negligible)
Use in emulsion polymerisation*	4	4	✓	✓ (negligible)
Use in non-metal surface treatment	5	-	Environmental exposure not assessed as considered negligible	
Use in electronics applications	6	5	Environmental exposure not assessed as considered negligible	
Use in textile applications	7	6	Environmental exposure not assessed as considered negligible	
General product formulation, predominantly PCPs	8	-	✓	✓
Industrial use of sealants	9	7	Environmental exposure not assessed as considered negligible	
Professional use of sealants	10	8	Environmental exposure not assessed as considered negligible	
Use in coatings	11	9	Environmental exposure not assessed as considered negligible	
Professional and consumer use of coatings	12	-	Environmental exposure not assessed as considered negligible	
Formulation of PCPs (PCPs)	-	10	✓	✓
Use of PCPs	-[x]	11	✓	✓
Use of household care products in industrial settings[+]	14	12	Environmental exposure 'not relevant'	
Professional and consumer use of washing and cleaning products[+]	15	13	Environmental exposure 'not relevant'	
Professional and consumer use of polishes and waxes[+]	16	14	Environmental exposure 'not relevant'	
Dry cleaning	-	15	Environmental exposure 'not relevant'	

Exposure Scenario	D4 CSR ES no.	D5 CSR ES no.	Emission to Air	Emission to waste water
Formulation of medical adhesives and pharmaceuticals	-	17	Environmental exposure 'not relevant'	
Processing aid in the pulp manufacturing industry	-	18	Environmental exposure not assessed as considered negligible in relation to other exposure scenarios[24].	
Use as laboratory agent	17	19	Environmental exposure not assessed as considered negligible in relation to other exposure scenarios	
Formulation and use of lubricants and release agents	18	16	Environmental exposure 'not relevant'	
Formulation of household care products[25]	-	20	✓	✓
D4/D5 present in silicone polymers used in PCPs	19	21	✓	✓
Polymers with residual D4, but with environmental emissions to air only	20	-	✓	×
D4/D5 present in silicone polymer antifoaming agents used in pulp and paper industry	21	22	×	✓
D5 present in silicone polymer antifoaming agents used in detergents	-	23	×	✓
D4/D5 present in silicone polymer antifoaming agents used in the oil drilling sector	22	24	×	✓

Note: * Emission scenarios combined as 'chemical intermediate off-site'.
× The lead Registrant removed this exposure scenario from their CSR in 2014. In the 2010 registration, it was identified as ES no. 13.
+ Emission scenarios combined as 'household products use by general public'.

Further details have been provided by both the Registrants (e.g. in socio-economic analysis (SEA) reports) and the cosmetics industry via the EU trade association Cosmetics Europe (formerly COLIPA) (e.g. amounts of D4 and D5 used). Aquatic emissions have subsequently been quantified using this industry information. Given the nature of the hazard and risk, total releases at the regional/continental scales are more relevant than local releases. However, Predicted Environmental Concentrations (PECs) have been estimated for those applications with significant releases to waste water, for comparison with the available monitoring data as a reality check.

Based on the information provided in the CSRs and SEA reports, the following exposure scenarios are considered to have the greatest potential to generate significant aquatic emissions and so were subject to more detailed assessment:

- Formulation of PCPs
- Use of PCPs
- D4/D5 present in silicone polymers used in PCPs
- D4/D5 present in silicone polymer antifoaming agents used in detergents
- D4/D5 present in silicone polymer antifoaming agents used in the pulp and paper industry

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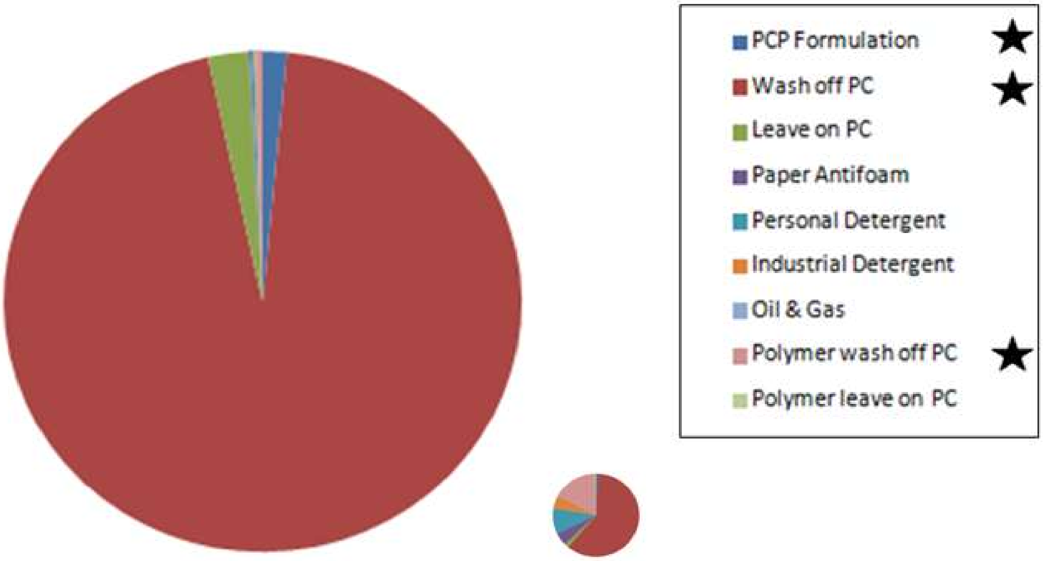
[24] The quantification of environmental emissions from this exposure scenario is presented in the SEA report for this sector (AMEC, 2013e).

[25] Relabelled ES 25 in AMEC (2013b). Although aquatic emissions are possible, the quantity used is over fifty times lower than that used to formulate PCPs, and since the use of this product type appears to have limited potential for environmental emissions, it is not considered further (details are provided in the confidential appendix).

- D4/D5 present in silicone polymer antifoaming agents used in the oil drilling sector[26]

Full information is provided later in this section, but Figure 2 (based on Table 10 in Section B.9.3.7) provides an overview of the total releases to surface water that have been identified for the purposes of this dossier. The area of the pie chart indicates the relative emissions for each substance; the amount of D4 is 40 times less than the amount of D5. It is also worth noting that the minor emissions (e.g. leave-on PCP) are sometimes upper limits and are probably even smaller in reality. N.B. The dossier submitter has performed a sensitivity analysis with different tonnage data and assumptions about release rates (See Appendix B.7).

Figure 2 Relative contributions to the total emissions of D4 (small circle) and D5 (large circle) to EU surface waters in 2012 (PC: personal care)



★ Use affected by the proposed restriction

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[26] Other uses of silicone polymer-based antifoams exist (e.g. in the food and WWTP industries). This type of product seems to make a very small contribution to wastewater emissions (see Section B.9.3.4-B.9.3.6). In the absence of data on amounts and impurity content, they have not been considered further.

B.9.1.1 Summary of the existing legal requirements

At present there is no EU legislation that specifically controls the use and/or environmental emissions of D4 or D5.

D4 and D5 are both registered under the **REACH Regulation**. The recommended environmental RMMs are effluent treatment in a WWTP and/or use of air emission abatement equipment (depending on the exposure scenario) to achieve PEC/PNEC ratios below 1, in the judgment of the Registrants. None of the CSRs identifies D4 or D5 as a PBT/vPvB substance, and so the RMMs do not specifically seek to minimise emissions. During Public Consultation the Registrants updated their CSRs to reflect on the MSC opinion about the PBT/vPvB properties, but still conclude that the substances are not PBT and vPvB. The Registrants updated their Risk Management Measures (RMMs) to show which measures are needed to achieve low emissions and/or minimise environmental releases. It is not clear whether the proposed RMMs will reduce all relevant emissions as it appears to be for PCP formulation sites only. This information can be considered if the need for further risk management is reviewed in due course (in the light of further monitoring data and any voluntary product stewardship).

Sites which manufacture or use D4 or D5 in large quantities (e.g. for the production of polymers and amorphous silica) may be subject to relevant legislation regarding air, land and water quality, in particular the **Industrial Emissions Directive (Directive 2010/75/EC)**. This aims to achieve integrated prevention and control of pollution arising from specific industrial activities, although some sites may be excluded by size considerations. Emission limit values (or equivalent) prescribed by the Member States' Competent Authorities are based on the best available techniques (BAT) without prescribing the use of one specific technique or technology and taking into consideration the technical characteristics of the installation concerned, its geographical location and local environmental conditions. BAT reference (BREF) documents have been developed for different industry sectors. The BREF on organic fine chemicals covers the manufacture of D4/D5 and the formulation of PCPs, but there are no specific handling measures for this type of substance in any part of the life cycle.

Regulation (EC) No. 1223/2009 (the Cosmetics Regulation)[27] governs the safety of substances used in cosmetic products from a consumer health perspective. However, environmental safety is explicitly excluded, and subject to the REACH Regulation.

The aim of the **Solvents Emissions Directive 1999/13/EC (as amended by Directive 2004/42/EC)** is to prevent or reduce the direct and indirect effects of emissions of volatile organic compounds (VOC) into the environment, mainly via air, for certain activities. Although D4 and D5 are both VOCs, it appears that none of the uses of D4 fall within scope. D5 is within scope because of its use in dry cleaning, and possibly also because of its use as a cleaning solvent and the manufacture of pharmaceutical products. It should be noted that in contrast to other organic compounds of similar reactivity, the breakdown of D4 and D5 in the atmosphere does not lead to the formation of ground-level ozone.

The **Waste Framework Directive (2008/98/EC)** sets out basic requirements for the management of defined wastes (including waste oils[28]). The classification for D4 under

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[27] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

[28] This could apply to silicone oils made from D4. Waste waters are excluded from the scope of this Directive to the extent that they are covered by other Community legislation.

the CLP Regulation could result in any waste mixture containing D4 at a concentration above 2.5% w/w being considered as hazardous waste. However, this legislation has limited applicability to the uses of D4 with the greatest aquatic emissions (i.e. consumer products and waste water emissions from specific industrial applications). Since D5 is not classified under the CLP Regulation for environmental endpoints, any waste mixture containing it would not be considered to be hazardous waste due to its presence.

The **Sewage Sludge Directive (86/278/EEC)** regulates the use of sewage sludge in agriculture, but there are no specific requirements for D4 or D5.

The **Water Framework Directive (2000/60/EC)** has no specific provisions for D4 or D5, but is considered as a risk management option in Section E.

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

The REACH Registrants do not identify either D4 or D5 as a PBT or vPvB substance so do not recommend any specific RMMs to limit emissions, other than an assumption that aquatic discharges will be released to a ‘standard’ WWTP, with an assumed removal efficiency of 96.4 per cent for D4 and 95.3 per cent for D5. The operational conditions and RMMs are therefore inadequate to ensure that emissions are minimised.

B.9.2 Human exposure

PBT/vPvB assessment requires an identification of the likely routes by which humans and the environment are exposed to the substance (REACH Annex I/4.2). Various sources and pathways are relevant to an assessment of human exposure to D4 and D5, such as exposure from food (e.g. fish), drinking water, inhalation of indoor and outdoor air, ingestion of dust as well direct contact with products containing them. Measured data for assessing human exposure are almost non-existent.

The most significant source of human exposure is likely to be through dermal or oral contact from the use of PCPs by consumers. The assessment of human health risks from this application is exempt from REACH. Under the Cosmetics Regulation (EC) No. 1223/2009, the published Scientific Committee on Consumer Safety (SCCS) opinion is that cyclomethicone (D4, D5 and D6) does not pose a risk for human health when used in cosmetic products (SCCS, 2010) (though a revised opinion is being drafted).

On this basis, no further quantification of human exposure has been performed.

B.9.3 Environmental exposure

This section provides additional detail for those parts of the life cycle that are believed to make the greatest contribution to aquatic emissions, as highlighted in Section B.9.1. Data were provided by Cosmetics Europe and the REACH Registrants[29]. The overall releases are summarised in Tables 10 and 11.

B.9.3.1 Formulation of PCPs

Tonnages

Cosmetics Europe (AMEC (2013f) and subsequent personal communication) performed

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[29] Tonnage information supplied by Cosmetics Europe has been claimed as confidential. Full details are given in a confidential appendix to this report, and the data have been replaced by ranges or limit values in this public report.

a member survey to establish the use pattern of D5 in PCPs in the EU-27 during 2012. The data relate to direct use of the substance (i.e. the survey did not consider the amounts of D5 that may be present indirectly as a result of impurities in other substances or polymers). Details of these calculations and the assumptions made are in the confidential appendix. All subsequent figures below are based on the results of this survey, but have been anonymised.

Using the information from the survey the quantities of D4 and D5 was estimated to be up to 25,000 tonnes for D5. For comparison, the REACH Registrants' exposure scenarios are based on a D5 volume of 9,000 tonnes / year for wash-off PCPs and 6,000 tonnes/year for leave-on PCPs, i.e. a total of 15,000 tonnes/year. This is lower than the amount estimated to be used during PCP formulation above based on Cosmetics Europe data. In addition, the amounts assumed to be used in wash-off PCPs by the Registrants is clearly significantly higher (and the amounts in leave-on PCPs lower) than suggested by the downstream user data. Further correspondence with the cosmetics sector suggests that some of this discrepancy may be due to the export of PCPs after they have been formulated, and also that there may be a gradual move by the sector away from the use of D5 in wash-off PCPs in the last couple of years.

In summary, whilst the approach based on market value share might over-estimate the total amounts of D5 directly used in PCPs, in the absence of further information on the indirect sources such as its presence as an impurity in higher molecular weight homologues and other substances, the estimate of **15,000 – 25,000 tonnes/year** of D5 formulated and supplied in PCPs to the EU-27 based on the Cosmetics Europe data was preferred as a reasonable worst case, since the downstream user industry are likely to be more aware of actual volumes used for this purpose than the D5 manufacturers/importers. However, the dossier submitter recognises that there is uncertainty in these figures, as well as the split between wash-off and leave-on PCPs.

New information

Non-confidential information submitted by Cosmetics Europe during the Public Consultation (comment #1452) indicates that the supply tonnage of D5 is 750 tonnes in wash-off PCPs and 14,350 tonnes in leave-on PCPs. These figures were agreed between the REACH Registrants (i.e. the substance manufacturers/importers) and Cosmetics Europe, and so should represent a much higher proportion of the overall EU market than the original Cosmetics Europe survey. It is possible that some users still exist that are not covered by these data (e.g. a company importing D5 from outside Europe below 100 tonnes/year does not need to register until 2018; several PCP manufacturers are not members of Cosmetics Europe). However, the amounts are likely to be relatively small, and the data provided are thought to include some tonnage that is subsequently exported. The dossier submitter therefore considers that the new information is likely to be close to the amount of substance actually on the market. It therefore supersedes the tonnage estimates used in the original proposal. This new information has been used for a reanalysis of emissions in the sensitivity analysis reported in Appendix B.7 and will be referred to in the remainder of this document as the "updated" tonnage.

The direct use of D4 in PCPs has been declining rapidly since 2002/3, as it has been substituted by D5 (AMEC (2013f)). There is believed to be very little direct use of D4 in PCPs remaining in the EU (the lead registrant removed this exposure scenario from its CSR in 2014). However, D4 will also be present in PCPs as an impurity in D5 and other substances/polymers (see Section B.2).

The actual quantity of D4 used in PCPs is unknown. The lead Registrant assumes that the total quantity of D4 is 0.015 times (1.5%)[30] that of D5 (from both direct and indirect sources). This is considered to be the most appropriate way to take account of the presence of D4 in PCPs in the absence of specific information.

Releases

In the CSRs (Reconsile Consortium, 2014b), emissions from the formulation of PCPs are calculated using an assumption that the majority of sites (60%) have a release factor of 0.09% with the others (40%) having a lower release factor of 0.009%. This is based on the approach adopted by EA (2009a&b), which used site-specific release factors for a number of representative sites[31].

Applying these release factors to the annual formulation tonnage calculated above results in an estimated annual wastewater emission of D5 of <25 tonnes at the continental scale (<2.5 tonnes at the regional scale). For comparison, the estimated annual waste water emission on a continental scale according to the CSRs is 8.6 tonnes and 0.86 tonnes at the regional scale.

The estimated annual wastewater emission of D4 of <0.05 tonnes at the continental scale (<0.005 tonnes at the regional scale). For comparison, the estimated annual waste water emission on a continental scale according to the CSRs would be 0.58 tonnes and 0.058 tonnes at the regional scale.

B.9.3.2 Direct use of D4 and D5 in PCPs

As described in Section B.9.3.1, the total amount sold in wash-off PCPs in the EU-27 is assumed to be <1,000 tonnes/year for D5. This is expected to correspond to <15 tonnes/year for D4.

Similarly, the total amount used in leave-on PCPs is <24,000 tonnes/year for D5, which corresponds to <360 tonnes/year for D4. [N.B. This estimate has been superseded in the sensitivity analysis reported in Appendix B.7]

Substitution of D5 in wash-off products may already be underway, as hinted at by the differences in use volumes reported by the producers and their downstream users. Representatives of the cosmetics industry have indicated that of new products placed on the European market between March 2012 and March 2013, only 2% of 2,500 'rinse-off' shampoos and conditioners contained D5[32] (AMEC (2013f)). This source does not indicate how many existing PCPs contain D5, and in the absence of further information on expected trends from the industry, no assumptions can be made about the extent to which this would affect the exposure calculations.

Releases

A small number of studies have examined the potential for D5 to be released following application of PCPs to the human body (full details are provided in Appendix B.2).

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[30] This figure was provided by the silicone polymer manufacturers, not the downstream users who make PCPs.

[31] A survey of 39 cosmetic formulation sites was reported by the Cosmetic, Toiletry & Perfumery Association (CTPA), including 36 non-UK formulation sites of the major multinational European PCP formulators. This contained site-specific information (mainly amounts of D5 used and details of the effluent treatment and water flows at the sites). These companies represented around 80 per cent of the total EU PCP market.

[32] This information is taken from the Mintel Global New Product Database. The geographical category "Europe" includes some countries (e.g. Turkey and Ukraine) that are not part of the EU-27, so this could overestimate use in Europe. However, a search for new products containing cyclomethicone (in which D5 is a significant constituent) has not been performed, so the figure could also be an underestimate.

Gouin *et al*. (2013) found that considerably less than 0.1% w/w of the D5 contained in leave-on PCPs such as antiperspirants and deodorants is likely to be available for washing off 24 hours after application. This is explained by the high volatility of the substance. Montemayor *et al*. (2013) also found that the fraction washed off 8 hours after application was below 0.1% w/w. Assuming that these studies are reasonably representative for all other leave-on PCPs, a release fraction of 0.001 (i.e. 0.1%) to waste water can be assumed for this product type as a reasonable worst case (this will cover use periods of less than 24 hours before washing). Although likely to be an over-estimate, this value will also include any substance that deposits on clothing that can subsequently be laundered.

Montemayor *et al*. (2013) (and HTR, 2011) also investigated waste water releases from a non-spray rinse-off conditioner containing D5. The paper cites a release rate of around 40%, but this is based on an average concentration from loading controls that includes an apparent dosing error. When corrected figures are used, the average release was around 73% (range: 54 – 93%, based on the 95% confidence intervals). It is unclear whether the method accurately mimics the use of the product by the majority of people (e.g. in terms of the amount of product applied or the time the product is left on the hair), or the volume/temperature of water normally used to wash hair. The representativeness of this study for this particular product type (considering that only 15 human hair tresses were included) and its applicability to other types of wash-off PCP containing D5 are both unknown.

The published Canadian assessments for D4 and D5 do not specify an environmental release rate for wash-off PCPs (Government of Canada, 2008a&b). However, an Expert Statement from the Canadian Cosmetic Toiletry and Fragrance Association submitted to the Canadian Board of Review for D5 (BoR, 2011) claimed a release to waste water of approximately 40% for PCPs such as hair conditioners that are rinsed off after in-shower use. The dossier submitter has established that this release figure is based on the study of Montemayor *et al*. (2013) (R van Egmond, *pers. comm*.), so is incorrect.

It seems likely that some of the D4/D5 in wash-off PCPs may be retained on the hair or body, and there is some evidence to suggest that there may be losses due to volatilisation for some products that are intended to be left on for a few minutes before wash-off (as indicated by Montemayor *et al.*, 2013). However, it is uncertain what proportion of wash-off PCPs is intended to be left on for several minutes in the shower or whether the majority of consumers actually use them in this way. The reasonable worst case assumption in the absence of reliable quantitative data for relevant product types is that all wash-off PCPs are entirely released to waste water in normal use, i.e. the release fraction is 1.00 (100%). This is consistent with the assumption made in the REACH registrations (Reconsile Consortium, 2014a&b)[33].

Applying these release rates to the tonnages given above results in a release to waste water of <1,000 tonnes/year for D5 and < 15 tonnes/year for D4 in wash-off PCPs, and

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[33] Previous versions of the CSRs used an estimated D5 release of 60% to waste water and 40% to air (evaporation) during use of wash-off PCPs. This assumption is explained in comment #1431 from the Public Consultation, which includes a report by PFA (2013). This performed some simplistic modelling that attempted to estimate the amount of D5 that may be evaporated during normal use under equilibrium conditions. The variables included the volume of product, the volume of air with which the product equilibrates before any wash down the drain (dependent on time and mode of use), and the "product to air" partition coefficient (estimated as being 10-fold larger than the octanol to air partition coefficient, on the grounds that products will contain a range of ingredients in formulations designed to retain the D5 within the product matrix). The amount of D5 was not a variable. For wash-off products, the key variable was the volume of air that can be considered as the immediate zone of contact around the user. A volume of up to 1 m^3 was assumed ("in line with occupational exposure modelling"). It was found that the fraction released to waste water was most probably in the range 20 to 80%, and that modelling to achieve more than 90% to water required "extreme assumptions about volume of product and air", and was therefore considered unlikely. However, the report does not really provide any further justification for the selection of 60% as the default release rate. Since it is highly unlikely that a product will achieve equilibrium during the short time it will be in use, the dossier submitter does not consider this modelling to be reliable.

ca. <25 tonnes/year for D5 and <1 tonne/year for D4 in leave-on PCPs (the figures for leave-on PCPs may be over-estimates).

New information

Applying these release rates to the updated tonnages results in a release to waste water of 750 tonnes/year for D5 and 11.25 tonnes/year for D4 in wash-off PCPs, and ca. 14 tonnes/year for D5 and <1 tonne/year for D4 in leave-on PCPs (the figures for leave-on PCPs may be over-estimates).

N.B. Following further discussion by the Risk Assessment Committee, the dossier submitter has re-evaluated the release rates from both wash-off and leave-on PCPs to better reflect the range of information available. These are discussed in the sensitivity analysis reported in Appendix B.7.

An additional exposure assessment for the use of D4/D5 in wash-off and leave-on PCPs, performed by the RAC Rapporteurs, is described in Appendix I. The RAC opinion is based on this additional analysis.

B.9.3.3 Use of silicone polymers in PCPs

Tonnages

Silicone polymers (and potentially other substances) used in PCPs can contain D4 and D5 as impurities. The residual concentrations of D4 and D5 in polymers are considered to be similar, based on information received from the Registrants (AMEC, 2013a&b), and these are considered to be available for release to the environment (polymer degradation is not considered to be a significant source of D4 and D5 in the aquatic environment; they will be removed to sludge in WWTP, and they are reported to degrade to dimethylsilanediols in soils, except at high loadings (e.g. Lehmann *et al*., 1994, 1995 & 2000)). These studies are described in more detail in section B.3.1.3 of Appendix B.

There is much less information available on the use of the polymers compared to the direct use of the substances in PCPs, although several different polymers are thought to be used for various applications. The survey undertaken by Cosmetics Europe did not collect data on the presence of D5 in PCPs due to its presence as an impurity in silicone polymers.

The use of silicone polymers in PCPs has been evaluated by PFA (2012) on behalf of the REACH Registrants. Assuming that 20,000 tonnes of silicone polymer are used in the EU each year, and assuming a maximum concentration of 0.5 per cent w/w for both D4 and D5, the total potential emission is 100 tonnes/year for each substance (PFA, 2012).

In the absence of other information the dossier submitter assumes that the distribution of the use of silicone polymers in PCPs follows the same pattern as the direct use of D5 in PCPs (i.e. ca. 96 per cent for leave-on applications). So, releases to waste water will be ca. 3.5 tonnes/year from wash-off products and ca. 93 tonnes/year for leave-on products, for each substance.

This is an area of remaining uncertainty, but is considered to be the most appropriate approach at present.

Releases

Release fractions for D4 and D5 within these polymers are considered to be the same as for direct use, i.e. 1.0 for wash-off PCPs and 0.001 for leave-on PCPs. So, releases to waste water will be ca. 4 tonnes/year from wash-off products and ca. 0.1 tonne/year for leave-on products, for both D4 and D5.

B.9.3.4 Silicone antifoaming agents for detergents

The 2010, 2012 and 2014 CSRs do not include any descriptive or quantitative information about this application, which appeared for the first time in an industry SEA in 2013 (AMEC, 2013a,b&c; PFA, 2012).

It appears that the use in detergents is relatively small compared to other sources (just over 3 tonnes/year of D4 and D5 are expected to be present in the polymers as impurities):

- Two-thirds of the silicone polymer antifoaming agents are used in domestic laundry detergents (in which D4 and D5 are present at levels “a lot” less than 0.1% w/w) with 100% release to domestic wastewater (Peter Fisk, pers comm.).

- The other third is used in the textile industry (with D4/D5 levels <0.01% w/w in the polymer), with the assumption that there is 100% release to wastewater, and treatment equivalent to a municipal WWTP at 90% of sites (i.e. 10% is discharged direct to surface water). This treatment is undertaken to meet local regulation of the activities carried out at the sites. Using the information from industry’s SEA, total continental releases of D4 and D5 to wastewater are expected to be 2 tonnes/year for domestic laundry detergents and 1 tonne/year from industrial (textile) detergents.

The resulting contribution to the overall emissions of these substances to surface waters is <1% for D5, and ca. 15% for D4 (emissions of both D4 and D5 are <1 tonne/year). The dossier submitter therefore currently considers these two scenarios to be of low relevance for further risk management.

B.9.3.5 Silicone antifoaming agents for the paper/pulp industry

The CSRs assume that 15,000 tonnes/year of silicone polymer are used as antifoaming agents in pulp processing and paper manufacture. The average D4 and D5 content is 0.15% w/w each, i.e. there are approximately 22.5 tonnes/year each of D4 and D5 (PFA, 2012).

Information provided to the dossier submitter by both the manufacturers of antifoam agents and the operators of pulp mills within the EU indicates that silicone-based antifoams are used in the pulp washing phase of chemical pulp production. The antifoam removes entrained air from within the pulp and surface foam generated during its production.

Chemical pulp is used to produce a high quality product, but with a much lower yield. Over 90% of chemical pulp production is via the Kraft process. Antifoam agents are necessary in this process as excessive foam reduces washing efficiency and can cause overflow from the washing vat, which in extreme circumstances can halt production. According to anecdotal evidence from the industry given via personal communication silicone-based antifoam agents are preferred in most cases to other antifoam agents due to high efficiency, efficacy and better antifoam removal from the pulp.

Addition rates of antifoam products vary between users depending on the process and technical and quality issues. However, due to issues with final product quality, the use of any antifoam is kept to a minimum.

The Emission Scenario Document (ESD) for the pulp, paper and board industry (OECD, 2009) indicates that all materials used for antifoaming should be assumed to be emitted via wastewater. The document indicates that effluents from these processes will at least undergo primary treatment before being discharged either to wastewater or surface water. The primary treated effluents are likely to undergo further biological treatment either on-site or off-site at a municipal WWTP[34].

The BAT Reference Document (BREF) for the pulp and paper industry (EC, 2015) indicates that use of antifoaming agents ("defoamers") occurs both within the paper making process and also during on-site wastewater treatment (see "Other applications" below). The antifoaming agents are considered to be predominantly discharged in the effluent. D4 and D5 however are much more volatile than the silicone polymers in which they are an impurity. Following information on the operating conditions in the Kraft process provided by the Finnish Safety and Chemicals Agency (responsible for regulating paper mills in Finland) (pers. comm.), it seems unlikely that residual D4 or D5 would be discharged to surface waters because:

- The chemical pulp washing process runs at a temperature of 80-95 °C. Some volatile components (including D4 and D5) are likely to be driven off at this stage. After the washing phase the separated weak black liquor is evaporated into dry matter. The temperature during evaporation rises up to ca. 135 °C. At this stage other volatile components, such as methanol and turpentine are recovered for further processing. Given the relatively high volatility of D4 and D5 it seems likely that they will also be volatilized at this stage and either released to air (with appropriate abatement measures) or present in the distillate as an impurity.

- The concentrated liquor from the evaporation stage is then incinerated at around 1000-1100 °C to generate electricity and heat. Any residual silicone polymers/siloxanes would be broken down in this process due to the very high incineration temperature.

- The air emissions containing the volatile components of the process are often controlled by steam stripping and then incineration. This process efficiently mineralizes all organic substances present. Another way to treat the air emissions is to discharge the condensates to the biological WWTP. Once discharged to waste water treatment the removal rate for both D4 and D5 is over 95%.

The relatively low concentration of residual D4 and D5 in silicone antifoams used in the pulp and paper industry suggests a maximum theoretical emission of between 1.5 and 22.5 tonnes/year for each substance, The practice of minimizing the amount used to ensure final product quality, the high temperatures of the pulp washing and evaporation stages causing volatilization of D4/D5, the incineration of liquors and steam-stripped air emissions, and/or the use of on-site and off-site waste water treatment for air emission condensates (leading to over 95% removal), implies that final releases of D4 and D5 to surface water from the paper and pulp industry will be *significantly* lower than 1 tonne/year for each substance across the whole EU. The actual amount cannot be estimated with certainty due to the lack of confirmatory analytical data for pulp mill effluents.

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[34] JS Seaman, Environment Agency (Regulated Industry - Site Based Regulation) (pers. comm.) suggested that 90% of UK paper mill sites would either discharge their wastewater for treatment at a municipal WWTP, or treat it on-site to an equivalent standard. The remaining 10% of sites discharge direct to surface water after onsite treatment.

B.9.3.6 Silicone antifoams for the oil/gas industry

Silicone polymer-based antifoam agents are used to eliminate foam in oil and gas production, refining and processing. In the CSRs, a total potential emission of four tonnes per year of both D4 and D5 was predicted due to their presence as a residual impurity in the polymers at an average concentration of 0.4% w/w in 1,000 tonnes/year of polymer (PFA, 2012). This application was assumed to result in a direct emission of 100% to surface (marine) waters.

- ***Use in drilling muds***: The presence of foams slows production and triggers maintenance operations, which is a particular problem on offshore rigs because of the limited space and weight restrictions (AMEC, 2013d). Antifoam agents are added to drilling muds to prevent foaming during separation of the cuttings from the fluid by centrifugation. One major oil producer (Statoil Norway, pers. comm.) has indicated to the dossier submitter that silicone-based antifoam agents were not used for this purpose in their operations in the EU in 2013. Due to the practice of recycling drilling muds following separation of the cuttings back into the well, some residual antifoam may be present in the muds.

- ***Use in well cementing***: Silicone-based antifoams are added to low viscosity cements used in well consolidation to remove bubbles from the cement and increase its strength. As the antifoam is added to the cement prior to use in the well, the application is considered by the operators to be well controlled. A small amount may be lost during application of the cement but this is considered minimal and infrequent so this application has not been considered further (Reconsile Consortium and Statoil Norway, pers comm.).

- ***Gas-oil separation***: Silicone-based antifoams are mainly used in gas-oil separation to prevent foam occurring during depressurisation (Reconsile consortium). Two main types of silicone polymer – i.e. PDMS (polydimethylsiloxane) and FS (fluorosiloxanes) – are used depending on process conditions and the nature of the gas/oil/water mix. The antifoam products typically contain 5-10% w/w silicone polymer, and the typical dosage of the antifoam products into the crude oil for separation is 5-20 ppm. Given the typical concentration for D4/D5 as an impurity in the silicone polymers (0.15% according to PFA, 2012), the range of residual D4 and D5 present in the crude oil is estimated to be 3 to 38 ppb. (Statoil Norway, pers comm.)

  The high octanol-water partition coefficients of D4 and D5 (6.49 and 8.02, respectively, as $\log_{10}$ values) mean that they will partition predominantly to the oil phase (i.e. the concentration in oil will be at least around 1000000 times higher than in water). This oil ends up at refineries, and it has been reported that residual D4 and D5 cause problems in crude oil refining (Reconsile Consortium and Statoil Norway, pers comm.), which is one reason why dosing of antifoams in separation is kept to a minimum.

  It is possible that a small amount of D4 and D5 may remain in the waste water produced during separation. Assuming that 4 tonnes/year is a reasonably accurate estimate of the total amount available for release, partitioning with oil should mean that there will be much less than 1 kg/year of each substance in the waste water. This wastewater is cleaned via flotation cells, hydrocyclones or different kinds of centrifuges, if necessary, prior to disposal. Disposal methods for the waste water depend on whether production is on- or offshore, but can include discharge back to the sea (provided the water meets local limits for oil content) or injection into the ground to provide pressure to extract further oil from the well, hundreds or thousands of metres below the ground/sea bed (Statoil Norway, pers. comm.).

In summary, the main source of D4 and D5 emissions from oil and gas operations is likely to be in waste water from gas-oil separation activities, which may undergo further treatment prior to discharge. Given the low dosage rates and the high partitioning of D4 and D5 into the oil phase, the use of silicone polymers in antifoams in the oil and gas industry is not considered to be a significant source of aquatic emissions.

B.9.3.7 Summary of releases

The releases estimated in Sections B.9.3.1 to B.9.3.6 are summarised in Table 10. Rather than present total emissions for each application, the releases are presented for both the regional and continental scales to allow subsequent exposure modelling for comparison with monitoring data.

An additional exposure assessment for the use of D4/D5 in wash-off and leave-on PCPs, performed by the RAC Rapporteurs, is described in Appendix I. The RAC opinion is based on this additional analysis.

Table 10 Summary of exposure scenarios contributing to aquatic emissions of D4 and D5 at the continental scale

Exposure scenario		**Substance**	**Amount on EU market (tonnes/year)**[35]	**Emission factor**	**Total EU emissions to waste water (tonnes/year)**[26]
PCP formulation		D4	<375	60% at 0.0009 40% at 0.00009	<0.25
		D5	<25,000		<25
Direct use of D4/D5 in PCPs	Wash-off	D4	<15	1.0	<15
		D5	<1,000		<1,000
	Leave-on	D4	<360	0.001	<0.36
		D5	<24,000		<24
Use of PCPs containing silicone polymers (indirect use)	Wash-off	D4	3.47	1.0	3.47
		D5	3.47		3.47
	Leave-on	D4	92.5	0.001	0.1
		D5	92.5		0.1
Use of antifoaming agents in domestic detergents		D4	2	1.0	2
		D5	2		2
Use of antifoaming agents in industrial detergents		D4	1	1.0	1
		D5	1		1
Use of antifoaming agents in the paper/pulp sector		D4	≤1	1.0	≤1
		D5	≤1		≤1
Use of antifoaming agents in oil and gas drilling)		D4	0.001	1.0	0.001
		D5	0.001		0.001

These data were used to estimate continental scale emissions to surface waters, assuming 80% connectivity to WWTP and WWTP removal efficiencies of 96% for D4 and 95% for D5 (with the exception of use of antifoaming agents in oil and gas extraction, which is assumed to be mainly discharged direct to marine waters). The results are presented in Table 11.

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[35] The data for PCP applications have been anonymised using limit values (the actual figures are provided in the confidential appendix to this report).

New information

The total amounts released to waste water based on the updated tonnages and the release assumptions made in the original proposal are 750 tonnes for D5 from wash-off PCPs and 14 tonnes from leave-on PCPs. Using a refined release rate of 73% for wash-off PCPs as discussed in Section B.9.3.2, the amount of D5 released is reduced to 547 tonnes. This refined release rate is based on the average release rate for wash-off PCPs from Montemayor *et al*. (2013) as discussed in Section B.9.3.2.

The relative contribution of each use to the overall emissions to surface waters is presented as a pie chart in Section B.9.1. The use of these substances in the PCP sector accounts for 99.5 per cent of D5 and 80 per cent of D4 emissions to the aquatic environment. The contribution of wash-off PCPs is 97 per cent for D5 and 78 per cent for D4. This is the most significant sector and the one being considered in the restriction proposal.

Table 11 Estimated total emissions of D4 and D5 to surface waters[36]

Application		**Percentage of total D4 emission**	**Percentage of total D5 emission**
Direct use	PCP formulation	1.8	2.8
	Wash-off PCP	59.9	93.8
	Leave-on PCP	1.6	2.5
Indirect use	Wash-off PCP	16.8	0.4
	Leave-on PCP	0.5	0.0
	Antifoaming agent for domestic detergent	9.7	0.2
	Antifoaming agent for industrial detergent	4.9	0.1
	Antifoaming agent for pulp/paper	4.9	0.1
	Antifoaming agent for oil & gas	0.0	0.0
Total		**100**	**100**

New information

The relative contributions based on the updated tonnages (and revised release rates) are broadly similar and do not change the conclusions (see the sensitivity analysis reported in Appendix B.7 for further details).

The contribution of silicone antifoams in detergents to overall emissions to surface waters is <1 per cent for D5 and ca. 15 per cent for D4, although the magnitude is the same for both substances. This scenario is therefore currently of low relevance in the context of this restriction proposal, and could be addressed through voluntary action by the relevant industrial stakeholders to reduce the level of impurities in the silicone antifoams.

The contribution of silicone antifoams in the pulp and paper sector to overall emissions to surface waters is <1 per cent for D5 and ca. 5 per cent for D4, although the magnitude is the same for both substances. This scenario is therefore currently of low relevance in the context of this restriction proposal, and could be addressed through voluntary action by the relevant industrial stakeholders to reduce the level of impurities in the silicone antifoams.

The contribution of silicone antifoams in the oil and gas sector to overall emissions to surface waters is negligible.

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[36] The emissions data are provided in the confidential appendix.

B.9.3.8 Comparison of release estimates with monitoring data

Estimation of surface water concentrations

As the release estimates are built on a number of assumptions, it is relevant to compare the resulting predicted environmental concentrations (PECs) with available monitoring data as a reality check. Given that the consumer and professional use of PCPs is by far the largest contributor to overall emissions for both D4 and D5, for simplicity this is the only part of the life cycle considered for this purpose.

The total amount of PCPs released to waste water at the continental scale is <20 tonnes/year for D4 and <1,000 tonnes/year for D5 (from direct wash-off and leave-on and polymer wash-off and leave-on scenarios) (Table 10).

As it is likely that the use of PCPs is spread evenly across the EU, regional releases are most relevant, and these are assumed to be 10 per cent of the overall emissions to waste water[37], i.e. <2 tonnes/year for D4 and <100 tonnes/year for D5. Release is assumed to occur over 365 days a year, and the region has a population of 2 × 10^7 inhabitants (ECHA, 2012). There is therefore a release to waste water of ca. 0.22 mg/capita/day for D4 and ca. 12 mg/capita/day for D5[38] from the use of PCPs (including direct uses and impurities in polymers). A 'standard' WWTP in the EU is assumed to serve a population of 10,000 inhabitants, with a flow rate of 2,000 m^3/d. ECHA (2012) recommends using an additional factor of 4 to take into account geographical or temporal peaks in use and release of a substance.

PECs for D4 and D5 have been calculated using the EUSES v2.1 environmental exposure model. PECs for surface freshwater (total and dissolved concentrations) and freshwater sediment are shown in Tables 12 and 13 for D4 and D5, respectively.

Table 12 Continental and regional PECs for D4

PEC	Continental	Regional	Local[39]
Surface water (total) (ng/L)	0.21	1.9	22.64
Surface water (dissolved) (ng/L)	0.21	1.8	22.64
Sediment (µg/kg wet weight (ww))	0.11	0.95	8.39

Table 13 Continental and regional PECs for D5

PEC	Continental	Regional	Local[40]
Surface water (total) (ng/L)	13	110	1,237
Surface water (dissolved) (ng/L)	0.1	81	1,237
Sediment (µg/kg ww)	61	521	3,985

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[37] It is noted that the Registrants used 5% for the regional emissions, based on a specific environmental release category. The dossier submitter has not assessed whether this is an appropriate value to replace the default value (10%) recommended in the ECHA guidance.

[38] The annual average consumption of D5 in PCPs in Canada was reported as 0.10 kg/capita/year or 283 mg/capita/day (Canadian Siloxane D5 Board of Review, 2011). The annual average exposure of D5 in PCPs in Canada was reported as 0.02 kg/capita/year or 53.7 mg/capita/day (Canadian Siloxane D5 Board of Review, 2011). This covers both wash-off and leave-on PCPs. The lead Registrant derived a use figure of 0.024 kg/capita/year for wash-off products (based on an indicative total use of approximately 9,000 tonnes) in the EU. Assuming 100% release, this is equivalent to 66 mg/capita/day.

[39] This figure is a total of all the PCP uses; both wash-off and leave on.

[40] This figure is a total of all the PCP uses; both wash-off and leave on.

The calculations demonstrate that sediments are an important sink for D5 in the aquatic environment (due to its high hydrophobicity; D4 is more volatile).

New information

Assuming a lower release rate of 73% for wash-off PCPs and the updated tonnage the results in PECs for D5 of the same order of magnitude (i.e. around 1 µg/L for surface waters and 3 µg/kg ww for sediment at the local scale)[41].

Comparison with measured concentrations

There are relatively few reliable measurements for either D4 or D5 in the European surface freshwater environment from recent years. However, where measurements have been made they have generally been in waters receiving WWTP effluents (see Appendix B.3 for further details). It is important to note that the measured data might not fully reflect the emission scenario that has been modelled (which is based on recent tonnage information). In addition, it is often unclear whether sampling points are broadly equivalent to the location, population size and level of dilution that has been modelled[42]. The treatment type and dissolved organic matter content of the influent will also affect removal efficiency, and the results also sometimes exceed the measured solubility in pure water, which provides an additional complication. Direct comparison of the PEC with the monitoring data is therefore inappropriate and only broad statements can be made.

D5 concentrations in receiving waters have been reported for 15 sites from three studies. Wang *et al*. (2013a) collected samples in Canada, so their findings might not be directly comparable with the EU (e.g. due to differences in wastewater treatment practice and environmental conditions). However, given the scarcity of data they are considered to be broadly representative, as uses of PCPs containing these substances are likely to be similar in North America and Europe (as suggested by the per capita usage/release amounts mentioned in Section B.9.3.8). Sparham *et al*. (2008) collected samples from the River Great Ouse and the River Nene in the UK and Kaj *et al*. (2005b) collected samples from the Nordic countries. Limits of detection were in the order of 10 – 15 ng/L, and D5 was detected in approximately half of the samples. The highest concentration reported is over 1 µg/L (1,000 ng/L), although the majority of the measured results were between 30 and 300 ng/L.

The predicted regional concentration in freshwater is approximately 100 ng/L, which is consistent with the measured D5 concentrations at a number of sites that were receiving WWTP effluents. The predicted local concentration in freshwater is approximately 1,237 ng/L, which is close to the upper end of the monitored range. The reasons for this are unclear, but there is more discussion on this in the sensitivity analysis in Section B.9.4.

D4 concentrations in receiving waters have been reported for 13 sites from two studies (Wang *et al*., 2013a and Kaj *et al*. 2005b, with samples taken from Canada and the Nordic countries, respectively). At almost half of these sites the D4 concentrations in the water were below the limit of detection of 4.5 ng/L (4 sites), or 30 ng/L (2 sites); the remaining seven sites had D4 concentrations ranging from 10 to 23 ng/L. The predicted regional concentration in freshwater is approximately 2 ng/L, which is below the limit of detection for half of the sites. However, measured concentrations are approximately one order of magnitude higher at other sites, which presumably reflects the higher usage of D4 in PCPs in previous years compared to now. The predicted local concentration in freshwater is approximately 20 ng/L, which is within the monitored range.

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[41] The surface water PECs are 80 ng/L and 917 ng/L at the regional and local scales, respectively. The sediment PECs are 387 µg/kg ww and 2,953 µg/kg wwat the regional and local scales, respectively.

[42] The local surface water PEC represents the concentration at the edge of the effluent mixing zone of a "standard" WWTP serving a population of 10,000, with the effluent diluted by a factor of ten.

A larger number of measurements have been reported for the sediments of rivers receiving WWTP effluents (64). Direct comparison with predicted concentrations is not possible, because the levels depend on the organic carbon content of the sediment (and conversion from wet weight to dry weight, where necessary, requires knowledge of the actual water contents of the sediments). Sites could also be influenced by a number of sources, some of which could be historical and no longer relevant (which is important given the persistence of these substances in sediment).

D5 concentrations were not quantifiable at approximately three quarters of the sites. The median reported sediment concentration was 0.04 mg/kg dw, which is lower than the regional predicted concentration for D5 in sediment of approximately 0.25 mg/kg dw (0.5 mg/kg ww). The 75th percentile concentration of 0.225 mg/kg dw is also lower, but much closer to the predicted concentration, which suggests that the prediction lies within the range of observed concentrations.

A similar situation is also seen for the measured and predicted concentrations of D4 in the sediments of rivers which receive WWTP effluents. D4 was detectable in approximately half of the samples (limit of detection 1.5 to 22 µg/kg dw), although the median measured concentration was below the limit of detection of 22 µg/kg dw. This is consistent with the predicted regional D4 concentration in sediment of approximately 0.5 µg/kg dw (1 µg/kg ww).

In conclusion, the predicted concentrations of D4 and D5 in the freshwater environment are comparable to the measured concentrations observed in the limited number of available monitoring studies. This suggests that the emission scenarios that they are based on are fairly reliable. Both measurements and model predictions indicate that sediments are an important sink for D4 and D5 in the environment.

<u>New information</u>

The predicted concentrations calculated using the revised tonnages and release rates are broadly similar and do not change the conclusions (see Appendix B.7 for further details).

B.9.4 Sensitivity analysis

There are a number of uncertainties in the exposure assessment, and these can be considered on a qualitative or quantitative basis depending on the level of information available. The overall calculation is as follows:

Release to waste water = tonnage used in wash-off PCPs x percentage release to water during PCP use/100
Release to surface water = [release to waste water x WWTP release fraction to water x percentage WWTP connection rate/100] + [release to waste water x (100 – percentage WWTP connection rate/100)]

The variables are therefore:

- Tonnage used in wash-off PCPs [assumed: < 1,000 tonnes/year]: As discussed in Section B.9.3, the tonnage is uncertain, but has been based on the best available information. There appears to be a gradual downward trend in use in wash-off PCPs, although the driver for this is unclear and if regulatory pressure were removed, an increase could occur. There is insufficient information to allow a quantitative uncertainty analysis to be performed, but any percentage change in the tonnage would affect the release to waste water in direct proportion.

The updated tonnage has been used in a refined assessment as detailed in the sensitivity analysis reported in Appendix B.7. Whilst this reduces much of this uncertainty it does not necessarily eliminate it entirely.

- Percentage release to water during PCP use [assumed: 100%]: The assumption of 100% is clearly a worst case, and in practice it is likely to be lower (one study suggesting around 75% for one product type; see Section B.9.3.2). However, exactly how much lower will depend on the releases from different product types, and their relative use volumes. This information is not currently available. As for tonnage, any percentage reduction in release during PCP use will be directly proportional to the change in release to waste water.

  As discussed in the sensitivity analysis reported in Appendix B.7, a refined assessment using a release rate of 73% for wash-off PCPs has been performed following discussions at the Risk Assessment Committee. Modified release rates for leave-on PCPs have also been considered.

- WWTP release fraction to water [assumed: ca. 0.05 for both substances]: As explained in Section E.1.1, there could be improvements in WWTP efficiency that could lead to an even higher level of removal than currently assumed. However, the available information does not allow this to be modelled and the costs are also unknown. It is also possible that some losses to air could occur within the sewerage network before the waste water arrives at the WWTP, but there is no reliable information available to assess the relevance of this.

- Percentage WWTP connection rate [assumed: 80]: As explained in Section E.1.1, there is likely to be a general improvement in WWTP connectivity in urban areas in future years, which should reduce the amount of substance released direct to surface water untreated, which is a significant fraction of the overall amount. For example, a 10% improvement in connectivity is predicted to lead to a 40% reduction in surface water emissions.

This qualitative uncertainty analysis suggests that the releases used in this dossier may be slightly over-estimated, although the actual level of over-estimation cannot be established with any confidence. The dossier submitter has performed some further calculations based on the limited amount of WWTP influent concentration data available (see the sensitivity analysis reported in Appendix B.7). These lend additional support to the notion that wash-off PCPs are the most significant contributor to aquatic emissions, but also suggest some over-estimation of overall releases. The overall emissions to surface waters should decline by a significant percentage over time as WWTP connectivity is improved.

B.9.5 Other sources

There are no known natural sources of D4 and D5.

B.10 Risk characterisation

The key concern for D4 and D5 is their PBT/vPvB properties, which are a surrogate for unpredictable long-term exposure and effects in the environment, including in remote regions and long-lived species. In general, the risks of PBT/vPvB substances to the environment or to humans via the environment cannot be adequately addressed in a quantitative way by deriving PNECs due to the high level of uncertainty (e.g. over the relevance of laboratory studies for such long-lived substances). Therefore, a qualitative risk assessment has been carried out.

Exposure/emissions are used as a proxy for risk for PBT/vPvB substances when considering the cost-effectiveness and proportionality of the proposed restriction (Section E and F). A detailed analysis of releases and exposure potential is provided in Section B.9, with the findings presented in Tables 10 (for waste water) and 11 (for surface waters).

B.10.1 Human health

Humans can be exposed to D4 and D5 in food (e.g. fish), drinking water, indoor and outdoor air (including dust) and by direct contact with products containing them. The most significant source is likely to be through dermal or oral contact from the use of PCPs by consumers. Under the Cosmetics Regulation (EC) No. 1223/2009, the published Scientific Committee on Consumer Safety (SCCS) opinion is that cyclomethicone (D4, D5 and D6) does not pose a risk for human health when used in cosmetic products (SCCS, 2010) (though a revised opinion is being drafted). On this basis, no further quantification of human health risk has been performed. However, by reducing risks for the environment, risks should also be reduced for people exposed via the environment.

B.10.2 Environment

D4 and D5 are both manufactured in the EU, and also imported as substances (on their own or in mixtures) and in articles. They are released from the formulation and processing stage ("production"), the service life of products and articles and from the waste stage (recycling, landfilling and incineration). These substances partition significantly to air, and re-deposition appears to be a relatively insignificant process. The focus is therefore on releases to the aquatic environment, since this is where the environmental risks are likely to be greatest (controls on aquatic emissions will also reduce emissions to land via sewage sludge spreading).

Since a PNEC is not relevant, no risk characterisation ratios can be produced.

The total releases to EU surface waters are estimated to be 4.7 tonnes/year for D4 and 205 tonnes/year for D5, respectively. The use of D4 and D5 in PCPs is widespread, so emissions can be expected across the EU and they can be found in aquatic biota in many locations. Releases from the use of wash-off PCPs are estimated to contribute 95 per cent of the total emissions for D5 (195 tonnes/year), and 63 per cent for D4 (ca. 3 tonnes/year). This use is considered to represent the greatest level of environmental risk for these substances.

Monitoring data are not sufficiently complete to allow any analysis of trends in environmental levels, but provide some support that the estimated releases are reasonably realistic.

B.11 Summary on hazard and risk

The hazard and risk of the use of D4 and D5 as an ingredient or impurity in wash-off PCPs are summarised as follows:

- D4 meets the definition of a PBT/vPvB substance in accordance with Annex XIII of the REACH Regulation, and thereby fulfils the criteria in Articles 57(d) and (e) of REACH.
- D5 meets the definition of a vPvB substance in accordance with Annex XIII of the REACH Regulation, and thereby fulfils the criteria in Articles 57(e) of REACH.
- Environmental exposure of D4 and D5 is widespread, and the recommendations in the REACH Registrants' CSRs are inadequate to minimise emissions.
- Air emissions are not considered to be of concern, but risks arise from surface water emissions, which are currently estimated at <5 tonnes/year for D4 and <500 tonnes/year for D5, respectively, as the EU baseline[43].
- Total emissions to wastewater are predominantly associated with the use of wash-off PCPs (78 per cent for D4 and 97 per cent for D5), rather than other product types. This use is considered to represent the greatest level of environmental risk for these substances, especially as releases from some of the other uses might be overestimated.

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[43] The actual emission figures are provided in the confidential appendix.

C. Available information on alternatives

C.1 Identification of potential alternative substances and techniques

This assessment focuses on the technical and economic feasibility of alternative substances to D4 and D5 in wash-off PCPs. The dossier submitter has not attempted to address different techniques by which the end-result of using wash-off PCPs could be produced.

Stakeholder consultation (AMEC, 2013h) identified up to around thirty substances that could potentially be used as alternatives to D4 and D5 in PCPs[44]. It is clear that this list is not fully comprehensive and it was also constrained by an apparent focus on substitution for leave-on, rather than wash-off, products.

C.2 Assessment of alternatives

The detailed assessment of potential alternatives is presented in Appendix C.

C.2.1 Availability of alternatives

No information has been provided by stakeholders about the future availability of potential alternatives. Therefore, market availability was assessed by checking registrations under REACH. Alternatives for which registration has been completed were considered to be commercially available, and the tonnage band indicates the relative level of supply. Substances without a registration can be considered to be less readily available in the quantities required for the wash-off PCP market, although they may still be used or could become significant in the longer term. It should be noted that polymeric potential alternatives are unlikely to be registered but may be available in significant amounts.

C.2.2 Human health risks related to alternatives

Human health considerations for the constituents of wash-off PCPs are regulated under EU cosmetics legislation, which constrains the consumer use of substances with particular human health-related hazardous properties. This section therefore focuses on environmental hazard classification under the CLP Regulation and (potential) PBT/vPvB properties (although information on human health classification is included in Appendix C for completeness). The data were obtained from public information on the ECHA website.

C.2.3 Environment risks related to alternatives

Conclusions on the environmental properties of potential alternatives are summarised in Table 14. Some of these substances will shortly be undergoing Substance Evaluation under REACH, and another is subject to a PBT screening analysis. Definitive hazard property information is also unavailable in some cases. Therefore, no definitive conclusions on their hazard profile can be reached for the time being.

C.2.4 Technical and economic feasibility of alternatives

Conclusions on the technical and economic feasibility of potential alternatives are summarised in Table 14.

Colipa-CTPA (2011a) states that D5 is preferred for PCPs because it:

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[44] D5 is currently the principal substitute for D4 in PCPs, and this was not considered.

- acts as a hydrophobic solvent/dispersant for silicone polymers and other PCP ingredients,
- has high skin compatibility, and is tasteless, odourless and colourless,
- evaporates very easily from hair and skin (in a matter of hours at room temperature, or more quickly with hair dryers),
- has low surface tension, allowing it to spread rapidly on skin and hair (and thereby deliver other PCP ingredients in a uniform manner), and
- has low chemical reactivity in acidic or aqueous products, can withstand processing temperatures up to 80 ºC, and provides a product shelf-life of up to three years.

The dossier submitter presumes that D4 offers similar benefits. In addition, D4 and D5 have excellent packaging compatibility and low ozone-formation potential.

AMEC (2013h) provides further information about the technical feasibility of alternatives, although this is almost entirely related to leave-on PCPs. They indicate that there is no single individual substance that can act as a universal one-for-one drop-in replacement for D4 or D5 in all PCPs in which they are currently used. For some products, a mixture of two or more substances may be required to provide a similar level of functionality. Nevertheless, products containing D4 and/or D5 only account for about 36% of PCPs in terms of EU market value. More importantly, only around 4% of the D4/D5 used in this sector is actually used in rinse-off[45] PCPs. Therefore it is clear that no major wash-off PCP group (shampoos, conditioners, shaving products, etc.) is completely dependent on their presence. It also means that there are many wash-off PCPs available that can deliver the intended function (e.g. hair washing) without containing D4 or D5.

The composition of PCPs that have been reformulated to remove D4 and D5 is likely to vary significantly between product groups. It is also complicated by the large range of concentration that may be used in a particular type of PCP. For example, the D4/D5 concentration in wash-off hair care products ranges from 0.1 to 75% w/w (the higher value is for a small number of products; the median is actually 2% w/w). Individual formulations might also be subject to trade secrecy. This makes it difficult to analyse alternative substances in terms of their technical and economic feasibility. It seems likely that reformulation would require more time and effort than if it were simply the replacement of D4/D5 by one single ingredient, especially as the success of any particular PCP depends on consumer satisfaction. The time needed for reformulation may also vary between companies and product types.

On the other hand, product diversity in the wash-off PCP sector is high, with a large amount of product turnover as new brands and formulations are brought to the market. According to EC (2008), around 20 – 30% of PCPs are reformulated every year (although much of this might involve minor modifications). As mentioned above, the major wash-off PCP groups are not completely dependent on the presence of D4 or D5. The main trade associations have known about UK government interest in regulating the use of these substances for a number of years, so individual companies will almost certainly have been investigating different reformulation strategies, and some may already have removed D4 and D5 from their products. The PCP industry has been aware of pressure to find substitutes for D4 and D5 since at least 2009, as indicated by stories in the trade press[46]. Indeed, a number of wash-off PCPs are now advertised as 'silicone-free',

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[45] See Section E for an explanation of how this term differs from "wash-off".

[46] For example, http://www.personalcaremagazine.com/Story.aspx?Story=9021 (dated November 2011), https://pubs.acs.org/cen/coverstory/89/8918cover.html (dated May 2011) and http://www.surfatech.com/pdfs/D5%20Article.pdf (dated 2009).

although it is not clear if this relates to specific silicon-containing substances (e.g. polymers). Market trends are also a factor.

Most of the potential alternatives identified in AMEC (2013h) are available on the market, but it is not known whether they would be available in sufficient quantities to replace D4 and D5 in wash-off PCPs.

The assessment of economic feasibility is also limited by lack of information on relative prices and required loading rates (i.e. concentration needed to achieve the functional requirement) of the alternatives. The dossier submitter obtained price-related information mainly from AMEC (2013h), supplemented by marketing literature and to some extent internet market places (alibaba.com). It has not been possible to confirm the prices presented in the internet market places. Substitution cost calculations and cost-effectiveness estimates (€ per kg of emission reduced) are presented in Section F based on a range of assumptions regarding required 'use ratio' loading rates. Information is not available about changes to production processes.

C.3 Conclusions

At present, stakeholder input suggests that there are generally no drop-in one-for-one replacements for D4 and D5 in the wash-off PCPs that currently contain them. A range of potential alternatives have been identified which may contribute to technical solutions for some wash-off PCP types. Their relative environmental concerns vary, and in some cases hazard property data are incomplete or subject to ongoing regulatory scrutiny. Whilst some have potential (as yet unconfirmed) concerns about PBT properties, the intrinsic properties of others appear to be of less environmental concern than D4 and D5.

In general, many alternatives appear to be more costly and/or less available than D4 or D5, but this is not necessarily the case for all. There is insufficient information to provide a relative ranking of technical and economic feasibility of the potential alternatives (e.g. in terms of required loadings, prices and the potential research and development activities or process changes needed). However, it appears likely that the supply volume of key alternatives would increase, with a reduction in price accordingly. It is also important to bear in mind that products containing D4 and/or D5 only account for a small percentage of the wash-off PCP market in the EU, and no major wash-off PCP group (shampoos, conditioners, shaving products, etc.) is completely dependent on their presence.

In summary, whilst the market reaction to the removal of D4 and D5 from wash-off PCPs cannot be predicted with certainty for the time being, the dossier submitter considers that substitution is both technically and economically feasible for many PCPs (although some specific products might be no longer viable), and could already have started. This conclusion is subject to revision in the future should additional reliable information on the intrinsic properties and/or technical and economic feasibility of alternative substances become available.

Table 14 Conclusion on the environmental hazard profile of some potential alternatives to D4 and D5 and their technical and economic feasibility for use in wash-off PCPs

No.	Substance	CAS No.	REACH registered?	Environmental hazard profile		Technical feasibility	Economic feasibility
				CLP	PBT		
1	Linear volatile methylsiloxanes, including PDMS, dimethicone, L2, L3, L4, L5, etc. [N.B. this covers a range of substances and polymers sharing a common structural repeating unit]	107-46-0, 107-51-7, 141-62-8, 141-63-9, 9006-65-9, 9016-00-6, 63148-62-9	Y	Aq Ac 1 (L2), otherwise NC	L2 – L5 are on CoRAP due to PBT concerns; polymeric substances may contain D4/D5	Y; may require changes in the production process due to flammability	Higher price, though some similar; some may be supplied in lower amounts
2	Dodecamethylcyclohexasiloxane (D6)	540-97-6	Y	NC	Potential vPvB but awaiting data; contains D4/D5	Y	No information, but likely to be similar to D4/D5
3	Ethyl methicone	63148-54-9	N	-	Potential PBT concerns, but requires further analysis	Y?	No information
4	Neopentylglycol diheptanoate	68855-18-5	Y	NC	N	Possibly?	No information, but supplied in lower amounts
5	PPG-3 benzyl ether ethylhexanoate	1073606-36-6	N	NC	N	Y for some types	No information
6	Isodecyl neopentanoate	60209-82-7	Y	Aq Chr 1	N	Y for some types?	Higher price; supplied in lower amounts
7	Dicaprylyl carbonate	1680-31-5	N	Aq Ac 1? Aq Ch 1?	N	Possibly?	Higher or similar price; supplied in lower amounts
8	Dicaprylyl ether	629-82-3	Y	NC	N	Y for some types, in combination with other substances	No information, but supplied in lower amounts
9	Hydrogenated polydecene.	68037-01-4	Y	N	Some constituents are potentially vPvB – further analysis needed	Possibly in combination with other substances?	No information, but supplied in higher amounts

Key: Y – Yes; N – No; Aq Ac – Aquatic Acute; Aq Ch – Aquatic Chronic; NC – not classified

Note: a) Even if technically feasible, it should be noted that the characteristics of a specific PCP may change if the alternative is used.
b) Price differences are categorised as lower, similar or higher. The price is lower or higher if the price difference with D4/5 is more than 10%.

D. Justification for action on a Union-wide basis

D.1 Considerations related to human health and environmental risks

As discussed in Section B.8, D4 has PBT and vPvB properties and D5 has vPvB properties. They can also undergo long-range transport via the atmosphere (although as explained in Section B.4.2.3, this is not considered likely to lead to significant re-deposition to surface media). They therefore have a high potential for long-term exposure to the aquatic environment (and humans via the aquatic environment). REACH calls for minimisation of emissions and exposures of substances with PBT/vPvB properties as far as technically and practically possible (recital 70). Existing risk management measures recommended by the REACH Registrants do not seek to minimise releases. The substances are widely used in rinse-off PCPs throughout the EU, and risks may therefore arise in all EU Member States.

D.2 Considerations related to internal market

The underlying socioeconomic rationale for risk management action is that a burden to society from the marketing and use of D4 and D5 exists, as the private (industry) costs of D4 and D5 use do not fully reflect the cost to society (through damage [external costs] to the environment – see Section F).

There is a need to act on a Union-wide basis due to the fact that D4 and D5 and their related products and applications are traded between EU Member States. Goods must be allowed to flow freely to maintain the single internal market, and so it is not appropriate for any individual Member State to take actions concerning the placing on the market or use of D4 and D5. Proposing measures to control the marketing and use of D4 and D5 at EU level ensures a “level playing field” so that no enterprise gains a competitive advantage due to its location in any particular Member State.

EU-level intervention is also desirable due to the non-excludable nature of PBT and vPvB emissions. EU Member States may be exposed to D4 and D5 emissions arising in neighbouring countries, regardless of action to reduce D4 and D5 use within their borders (due to the long environmental half-life).

No other EU Member State has stated an intention to propose risk management action for these substances at the EU level.

D.3 Other considerations

Having an EU-wide regulation could facilitate communication of legal requirements between all relevant actors. In particular, this could help with supply chains including importers from outside the EU.

D.4 Summary

The primary reason to act on an EU-wide basis is the protection of the aquatic environment from the adverse effects of D4 and D5. Furthermore, the fact that D4 and D5 and their related products and applications need to circulate freely to enhance the proper functioning of the internal EU market stresses the importance of EU-wide action.

E. Justification why the proposed restriction is the most appropriate Union-wide measure

This section provides justification that the proposed restriction is the most appropriate Union-wide measure to minimise the environmental risks from D4 and D5. It gives an assessment of the effectiveness, practicality and monitorability of the proposed restriction as well as of other risk management options.

E.1 Identification and description of potential risk management options

E.1.1 Risk to be addressed – the baseline

D4 has PBT and vPvB properties and D5 has vPvB properties. Both are very persistent substances, so there is potential for long-term impacts some distance from the sources of release. Existing risk management measures recommended by the REACH Registrants do not ensure the minimisation of releases to water of D4 and D5 from some of its uses. The releases are widely distributed in the European environment.

As explained in Section B.9.3.7, use in PCPs is expected to be the biggest source of releases to waste water. When considering releases to surface water from all sources, wash-off PCPs account for 78% for D4 and 97% for D5, respectively. Table 11 in Section B.9.3.7 (see also the confidential appendix) provides estimates of annual emissions to surface water from different types of PCPs. The total annual emissions to surface water from PCP uses are estimated to be <5 tonnes for D4 and <500 tonnes for D5. Of this, wash-off PCPs (in which the substances may be present as either an intentional component or unintentional impurity) are predicted to be the most significant source of emissions to surface water for this product type, i.e. >95% for both substances. The releases from leave-on PCPs are relatively much smaller, and may also be over-predicted (as explained in Section B.9.3.2). Consequently, the focus of this proposal for EU-wide measures to minimise environmental risks is on wash-off PCPs. Preventing release to water from direct use in wash-off PCPs would reduce releases to surface waters by at least 70 per cent for D4 and 95 per cent for D5.

It should also be noted that these exposure estimates will be affected by future improvements in WWTP connection rate and/or sewage treatment technology. The applicability and removal efficiency of available abatement options has been assessed for both industrial processes and sewage treatment (see Appendix B.1). The vast majority of industrial installations which have discharges of D4 and D5 to wastewater operate biological WWTP which function in a very similar manner to a municipal WWTP. A wide range of removal efficiencies are observed for WWTP (as summarised in Section B.4.2.2), and this is likely to be due to site-specific factors regarding the configuration of the plant, including retention times. This assessment already assumes a high level of WWTP removal efficiency (ca. 95%) based on monitoring evidence, even though there are examples of WWTP with much lower efficiencies. Improvements in removal efficiency (for example more general use of enhanced aeration) could make a difference to surface water emissions, but in the absence of detailed information about the level of treatment at the various WWTP analysed, this cannot be modelled with any certainty. Establishing the costs of upgrading existing WWTP is very difficult. It will depend on the starting point (i.e. actual levels in sewage influent / effluent), the end point (i.e. the ‘target’ concentration in receiving waters), the removal rates provided by additional treatment technologies, and how many WWTP would need improvement (as well as the size of populations they serve). None of these is known with any certainty for D4 and D5. However, the main driver for improving removal efficiencies [of harmful chemicals] at WWTP is the Water Framework Directive (WFD). The costs of several ‘enhanced’ treatment options (nitrifying tertiary filters, nitrifying sand filters, reedbeds, granular activated carbon and microfiltration/reverse osmosis (MF/RO)) have been considered as part of investigations into improving removal of certain Water Framework Directive priority substances in the UK (UKWIR, 2014). For substances such as DEHP, PAHs and PBDEs, cost estimates for improvements at an arbitrary 400 WWTP (of mixed size) were in the region of €1.2 billion to >€20 billion depending on the technology (with the greatest cost associated with MF/RO); the average cost was around €3 billion. Data held by the European Environment Agency suggest that there are around 20,000 WWTP in the EU[47]so WWTP upgrade costs across the EU could be significant. On this basis, improvements in WWTP efficiency are not considered further.

The Urban Wastewater Treatment Directive (91/271/EC) requires that treatment is in place for centres of population with greater than 2,000 inhabitants. The ultimate overall extent of wastewater treatment for a particular Member State will therefore depend on how urbanised the population is. The change from 80% of sewage being treated (current risk assessment default) to 90% of sewage being treated (which is more typical of the current situation in countries such as the UK and Germany) would be expected to result in a reduction in D5 emissions of approximately 40%[48]. Improvements in urban WWTP connectivity are therefore likely to lead to some emission reduction even if no regulatory action were taken. However, this would still leave 60% of the emissions unaffected. In addition, the overall level of improvement actually achieved in practice and the associated timescale are very difficult to predict, and may vary by Member State. Therefore the baseline has not been adjusted to take this information into account. N.B. The REACH CSRs assume a WWTP connection rate of 90% for the whole of Europe, citing Statistical Office of the European Communities (EUROSTAT) data for 15 EU Member States (Reconsile Consortium, 2014a&b).

E.1.2 Proposed restriction

E.1.2.1 Scope

The proposed restriction concerns placing on the market and use of wash-off PCPs containing greater than 0.1% w/w D4 or D5. This will include the formulation of products for subsequent export outside the EU.

The Cosmetics Regulation uses the term “rinse-off” for products that are washed off, but including wipe-off products such as baby wipes. As wipe-off products do not normally lead to aquatic emissions it was not considered appropriate to include them within the restriction and therefore the term “wash-off” has been used and defined within the restriction wording in Section A. This restriction proposal is not intended to address therapeutic shampoos, such as for head lice treatment. Compared to other products, these are likely to be a very insignificant source as the product is intended to be left on the hair overnight before washing, so a large proportion of the D5 would evaporate before washing.

Although other uses contribute to waste water emissions, they are much less important than wash-off PCPs, as indicated in Section B.9.3.7. Given the uncertainties associated with the release estimates (particularly from leave-on PCPs), and the consequences of voluntary activities by the industry (see Section E.1.3.2), the dossier submitter recommends that a review period is included in the restriction wording so that further regulatory action can be considered if trends in environmental concentrations following

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[47] http://www.eea.europa.eu/data-and-maps/uwwtd/waste-water-infrastructure/urban-waste-water-treatment-plants

[48] A further improvement in wastewater treatment coverage to 95% would result in a reduction of D5 emissions of about 60% compared to the estimate provided in this report.

the introduction of the restriction indicate the need.

E.1.3 Other Union-wide risk management options than restriction

E.1.3.1 Other legislative measures[49]

The supply of D4 and D5 onto the European market is within the scope of REACH. In particular, REACH would appear to be the primary mechanism that could be used to apply controls on imported goods. The following elements of REACH have the potential to address the issues with D4 and D5:

- An update to the existing registration dossiers
- Authorisation (including candidate listing)

Since the risks arise principally from emissions to waste water, the Water Framework Directive is also relevant.

Registration under REACH

The REACH Registrants should (in theory) update their CSRs to indicate that D4 and D5 are PBT/vPvB substances, together with recommended RMMs to specifically minimise emissions (although what these might be is unclear). This could include the identification of uses that are no longer supported. This will not necessarily take account of socio-economic factors, so a downstream user could still send a notification to ECHA for their use even if it is not supported by the Registrants, so this would not necessarily have the desired effect. In addition, the Registrants are only legally obliged to consider the tonnage that they supply individually, not collectively. Therefore whilst this risk management option has the potential to make a significant impact on environmental emissions, it is not guaranteed.

REACH Authorisation (including candidate listing)

D4 and D5 have PBT and/or vPvB properties so are considered to meet the Article 57(d) and (e) criteria for identification as a Substance of Very High Concern. They are supplied in high tonnages and used as an additive in a variety of consumer products. They would therefore seem to meet the relevant criteria as candidates for inclusion in Annex XIV. Candidate Listing triggers hazard communication requirements, although this is of limited usefulness in terms of emission reduction. Inclusion on Annex XIV would set a sunset date beyond which the substances would no longer be allowed to be used without an authorisation, provide pressure to find substitutes and allow companies that wish to carry on using the substances to apply for authorisation on the basis of socio-economic need. Nevertheless, there are some additional considerations to bear in mind:

i) The principal use of the substances is as chemical intermediates in the production of various silicone polymers. Authorisation does not apply to this use. To address potential risks from the presence of these substances as impurities in the polymers would require either restriction or separate listing of the polymers on Annex XIV. The latter option seems disproportionate given the very large amounts of polymer supplied, the diversity of uses and the fact that many polymers may contain the substances below 0.1% w/w.

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[49] The Cosmetics Regulation (EC) No. 1223/2009 provides a means of restricting a chemical for use in PCPs, but only on the basis of human health risks, whereas the concern here is in relation to potential environmental effects. It is therefore not considered relevant in this context.

ii) Candidate listing could have a black-listing effect, creating commercial pressure to move away from the use of both substances in any application. This dossier shows that most areas of use are judged to be of low environmental risk and therefore such a move would be unnecessary, particularly if it involved replacement with less well-understood substances with the potential to be equally or more harmful[50].

iii) Modelling in the lead Registrant's CSR suggests that reductions in D4 and D5 concentrations in water and sediment can be achieved by reducing emissions to water but would not be affected significantly by reducing emissions to air. A requirement for Authorisation would capture any use, regardless of the threat posed, and therefore provides a somewhat blunt tool to address the relevant risks in this case.

iv) D4 and D5 can be impurities in other substances, including linear siloxanes and higher molecular weight homologues such as D6[51]. Authorisation would not be able to address this source, unless these other substances were also added to Annex XIV. Since some suppliers might be able to produce them with D4 or D5 levels below 0.1% w/w, this would raise issues relating to unfair treatment unless the concentration limit was specified in the Candidate List entry.

For these reasons, candidate listing and inclusion on Annex XIV are likely to be a disproportionate response to the risks posed by these two substances, and would in any case not capture all possible sources. Since the main source of aquatic exposure is a specific use, a targeted restriction is more appropriate.

Regulation (EC) No 850/2004 on persistent organic pollutants

The POP Regulation incorporates the provisions of international agreements on persistent organic pollutants (POPs). Both D4 and D5 are very persistent in sediments, and can be subject to long-range transport in the atmosphere (see Section B.4). However, as discussed in Section B.4.2.3, the potential for deposition to surface media is low, and concentrations of both substances in remote environments tend to be close to current limits of analytical detection (especially at locations some distance from sewage outfalls). Whilst both substances can cause toxicity in organisms, only D4 triggers the Annex XIII criteria. The potential for harm, in the context of remote environments, is therefore lower than other substances that are currently considered to be POPs (such as some halogenated pesticides, dioxins and polychlorobiphenyls).

Negotiation with countries outside the EU may take several years to complete, and is not guaranteed to reach consensus. It is therefore not the quickest way to achieve significant emission reduction. In addition, if either substance were to be nominated as a POP, the socio-economic consequences would need to consider all uses (including the major use in silicone polymers), which would require significantly more resource to investigate than has been used to prepare this dossier. The dossier submitter does not consider that identification of either D4 or D5 as a POP is necessary to ensure a proportionate level of environmental protection.

Water Framework Directive (WFD) (2000/60/EC)

The WFD provides a framework for the protection of inland surface waters, transitional

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[50] Several linear siloxanes are on the Community Rolling Action Plan to investigate their potential PBT properties.

[51] These are a source of environmental exposure for D4 and D5, but to establish the relevance of different uses to the level of risk would require extensive analysis, which is not considered necessary for the purposes of this restriction. They are used in similar applications to D4 and D5, so risks are likely to be linked to the same broad applications.

waters, coastal water and groundwater. It places duties on the governments of Member States to regulate the release of discharges into the aquatic environment. The Directive itself does not provide any mechanisms to gather information about a substance/product or to regulate emissions directly. Local emissions to the environment would be controlled by national measures including environmental permits. D4 and D5 are not currently designated as Priority Substances (PS) or Priority Hazardous Substances (PHS) under this Directive; they are being considered for such later this year.

Identification of D4 or D5 as a Priority (Hazardous) Substance would require the Commission to establish an Environmental Quality Standard (EQS) at the European level. Member States' governments would then be obliged to carry out measures to achieve the EQS, where it is technically feasible and not disproportionately costly to do so. If either substance were to be designated as a Priority Hazardous Substance then Member States' governments would also have to carry out measures for the cessation or phasing out of discharges, emissions and losses to the aquatic environment.

The WFD is potentially a relevant risk management tool in this case because the primary concern relates to aquatic discharges. However, these two substances are not current priorities under this Directive and even if they become so, the Directive still does not provide an effective way to reduce emissions. Measures may also vary across the EU due to differences in national priorities. Supply controls such as a restriction proposal are likely to be much more cost-effective than improvements at wastewater treatment plants. Nevertheless, the WFD might provide a useful supplementary control tool, in that, if these substances were to be designated as PS or PHS, then monitoring would be required, the results of which could be used to assess whether or not aquatic emissions are declining following the introduction of relevant risk management under REACH. Whilst attractive as a joined-up approach to the regulation of substances posing risks to the aquatic environment, it should be borne in mind that this would place the burden of monitoring on EU Member States' governments rather than on the industry.

E.1.3.2 Voluntary measures

Industry has set up a voluntary product stewardship arrangement. The industry's objective is to assess emissions to the aquatic environment by targeting the most significant sources directly (e.g. manufacturing sites, PCP formulation sites, etc.) and to demonstrate that they do not pose a risk to the environment.

The D4 and D5 REACH consortia have a range of activities under assessment, ongoing or planned, including a proposed environmental monitoring programme, investigation of mass loadings in wastewater treatment plant (WWTP), studies of PCP wash-off, emission surveys and site audits. The plan is to identify sites with the highest emissions and audit them to find ways of improving waste management practice. The monitoring work started in 2011 and will run until 2016.

The dossier submitter does not have full details of all planned activities. As a voluntary initiative, the take up rate by downstream users may vary between sectors as well as suppliers, and it is not clear what overall level of emission reduction will be achieved or when the results of the initiative will be available. The applicability of this voluntary initiative to wash-off PCPs in particular is unknown.

It is also possible to produce silicone polymers with D4/D5 contents below 0.1% w/w (e.g. using enhanced distillation and vacuum stripping techniques). Whilst this will entail an investment cost and an increase in energy consumption, there could be market advantages in being able to offer high purity polymers for applications with wastewater emissions. It is therefore possible that at least some current polymer producers will take steps voluntarily to make purer polymer grades (the same applies to producers of other substances that may contain D4 or D5 as constituents or impurities).

E.1.4 Transitional period

With respect to the timing of a Restriction it is necessary to consider a number of factors:

- The magnitude of risks to the environment and rapidity of the change in environmental concentrations.
- The time needed to reformulate or otherwise reduce the concentration of D4 and D5 in relevant products, which depends on the availability of suitable alternatives.

Whilst the actual impact of D4 and D5 on ecosystem structure, function and sustainability is unknown, the restriction aims to minimise the possibility of any adverse environmental impacts. The magnitude of the risk is therefore simplistically associated with the amount of emission.

The availability of substitutes is discussed in Section C. Information provided by Cosmetics Europe (AMEC, 2013g) suggests that the whole reformulation process might take between 8 and 11 years to complete. The main steps include research to identify and evaluate potentially suitable alternatives, reformulation in the laboratory, packaging modification and industrial development. The length of the transitional period should take this into account, although another option is that PCPs containing D4 and D5 will be taken off the market.

The industry has been aware of the intention to produce a restriction proposal for wash-off PCPs in the EU since April 2013. As described in Section B.9.3.2, only 2% of new wash-off hair care PCPs placed on the market between March 2012 and March 2013 contained D5, and the proportion is even lower if other wash-off PCP types are included. Hence it appears that there may have been already some movement away from the use of D5 in at least some wash-off PCPs. As reformulation progresses, it is possible that alternatives will be identified for some product types that may be transferable to others. The time and costs associated with reformulation might therefore be mitigated to some extent.

There are many wash-off PCPs on the market that do not contain D4 or D5, so from that point of view, plenty of alternative PCPs are already available. The cosmetics industry has indicated that PCPs containing D5 offer additional benefits to alternative products, and this is considered in Section F.

Compared to previous restrictions[52], a transitional period of 2 years would appear to be a suitable starting point, and Section F makes calculations on this basis along with a 5-year period for comparative purposes. It may be possible for stakeholders to provide additional information during public consultation to justify a longer period.

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[52] For comparison, transition periods for previous EU restrictions for substances with PBT/vPvB or equivalent properties have usually been 18 months (e.g. for perfluorooctane sulfonates, short-chain chlorinated paraffins, and penta- and octabromodiphenyl ethers), although 60 months (5 years) was allowed for phenylmercury compounds. The transition period for the proposed restrictions of both decabromodiphenyl ether and perfluorooctanoic acid is suggested to be 18 months. An 18-month transition period has also been used in other types of restriction legislation such as Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

E.1.5 Assessment of the effect of different concentration limits

As indicated in Section C.2.4, there is a very wide range in D4/D5 concentrations in PCPs (up to 75% w/w in some products). It may be possible to establish a concentration limit that could provide a substantial level of emission reduction while minimising the number of PCP formulations affected. However, there are no details about the actual distribution of concentrations in different wash-off PCPs or the relative amounts of such PCPs and so this cannot be investigated. A concentration limit of 0.1% w/w will capture all wash-off PCPs containing these substances as an intentional constituent (AMEC, 2013e) and ensure that emissions from direct use are removed. A higher concentration limit has not been considered since some products would be left out of scope, and there are insufficient data on the composition and supply tonnage of all relevant products to assess the implications of this. A lower limit has not been considered either, because it would capture products that may only contain the substances as unintentional impurities (e.g. due to the use of other siloxanes or polymers). It is not possible to reliably assess the remaining environmental emissions arising from such products because of the lack of detailed information on composition and supply tonnages of the relevant products, although some products may need reformulation if the impurity levels are high. Not specifying a limit at all would create problems for enforcement in addition to the issues raised for a lower concentration limit. The dossier submitter notes that a limit value of 0.01% w/w has been specified for D4 in PCPs to comply with ecolabelling requirements for cosmetic products[53], although the basis for this limit (and practicality in achieving it for products currently containing silicon-containing substances) is unknown.

E.2 Assessment of risk management options

As described above, the alternative risk management options are limited in various ways, and only restriction can achieve the targeted removal of a key use that dominates aquatic emissions. For this reason, this section only considers the restriction proposal itself.

E.2.1 Restriction on placing on the market and use of wash-off PCPs containing greater than 0.1% w/w D4 or D5.

This restriction is targeted because a very large share of annual emissions of D4 and D5 to waste water are associated with wash-off PCPs. Although direct use of D4 in these products has declined significantly in the last ten years, it is included in the restriction to prevent manufacturers switching back to D4.

Formulation of wash-off PCPs is included as it gives rise to point source releases and formulation of products intended solely for export could still potentially subject the EU to aquatic emissions following use of the final products (e.g. in bordering countries with rivers that flow into the EU). The dossier submitter also considers that restricting these substances for use in wash-off PCPs in the EU while allowing their export is morally questionable. Whilst formulation could in theory be controlled under the Industrial Emissions Directive, the cosmetics industry has indicated that if use in wash-off PCPs were restricted in Europe, they would not continue making such PCPs solely for export. However, since it cannot be guaranteed that export will be avoided voluntarily, the dossier submitter included formulation of wash-off PCPs within the scope of the original proposal (using the term “use” to cover this part of the life cycle). The SEA covers the impacts and costs of export.

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[53] Commission Decision of 9 December 2014 establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products (2014/893/EU).

E.2.1.1 Effectiveness

E.2.1.1.1 Risk reduction capacity

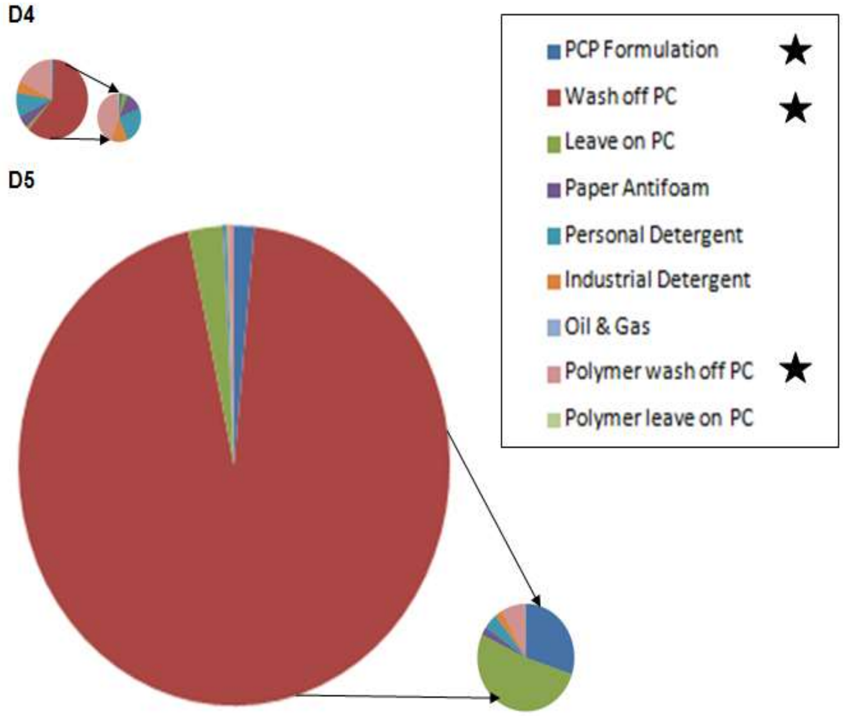
E.2.1.1.1.1 Changes in human health risks/impacts

Although direct risks to human health are not the subject of this proposal, the restriction will reduce environmental exposure and therefore any unforeseen risks to people exposed via food and water.

E.2.1.1.1.2 Changes in the environmental risks/impacts

The likely effectiveness of the proposed restriction is that there will be a reduction in total emissions/risks to surface waters of around 97% for D5 and about 78% for D4. Figure 3 provides a visual representation of this. The area of the pie charts is proportional to the emission.

Figure 3 Change in total emissions of D4 and D5 following restriction of use in wash-off PCPs (PC: personal care)



★ Use affected by the proposed restriction

This assumes removal of direct use in wash-off PCPs only. Releases from polymer uses could be affected, but the size of the reduction is very uncertain since this will depend on polymer purities/concentrations in individual formulations. Therefore this is a minimum level of emission/risk reduction.

The effect on environmental concentrations has been predicted using EUSES, and the results are presented in Tables 15 and 16 (current PECs were presented in Tables 12 and 13 in Section B.9.3.8).

Table 15 Continental and regional PECs for D4 following restriction

PEC	**Continental**		**Regional**	
	Before restriction	**After restriction**	**Before restriction**	**After restriction**[54]
Surface water (total) (ng/L)	*0.21*	0.084	*1.9*	0.745
Sediment (µg/kg wwt)	*0.11*	0.042	*0.95*	0.37

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[54] For illustrative purposes, if the restriction included leave-on PCPs, the regional concentrations would reduce to 0.07 ng/L in surface water and 0.35 µg/kg wwt in sediment.

Table 16 Continental and regional PECs for D5 following restriction

PEC	Continental		Regional	
	Before restriction	After restriction	Before restriction	After restriction[55]
Surface water (total) (ng/L)	*13*	0.6	*110*	5.3
Sediment (µg/kg wwt)	*61*	2.9	*529*	25

The restriction should therefore reduce concentrations in surface water and sediments by a factor of 2.5 for D4 and 20 for D5. Although both substances are expected to still be present in surface water and sediments following the introduction of the restriction, they will be at much lower concentrations than at present, below 0.01 µg/L (10 ng/L) for surface waters at the regional level. This is very close to or even below the limit of analytical detection (LoD) achievable for water with current methods (0.03 – 6.2 ng/L (see Appendix E); the industry product stewardship programme uses an LoD of 31 ng/L for D4 and 179–467 ng/L for D5). Sediment concentrations will be detectable for D5 at least (current LoDs are 2-5 ng/kg dw for sediment (see Appendix E)).

Surface water concentrations are likely to respond fairly quickly to a reduction in aquatic emissions. The timescale for changes in the sediment compartment has also been modelled by the dossier submitter, with the results presented Figures 3 and 4. The modelling uses some assumptions about release rates and sediment removal rates, but shows how concentrations are broadly expected to respond following the removal of wash-off PCPs as a source. Therefore the curve to the left of the t=0 point is most relevant.

The figures show that sediment concentrations of D5 will take much longer to respond to a reduction in wastewater emissions than those of D4, which is a function of both continuing releases and the degradation half-life.

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[55] For illustrative purposes, if the restriction included leave-on PCPs, the regional concentrations would reduce to 0.09 ng/L in surface water and 4.6 µg/kg wwt in sediment

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Figure 4 Estimated decline in sediment concentrations for D4

Overall removal rate constant (per day): at 12 ºC	0.00101	
Half-life (days)	686	
Original regional emission rate (kg/d)	1.23	
Percentage reduction in emissions as a result of control (%)	78.4	
Estimated decline in concentration	after 2 years	41%
	after 5 years	66%

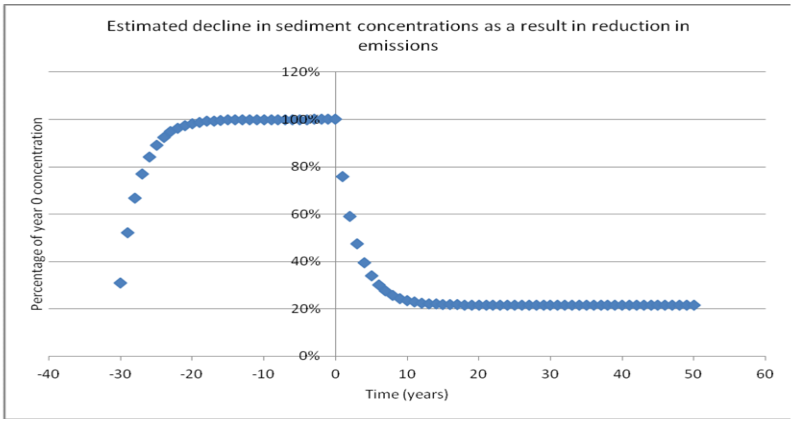
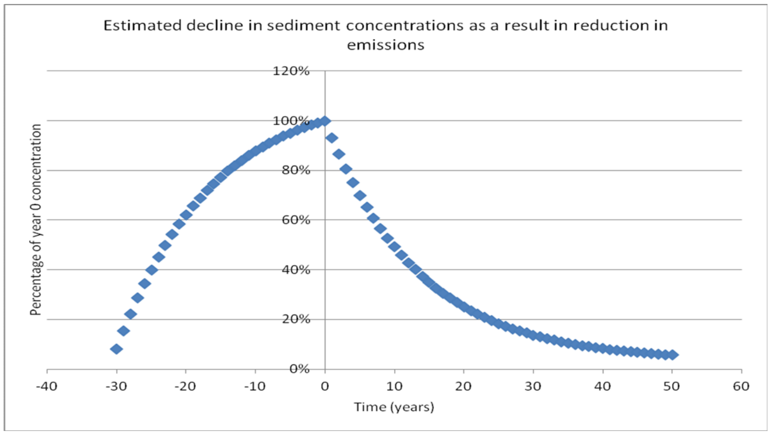


Figure 5 Estimated decline in sediment concentrations for D5

Overall removal rate constant (per day): at 12 ºC	0.000204	
Half-life (days)	3400	
Original regional emission rate kg/d	56.4	
Percentage reduction in emissions as a result of control%	97	
Estimated decline in concentration	after 2 years	13%
	after 5 years	30%



E.2.1.1.2 Proportionality

An assessment of the proportionality of the proposed restriction is undertaken in Section F.2.8. In accordance with that assessment, the emission reduction achieved by the proposed restriction is considered proportionate to the costs.

E.2.1.1.2.1 Economic feasibility (including the costs)

A full assessment of the economic feasibility of the proposed restriction is described in

Section F.2 of Appendix F (part of the confidential appendices to this restriction proposal). In accordance with that analysis, the costs of substituting D4/D5 in wash-off PCPs are shown in Table 17, which also shows the compliance cost-effectiveness of the proposal, as well as the compliance costs as a percentage of the retail sales price per kg of wash-off PCP.

Table 17 Economic feasibility of the proposed restriction

Compliance period (years)	Compliance Costs per annum			Cost-effectiveness (€/kg)	Total cost of compliance per kg of wash-off PCP sold (€/kg)	% Retail Sales Price increase (%)
	Raw material substitution Costs (€)	Reformulation Costs[1] (€)	Total cost of compliance (€)			
2	**3,420,000**	**19,664,952 - 58,044,340**	**23,084,953 – 61,464,340**	**115.66 – 307.94**	**0.0636 – 0.1692**	**0.34 – 0.91**
5	**3,420,000**	**4,188,567 - 38,307,702**	**7,608,567 – 41,727,702**	**38.12 – 209.06**	**0.0209 – 0.1149**	**0.11 – 0.62**

[1] Cost estimates refer to the upper and lower bound estimate figures calculated in the various analyses (see Table F.7 and F.8 – Appendix F). See Section F.2 (Appendix F).

The cost-effectiveness of the proposed restriction option is estimated to be between €38 and €307 per kg of D5 emissions reduced. The cost-effectiveness of the proposed restriction is of the same order of magnitude or lower than the cost-effectiveness of previous restrictions under REACH (see Section F.2 – Appendix F). Furthermore the percentage retail sales price increases are very small, ranging from 0.11-0.62% and 0.34-0.91% for the 5- and 2-year compliance periods, respectively. Given the retail price of a typical wash-off PCP, such increases can be considered minor.

E.2.1.1.2.2 Technical feasibility

During stakeholder consultation, some companies reported concern regarding the technical feasibility of alternatives, claiming that there was no direct one-to-one alternative available and that significant reformulation would be needed for each product. As the responses concerned the whole cosmetics sector, the extent to which this relates to the wash-off PCP market is unclear. However, as discussed in Section C and F, there are many alternative PCPs available that do not contain D4 or D5. The efficacy of these alternatives compared with those PCPs containing D4 and D5 is not known, and this may vary depending on the particular product (e.g. for specific hair types).

E.2.1.2 Practicality

E.2.1.2.1 Implementability and Manageability

The proposed restriction is considered to represent an implementable option for the duty holders involved, depending to some extent on the ability of the formulators to find adequate substitutes (which will affect the length of time needed for reformulation). However, another option is that PCPs containing D4 and D5 will simply be taken off the market. As described in Section C it appears that the necessary technology, techniques and alternatives are available and economically feasible, at least at a generic level.

E.2.1.2.2 Enforceability

The restriction addresses the placing on the market and use of wash-off PCPs. Compliance checking of these products could be done in a number of ways:

- Cosmetics legislation requires the naming of cosmetic ingredients on the product label. Relying on labelling alone will not be sufficient as the substances are not usually named individually[56], and they would not be mentioned if only present as minor impurities in silicone polymers.

- Purchase of products by enforcement authorities and analysis to ensure that D4 and D5 are both below 0.1% w/w.
- Retailers may request declarations from their suppliers that none of their products contains D4 and D5 above 0.1% w/w.

For the duty holders (including distributors and retailers), agreements could be put in place that all products they buy from their suppliers do not contain greater than 0.1% w/w of either D4 or D5. This, along with review of ingredient lists and subsequent analysis of any suspected non-compliant product would be one way of demonstrating compliance.

Formulators of products that currently contain intentionally added D5 should reformulate their products prior to the deadline set out in the restriction. Where the formulators are using silicone-based polymers they should ensure that the final product does not contain D4 or D5 above the concentration limit. Depending on the concentration of the impurities in a particular polymer, one way could be to limit the polymer concentration. For example, if the maximum concentration of D4 and D5 in polymers is 0.48% w/w, the maximum allowable polymer concentration would be 20% w/w (assuming that there is no formation of D4 or D5 during storage). Alternatively they could use a purer polymer product. The formulators may need to seek confirmation from their suppliers about the concentration of D4 and D5 in all the polymers they purchase.

Enforcement authorities could review any such agreements, along with assessment of ingredient lists on the products to enable targeting of any sampling of products more likely to be non-compliant. Subsequent sampling and analysis would then show the levels of compliance. Ultimately sampling and analysis are the only way to completely demonstrate compliance with this restriction.

There are no standard analytical methods to measure the content of D4 or D5 in PCPs; however details of suitable reproducible methods have been included in Appendix E. The limit of detection is typically approximately 0.1 ppm, which is four orders of magnitude below the concentration limit of 0.1% w/w (1,000 ppm). The restriction is therefore considered enforceable.

E.2.1.3 Monitorability

The main elements of monitoring are described in Section E.2.1.2.2. Additional environmental monitoring could be used to demonstrate that concentrations in relevant environmental media (e.g. WWTP influent, receiving waters or sediment) are in fact reducing in response to the restriction. Such monitoring of the receiving environment may be problematic due to surface water concentrations often being close to the lowest limits of analytical detection (see Appendix E for a detailed assessment of techniques for recovery of siloxanes in various matrices). However, these substances are routinely detectable in many wastewaters and WWTP effluents when sensitive methods of analysis are used, and monitoring in these media would provide a means of assessing the extent of changes in emissions to the aquatic environment. This could potentially be achieved through voluntary industry programmes (either from the water companies or the Registrants and/or their downstream users), as well as by individual EU Member States.

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[56] Under the Cosmetics Regulation, D4 and D5 can be identified by names such as cyclomethicone, which also includes D6.

E.2.1.4 Overall assessment of restriction option

The proposed targeted restriction fulfils all the criteria used in the assessment of risk management options in terms of proportionality, effectiveness, monitorability, technical feasibility, practicality, manageability and implementability. The restriction would substantially reduce the concern for the aquatic environmental compartment receiving discharges of D4 and D5 whilst allowing their continued use in many other applications that do not pose such a concern. Further monitoring of environmental concentrations following the introduction of the restriction should enable a decision to be made at a suitable future point about whether any further regulatory action needs to be considered. The dossier submitter therefore proposes to include a review clause in the restriction text.

F. Socio-economic Assessment of Proposed Restriction

This section presents a summary of the Socio-Economic Analysis (SEA) undertaken to estimate and compare the costs and benefits associated with the proposed restriction. The full SEA is presented in Appendix F (confidential).

Additional non-confidential analysis, performed by the SEAC Rapporteurs, is described in Appendix I.

F.1 Human health and environmental impacts

Quantification of environmental impacts of regulatory policy changes is difficult. In the case of D4/D5 the benefits of the proposed restriction are estimated by considering society's Willingness to Pay (WTP) for a reduction in potential risks to the aquatic environment (see Appendix F.4 for full details). In addition, given the conceptual and empirical difficulties of obtaining robust benefits estimates in the context of PBT substances (ECHA 2013), cost-effectiveness analysis is also undertaken in order to obtain the cost of reducing a kilogram (or tonne) of emission of the substance.

A representative sample of the UK population (sample size = 829) stated that they were willing to pay €46 per year per person to reduce the risks associated with the PBT substance - D4, and €40 per year per person to reduce the risks associated with the vPvB substance - D5. The WTP for superior quality personal care products (i.e. those that use D4/D5) was estimated at €5 per year per person. This indicates that respondents value the precautionary benefits of reduced potential risk of accumulation of D4/D5 in the aquatic environment at around seven times the value of the loss of beneficial properties provided by D4 and D5 in personal care products.

The cost effectiveness of the proposed restriction, expressed as the cost of reducing a kilogram (or tonne) of emission of the substance, is estimated and presented in Section F.2. These results are considered alongside those from the WTP survey to provide a stronger assessment of the proportionality of the proposed restriction (considered in Section F.7).

F.2 Economic impacts

The proposed restriction is likely to affect both production decisions for the manufacturers of wash-off personal care products containing D4/D5 and consumption decisions for consumers. Manufacturers of personal care products containing D4/D5 above the set concentration limit will essentially have two compliance options: i) reformulate the products so that they comply with the restriction; ii) remove the products from the market. The reformulated products and their alternatives will have an impact on consumer's WTP and selection of personal care products.

One of the costs incurred by manufacturers of wash-off personal care products who choose to reformulate would be the additional costs from purchasing alternative raw materials to replace D4/D5 in wash-off personal care products.

AMEC (2013h) identified only one suitable alternative for D5 in wash-off products. The unit cost for the alternative is less than 50% (actual figure confidential) more expensive than D5, but a similar quantity is required. According to AMEC (2013h) an indicative price paid for D5 is less than €10,000/t (actual figure confidential) and a similar price is assumed for D4. Taking into account uncertainties regarding the use ratio, as well as possible costs associated with price and/or quantity changes for other raw materials, the subsequent analysis uses a +100% price difference of the alternative (% of D4/D5 price).

When taking into account the amount of D4/D5 currently used in wash-off products[57] and a price increase of 100% for an alternative to D4/D5, the total raw material cost increase is estimated at €3,420,000. This estimate assumes that 1 kg of the alternative would be needed to replace 1 kg of D4/D5.

According to AMEC (2013h), there is no direct like-for-like substitute for D5 used in personal care products that could effectively duplicate all the specific product performance characteristics, such that a wider reformulation of many products would be required. As such the cost estimates are potentially underestimated, but this cannot be quantified on the basis of the information available to the dossier submitter. Nevertheless, the use of the +100% price difference for the raw material price increase rather than the actual figure (confidential, but less than 50%) provides some margin for any uncertainties.

The other cost incurred by manufacturers of wash-off personal care products would be the one-off costs associated with reformulating non-compliant wash-off personal care products to replace D4/D5. The total (annualised) net cost of product reformulation is estimated by considering:

- Reformulation cost per product
- Number of products facing formulation
- Costs that would have been incurred in the absence of the restriction ("baseline costs")
- Useful life of the formula (annualisation period)

For comparison the total (annualised) gross cost of product formulation is also estimated. This gross calculation does not take into consideration the costs that would have been incurred in the absence of the restriction.

The annualised net costs of reformulation arising from the proposed restriction are substantially less than the annualised gross costs of reformulations, irrespective of the compliance period and annualisation period selected. Across the EU, about 3,761 product formulations are estimated to be subject to reformulation under the proposed restriction (as a worst case). The initial lump sum cost to reformulate these product formulations (at €350,000 per product) is around €1.1 billion and €1.2 billion for a 5- and 2-year restriction compliance period respectively. Taking into account reformulation costs that would be incurred in any case in the absence of the restriction, the estimates of annualised net costs of reformulation (using the analytically consistent and thus preferred 20 year annualisation period) range from around **€4-38 million per annum and €20-58 million per annum for a 5- and 2-year restriction compliance period respectively**[58].

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[57] D4 use in wash-off PCPs has ceased to be supported by the lead registrant. Although this does not necessarily mean that D4 is no longer used in wash-off PCP, the analysis proceeds on this basis. As such, although Section F refers to D4 and D5 use in wash-off PCPs it is assumed that D4 use is equivalent to D5 use for the purposes of the analysis.

[58] Leaving aside all other costs associated with the restriction, these estimates may overstate the expected costs of the restriction since they do not account for the PCP producers' best response (i.e. their lowest cost option) to the restriction. So for example, the lowest cost option may not be for companies to pay the costs of reformulation and remain in the market. The benefits of the compliance action for companies are the net returns obtained from continuing to produce the product by reformulating. In fact, depending on the size of the reformulation compliance costs, product withdrawal may be the firm's least cost option. In this respect, the costs of the restriction to PCP producers are bounded by the reformulation compliance costs.

Additional analysis, relaxing some of the assumptions used to estimate reformulation costs is described in Appendix I, section I.4. This indicates that the reformulation costs are likely to lie in the interval €30 million - €100 million for the 2 year compliance period, and €30 million – €90 million for the 5 year compliance period. The SEAC opinion is based on these additional cost estimates.

The analysis on reformulation costs assumes that the performance and quality of the reformulated wash-off personal care products is the same as the pre-restriction wash-off personal care products containing D4/D5. However, if the reformulated products possess different quality characteristics that affect their demand, then the effect of this change needs to be taken into account.

The impact of ‘product performance reduction’ in terms of cost can be estimated by using data from the WTP study discussed in Section F.1. Assuming that the UK population is representative of the EU population in terms of their WTP for the higher functional performance/quality attributes of the D4/D5-based products, the aggregate annual WTP for the EU population would be equal to: EU population (Approx 500 million) x WTP per person per year (€5.33)

= €2.665 billion per year

This figure is reduced to approximately €45 million per year if:

- The population of children (around 15.4% of the population are aged 0-14) is removed.
- It is assumed that the reformulated products are only able to replicate 50% of the quality of D4/D5-based products.
- Only the portion of WTP related to wash-off personal care products is included.

Using the estimates of raw material formulation costs, product reformulation costs and product performance reduction costs (economic impact costs) described above the cost-effectiveness of the proposed restriction can be estimated. Cost-effectiveness is calculated by dividing the sum of economic impacts by the reduction in emissions of D4/D5 as a result of the proposed restriction. In accordance with modelling undertaken in Section B.9.3.7, the emissions reduction estimate used is 199600 kilograms of D4/D5. Results are presented in Table F.1.

Table F.1 Aggregate annual economic impact and cost-effectiveness estimates

Measure of annualised reformulation costs used[1]	Compliance Period	Economic Impact Component			Agg Annual Impact (excluding PPR loss) (€) (d)= (a)+(b)	Agg Annual Impact (including PPR loss) (€) (e)=(d)+(c)	Cost-effectiveness (excluding PPR loss) €/kg (f)=(d)/199600	Cost-effectiveness (including PPR loss) €/kg (g)=(e)/199600
		Raw material substitution Costs[2] (€) (a)	Reformulation Costs[3] (€) (b)	Product performance reduction loss[4] (€) (c)				
Annualised net costs (20 y)	**2**	**3,420,000**	**19,664,952 - 58,044,340**	**45,000,000**	**23,084,953 – 61,464,340**	**68,084,953 – 106,464,340**	**115.66 – 307.94**	**341.11 – 533.39**
	5	**3,420,000**	**4,188,567 - 38,307,702**	**45,000,000**	**7,608,567 – 41,727,702**	**52,608,567 – 86,727,702**	**38.12 – 209.06**	**263.57 – 434.51**
Annualised net costs (5 y)	2	3,420,000	60,032,299 - 177,195,193	45,000,000	63,452,299 – 180,615,193	108,452,299 – 225,615,193	317.90 – 904.89	543.35 – 1130.34
	5	3,420,000	12,786,673 - 116,944,059	45,000,000	16,206,673 – 120,364,059	61,206,673 – 165,364,059	81.20 – 603.03	306.65 – 828.48
Annualised gross costs (20 y)	2	3,420,000	89,551,902 - 127,931,288	45,000,000	92,971,902 – 131,351,288	137,971,902 – 176,351,288	465.79 – 658.07	691.24 – 883.52
	5	3,420,000	79,611,315 - 113,730,450	45,000,000	83,031,315 – 117,150,450	128,031,315 – 162,150,450	415.99 – 586.93	641.44 – 812.38
Annualised gross costs (5 y)	2	3,420,000	273,380,086 - 390,542,980	45,000,000	276,800,086 – 393,962,980	321,800,086 – 438,962,980	1386.77 – 1973.76	1612.22 – 2199.21
	5	3,420,000	243,033,901 - 347,191,287	45,000,000	246,453,901 – 350,611,287	291,453,901 – 395,611,287	1234.74 – 1756.57	1460.19 – 1982.02

Note: [1] The measure of annualised reformulation costs used refers to whether a 20 or 5 year annualisation period and net or gross costs has been used in the calculation.

[2] The cost estimates indicated in this column refers to the central case estimate figure calculated in table F.3 (see Appendix F).

[3] The cost estimates indicated in this column refers to the upper and lower bound estimate figures calculated in table F.7 (see Appendix F).

[4] The ‘product performance reduction’ loss figure is based on the illustrative example shown in section F.2.4 (see Appendix F). Given that the actual product performance reduction that might ensue following reformulation is unknown, a 50% mid point is used for the case whether some performance reduction is assumed.

Under a restriction compliance period of 5 years, the aggregate annual economic impact (cost) of the restriction is in the range of around €8-42 million assuming there is no reduction in product performance from the reformulated products, which corresponds to a cost-effectiveness in the range of around €38-209 per kg of D4/D5 emissions reduced. If on the other hand, a reduction in product performance from the reformulated products of 50% is assumed, then the corresponding figures would be in the range of around €53-87 million and €264-435 per kg respectively. The corresponding figures for a restriction compliance period of 2 years are €23-61 million and €116-308 per kg and €68-106 million and €341-533 per kg respectively.

An additional cost effectiveness analysis is described in Appendix I, section I.6, which is based on the alternative emission factors for wash-off products proposed by RAC. This analysis also incorporates revised total costs estimates based on the additional reformulation cost analysis mentioned earlier (as well as some other changes to the components of aggregate cost – these are described in Appendix I, section I.5). Based on this additional analysis, the cost-effectiveness ranges from below zero to 1200 €/kg D4/D5 reduced. Using the average emission reduction and the average costs, the estimates are around 400 €/kg for a 2 year compliance period and 430 €/kg for the 5 year compliance period. The SEAC opinion is based on using the figures from this additional cost effectiveness analysis.

The % increase in retail sales price of the reformulated wash-off PCPs would be less than 1% (using the methodologically preferred measure of costs to base the calculations on). Even in the case where the gross estimates of reformulation costs are used, the increase in retail sales price would be around 5%.

Using the additional cost analysis described in Appendix I, section I.5, the sales price increase is likely to be <1.5% for the high cost scenario and <1% for the low cost scenario. The SEAC opinion is based on using the figures from this additional cost analysis.

The costs associated with the economic impacts, as well as the cost-effectiveness estimates and retail sales impact are considered further in Section F.7, in terms of the proportionality of the proposed restriction.

F. 2.1 Testing and enforcement costs

It should be noted that some limited costs may be expected as a result of any testing (and associated administrative/reporting tasks) undertaken either by industry or enforcement authorities in order to ensure compliance with the restriction. Although industry will be required to ensure they are in compliance with the restriction, the extent that they will need to perform additional testing (to that currently undertaken) to demonstrate due diligence to authorities is unclear, since this does not necessarily require testing to be undertaken (and indeed this is not a requirement of the restriction *per se*). Moreover, it is possible that existing quality control testing performed by industry may already provide the necessary information requirements. As such it has not been possible to assess the extent of any such costs on industry. These are not considered further in the analysis.

With regards to enforcement and testing costs incurred by enforcement authorities to ensure compliance, these are considered in more detail in Appendix F.5. As indicated in the appendix, the minimum total cost of a product testing campaign is estimated at €6,400, whilst the total cost of a complex product testing campaign is estimated at €142,000. For a campaign which includes monitoring and sampling of selected water courses, etc., to identify the presence of chemicals, an additional cost of €46,000 is estimated. These costs are indicative costs to an individual enforcement authority and do not represent aggregate EU wide costs. These will clearly depend on the type and extent of campaigns in individual Member States. Irrespectively, aggregate EU wide enforcement costs are likely to be a small proportion of total compliance costs and hence given their relative scale these are not considered further in the analysis.

F.3 Indirect economic costs

In addition to the environmental benefits noted in Section F.1, the proposed restriction will also generate benefits in the form of cost savings at EU anaerobic digestion plants. During anaerobic digestion D4/D5 is released as a biogas. When this gas is combusted to produce useful energy, silicates are formed which strongly bond to the heated metal surfaces of the energy recovery equipment. The deposits are highly abrasive and cause excessive wear to the moving parts of the combustion chambers. This results in early failure of the engines resulting in higher engine maintenance costs or early overhaul and replacement requirements (HDR, 2010).

The proposed restriction would result in cost savings as a consequence of avoided maintenance/early overhaul and replacement requirements.

According to work undertaken by WCA (2013) – see Appendix F.1 and updated in Appendix I, section I.4, the following benefit estimates would result from these avoided costs[59]:

- A present value savings to the EU water industry over 20 years of between €53m and €533m with a 2 year restriction compliance period; and
- A present value savings to the EU water industry over 20 years of between €42m and €416m with a 5 year restriction compliance period;
- Equivalent annual saving to the EU water industry of between €4m and €39m, with a 2 year restriction compliance period; and
- Equivalent annual saving to the EU water industry of between €3m and €31m, with a 5 year restriction compliance period.

[Equivalent annual saving is based on the standard formula for annualising the lump sum present value investment given in the first two bullet points.]

It should be noted that these cost savings should be considered potential savings, since it is unclear the extent to which they would materialise fully. As the proposed restriction will not reduce all relevant silicon-containing substances from waste waters, there will still be a need, albeit reduced, to maintain, overhaul and replace the bioenergy generation equipment. It should also be noted that according to consultation undertaken by WCA (2013) with UKWIR (the UK Water Industry's Research Body), the costs associated with silicate damage, at least in the UK, could be an order of magnitude higher than those postulated in the WCA calculations. As such, the approach and estimates above may well be fairly conservative.

Once again these potential benefits from the proposed restriction are considered alongside the other estimates of costs and benefits in the section on proportionality (F.7).

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[59] Only the updated costs calculated as described in Appendix I are reported

F.4 Social impacts

Restricting the placing on the market and use of D4/D5 in wash-off personal care products may affect employment in those companies who currently produce such products as well as those companies who produce alternative products.

Given that the wash-off personal care product market is a small proportion of the total personal care product market (4% by volume), the expectation is that there would few job losses, particularly in firms which also manufacture the alternatives to wash-off products. AMEC (2013i) suggest that employment associated with products sold on the EU market would not necessarily be lost, though people would initially be reallocated to development of alternative products. It is difficult to place a figure on any adjustment costs incurred as a result of redeployment.

The restriction may also have a social impact on wellbeing, self-esteem and health derived from the use of wash-off personal care products containing D4/D5. Such impacts are already accounted for in the economic impact measure related to product performance reduction losses.

In summary, the social impacts of the proposed restriction appear to be limited (or at least taken into account in the impacts measured elsewhere).

F.5 Wider economic impacts

According to AMEC (2013i), the main wider economic impacts of a potential restriction are likely to relate to international trade and competitiveness.

Specifically, AMEC notes that if D5 is restricted in cosmetic products in the EU and not in other parts of the world, some of the current exports associated with D5-containing products would be lost, hence reducing the competitiveness of the EU as a whole. Any such wider economic impacts are premised on the assumption that reformulation does not work. Moreover, the analysis in section F.2 already assesses the economic consequences of such impacts in any case. Although there is uncertainty, the expectation is that such impacts may well be minor, but could be moderate depending on how well reformulation works or not.

Some arguments have been raised that the restriction of wash-off personal care products containing D4/D5 may have wider consequences on the market for all products containing D4/D5. This is on account of their listing as restricted substances, thereby giving a negative signal to downstream users and consumers as to the safety of the substances. However, it should be noted that the purpose of the proposal is to ensure that risk management is kept proportionate (i.e. that only action related to wash-off personal care products is necessary in order to ensure the risks from D4/D5 are minimised).

In summary, the possibility of wider economic impacts from the proposed restriction appears to be limited.

F.6 Distributional impacts

The proposed restriction can be expected to have distributional impacts in the personal care product market. The distributional impacts are not societal costs as such, as the negative impacts (if any) faced for example by one producer of affected personal care products would be compensated by positive impacts on the producers of products based on alternative formulations.

WCA (2012) with data provided by Cosmetics Europe estimate there are around 4,000 small and medium sized enterprises (SMEs) in the personal care product industry and 300 larger firms in the sector (who generate around 60% of turnover) as a whole. The SME's may be disproportionately impacted by the proposed restriction as they may need to cease production, especially if they do not produce the alternatives and are not able to adapt their production process.

To the extent that the increased costs of production arising from compliance costs are passed on to consumers then there will be 'distributional' impacts on them. However, as indicated in F.2 the increase in retail sales price of wash-off personal care products would be less than 0.5%, which is minor given the price of a typical wash-off personal care product.

F.7 Proportionality assessment

It should be noted at the outset that given the fulfilment of SVHC criteria, REACH calls for the minimisation of the emissions and exposures of substances meeting SVHC criteria as far as technically and practically possible (REACH Recital 70). The general objective is thus to achieve minimisation of emissions and exposures resulting from the uses of D4/D5 either via substitution or technical and operational measures to control the emissions in the most effective, proportionate and practical manner, whilst taking into account the availability of suitable safer alternatives substances and technologies, and the socioeconomic benefits from the use of D4/D5. Proportionality in economics is typically considered in terms of a comparison of benefits and costs.

In the context of PBT/vPvB substances, and as described in Section F.1, benefits assessment related to PBT/vPvB substances is often challenging, if not impossible. The approach to proportionality assessment taken in this dossier is based on the comparison of a benefits valuation study (described in Section F.1) and costs, but also includes a number of other lines of evidence and argumentation.

i) Comparison of costs and benefits of the proposed restriction

Assuming that reformulation is completely successful in replacing the wash-off PCPs containing D4/D5, the methodologically preferred measures of costs proposed in this dossier are estimated at €7.6-42 million and €23-61 million per year under a 5- and 2-year compliance period respectively. If reformulation was only partly (50%) successful, the costs are estimated at €53-87 million and €68-106 million per year under a 5- and 2-year compliance period respectively. Once again, it should be noted that even the methodologically preferred measures of costs are based on the highly conservative (and naive) assumption that no transferable R&D knowledge is gained in the process of reformulating the 3761 wash-off PCPs, or that product formulae cannot be reformulated simultaneously.

An additional analysis was undertaken, reported in Appendix I, which re-estimates the cost figures on the basis of some alternative assumptions. Based on taking the average of the three most likely scenarios (low, medium and high) across the different assumptions used, a central estimate has been computed, equal to **€50 million per year** for the 2 year compliance period, and **€45 million per year** for the 5 year period. The SEAC opinion is based on this additional analysis.

The proposed restriction results in benefits from indirect economic impacts that arise from avoidance of damage to energy generation equipment at anaerobic digestion plants. The avoided damages result in cost savings in the interval €4 million - € 39 million per year for a 2 year compliance period, and €3 million - €31 million for a 5 year period..

The environmental benefits arise from the reduction in potential risks associated with accumulation of D4/D5 in the aquatic environment. The aggregate benefits to the EU population, calculated from the stated preference valuation study, were of the order of around €19.3 billion annually (around €16 billion if only adults are included). If the ratio of the volume of wash-off to total personal care products containing D4/D5 (i.e., 4%) is considered, the share of environmental benefits attributable to reductions in the accumulation of wash-off personal care products containing D4/D5 is around €0.65 billion[60].

Comparing benefits and costs, it is clear that on the basis of the central estimates cited above the benefits of the restriction significantly outweigh the costs. This is supported by findings of the WTP study where individuals were found to value the reduction in potential risk of accumulation of D4/D5 in the aquatic environment around seven times more than the loss of product quality provided by D4/D5 in personal care products.

Another way to consider the proportionality using benefits and costs is to determine what the environmental benefits would have to be to equal the net economic impact costs of the restriction (i.e. to 'break-even). It is estimated that environmental benefits would have be around €35-69 million per year for the restriction to 'break even'. This amounts to an increase in retail sales price of around 0.5-1.0% for wash-off PCPs containing D4/D5 or a WTP for the environmental benefits of the restriction of around €0.07-0.14 per person in the EU.

Revised estimates of the break-even level of WTP can be calculated based on the additional cost analysis undertaken in Appendix I, section I.7. The necessary WTP ranges between €0.12 and €0.11 per person in accordance with the original break-even calculation procedure. An alternative break-even procedure has also been undertaken by SEAC in order to be consistent with the benefits estimation approach in this Background Document. This procedure, which is outlined further in Appendix I, recognises that the WTP values would be different depending on whether they are connected to removing the use of the substance (precautionary valuation) or to removing the emissions (impact valuation). Based on this procedure, the necessary WTP ranges between €0.2 and €6.5 per person if the WTP is assumed connected to the use. If the WTP is connected to emissions the range is reduced to €0.01 – €0.5. In all cases, the necessary WTP is higher for the 5 year compliance period.

Additional evidence on proportionality is considered based on a consideration of an alternative approach (from comparing benefits and costs) to assessing proportionality proposed by ECHA (2013), making use of cost-effectiveness analysis (described below).

ii) Cost-effectiveness of the proposed restriction

The measure of cost-effectiveness is calculated as the sum of the economic impacts divided by the reduction in emissions of D4/D5 as a result of the proposed restriction. under the assumption that reformulation is completely successful, the costs per kg of reducing emissions of D4/D5 are estimated at around €38-209 and €116-308 per kg under a 5- and 2-year compliance period, respectively. If on the other hand reformulation is only partly (50%) successful then the respective cost-effectiveness estimates are €264-

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[60] In fact, this takes a conservative view of the benefits, since there is good reason not to divide the benefits according to the share of the volume of wash-off to total PCPs containing D4/D5. This is because environmental benefits would only materialise from the emissions related to wash-off PCPs, hence the entire benefits (i.e. all €16 billion) should be attributable to just the wash-off PCPs.

435 and €341-533 per kg. The cost-effectiveness estimates using the worst case estimates under the ‘gross’ reformulation cost measure would be around €1,600-2,200 and €1,500-2000 under the 2- and 5-year compliance periods, respectively.

Additional cost effectiveness analysis was undertaken based on the alternative emission factors for wash-off products proposed by RAC. This analysis also incorporates revised total costs estimates based on the additional reformulation cost analysis mentioned earlier (as well as some other changes to the components of aggregate cost – these are described in Appendix I, section I.5). Based on this additional analysis, the cost-effectiveness ranges from below zero to 1200 €/kg D4/D5 reduced. Using the average emission reduction and the average costs, the estimates are around 400 €/kg for a 2 year compliance period and 430 €/kg for the 5 year compliance period.

When the cost-effectiveness measures are compared to the cost-effectiveness of previously proposed REACH restrictions, it appears that the risk reduction achieved by the proposed restriction is proportionate to the costs.

iii) Percentage retail sales price increase as a result of the proposed restriction

The final way that the proportionality of the proposed restriction can be assessed is in terms of its impact on the price of wash-off personal care products purchased by consumers. Assuming that the entire amount of compliance costs are passed onto consumers, then the increase in the retail prices paid for wash-off personal care products whilst technically not a measure of proportionality, gives an indication of its “affordability’.

Irrespective of the measure used, the percentage increase in retail sales price is very small, ranging from 0.11-0.62% and 0.34-0.91% for the proposed methodologically preferred measure of costs under the 5- and 2-year compliance periods, respectively. Even using the worst case estimates under the ‘gross’ reformulation cost measure, the percentage increase ranges from 3.64-5.17% and 4.08-5.81%, respectively. Given the retail price of a typical wash-off PCP, such increases can be considered rather small. As such, this measure also suggests that the restriction appears to be proportionate.

Using the additional cost analysis described in Appendix I, section I.5, the sales price increase is likely to be <1.5% for the high cost scenario and <1% for the low cost scenario.

In summary, the proportionality of the proposed restriction appears to be obvious even if the actual environmental impact of these substances was relatively low. Cost-savings related to reduction in damage arising in energy generation machinery at anaerobic digestion plants as a result of wastewater treatment of emissions of D4/D5 contained in wash-off personal care products alone appear to be sufficient to justify the proposed restriction under some cost-assessment scenarios. If the benefits related to the reduction in potential risks of accumulation of D4/D5 in the aquatic environment are included then the benefits appear to significantly outweigh the costs by around a factor of 7 to 1. The proposed restriction appears to be relatively cheap, when the cost-effectiveness is compared with previous measures to control similar substances under REACH. Finally, when using the affordability of the proposed restriction to consumers of wash-off personal care products to provide a ‘broader’ view of proportionality, the evidence suggests that consumers would not be noticeably affected.

F.8 Main assumptions

A number of analytical assumptions are used in the analysis. Of key importance were the methodological assumptions concerning the time pattern of the reformulation process and how to account for reformulation costs that occur in the absence of restriction for wash-off personal care products containing D4/D5. The key parameter assumptions that drive the outcome of the cost analysis are the number of products that would require reformulation and the reformulation rates of products in the absence of the restriction.

The number of products requiring reformulation and reformulation rates are highly uncertain.

On the benefits side, the key methodological assumptions reside in the validity of the benefits valuation study undertaken in the UK.

F.9 Uncertainties

According to the comparison of benefits and costs undertaken in Section F.7, the restriction appears to be proportionate, even under the alternative sensitivity assumptions used to derive the costs of the restriction.

In terms of the estimation of compliance costs, the key uncertainties concern the number of products that would be affected and the baseline levels of reformulation that would be undertaken in the absence of the restriction.

The baseline costs of reformulation are derived from a simplified account of the reformulation process of products that would be undertaken in the absence of the restriction. Clearly there are uncertainties about how well this approach and the parameters used characterise the actual process. The directional effect of this uncertainty is unclear.

The welfare losses related to any reduction in product performance and quality is also highly uncertain, primarily because it is not known how successful reformulation will be in replicating the beneficial characteristics and attributes that D4/D5 provides for wash-off personal care products that contain them. Moreover, there is uncertainty with the WTP value used as a proxy to estimate the value that is placed on the reduction in product quality. The valuation study is novel and the values obtained can be questioned due to respondents' understanding of the nature and scope of the environmental change they were asked to value. Nevertheless, the validity of the relative WTP values for the environmental and product performance attributes used in the study is internally consistent. As such any uncertainties arising from the validity of the absolute values applies to both sets of the values derived, namely the product performance and environmental benefit values. The impact of this uncertainty can thus be considered neutral overall.

Regarding the indirect economic impacts of the restriction, there are uncertainties regarding the size of the cost savings arising from the avoided damage to anaerobic digestion plant equipment. The uncertainties associated with the environmental benefit values derived from the stated preference study have been extensively covered both above and in the main body of this section.

G. Stakeholder consultation

During the drafting of the restriction proposal several stakeholders were consulted including the REACH Registrants and representatives of the European cosmetics industry (in particular the trade body Cosmetics Europe), EU Member States and non-EU authorities. The information provided covered uses, tonnages and emissions of D4 and D5, and the availability and technical and economic feasibility of alternatives. Previous consultations from the identification of D4 and D5 as PBT/vPvB substances were also taken into consideration in the preparation of this Annex XV report. For more details see Appendix G.

G.1 Public consultation on the Annex XV restriction report (18 June – 18 December 2015)

After submission of the Annex XV restriction report, ECHA organised a six-month public consultation on the restriction report from 18 June to 18 December 2015. During the consultation, 32 comments were received from stakeholders, representing individuals, industry, trade and NGOs, as well as Member State Competent Authorities. The comments (non-confidential) received, as well as the responses from the dossier submitter (UK) and from the rapporteurs of the Committees for Risk Assessment and Socio-economic Analysis are to be made available on the ECHA website[61].

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[61] http://echa.europa.eu/web/guest/previous-consultations-on-restriction-proposals

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Appendices

Non-confidential

Appendix B	Information on hazard and risk (non-confidential parts)
Appendix C	Available information on alternatives
Appendix E	Justification why the proposed restriction is the most appropriate Union-wide measure
Appendix G	Stakeholder consultation
Appendix I	Additional calculations and analysis by RAC and SEAC Rapporteurs

Confidential

Appendix B	Information on hazard and risk (confidential parts)
Appendix F	Socioeconomic analysis