

Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on

**OCTAMETHYLCYCLOTETRASILOXANE,
DECAMETHYLCYCLOPENTASILOXANE**

ECHA/RAC/RES-O-0000001412-86-97/D

Adopted

10 March 2016

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Opinion of the Committee for Risk Assessment

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation on the proposal for restriction of

Chemical name: Octamethylcyclotetrasiloxane (D4)

EC No.: 209-136-7

CAS No.: 556-67-2

Chemical name: Decamethylcyclopentasiloxane (D5)

EC No.: 208-764-9

CAS No.: 541-02-6

This document presents the opinion adopted by RAC. The Background Document (BD) provides support to both RAC and SEAC opinions, giving detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINIONS

United Kingdom has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at: <http://echa.europa.eu/web/guest/restrictions-under-consideration> on **18 June 2015**. Interested parties were invited to submit comments and contributions by **18 December 2015**.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: **Michael NEUMANN**

Co-rapporteur, appointed by RAC: **Marian RUCKI**

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on **10 March 2016**.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted **by consensus**.

THE OPINION OF RAC

The restriction proposed in the original dossier:

| 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 | 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. |
| b) Decamethylcyclopentasiloxane EC Number: 208-764-9 CAS Number: 541-02-6 | 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. |

The Dossier Submitter's proposal is intended to cover personal care products (PCPs) that are washed off the hair or body within several minutes of application in accordance with normal use instructions, with the rinsate discharged to wastewater. The restriction is not intended to cover PCPs that are removed from skin without water (e.g. with wipes or tissues) or that perform their function by being left on the hair or body for several hours and which are only subsequently removed as a result of normal washing routines (e.g. moisturisers, leave-on hair conditioners). The proposed restriction is not intended to cover therapeutic shampoos since they are normally left on overnight.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the

Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on **octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5)** is the most appropriate EU wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the conditions are modified.

The conditions of the restriction proposed by RAC are:

| 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 | 1. Shall not be placed on the market in cosmetic products used or disposed with water intended for consumer or professional use in concentrations equal to or greater than 0.1% by weight of each of the substances. |
| b) Decamethylcyclopentasiloxane EC Number: 208-764-9 CAS Number: 541-02-6 | 2. Cosmetic products are defined as being within the scope of Regulation (EC) 1223/2009 3. This restriction shall come into force on DD/MM/YY [18 months after publication in the Official Journal]. |

The term 'personal care product (PCP)' is used throughout the Background Document and opinion and is intended to have the same meaning as 'cosmetic product' in this context. The wording "used or disposed with water" refers to the intended conditions of use as described on a product's use instructions or packaging.

JUSTIFICATION FOR THE OPINION OF RAC

IDENTIFIED HAZARD AND RISK

Description of and justification for targeting of the information on hazard and exposure (scope)

Both *octamethylcyclotetrasiloxane* (D4) and *decamethylcyclopentasiloxane* (D5) are high tonnage substances in Europe. D4 is registered under REACH in the 100 000 to 1 000 000 tonne per year band and D5 is registered under REACH in the 10 000 to 100 000 tonne per year band. They are mainly used as monomers in the manufacture of silicone polymers, but also have direct uses in personal care products (PCPs), cleaning products and a range of other uses. Their presence as intentional constituents or impurities in a very wide variety of consumer products means that they have significant potential for environmental release.

Cyclic siloxanes perform three main functions in PCPs (1) hair-conditioning agents, (2) skin-conditioning agents (emollient) and (3) solvents. They have unique functions as antistatic, emollient, humectant, solvent, viscosity controlling and hair conditioning agent. Their low surface tension allows them to spread rapidly on skin and hair (CTPA, 2008). The Scientific Committee on Consumer Safety (SCCS, 2015) states that the main uses of D5 in PCPs are in skin care products, deodorants/antiperspirants, hair care products and make up products. A survey by Cosmetics Europe (CoE, 2014) identified over 15 different types of categories and over 75 types of products with D5 concentrations from close to 0% to nearly 100%.

The restriction proposal is justified by the PBT and vPvB properties of D4 and the vPvB properties of D5. Experience with PBT/vPvB substances has shown that they give rise to broad 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). The aim for any regulatory action on D4 and D5 therefore has to be to minimise any releases to the environment as far as technically and practically possible.

Registration dossiers do not identify D4 and D5 as fulfilling the REACH Annex XIII criteria for PBT and/or vPvB substances. The Dossier Submitter considers that, despite recent updates during the preparation of this opinion, the operating conditions and risk management measures in REACH Registration CSRs are inadequate to minimise emissions into the environment. During public consultation, Candidate Listing as a regulatory action was proposed and the Dossier Submitter states that this might be the only way to oblige Registrants to take full account of the implications of the PBT/vPvB properties of D4 and D5 (see comments of Public Consultation #1411, 1444 and 1446).

The Dossier Submitter considers that whilst releases of D4 and D5 to air from the wide range of different uses can be significant and result in long-range transport to remote regions, they are unlikely to lead to significant exposure in surface media or accumulation in biota. Therefore, based on the results of the Dossier Submitter's risk assessment, the restriction proposal is targeted on uses that result in emissions to the aquatic environment and specifically on the use of D4 and D5 in wash-off personal care products (PCPs) e.g. shower gels, shaving foams and shampoos. The Dossier Submitter considers these uses to be the major source of D5 to the aquatic environment in the EU. Releases of D4 from wash-off PCPs are relatively much smaller, but D4 was included in this restriction as a contribution to its emission reduction and to prevent substitution of D5 with D4.

RAC notes that wash-off PCPs are cosmetics defined under Regulation (EC) 1223/2009

(Cosmetics Regulation). However, the Cosmetics Regulation considers that environmental risks posed by substances used in cosmetics, including PBT and vPvB properties, should be considered under the REACH regulation (EC 1223/2009 – recital 5). In this specific case the decision to target the restriction on wash-off PCPs was based on a thorough analysis of the environmental fate and behaviour characteristics of D4 and D5 by the Dossier Submitter (see B.4 in the Background Document), a review of registered uses in CSRs and the conclusions of a quantitative emissions assessment.

RAC notes that the Dossier Submitter intended that the proposed restriction addressed three potential sources of D4 and D5 to the aquatic environment:

1. Formulation of wash-off PCPs;
2. Use of wash-off PCPs by consumers or professionals that intentionally contain D4 or D5 as a substance (referred to by the Dossier Submitter as direct uses); and,
3. Use of wash-off PCPs by consumers or professionals that unintentionally contain D4 or D5 as impurities, most likely in silicone polymers (referred to by the Dossier Submitter as indirect uses).

Equally, RAC notes that the Dossier Submitter does not intend to restrict D4 or D5 in the formulation and use by consumers or professionals of leave-on PCPs, or PCPs that are not used, removed or disposed of using water. The rationale behind this targeting was that the Dossier Submitter considered that these uses do not result in significant emissions to water as D4 and D5 evaporate rapidly after use and before they can be removed by washing. Similarly, the Dossier Submitter does not intend to restrict the use of D4 or D5 in therapeutic shampoos (such as those used for the treatment of headlice) or products like sunscreens. RAC notes that therapeutic shampoos for the treatment of headlice that contain D5 are medicinal products for human use and would therefore not be considered as PCPs or cosmetics within the scope of this proposed restriction.

RAC has undertaken an evaluation of the Dossier Submitter's decision to target wash-off PCPs. RAC outlines the conclusions of this evaluation in subsequent sections of this opinion.

Assessment of environmental risks

Information on hazards(s)

RAC notes that the Member State Committee at its 41st Meeting in 2015 adopted an opinion on the persistence (P/vP) and bioaccumulation (B/vB) of D4 and D5 at the request of the Executive Director of ECHA under Art. 77(3)c of REACH. MSC was of the opinion that both D4 and D5 fulfil the REACH Annex XIII criteria for vP and vB (see MSC Opinion on persistence and bioaccumulation of D4 and D5 Adopted on 22 April 2015). RAC has not reassessed the P/vP and B/vB properties of D4 or D5 as part of this opinion. However, as described below, RAC has examined the T properties of both D4 and D5.

D4 has a long-term NOEC of around 4 – 6 µg/L for rainbow trout (*Oncorhynchus mykiss*), although RAC notes that there is some uncertainty in this value, and a long-term NOEC of 7.9 µg/L for *Daphnia magna* survival. D4 meets the criteria for classification according to the CLP Regulation as Aquatic Chronic 1 (H410) based on the lowest reliable aquatic chronic NOEC of around 4.4 µg/L. The M-factor would be 10. Significant toxicity to invertebrates is also apparent in sediment organism studies. In addition, D4 has a harmonised classification as toxic to reproduction in category 2. The classification was based on evidence that inhalation exposure of female rats to D4 around the time of mating causes, in the absence of marked maternal toxicity, a dose-related reduction in the number of *corpora lutea*, implantation sites and litter size. Inhibition of the LH surge and subsequent ovulation is the mode of action, which is relevant to humans.

Conclusion 1: D4 meets the REACH Annex XIII criteria for both a PBT and vPvB substance. RAC agrees with the Dossier Submitter that D4 meets the REACH Annex XIII criteria for toxicity based on both aquatic and mammalian end points.

The available aquatic toxicity data for fish, invertebrates and algae indicate that D5 does not cause severe toxic effects in either short- or long-term studies at concentrations up to (or close to) its water solubility limit. Therefore the available toxicity data for pelagic organisms seem not to fulfil the REACH Annex XIII criteria for toxicity.

D5 is toxic to sediment and soil organisms with the calculated pore water concentration in sediment tests corresponding to the lowest NOEC of around 0.014 mg/L (close to the water solubility limit of the substance). However, the available sediment toxicity data does not fulfil the REACH Annex XIII criteria for toxicity. In addition, the available data on soil toxicity do not allow a comparison with the REACH Annex XIII criteria for toxicity.

D5 does not meet the REACH Annex XIII criteria for toxicity, although RAC notes that a full dataset for human health hazards classification is not available. 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 REACH Annex XIII criteria for toxicity.

Conclusion 2: D5 meets the REACH Annex XIII criteria for a vPvB substance. RAC agrees with the Dossier Submitter that D5 does not meet the REACH Annex XIII criteria for toxicity on the basis of the available evidence.

Information on emissions and exposures

Fate and behaviour in the environment

The proposed restriction is based on a thorough analysis of the environmental fate and behaviour characteristics of D4 and D5 (see section B.4 of the Background Document) by the Dossier Submitter. Behaviour in water and air is fundamental to the Dossier Submitter's justification for the targeting of the proposed restriction on wash-off PCPs. Only a brief summary of the key information is given here.

Water

In the freshwater compartment under relevant environmental conditions (including 12°C and the presence of organic matter in suspended solids and sediment) D4 and D5 are both assessed to be very persistent (MSC-41). D4 and D5 have a high tendency to adsorb to sediments and particles which hinders hydrolysis. The significance of hydrolysis was proven in clean water test systems but not under environmentally relevant conditions.

Sediment

In the freshwater sediment compartment D4 and D5 have degradation half-lives of between 242-365 and 800-3 100 days at 24 °C, respectively. Under environmentally relevant conditions (e.g. 12°C) negligible biodegradation of D4 and D5 should be assumed.

Soil

In the soil compartment the available data do not allow the derivation of reliable degradation half-lives for D4 and D5 (MSC-41). However, under environmentally relevant conditions (e.g. 12°C) the REACH Annex XIII criteria for very persistent (vP) is clearly fulfilled (MSC-41).

WWTP

Based on the values for vapour pressure and mean K_{OC} , and noting that the substances are not readily biodegradable, the overall removal in a 'typical' WWTP predicted using SimpleTreat modelling within EUSES 2.0.3 is around 96% (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. It must be noted that this removal from the water phase is not degradation but dissipation to the air compartment (volatilisation) and sludge.

Air

Both substances are volatile (with a Henry's Law constant of 1.21×10^6 Pa·m³/mol at 21.7 °C for D4 and 3.34×10^6 Pa·m³/mol at 24.6 °C for D5, respectively). The volatilisation half-life from water is reported by the Dossier Submitter 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 in soils 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.

Long-Range Transport

D4 and D5 have the potential to undergo long-range transport to remote regions via the atmosphere. Their atmospheric half-lives (D4 ca. 14 days; D5 ca. 10.4 days) are extremely long. Several modelling studies and air monitoring data are reflected in the Background Document, demonstrating that the travel distance is long (several thousand kilometres).

The Background Document outlines that atmospheric emissions of D4 and D5 are unlikely to result in significant deposition to surface media (see Section B.4 of the Background Document). However, a recent study submitted by industry in the public consultation (Sanchís, et al. 2015a,b), may indicate the opposite. This article presents new monitoring data for Antarctica and concludes that cyclic volatile methylsiloxanes (including D4 and D5) are "hoppers"¹ rather than "flyers"¹. In this study, D4 and D5 were found in soil (median concentration 13.9/19.0 ng/g dw), vegetation (median concentration in moss, lichen and grass of 5.38/10.0 ng/g dw), phytoplankton (median 0.70/0.80 ng/g dw) and krill (median 41.1/33.9 ng/g dw, max. 117/63.1 ng/g dw). Sanchís, et al. (2015a,b) consider that D4 and D5 can undergo atmospheric deposition by snow scavenging during the Antarctic winter and accumulate in the Antarctic biota and soil after the summer snow melt.

Some comments received during public consultation (comments # 1450 and 1454) questioned the reliability of the Sanchís et al (2015a,b) study. Although the findings of this study are currently considered controversial, RAC considers that they cannot simply be overlooked. The analytical procedures may be reliable even if background levels of D5 in the analysed samples are high but consistent through all samples.

In contrast to modelling studies indicating a low potential for subsequent deposition to surface media (see section B.4.2.3 of the Background Document) the findings of Sanchís et al (2015a,b) raise concerns that the contamination of remote areas by D4 and D5 is possible. Despite of the fact that D4 and D5 may ultimately degrade in the atmosphere during Antarctic summer the concentration of OH radicals during the Antarctic winter is lower, resulting in slower degradation of D4 and D5 in the atmosphere. Consequently, deposition of D4 and D5 seems to be possible during extremely low temperatures. The

¹ After long-range transport "hoppers" can deposit in remote areas to surface media while "flyers" do not deposit and stay in the atmosphere till degraded.

Dossier Submitter states that the available information does not permit a detailed consideration of deposition in the Arctic because the data available are limited and uncertainties have been noted in some of these studies. The Dossier Submitter considers that the findings of the Sanchís et al study need confirmation before they can be considered reliable. RAC supports the Dossier Submitter's conclusions (see justification that the suggested restriction is the most appropriate EU wide measure).

The risks to non-human, air breathing organisms, including mammals, from exposure to D4 and D5 via air are not considered in detail by the Dossier Submitter as the focus of the restriction proposal is on aquatic emissions. However, they consider that these risks are likely to be low. As the scope of the restriction proposal was limited to emissions to the aquatic environment, RAC did not consider the risks of D4 and D5 via air exposure in this opinion.

Conclusion 3: RAC agrees with the Dossier Submitter that emissions of D4 and D5 to surface water from municipal WWTPs are assumed to be around 5% of the influent concentration. Removal from the WWTP will result in dissipation into the air compartment via volatilisation and dissipation into the sludge via adsorption. RAC notes that accumulation in the sediment compartment is expected to form a sink for D4 and D5 in the environment which can in turn lead to bioaccumulation in aquatic biota.

Conclusion 4: RAC agrees with the Dossier Submitter that emissions of D4 and D5 to air can result in long-range transport to remote regions via the atmosphere due to their extremely long atmospheric half-lives. While it is clear that the major fraction of emitted D4 and D5 will reside in the atmosphere until degraded, it is unknown how much could be deposited to surface media. RAC notes that due to the high volume of total emissions into air from various different uses (not only in PCPs) of these substances, even if deposition rates were low, this exposure route would be a potential source of risk to remote areas.

PCPs as a source of D4 and D5 into the aquatic environment

Summary of the emission scenarios developed by the Dossier Submitter

Cyclic siloxanes (such as D4 and D5) perform three main functions in PCPs (1) hair-conditioning agents, (2) skin-conditioning agents (emollient) and (3) solvents. Their low surface tension allows them to spread rapidly on skin and hair (CTPA, 2008). The Scientific Committee on Consumer Safety (SCCS, 2015) states that the main uses of D5 in PCPs are in skin care products, deodorants/antiperspirants, hair care products and make up products. A survey by Cosmetics Europe (CoE, 2014) identified over 15 different types of categories and over 75 types of products with D5 concentrations from close to 0% to nearly 100%.

The proposed restriction is targeted by the Dossier Submitter at reducing emissions of D4 and D5 to the aquatic environment from wash-off personal care products (PCPs). The Dossier Submitter selected relevant uses of D4 and D5 for the restriction based on information on their potential for aquatic emissions as described in registration dossiers and on the basis of a risk assessment. The Background Document identifies the uses considered during the development of the restriction (see Table 9 in the Background Document). D4 and D5 are widely used in both "leave-on" and "wash-off" PCPs either directly as components of PCP formulations (mixtures) or unintentionally as an impurity in other substances or silicone polymers (termed as indirect uses by the Dossier Submitter).

Environmental emissions of D4 and D5 from leave-on PCPs were not considered sufficiently significant by the Dossier Submitter to include them within the scope of the proposed restriction. The Dossier Submitter considered that D4 and D5 would evaporate before they could be removed through normal washing routines.

Information on releases of D4 and D5 from different types of PCPs to wastewater during use are limited. Available data are restricted to a small number of specific product types i.e. deodorant and antiperspirant products, skin care products and rinse-off hair conditioner as described by Gouin et al. (2015) and Montemayor et al. (2013). Releases of D4 are read-across from data for D5. In each study only relatively few samples are investigated. The Dossier Submitter considers that the Gouin et al. (2015) and Montemayor et al. (2013) studies are reliable but acknowledge that they have some methodological limitations, which are described further in the Background Document (see section B.9.3.2 and Appendix B.2).

The Dossier Submitter's risk assessment, which established the scope of the proposed restriction, was initially based on two release factors. One factor for PCPs which are washed-off after application within a few minutes ("wash-off" PCPs) and a second release factor for PCPs which are left on the body under normal use ("leave-on" PCPs).

In their initial approach the Dossier Submitter selected a worst-case release factor of 100% w/w to wastewater for all types of wash-off PCPs. This was based on the findings of Montemayor et al. (2013) and HTR (2011) that the average release from wash-off PCPs was around 73% (range: 48% to 160% with 95% confidence interval of 54 – 93%).

For all types of leave-on PCPs the Dossier Submitter selected a release factor of 0.1% w/w to wastewater based on the findings of Gouin et al. (2013) 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 and Montemayor et al. (2013) that the fraction washed-off 8 hours after application is below 0.1% w/w.

Applying these release factors to the tonnages used by the Dossier Submitter in their initial approach resulted in a release to wastewater of <1 000 tonnes/year for D5 and < 15 tonnes/year for D4 in wash-off PCPs, and ca. <24 tonnes/year for D5 and <0.36 tonne/year for D4 in leave-on PCPs.

Initial discussions in RAC focussed on the uncertainties on the release factors selected by the Dossier Submitter for wash-off and leave-on PCPs. In response to these discussions the Dossier Submitter established a series of six emission scenarios, each based on different combinations of release factors for wash-off and leave-on PCPs (see Background Document Appendix section B.7). The Dossier Submitter considers that scenarios 1 and 3 represent the boundaries of the likely actual emissions and that scenarios 4, 5 and 6 are unrealistic because the overall level of emission is not consistent with the available wastewater influent monitoring data.

The Dossier Submitter states in Section B.9.3.2 of the Background Document that it seems likely that some of the D4 and 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 PCPs that are intended to be left on for a few minutes before wash-off (as indicated by Montemayor et al., 2013). Following the discussion in RAC the Dossier Submitter selected in emissions scenarios two and three an alternative release factor of 73% w/w to wastewater for all types of wash-off PCPs based on the measured mean value of Montemayor et al. (2013).

Following the discussion in RAC the Dossier Submitter uses in scenarios three and five separate release factors for different (sub)categories of leave-on PCPs: 0.21% w/w for leave-on skin care products, 0.02% w/w for leave-on hair care products and 1% w/w for all other leave-on PCP sub-categories (including deodorants) based on the findings of the Montemayor et al. (2013) study. The Dossier Submitter assumes, based on the available data, that on average people will have a full body wash once per day and that this will occur at the end of the day, which would make it likely that at least 10 hours will have elapsed before any applied PCPs would be washed off.

RAC evaluation of the emission scenarios

RAC notes that only very few studies have examined and measured the potential for D5 to be released to wastewater following application of PCPs to the human body (see section B.9.3.2 of the Background Document). The reliability of these studies is burdened by experimental shortcomings and unexplained findings. Equally, RAC is unable to evaluate how representative the available information is for the wide range of different PCP categories and product formulations available on the market. No information is available about how some of the various products are applied to the body/hair. What can be concluded is that the various direct uses of D5 (and D4) in PCPs will cause emissions into the aquatic environment in different amounts depending on the type of PCP, the amount of D5 (and D4) contained in the formulation, the use condition, the behaviour by the consumer and the tonnage of the specific type of PCP on the EU market.

RAC therefore supports the approach by the Dossier Submitter to use different release factors in separate emissions scenarios for wash-off and leave-on PCPs.

Modelling indicates that as a pure substance D5 may evaporate rapidly from the various external parts of the human body even though exact evaporation time and rate depend strongly on temperature and the amount applied per cm² of skin. During public consultation (comment # 1419), D4 and D5 removal from skin of 99.3% and 97.2%, respectively, was modelled after 24 hour dissipation period. Similarly, the draft of an SCCS opinion (2015) states that D5 as a volatile excipient in cosmetic products evaporates from skin or hair within 4 to 12 hours after application. This mechanism reduces emissions into the wastewater caused by leave-on PCPs but results in emissions to air and the atmosphere.

In contrast to the approach by the Dossier Submitter, RAC considers that because of the high uncertainty and limitations of the available information on releases it is not possible to select reliable and representative release factors for individual types of PCPs within the two groups of wash-off and leave-on PCPs e.g. to distinguish between leave-on skin care products and leave-on hair care products. RAC considers that in the evaluation of the restriction proposal the emission scenarios for wash-off and leave-on PCPs must represent the underlying uncertainty and the limitations of the available information in a consistent way. Equally, the conservatism of assumptions on emissions factors for leave-on and wash-off PCPs should be comparable.

In the view of RAC, the Dossier Submitter initially used different approaches when selecting representative release factors for wash-off and leave-on PCPs. For wash-off PCPs an absolute worst case assumption (100% release factor) was selected. In contrast, in the Dossier Submitter's initial approach for leave-on PCPs, a release factor of 0.1% for all types of leave-on PCPs was assumed, which was not consistent - concerning the level of conservatism and protectiveness - with an absolute worst case for wash-off PCPs. Also, in scenarios three and five of the Dossier Submitter's updated approach, use of separate release factors for different types of leave-on PCPs is not comparable to the approach for wash-off PCPs. In the view of RAC the selection of different release factors for different product types within one of the groups is not supported by the available data and information.

RAC discussed and evaluated the release factor selected by the Dossier Submitter for leave-on PCPs. Gouin *et al.* (2013) found that between 0.004 and 5.8% w/w of the amount of D5 initially applied in a deodorant product was washed off after 7 hours. The variability of this experiment is extremely large caused by several low measured release values and a single high measured release value. RAC notes that sampling and analysis of D5 seems not to be an easy task. This is supported by the fact that Gouin *et al.* (2013) measured a release factor of only 5.5–17.7% w/w for a deodorant directly after application (time =0). This low recovery is not explained by the authors. Perhaps more significantly, the mean recovery

rate of the whole experiment as measured in a spiked experiment was only 81.0%. Taken together, RAC considers that there is enough evidence to question the reliability of the low measured values in this experimental set up by Gouin et. al. (2013). RAC therefore assumes that experimental and analytical shortcomings could be responsible for the low measured values and that this is not reflected sufficiently by the Dossier Submitter when they chose release factors for leave-on PCPs, neither in their original or revised approach.

In the view of RAC, the maximum measured release factor of 5.8% w/w for a leave-on PCP (Gouin et. al. 2013) indicates that the variability in reality could be extremely high and that greater release factors for leave-on PCPs than those measured in the available studies might occur. RAC sees the need to take this into account when selecting release factors for leave-on PCPs. RAC considers that the highest release factor measured by Gouin et al. (2013) must not be disregarded as an outlier, as proposed by the Dossier Submitter, based on statistical considerations without incorporating the possible experimental shortcomings in a scientific justification.

In addition to release factors for wash-off and leave-on PCPs the Dossier Submitter describes further release factors for the formulation of PCPs and for "other uses" of D4 and D5 in section B.9.3 of the Background Document. RAC agrees with the derivation of these release factors.

RAC agrees with the Dossier Submitter that D4 and D5 present as impurities in silicone polymers or other substances used in wash-off PCPs (referred to by the Dossier Submitter as indirect uses) could contribute to overall releases of D4 and D5 to wastewater and ultimately surface waters. Equally, RAC notes that the Dossier Submitter considers that the information available to estimate the likely magnitude of these emissions is rather limited and based on assumptions of tonnage and a maximum concentration of 0.5% w/w in PCPs. As such, whilst RAC acknowledges that indirect uses could be a potentially significant source of emissions to wastewater, particularly for D4, the limited information available to the Dossier Submitter prevents a reliable assessment of the likely size of these emissions. As such, RAC considers that the quantitative estimates of emissions for indirect uses of D4 and D5 in wash-off and leave-on PCPs should be interpreted with care.

Release factors proposed by RAC

To take account of the uncertainties in the release factors, RAC has undertaken a further exposure assessment using a modified approach based on lower and upper bound release factor ranges. The RAC approach incorporates the high uncertainty and the limited representativeness of the available information in a consistent way. Different release factor ranges were selected for wash-off and leave-on PCPs. Release factors for specific types of PCPs within each of these groups were not derived. The release factors are equally applicable to D4 and D5 present as an intentional component (direct use) or as an unintentional impurity (indirect use).

Wash-off PCPs

For wash-off PCPs, RAC concludes to use the 95% confidence interval of the measured data from Montemayor et al. (2013) of 54% to 93% (mean: 73% and range: 48% to 160%) as lower and upper boundary of the release factors (Figure 1).

Leave-on PCPs

RAC proposes a lower boundary release factor of 0.1% for all leave-on PCPs. This value is in line with the original approach of the Dossier Submitter. As an upper boundary RAC proposes a release factor of 2.6%. This value is derived from the mean plus one standard deviation (at 7h) of measured releases from Gouin et al (2013). This upper bound release factor is greater than the values used by the Dossier Submitter in their various emission scenarios but is still well below the maximum measured release factor of 5.8% for a leave-

on PCP (Gouin et. al. 2013). The lower bound release factor assumes a full body wash 24 hours after application whilst the upper bound assumes a full body wash occurs no later than 10 hours after application (Figure 2).

This release factor range takes into account the potential that the variability of releases in reality might be extremely high and that greater release factors for specific categories of leave-on PCPs might occur. It also takes into account that around 28% of the population have washing frequencies of more than seven full body washes per week i.e. more than once per day (Pullinger *et al.* 2013).

RAC is aware that this upper bound is likely to be conservative but it was derived in response to the absence of reliable and representative measured data. If more reliable data would become available it may be reasonable to select different values for these release factors.

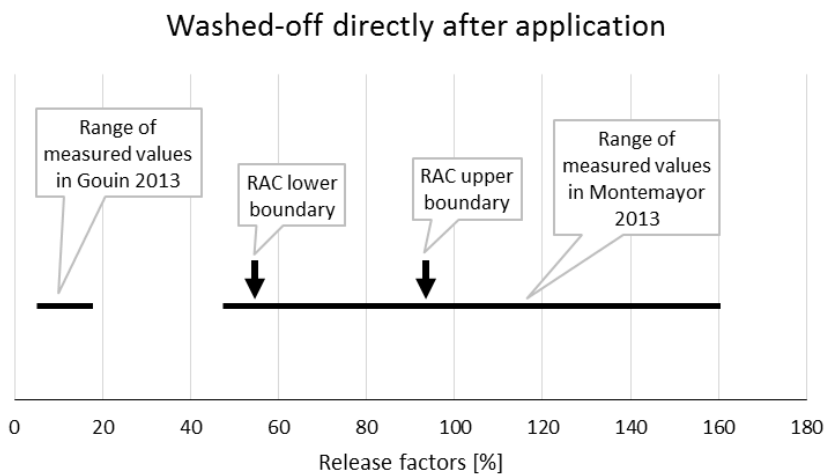


Figure 1. PCPs washed off directly after application (wash-off PCPs). Range of measured release factors from Gouin et. al. (2013) and Montemayor et al. (2013) and selected by RAC: lower and upper boundary

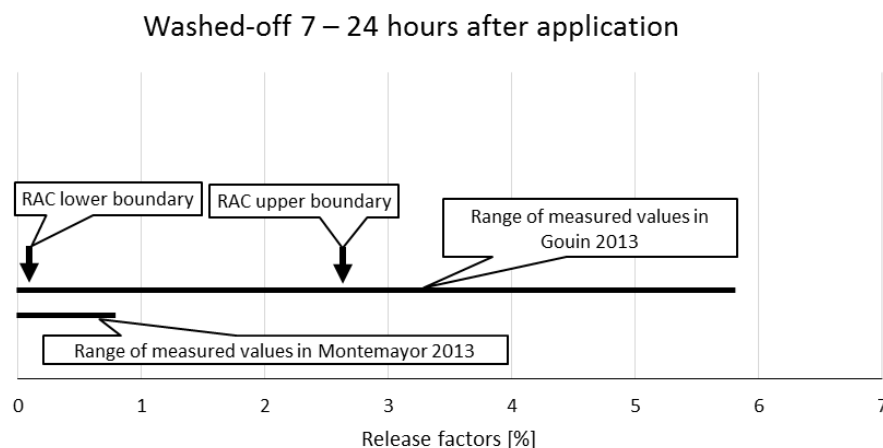


Figure 2. PCPs washed off 7 to 24 hours after application (leave-on PCPs). Range of measured release factors from Gouin et. al. (2013) and Montemayor et al. (2013) and selected by RAC: lower and upper boundary

Tonnages

The Background Document (Section B.9.3.1 of the Background Document) highlights the uncertainty in the available tonnage data. The minimum amount of D5 in wash-off and leave-on PCPs was based on a survey of Cosmetics Europe members. This was then extrapolated by the Dossier Submitter (using a factor of 1.6) to a hypothetical 'maximum' EU tonnage by making an assumption about the market share represented by the survey respondents. This initially gave an amount of D5 in wash-off and leave-on PCPs of <1,000 and <24 000 tonnes/year, respectively. Although uncertain, this was the best information initially available to the Dossier Submitter.

Cosmetics Europe stated during the public consultation (comment #1431) that the amounts used in PCPs might be overestimated by using this approach, but had no information to verify or refute the assumption used in the dossier. Additional non-confidential information submitted by Cosmetics Europe later in the public consultation (comment #1452) gave quantities of D5 in wash-off and leave-on PCPs of 750 and 14 250 tonnes/year, respectively. These figures had been agreed between the REACH Registrants (i.e. the substance manufacturers and importers) and Cosmetics Europe, and so should represent a much higher proportion of the overall EU market than the Cosmetics Europe survey alone. 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 and several PCP manufacturers are not members of Cosmetics Europe). It might therefore be appropriate to consider a higher tonnage figure. However, the Dossier Submitter has no way of assessing what further tonnage might be relevant outside of the public consultation process and consider that the amounts are likely to be relatively small in any case. In addition, the data provided is thought to include some tonnage that is subsequently exported and not used in PCPs in Europe.

The Dossier Submitter therefore considers that the new information is likely to be close to the amount of substance actually on the market. On this basis, the Dossier Submitter concludes a representative amount of D5 used in leave-on PCPs of 14 250 tonnes/year (and 750 tonnes/year for wash-off PCPs). In contrast, the relative total amount of D4 in wash-off and leave-on PCPs is estimated to be 11 and 214 tonnes/year, respectively, assuming the quantity of D4 is 0.015 times (1.5%) that of D5 (Section B.9.3.1).

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

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

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

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

Conclusion 5: RAC agrees with the Dossier Submitter that the available data and information allow the conclusion that wash-off PCPs with an estimated amount on EU market of 11 tonnes/year of D4 and 750 tonnes/year of D5 account for a significant amount of emissions to the aquatic environment in the EU. Based on the uncertainties in the underlying experimental data, RAC considers that upper and lower bound release factors of 93% and 54%, respectively, should be used to estimate emissions of D4 and D5 to the aquatic environment.

Conclusion 6: The Dossier Submitter considers that leave-on PCPs with an estimated amount on EU market of 14,250 tonnes/year D5 and 214 tonnes/year D4 will lead to negligible emissions to the aquatic environment. However, RAC considers that emissions to wastewater may be significantly greater than this and that upper and lower bound release factors of 0.1 and 2.6%, respectively, should therefore be used to calculate emissions of D4 and D5 to the aquatic environment.

Characterisation of environmental risk(s)

EU emissions to surface waters

Based on the lower and upper release factors agreed by RAC and the updated tonnage information provided by industry during the public consultation the use of wash-off PCPs will result in EU emissions to surface waters of between 97.8 and 168.3 tonnes/year for D5 (including ~0.5% from indirect uses) and between 1.9 and 3.2 tonnes/year for D4 (including ~20% from indirect uses), respectively (see Table 3 and Appendix I of the Background Document).

Corresponding emissions to surface waters from the use of leave-on PCPs are calculated to be between 5.5 and 91.5 tonnes/year for D5 (including ~2% from indirect uses) and between <0.3 and 2.0 tonnes/year for D4 (including ~33% from indirect uses), respectively (see Table 4 and Annex I of the Background Document).

Emissions to surface waters from "other" uses (i.e. anti-foam applications in the pulp and paper, detergents and the oil and gas industry) are estimated to be <1 tonne/year for D4 and < 1 tonne/year for D5, despite the use of a conservative emission factor to wastewater of 100%.

Emissions to surface waters from the formulation of wash-off PCPs are estimated to be 0.1 tonnes/year, whilst emissions to surface waters from the formulation of leave-on PCPs are estimated to be significantly greater at 2.0 tonnes/year. RAC notes that the Dossier Submitter's proposal intends to restrict the formulation of wash-off PCPs, but not the formulation of leave-on PCPs, despite the emissions from the formulation of leave-on PCPs being estimated to be a factor of 20 times greater. RAC notes that for both wash-off and leave-on PCPs emissions from the use phase seem to be greater than from the formulation stage.

Table 3. Emission calculations for uses of D4 and D5 in wash-off PCPs

| Substance | Source | Annual tonnage | Release factor (%) [lower – upper] | Release to wastewater (tonnes/year) [lower – upper] | Release to surface water (tonnes/year) ^a [lower – upper] |
|-----------|--|----------------|---------------------------------------|--|--|
| D5 | Formulation of wash-off PCPs | 750 | see note b | 0.4 | 0.1 |
| | Direct use in wash-off PCPs | 750 | 54.0 - 93.0 | 405.0 – 697.5 | 97.2 – 167.4 |
| | Indirect use in wash-off PCPs ^c | 3.47 | 54.0 - 93.0 | 1.9 – 3.2 | 0.5 – 0.8 |
| | Sum of emissions | | | 407.3 – 701.1 | 97.8 – 168.3 |
| D4 | Formulation of wash-off PCPs | 11.25 | see note b | 0.01 | <0.01 |
| | Direct use in wash-off PCPs | 11.25 | 54.0 - 93.0 | 6.1 – 10.5 | 1.4 – 2.4 |
| | Indirect use in wash-off PCPs ^c | 3.47 | 54.0 - 93.0 | 1.9 – 3.2 | 0.4 – 0.7 |
| | Sum of emissions | | | 8.0 – 13.7 | 1.9 – 3.2 |

Table 4. Emission calculations for uses of D4 and D5 in leave-on PCPs

| Substance | Source | Annual tonnage | Release factor (%) [lower – upper] | Release to wastewater (tonnes/year) [lower – upper] | Release to surface water (tonnes/year) ^a [lower – upper] |
|-----------|--|----------------|---------------------------------------|--|--|
| D5 | Formulation of leave-on PCPs | 14250 | see note b | 8.2 | 2.0 |
| | Direct use in leave-on PCPs | 14250 | 0.1 – 2.6 | 14.3 – 370.5 | 3.4 – 88.9 |
| | Indirect use in leave-on PCPs ^c | 92.5 | 0.1 – 2.6 | 0.1 – 2.4 | <0.1 – 0.6 |
| | Sum of emissions | | | 22.6 – 381.1 | 5.5 – 91.5 |
| D4 | Formulation of leave-on PCPs | 213.75 | see note b | 0.1 | <0.1 |
| | Direct use in leave-on PCPs | 213.75 | 0.1 – 2.6 | 0.2 – 5.6 | <0.1 – 1.3 |
| | Indirect use in leave-on PCPs ^c | 92.5 | 0.1 – 2.6 | 0.1 – 2.4 | <0.1 – 0.6 |
| | Sum of emissions | | | 0.4 – 8.1 | <0.3 – 2.0 |

Notes for Tables 3 and 4:

a. assuming 80% connection rate and removal in WWTW of 95% for D5 (i.e. factor applied is 0.24) and 96% for D4 (i.e. factor applied is 0.23); b. 40% of formulating sites are assumed to be well controlled (emission factor of 0.009%) and 60% of formulating sites are assumed to be less well controlled (0.09%), resulting in a release factor of 5.76×10^{-4} ; c. derivation as described in section B.9.3.3/B.9.3.7 of the Background Document, acknowledged as a potentially significant source of emissions to the aquatic environment by RAC but excluded from cost-effectiveness calculations by SEAC as emission estimates were considered to be too uncertain.

'Reality check' on the assumptions about release factors and tonnages

The Dossier Submitter uses back-calculations from WWTP influent data as a 'reality check' on the assumptions about release factors and tonnages. The method is described in Appendix B.7 of the Background Document. The Dossier Submitter states that it is difficult to establish a representative influent concentration from the limited available information. 50 µg/L D5 is the maximum concentration observed worldwide, while 36 µg/L D5 is the maximum of the available European data (covering 19 sites with a total of just 22 samples). An influent concentration of 10 µg/L D5 is considered by the Dossier Submitter to represent both the arithmetic mean (9.91 µg/L) and median (9.8 µg/L) of observed EU influent concentrations. 15 µg/L is suggested by Rucker and Kümmerer (2015) as an upper measured concentration of D5 in European wastewater samples (i.e. 9 – 11 µg/L in the UK; <1 – <12 µg/L in the Nordic countries; 5 – 9 µg/L in Spain).

Table 5 presents the back-calculated tonnages released to EU wastewaters for D5. These are compared with the tonnage ranges of direct uses of D5 in wash-off and leave-on PCPs estimated by the Dossier Submitter and RAC.

Table 5. Back calculated tonnage/year of D5 released to EU wastewaters based on WWTP influent concentrations of 10, 15, 36 and 50 µg/L compared with the tonnage/year calculated by the Dossier Submitter and RAC for direct uses of D5 in wash-off and leave-on PCPs .

| Influent concentration of D5 µg/L | D5 release to EU wastewater from direct uses in wash-off and leave-on PCPs (tonnes/year) | | |
|-----------------------------------|--|--------------|------------------------------|
| | Back-calculated from influent | DS scenarios | RAC lower and upper boundary |
| 50 | 920 | 562 – 893 | 420 – 1068 |
| 36 | 660 | | |
| 15 | 275 | | |
| 10 | 180 | | |

Releases of D5 to EU wastewaters calculated by either release factors and tonnages or by back calculation from influent concentrations are considered comparable and overlap in the upper tonnage range. In general, the back-calculations of the Dossier Submitter corroborate the approach adopted by the Dossier Submitter and RAC to base the emission assessment on release factors and tonnages derived from the available empirical studies. Using the upper range influent values of 36 and 50 µg/L leads to EU wastewaters back calculated tonnages per year well inside the range estimated by RAC. Upper influent values also mimic the range of the Dossier Submitter scenarios much better than the lowest back calculated values.

The two lowest back calculated wastewater tonnages, based on the influent concentrations of 10 µg/L and 15 µg/L, are a factor of three lower than the lowest Dossier Submitter scenario. The lowest RAC scenario overestimates by factor of two.

The Dossier Submitter considers that these back calculations support the view that the influent concentrations observed can be explained predominantly by the use of D5 in wash-off PCPs.

RAC emphasise that the back-calculations are highly dependent on model inputs and assumptions (e.g. spERC). Equally, RAC considers that the representativeness of influent

monitoring data (22 samples from 19 sites for the EU) is potentially limited. In addition, the fate and behaviour of D5 in sewerage systems after release (but before WWTP) is also uncertain. Overall, these factors are considered to potentially affect the reliability of the back-calculation. As such, whilst acknowledging that overall these calculations broadly corroborate the emissions assessments of both the Dossier Submitter and RAC, RAC does not consider that these data provide conclusive evidence that emissions of D5 to wastewater and the environment can be explained solely by uses in wash-off PCPs and prefers to use the results from the empirical release studies and updated tonnage values for the emissions estimates.

The key concern for D4 and D5 is their PBT/vPvB properties, which are considered to lead to 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 must be carried out.

Conclusion 7: RAC agrees with the Dossier Submitter that since D4 and D5 are PBT/vPvB substances their risks cannot be quantified adequately and that therefore, their emissions to the environment can be considered as a proxy for risk.

Assessment of human health risks

RAC notes that risks to human health from the use of substances in cosmetic products, as defined by Directive 76/768/EEC, are not within the scope of Title VIII of REACH (REACH Article 67(2)).

Therefore, RAC has not evaluated the hazards for human health of D4 or D5 including information from public consultation (comment # 1427) on possible endocrine modes of action. RAC however takes note of the draft opinion of the Scientific Committee on Consumer Safety (SCCS, 2015) on D5 in cosmetic products, which states that the use of D5 in cosmetic products is safe except for use in body lotion and hair styling formulations in product forms that can give rise to lung exposure of the consumer through inhalation, e.g. aerosols, pressurised sprays, powders, etc. SCCS recommended that the level of D4 as an impurity should be as low as possible and that the level of purity of D5 in the cosmetic products put on the market should be > 99%.

Human biomonitoring

Cyclosiloxanes seem to be ubiquitously distributed. RAC agrees with the Dossier Submitter that the exposure is mainly caused by direct exposure to consumer products. During the public consultation, information was submitted on the cooperation between the German Ministry of the Environment (BMUB) and the German Chemical Industry Association (VCI) launched in 2010 to develop analytical methods for D4, D5 and D6 in humans (see comment # 1425). RAC takes note that D4, D5 and D6 have the same metabolite in urine (Me₂Si(OH)₂) and that the limit of detection is too high to detect relevant quantities. Consequently, it is not possible to distinguish which of these substances causes exposure to humans. It can be concluded that it is currently not possible to determine the exposure to D4 and D5 in the general population with human biomonitoring (HBM) programmes.

ASSESSMENT OF ALTERNATIVES

Environmental and human health evaluation of alternatives for D4/D5

The Dossier Submitter has identified more than fifteen potential alternative substances (including linear volatile methylsiloxanes, D6, ethyl methicone, isodecyl neopentanoate, dicaprylyl carbonate, dicaprylyl ether, hydrogenated polydecene etc.), although other substances might also be suitable. Some are subject to Substance Evaluation under REACH, and others are subject to a PBT screening analysis. Definitive hazard property information is unavailable in some cases. No information on risk assessment is available in the Annex XV dossier or was submitted in the public consultation. In consequence, no definitive conclusion even on their hazard profile can be reached for the time being.

Based on the public consultation (comment # 1428), there is no universal and direct one-for-one substitute for D5 used in PCPs that could effectively duplicate all the specific product performance characteristics. For a number of product types, replacing D5 may require more than one alternative substance in order to achieve the desired performance characteristics of the finished product.

Comments (# 1412 and 1428) on possible alternatives were also received. The linear volatile methylsiloxanes (L2 - L5) are either considered too volatile to be used in both hair care and skin care applications (L2) or are potential alternatives at a higher cost and supplied in lower amounts (L3 - L5). D6 is used primarily in skin care. As a potential alternative to D4 and D5, D6 does not have the volatility to be used directly as a replacement.

Conclusion 8: The analysis of alternative substances is hampered by lack of comparable hazard and risk data and/or ongoing evaluations that prevent definitive hazard conclusions from being drawn at this stage. RAC has concerns that some alternatives could pose similar hazards to D4/D5, the intrinsic properties of others appear to be of less environmental concern than D4 and D5.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

D4 has PBT and vPvB properties and D5 has vPvB properties and both substances fulfil the criteria for Substances of Very High Concern (SVHC) (article 57 of REACH). Emissions into the aquatic environment result in long-term environmental exposure and accumulation and to exposure of humans via the environment.

Emissions into air result in long-range transport via the atmosphere to remote areas. Cyclic volatile methylsiloxanes (including D4 and D5) are widely dispersed in the environment in Europe and are found in remote regions. D4 and D5 have already been found in environmental monitoring in significant concentrations. RAC is of the opinion that in general for this type of hazardous substance any emissions into the environment must be minimised and regulatory action and risk management on an EU wide basis should apply well before contamination of the environment is demonstrated in environmental monitoring.

Thus, RAC considers that the primary reason to act on a Union-wide basis is to effectively reduce the environmental exposure to D4 and D5 in the EU. Because they are PBT/vPvB substances, in general any emissions to the environment have the potential to give rise to risks (including indirect risks to the general public because of potential long-term effects on the food chain). The aim for any regulatory action on D4 and D5 therefore is to minimise releases to the environment as far as technically and practically possible.

Action on a Union-wide basis would also limit the potential for trans-boundary exposure to D4 and D5 from EU sources.

Conclusion 9: RAC agrees that action to reduce the risks arising from D4 and D5 needs to be taken on an EU-wide basis.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Effectiveness in reducing the identified risks

Aquatic emissions

By applying lower and upper boundary release factors for direct uses in wash-off and leave-on PCPs RAC is able to evaluate the range of the effectiveness (emission reduction potential) of the restriction. If the lower bound for wash-off PCPs is assumed, the proposed restriction may reduce emissions in the range of **between 51.4% and 93.9%**. If the upper bound for wash-off PCPs is assumed then the proposed restriction may reduce emissions in the range of **between 64.6% and 96.3%**.

This means that if the upper bound scenario for leave-on PCPs is assumed the proposed restriction may reduce emissions only in the range of **between 51.4% and 64.6%**.

Table 6. Effectiveness (emission reduction potential) of the restriction in reducing emissions into surface waters in Europe

| D5 | Inside scope ^a | |
|---|-----------------------------------|------------------------------------|
| Outside scope ^b | Lower boundary 97.8 t/y | Upper boundary 168.3 t/y |
| Lower boundary 6.4 tonnes/year | 93.9% | 96.3% |
| Upper boundary 92.4 tonnes/year | 51.4% | 64.6% |

Notes: a. **inside scope** refers to the emissions that are considered to be within the scope of the proposed restriction i.e. formulation and direct and indirect uses in wash-off PCPs; b. **outside scope** refers to emissions that occur that are outside of the scope of the proposed restriction i.e. formulation and direct and indirect uses in leave-on PCPs as well as "other" uses as an anti-foam agent in the pulp and paper, detergent and oil and gas sectors.

If emissions from leave-on PCPs would be as high as assumed in the upper boundary scenario it could be questioned if the proposed restriction, which only targets wash-off PCPs, would be the most appropriate EU wide measure for addressing aquatic emissions of D4 and D5. If this scenario would realistically represent actual emissions a broader restriction, including leave-on PCPs, would be more effective in reducing the risks.

Nevertheless, RAC concludes that PCPs containing D4 or D5 that are intentionally washed-off or are disposed of via water within a few minutes of application will result in significant emissions of D4 and D5 to the aquatic environment. The suggested restriction is the most appropriate EU wide measure for addressing the emissions from wash-off PCPs, particularly noting the potential significance of D4 and D5 as impurities in other substances (silicone polymers or other silicone substances) that would not be efficiently controlled by other RMOs, such as inclusion on Annex XIV.

Review of the effectiveness of this proposed restriction

RAC considers that the relative contribution to total emissions from leave-on PCPs remains uncertain and could be significant (particular for categories of leave-on PCPs that have potential for direct release to water, such as sun protection products). Equally, RAC considers that the relative importance of emissions from the formulation of wash-off PCPs (should this continue after the entry into force of the restriction for export) as well as anti-foam uses in pulp and paper, detergents and the oil and gas industry may continue to

contribute to emissions of D4 and D5 to the aquatic environment after the entry into force of this restriction. In addition, whilst not specifically assessed by the Dossier Submitter, inappropriate disposal of wipe-based PCPs containing D4/D5 by flushing is considered to be reasonably foreseeable and could lead to emissions to the environment. However, information on recent trends from industry² suggests that D4 or D5 are no longer in common use in wipe-based PCPs in the EU.

RAC agrees with the Dossier Submitter that the significance of all of these potential sources to the aquatic environment might usefully be investigated as part of a review of the effectiveness of this proposed restriction by the Commission. RAC recommends, given the level of remaining uncertainty surrounding the emissions assessment, that this review should take place no later than five years after the entry into force of this restriction. The monitoring programme described by industry in their public consultation comments may provide information for such a review.

Conclusion 10: RAC evaluates the proposed restriction as a targeted and appropriate EU wide measure to minimise any emissions caused by wash-off PCPs. The proposed restriction targets less than 0.2% D4 and less than 1% D5 of the total volume manufactured and used in the EU. However, if direct use of D4 and D5 in other types of PCPs or other uses of D4 and D5 in the EU also cause emissions to the aquatic environment in significant amounts, further regulatory action and risk management measures to reduce those emissions may be necessary.

Further minimisation of emission of D5

The Commission decision of 9 December 2014 established criteria for the award of the EU Ecolabel for rinse-off cosmetic products (2014/893/EU) and currently includes a maximum limit value for D4 but not D5. To be able to use the Ecolabel, D4 shall not be included in cosmetic products, either as part of the formulation or as part of any mixture, in concentration equal or exceeding 0.01% by weight of the final formulation. RAC considers that this decision could contribute to the minimisation of emissions of D4 into the environment. Equally, in addition to the proposed restriction, RAC considers that including D5 with the same limit as D4 (0.01% by weight of the final formulation) in the EU Ecolabel criteria for rinse-off cosmetic products would be appropriate to its status as a vPvB substance and may further minimise emissions of D5 (and D4 as impurity of D5) into the environment.

Opinion on proposed concentration limit of 0.1%

The proposed restriction focuses on the presence of D4 and D5 in the final PCP at a particular concentration limit, regardless of their source. A concentration limit of 0.1 per cent w/w is proposed by the Dossier Submitter to stop all intentional use of D5 and D4 in wash-off PCPs. During RAC consultation and public consultation (comment #1447) a lower concentration limit was requested to also stop all emissions into the environment caused by indirect and unintentional uses in wash-off PCPs.

RAC is of the opinion that in case of PBT/vPvB substances a concentration limit must fulfil both tasks: to stop all intentional uses and to minimise emissions to the environment. In general, RAC is of the opinion that PBT/vPvB substances should not become unintentional trace contaminants in products.

The ecological criteria for the award of the EU Ecolabel for cosmetic products already established a limit value of 0.01% w/w for D4. The SCCS is of the opinion that the level of

² Mintel Global New Products Database (www.gnpd.com) – health & hygiene category: 0/365 wipe-based products in EU labelled as containing D5; beauty & personal care category/face & neck care subcategory: 9/199 wipe-based products in EU labelled as containing D5.

D4 as an impurity of D5 should be as low as possible and recommends that the level of purity of D5 in cosmetic products put on the market should be > 99% (SCCS, 2015). The limit of detection of D4 and D5 is typically approximately 0.1 ppm (Background Document) which indicates that a lower limit value is technologically achievable.

The Dossier Submitter's assumption is that indirect uses of D4 and D5 in wash-off PCPs are within the scope of the restriction (section B.9.3.3 in the Background Document). When evaluating the significance of indirect emission caused by impurities of D4 and D5 in the final wash-off PCP, the Dossier Submitter assumed that residual concentration of both D4 and D5 in PCPs containing silicone polymers was the same for both substances and available for release. The assessment by the Dossier Submitter was based on an assumed tonnage of 20,000 tonnes/year of silicone polymers used and a maximum concentration for both D4 and D5 as an impurity of 0.5% w/w. After allocating the overall tonnage of silicone polymers between wash-off and leave-on products (by assuming the same relative proportion as the use of D5) this results in a volume of 3.47 tonnes/year used in wash-off PCPs (92.5 tonnes/year in leave-on PCPs) of both D4 and D5.

Based on the RAC release factors for wash-off PCPs the emissions to surface water caused by impurities in wash-off PCPs and the contribution to the overall emissions are presented in Table 7.

Table 7. Contribution of impurities to emissions to surface water caused by wash-off PCPs

| substance | Emissions to surface water caused by impurities ^a | Relative contribution to overall emissions to surface water caused by wash-off PCPs |
|-----------|--|---|
| D5 | 0.5 – 0.8 tonnes/year | 0.5% |
| D4 | 0.4 – 0.7 tonnes/year | 21% |

Notes: a. for example, contained in silicone polymers in wash-off PCPs

The absolute tonnage of D4 and D5 released as a result of its presence as an impurity is comparable and is estimated at <1 tonne/year for each of the substances. However, as the tonnage of D5 used in wash-off PCPs is much greater than the tonnage of D4, the relative contribution of impurities to overall emissions is much greater for D4 than for D5. This suggests that a proposed restriction with a concentration limit of 0.1% could be less effective in terms of relative emission reduction for D4 than for D5. However, there are many assumptions and uncertainties inherent in this analysis, particularly in relation to the assumed tonnages of silicone polymers used in personal care products and the concentration of D4 and D5 present as an impurity in these formulations.

As the Dossier Submitter assumes a maximum concentration for both D4 and D5 as an impurity of 0.5% w/w in wash-off PCPs a proposed concentration limit of 0.1% w/w would prevent 80% of the assumed emissions from impurities. A lower concentration limit of 0.01% w/w would prevent 98% of the assumed emissions from impurities.

This highlights that whilst a concentration limit of 0.1% is likely to be effective to prevent emissions from intentional (direct) uses, emissions of D4 and D5 as a result of its presence as an impurity in silicone polymers (and other substances) used in wash-off PCPs could still occur up to 21% for D4 (see Table 7).

Conclusion 11: RAC concludes that the proposed concentration limit of 0.1% w/w effectively stops all intentional uses and also sufficiently minimises emissions from indirect uses in wash-off PCPs. The significance of indirect emissions could be further explored as part of a review of the effectiveness of this restriction by the Commission in the future.

Emissions to air

While it is proven that D4 and D5 undergoes long-range transport to remote regions via the atmosphere due to their long atmospheric half-lives, it remains unclear if D4 and D5 stay in the atmosphere until degraded ("flyers") or if they deposit back to surface media to a certain extent ("hoppers"). Due to the extremely high total emissions into air of D4 and D5 from all EU uses and dissipation from WWTP, even if deposition rates in remote areas might be relatively low, this exposure route would be a potential source of risk to remote areas.

RAC recommends, given the level of remaining uncertainty surrounding the potential significance of emissions of D4 and D5 to air, that a review by the Commission should take place no later than five years after the entry into force of any restriction. It is likely that the monitoring programme described by industry in their public consultation comments (# 1416) would provide valuable information to any review. The results of the review may indicate a need for further risk management.

Industry is also working on a voluntary emission reduction plan (VERP) restricting industrial releases of D4 and D5 from manufacturing, processing, and formulating sites (public consultation comment # 1416). The initiation of this plan is set up for 2016. As RAC we appreciate this effort but we are currently unable to assess its effectiveness.

Candidate Listing

During Public Consultation several comments (see comments # 1411, 1449, 1455, 1456) were received which recommended the identification as SVHC through the Article 59 process. RAC has not discussed Candidate Listing as a risk management option.

Conclusion 12: RAC agrees with the Dossier Submitter that both substances fulfil the criteria for Substances of Very High Concern (SVHC) and that Candidate Listing might be the only way to oblige Registrants to take full account of the implications of the PBT/vPvB properties of D4 and D5 (see comments # 1411, 1444 and 1446).

Opinion on proposal for a review after entry into force

The Dossier Submitter proposes that the Commission shall carry out a review of the other sources of D4 and D5 to investigate whether any further emission reduction measures are necessary. RAC strongly supports this approach. RAC is currently unable to exclude the possibility that leave-on PCPs could be a significant source of emissions to wastewater, even if the release factor from these uses might be low.

Also if there would be no significant decreasing trend in environmental concentrations following the introduction of the proposed restriction, this would clearly indicate the need for further regulatory action. Also if the deposition of emissions into air to surface media is shown to occur this would indicate the need for further regulatory action.

Conclusion 13: RAC concludes that, because of the uncertainties in the exposure assessment, the restriction should be subject to a review 5 years after entry into force.

Practicality, incl. enforceability

Implementability and manageability

During PC (see comment # 1455) it has been confirmed that an important portion of the market of wash-off PCPs has already phased out of D4 and D5. In addition, alternative substances and substitutes are available for all types of wash-off PCPs. The implementation

of the proposed restriction (by switching to alternative substances and substitutes) is clear and understandable to all actors involved. Also the public consultation has shown that analytical methods are likely to be available.

RAC is of the opinion that the proposed restriction should come into force no later than 2 years after publication in the Official Journal, preferable after 18 months (in line with the RAC opinion on the restriction of decaBDE and PFOA). From the risk (reduction) perspective the minimisation of emissions into the environment from PBT and vPvB substance should be achieved as soon as possible. This is of particular importance in this specific case, because the registration dossiers do not identify D4 and D5 as fulfilling the REACH Annex XIII criteria for PBT and/or vPvB substances and consequently the operating conditions and risk management measures in REACH Registration CSRs are inadequate to minimise emissions into the environment. **Conclusion 14: RAC concludes that the proposed restriction is implementable and manageable and shall preferably enter into force after a transitional period of 18 months.**

Monitorability

Monitoring of the proposed restriction will be conducted through regular enforcement activities for wash-off PCPs on the market. Ongoing environmental monitoring might also illustrate the effectiveness of the restriction.

During the public consultation an issue was raised regarding analytical artefacts that can be introduced during the analysis of D4/D5 during sample injection. RAC notes that industry (see comment # 1419) is currently working on the development of a suitable standardised method for the analysis of D4 and D5 in PCPs.

BASIS FOR THE OPINION

The Background Document, provided as a supporting document, gives the detailed grounds for the opinions.

Basis for the opinion of RAC

The main changes introduced in the restriction as suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by UK are:

- At RAC-35 the use of the term “rinse-off” cosmetic product (defined as per the Cosmetics Regulation (EC) 1223/2009) was introduced to replace the Dossier Submitter’s term “wash-off personal care product”. This change was proposed by the Dossier Submitter to enhance enforceability and was endorsed by the Forum. At RAC-35 comments from industry highlighted that certain “rinse-off cosmetics” are not intended to be used with water and would therefore not result in wastewater emissions (e.g. certain make-up removing PCPs, including wipes). As the Dossier Submitter’s intention was not to capture in the restriction PCPs that are not used or disposed with water a derogation³ was proposed to ensure that rinse-off PCPs that are not intended to be used, removed or disposed of with water were not included within the scope of the restriction. The proposal derogation text was provided to the Forum and Industry Stakeholders (Cosmetics Europe) for their comments. Forum considered that the wording of this derogation could be difficult to enforce and that restrictions should be as simple as possible. Industry Stakeholders were concerned by use of the “rinse-off” terminology that they considered was not appropriate to a restriction proposal intended to address environmental risks. At RAC-36 the term “rinse-off” was replaced with a proposed wording to specify “*cosmetics used or disposed with water.....*”. The term “used” refers to the intended use of the product as described on packaging instructions. This wording reflects the intended scope of the Dossier Submitter and avoids the uncertainty introduced by the use of “rinse-off” cosmetics that includes products that are intended to be used both with and without water.
- At RAC-35 the ECHA Secretariat elaborated the proposed wording to highlight the implications of including the term “use” in the restriction, particularly with respect to its applicability to substances that could contain D4 or D5 as impurities during the formulation of PCPs based on alternatives to D4 or D5. Comments from the Dossier Submitter highlighted that it was not the intention of the restriction to prevent the formulation of PCPs using alternatives to D4/D5. At RAC-36 the wording of the proposal was modified to refer to “placing on the market” only, rather than use, reflecting that risks arise through the use of PCPs containing D4 or D5 by consumers and professionals.
- RAC notes that the intention of the proposed restriction is described in the BD and the opinion and that it could be achieved in a variety of ways. RAC has not intended to modify the intended scope of the restriction by proposing revisions to the Dossier Submitter’s proposal, but reflect advice received during opinion development. RAC notes that further versions of the wording could equally be effective in capturing the proposed scope of the restriction and that the Commission will decide on the final wording of the proposal.
- RAC considers that the relative contribution to total emissions from leave-on PCPs remains highly uncertain, and could be significant. Equally, RAC considers that emissions from the formulation of wash-off PCPs as well as from anti-foam uses in pulp, paper and

³ By way of derogation, paragraph 1 shall not apply to rinse-off cosmetics that are not used, removed or disposed with water under normal use conditions where use instructions are product labelling advise how to use the product without water and to dispose of waste materials, including used pads, tissues or wipes, in solid waste.

detergents and direct emissions from oil and gas industry may continue to contribute to emissions of D4 and D5 to the aquatic environment after this restriction comes into force. RAC recommends, given the level of remaining uncertainty surrounding the emissions assessment, that a review should be carried out no later than five years after any restriction coming into force.