**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restriction on

**Siloxanes D4/D5/D6**

**Non-confidential**

**ECHA/RAC/RES-O-0000006700-80-01/F**

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

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| **Substance name** | **EC number** | | **CAS number** | |
| Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), dodecamethylcyclohexasiloxane (D6) | | 209-136-7; 208-764-9; 208-762-8 | | 556-67-2; 541-02-6; 540-97-6 |

5 December 2019

General Comments and answers to specific information requests

## Specific information requests:

1. Cosmetic products: According to the Annex XV report (Annex C), there is no single ‘drop-in’ or ‘one-for-one’ alternative substance that could be used to replace D4, D5 or D6 in leave-on cosmetic products or D6 in rinse-off cosmetic products. However, as noted in the report, many cosmetic products within the same product category do not contain D4, D5 or D6. On this basis, the Dossier Submitter has concluded that alternatives are available. Please tell us which ingredients are used in these alternative cosmetic product formulations (differentiated between product groups). In addition, where you have knowledge in substituting D4, D5 or D6 in cosmetic formulations, is your experience different from the assumptions outlined in section 2.5.1?
2. Dry cleaning: According to the Annex XV report, it is proposed that 10 years after the entry in force the use of D5 for dry-cleaning will continue to be permitted only if ‘D5 is fully recycled or incinerated, and where there is no release to air or wastewater.’ Do you have information on the availability of dry cleaning equipment that would fulfil these criteria either now or in the future? When could these criteria be fulfilled and how much would this cost? What would be the impact of (i) bringing the date forward by five years or (ii) if no derogation for dry cleaning was proposed.
3. Use of D4, D5 and D6 in pharmaceutical products and medical devices: The Annex XV report provides aggregated tonnage data for all types of pharmaceutical products/medical devices. This includes two types of products (scar and wound treatments and stoma care products) for which a derogation is proposed. In order to support the proposed derogation, can you provide information on the tonnage of D4, D5 and D6 placed on the market in scar and wound treatments and stoma care products?
4. Presence of D4, D5 or D6 as residues in silicone polymers used by consumers and professionals: According to the Annex XV report, it is possible that some silicone polymers mixtures, used by consumers and professionals, may unavoidably contain D4, D5 or D6 residues above 0.1% w/w of each substance. Under the proposed restriction, these mixtures would no longer be allowed to be placed on the market after the proposed transitional period ends. This may particularly affect mixtures containing silicone polymers used as sealants in construction or as medical devices (e.g. dental impressions/imprints). However, sufficient detailed information was not available during the preparation of the restriction proposal to allow the Dossier Submitter to conclude on the precise conditions of a derogation that would prevent these unintended impacts. For a derogation to be considered you must provide specific, concrete and detailed information in the public consultation on:
   1. the identity of the mixture (brand name if relevant),
   2. the specific function of the mixture, its sector of use (e.g. construction, dentistry), and the quantity of mixtures placed on the market,
   3. the residual concentration (%w/w) of D4, D5 or D6 in the mixture,
   4. information on why it is not feasible to reduce these concentrations below 0.1% w/w, and
   5. analysis to demonstrate and if possible quantify the negative impact of not derogating the use.

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| **Ref.** | **Date/type/Org.** | **Comments** |
| **2022** | **Date:** 2019/05/06 11:52  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** European Automobile Manufacturers Association - ACEA  **Org. country:** Belgium | **Comment:**  The EU Automotive Industry welcomes the proposed derogation in the current restriction proposal about the uses at industrial sites.  Although the following is not covered by the current restriction proposal, we would like to take the opportunity to make you aware that the automotive sector cannot waive the usage of silicone polymers, which may contain residues of D4|D5|D6, especially for the production of applications such as grommets, sealants or special adhesives, which are especially of importance for E-vehicles & Li-Batteries because here, no substitution is possible today. |
| **Dossier Submitter response:**  Thank you for your participation in the consultation. We note your points about the use of silicone polymers in the automotive industry and that you do not expect the restriction to affect your industrial applications. |
| **RAC Rapporteurs comments:**  Thank you very much for your information on use of silicon polymers in the car industry, especially its importance for E-vehicles. |
| **SEAC Rapporteurs comments:**  No additional comments. |
| **2034** | **Date:** 2019/05/13 12:38  **Content:**  Scope or restriction option analysis;  Environmental emissions;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** Norwegian Environment Agency  **Org. country:** Norway | **Comment:**  Norwegian comments to the restriction proposal for D4, D5, D6  General comments  The Norwegian Environment Agency welcomes the restriction proposal on D4, D5, D6 and thanks ECHA for their efforts on preparing the proposal. The Norwegian CA agrees that there is a need for action at EU level to prevent emissions and reduce risks from D4, D5, D6 due to their PBT/vPvB properties and hence supports the inclusion of D4, D5 and D6 in Reach Annex XVII.  The Norwegian CA welcomes the inclusion of D6 wash off products in the scope of the restriction proposal to avoid switching to D6 as alternative for D4 and D5 in wash off products, which already have been restricted.  In Norway the cyclic siloxanes D4, D5, and D6 are on a national priority list due to their PBT/vPvB properties. This list includes more than 30 named substances and groups of substances of high concern to human health and the environment. Norway aims to reduce emissions of these substances continuously, with a view to eliminating them completely by 2020.  We recognise that a definition of the term "art and antiques" is missing in the restriction proposal.  Comments on the scope:  In the restriction proposal the abbreviation D4, D5 and D6 are not specifically mentioned in the left column of the proposed restriction, table 13. This might be helpful since the abbreviations are used throughout the restriction proposal.  We recognise that for the restriction of D4 and D5 in wash- off personal care products a transition period of 2 years was agreed. In the recent restriction proposal, a transition period of 5 years is proposed for D4, D5, D6 for leave-on cosmetic products. We recommend that a better justification for the longer transition period of 5 years should be elaborated.  For the use of D5 in dry cleaning a transition period of 10 years is proposed. Since specific information requests on dry cleaning is launched in the public consultation the Norwegian CA recommend reconsidering the 10-year transition period based on the input from stakeholders.  Some of the derogations are limited to a specific restricted substance in the mixture (for instance 3b), and we assume that when no substance is mentioned the derogations is valid for D4, D5 and D6 (like for instance for 3a).  In our opinion the derogation in paragraph 3a) "dry cleaning industrial sites" is not specific enough for enforcement purposes.  In the derogation 3g) "placing on the market of D5 for the cleaning or restoration of "art and antiques" we recommend specifying that it applies for professional use.  Comment on monitorability  With the scope of the current restriction compared to entry 70 in Annex XVII, D6 should also be included in the industry-led voluntary monitoring program on siloxanes in WWTPs. Further, due to the scope and concern on the current restriction proposal compared to the D4 and D5 restriction in wash off products, air-samples should also be considered. This would allow monitoring of releases from other products than wash off and to assess the effects of the restriction.  Comment to annexes to the restriction report, tonnages  Table 10 in the annex to the restriction report gives an overview of the considered annual EU tonnage across the various exposure scenarios. We recommend looking closer into the SPIN database (SUBSTANCES IN PREPARATIONS IN NORDIC COUNTRIES), where information of substances in mixtures can be found http://www.spin2000.net/spinmyphp/  A search on D4 in the database showed that the substance is notified in Denmark in 2017 with 0,4 tons for the industrial use category (NACE) G 45: wholesale and retail trade and repair of motor vehicles and motorcycles, whereas no such use is reported in table 10 of the annex. |
| **Dossier Submitter response:**  Thank you for your participation in the consultation, and your support for the proposed restriction.  We have taken into account the comments on the proposed restriction wording, and updated the Background Document accordingly. Note that the current wording aims at expressing the intention of the Dossier Submitter and that the European Commission will ultimately decide on the wording of the conditions of the restriction in Annex XVII.  The inclusion of D6 in the industry-led voluntary monitoring programme on siloxanes in WWTPs is already mentionned in the Annex XV restriction report (section 2.8), and we have taken note of your suggestion that D4, D5 and D6 could also be monitored in the atmosphere as part of this programme.  With regard to the proposed transitional periods, the Dossier Submitter notes your request to (i) better justify the proposed five year transition period for leave-on cosmetics, especially when compared to the two year transition period that was granted for the D4 and D5 restriction in wash-off cosmetic products, and (ii) to reconsider the 10 year transition period for use of D5 in dry cleaning.  In both cases, we have reviewed and taken into consideration the justifications and information provided in this consultation, and we have updated the Background Document accordingly. The committees will evaluate the information provided.  Finally, we recognise that not all uses of D4, D5 and D6 might have been captured in the tonnage reported in the Annex XV restriction report in which the main sources of information were the call for evidence, market survey and REACH registration dossiers. The information contained in the SPIN database comes from mixture composition notifications to the product registries of Norway, Sweden, Denmark and Finland. The companies reporting to the product registries are placing mixtures on the market that might not reach the 1 tpa threshold for REACH registration obligations; this might be a reason why some uses are not captured in the REACH Registration dossiers. We also note that the scope of the proposed restriction is generic and this will capture all of the uses identified in the SPIN database (unless specifically derogated). |
| **RAC Rapporteurs comments:**  Thank you very much for your support of proposed restriction. We also appreciate you proposal for clarification of restriction wording.  It should be noted that the inclusion of D6 in the industry-led voluntary monitoring programme on siloxanes in WWTPs is already mentionned in the Annex XV restriction report (section 2.8). The suggestion for monitoring of D4, D5 and D6 in the atmosphere is noted.  We agree with your comment regarding the better justification for transition period. From a risk perspective, the transitional periods for PBT/vPvB substances should be as short as possible. Therefore, the justification for the proposed five year transition period for leave-on cosmetics, especially when compared to the two year transition period that was granted for the D4 and D5 restriction in wash-off cosmetic products, should be elaborated and critically evaluated by SEAC. The 10 year transition period for the use of D5 in dry cleaning is acknowledged to be long but is necessary to develop fully closed systems with no emission of D5 to the environment.  We appreciate that the Dossier Submitter has reviewed and taken into consideration the justifications and information provided in this consultation, and updated the Background Document accordingly.  We also appreciate the other uses of cyclic siloxanes that are not specifically mentioned in the Annex XV report. We agree with the Dossier Submitter that not all uses of D4, D5 and D6 might have been captured in the tonnage reported in the Annex XV restriction report in which the main sources of information were the call for evidence, market survey and REACH registration dossiers. The companies reporting to the product registries are placing mixtures on the market that might not reach the 1 tpa threshold for REACH registration obligations; this might be a reason why some uses are not captured in the REACH Registration dossiers. We also agree with the Dossier Submitter that the scope of the proposed restriction is broad enough to capture all of the uses identified in the SPIN database. |
| **SEAC Rapporteurs comments:**  The SEAC Rapporteurs have noted that the comments received in the consultation have resulted in a number of adaptations in the text of the scope, e.g. professional use was added to cleaning and restoration of art and antiques, the reference to industrial sites in dry cleaning has been changed into ‘in strictly controlled closed dry cleaning systems for textile, leather and fur where the cleaning solvent is recycled or incinerated’. The Dossier Submitter has also extended the argumentation for a five year transitional period for leave-on cosmetics and 10 year transition period for dry cleaning. |
| **2052** | **Date:** 2019/05/17 12:19  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** The information shared in this letter includes volumes, compositions and application related information which are confidential to our company. Confidentiality is requested to protect the commercial interest of our company. | **Comment:**  - |
| **Answer to specific info request 3:**  See attached confidential letter |
| **Answer to specific info request 4:**  See attached confidential letter |
| **Dossier Submitter response:**  Thanks for your (confidential) comment. |
| **RAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **SEAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **2078** | **Date:** 2019/05/17 18:25  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United States  **Country:**  United States  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** <redacted> intellectual property includes the know how associated with maximizing the sustainability of utilizing D5 in the dry cleaning process and disclosing some of this information would undermine our intellectual property position. | **Comment:**  See Specific Information Request #2 Below. |
| **Answer to specific info request 2:**  See attachment. |
| **Dossier Submitter response:**  Thanks for your (confidential) comment. |
| **RAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **SEAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **2084** | **Date:** 2019/05/17 23:12  **Content:**  Hazard or exposure;  Environmental emissions;  Information on alternatives;  Information on costs;  Information on benefits;  Other socio economic analysis (SEA) issues;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Personal Care Products Council  **Org. country:** United States  **Attachment:** | **Comment:**  Please see attached |
| **Dossier Submitter response:**  Thank you for the comments provided on the following topics: (i) uses in cosmetic products, (ii) PBT/vPvB status, and (iii) time required for substitution.  Please note that the PBT/vPvB status of D4, D5 and D6 was decided by the ECHA Member State Committee (MSC) and is not under consideration during the opinion-making process for this restriction proposal. PBT/vPvB substances under REACH are non-threshold substances where releases to all compartments shall be minimised.  Regarding the transitional period proposed, we have reviewed the responses on this aspect to the consultation, both in confidential and non-confidential submissions. We have received information on the difficulties of reformulation, particularly for some products, as well as the potential timelines for the process. We have also received information supporting the possibility of reformulation taking place more quickly in some cases. We have considered all the information available to us when proposing the transitional period for this restriction and this is reflected in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment. We agree with Dossier Submitter that the PBT/vPvB status of D4, D5 and D6 is decided by the ECHA Member State Committee (MSC) and is not under consideration during the opinion-making process for this restriction proposal. Comments on proposed transitional period are noted.  We appreciate that the Dossier Submitter has reviewed and taken into consideration the justifications and information provided in this consultation, and updated the Background Document accordingly. |
| **SEAC Rapporteurs comments:**  The respondent indicates that the reformulation process is not only financially costly, which is recognised by the Dossier Submitter, but also very time consuming. They further indicate why they would need a 10 year implementation period in the case the proposal will be implemented, specifically in the case there are no alternatives. The argument by the Dossier Submitter that alternatives are available for all product groups is not rejected nor discussed. The SEAC Rapporteurs support the argumentation provided by the Dossier Submitter on the variability of the submissions considering the transitional time. |
| **2089** | **Date:** 2019/05/19 22:01  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** FEICA - Association of the European Adhesive & Sealant Industry  **Org. country:** Belgium  **Attachment:** | **Comment:**  - |
| **Answer to specific info request 4:**  FEICA, the Association of the European Adhesive and Sealant Industry, is a multinational association representing the European adhesive and sealant Industry. This speciality chemical sector represents more than 2% of the total European chemical industry’s turnover and contributes more than 14 billion euros to the EU economy. Within the sealant sector, silicone sealants represent the biggest market  • D4/D5/D6 ends up in silicone sealants as an impurity of the silicone polymer used as raw material.  • D4, D5 and D6 have no known technical function in silicone sealants and sealant producers do not add D4/D5/D6 to their sealants intentionally.  • For a given formulation, the concentration of D4/D5/D6 in the silicone sealant depends solely on the content of impurities (D4/D5/D6) in the silicone polymer which has been used as raw material.  • Formulators of silicone sealants are not able to reduce the content of impurities (D4/D5/D6) in purchased silicone polymers.  • Consequently, the manufacturers of silicone sealants are not in the position to indicate what the maximum concentration of D4/D5/D6 in their sealants should be.  • However, in view of the usual criteria for environmental labels (SVHC < 0.1%) such as green building schemes (Nordic Swan, Basta, LEED, DGNB etc), Blue Angel and company policies, formulators of silicone sealants expect silicone polymers to have a concentration of D4/D5/D6 below 0.1% as soon as possible.  • Silicone sealants make up a significant share of the sealant market because of their specific properties such as durability, weathering resistance and chemical resistance.  • Silicone polymers are essential and indispensable as the main raw material, with up to 90% content in the finished silicone sealant. It is crucial that silicone polymers remain available as raw materials for silicone sealants to ensure the continued availability of silicone sealants,).  • To avoid market interruption, it is important that a sufficient transition period is foreseen to allow the producers of silicone polymers to meet their reduction targets for D4, D5 and D6. |
| **Dossier Submitter response:**  Thank you for your participation to the consultation. We note your points about the use of silicone polymers in the adhesive and sealant industry and that you do not expect the restriction to affect the placing on the market of silicone sealants and adhesives. |
| **RAC Rapporteurs comments:**  Thank you very much for your comments regarding the use of silicone polymers in the adhesive and sealant industry. |
| **SEAC Rapporteurs comments:**  The formulators of silicone sealants indicate that they are not able to reduce the content of D4, D5 and D6 (as an impurity) in purchased silicone polymers. However, it is not indicated in the submission whether the amount of impurities in the polymers can be reduced in the future and what time is needed for that. The formulators further indicate that to avoid market interruption, it is important that a sufficient transition period is foreseen to allow the producers of silicone polymers to meet their reduction targets for D4, D5 and D6. No further argumentation is provided on the time necessary for that. |
| **2094** | **Date:** 2019/05/20 04:24  **Content:**  Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Japan Cosmetic Industry Association  **Org. country:** Japan  **Attachment:** | **Comment:**  Regarding PBT Judgment  In this proposal, these cyclosiloxanes are categorised as PBT. However, the Chemical Substance Control law in Japan, at least, D5 was not regarded as PBT because of lack of toxicity. Although D4 and D6 are categorized as monitoring substances instead of PBT, none of these siloxanes are prohibited for use in cosmetics in Japan. 1) Considering the situation in Japan, we believe there is no sufficient scientific evidence to conclude PBT judgment of these substances.  Regarding vPvB Judgment  In general, vB judgment is based on result of a test evaluating BCF. With this evaluation, usual environmental monitoring corresponds well to bioconcentration as seen for chemicals such as PCB. However, in the case of cyclosiloxane (D4), a discrepancy is observed in publicly available monitoring results of bioaccumulation in an actual environment.2) This result demonstrates that solely use of BCF is not appropriate for assessment of environmental impact of chemicals. In addition, the judgments of vPvB for D5 and D6 by ECHA are based on BCF data determined in a closed system, however it is reported that cyclic volatile methyl siloxanes show lower bioconcentration due to their superhydrophobicity.3) These results suggest that various parameters should be applied in order to assess bioconcentration and/or bioaccumulation impact of substances with properties of cyclosiloxanes (hydrophobicity and volatility).  References:  1) https://www.meti.go.jp/shingikai/kagakubusshitsu/shinsa/pdf/173\_01\_00.pdf  2) Powell D., et.al. Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) in the aquatic marine food webs of the Oslofjord, Norway. Sci. Total Environ. (2018) 622-623, 127-139  3) Mackay D., et.al. Bioconcentration and Aquatic Toxicity of Superhydrophobic Chemicals: A Modeling Case Study of Cyclic Volatile Methyl Siloxanes. Environ. Sci. Tec. (2015) 49, 11913-11922 |
| **Answer to specific info request 1:**  Cyclosiloxanes (D4, D5 and D6) are highly versatile principal raw materials that have been used in cosmetics for a long period (more than 40 years), and the replacements of cyclosiloxanes (D4, D5 and D6) with other raw materials are very difficult from a technical perspective. Cyclosiloxanes (D4, D5 and D6) are physiologically inactive, highly safe to the human and highly stable in cosmetic products. And as a special function, they enable to exert water-proof, long-lasting make-up effects, and provide cosmetics with excellent usability to the market. As a result, they have contributed greatly to the improvement of QOL of consumer in a unique manner, which will be lost once they are removed from the formulas.  A surveys recently conducted in several countries reports that “cyclosiloxanes do not pose a danger to the environment or its biological diversity.” Cyclosiloxanes are volatilized in the air after used for cosmetics as a human body, and is decomposed into silicon dioxide, carbon dioxide and water in a short period of time. The impact is considered to be minor.  In the ECHA's report “potential overlapping between proposed restrictions on D4, D5, D6 and microplastics”, the socio-economic analysis is conducted for both products which contains both D4, D5, D6 and microplastics, assuming that in the event both restrictions are implemented at the same time. However, we are concerned that it might not be regarded as accurate analysis data that handling two substances with completely different environmental impact and substitution difficulty together. |
| **Dossier Submitter response:**  Thank you for the comments provided on the following topics: (i) PBT/vPvB status, and (ii) overlap with the restriction proposal on intentionally added microplastics.  Please note that the PBT/vPvB status of D4, D5 and D6 was decided by the ECHA Member State Committee (MSC) and is not under consideration during the opinion-making process for this restriction proposal. PBT/vPvB substances under REACH are non-threshold substances where releases to all compartments shall be minimised.  Regarding the potential overlap between the restriction proposal for D4, D5 and D6 and that on intentionally added microplastics, we note that the cost calculations undertaken in each of the restriction proposals were done without account of any potential cost-savings resulting from the overlap. We will take note of the evidence provided on the potential impact of the overlap on costs in the report mentioned. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment. We agree with the Dossier Submitter that the PBT/vPvB status of D4, D5 and D6 is decided by the ECHA Member State Committee (MSC) and is not under consideration during the opinion-making process for this restriction proposal. The comment on potential overlap between this restriction and the intentionally-added microplastics restriction is noted. |
| **SEAC Rapporteurs comments:**  The SEAC Rapporteurs took note of the answer of the Dossier Submitter that they did their cost estimations for D4, D5 and D6 and the microplastics independently. |
| **2109** | **Date:** 2019/05/20 10:51  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Medicines for Europe  **Org. country:** Belgium  **Attachment:** | **Comment:**  - |
| **Answer to specific info request 3:**  see Non-confidential attachment |
| **Dossier Submitter response:**  Thank you for the comment requesting a derogation for the use of D5 and D6 in topical pharmaceutical products. We note that we requested further information from you on the following issues to substantiate your request, and that you provided additional confidential information in a follow-up comment:   * The function of D5 and D6 in this use, and whether it is the same function for both. * Alternatives to D5 and D6 for these pharmaceutical products, and if not, what analysis this conclusion is based on. * Information on the impact to society if a derogation is not granted (including both financial impact to the companies in question, but also the potential impact on patients if these pharmaceutical products are not available to them) * Evidence supporting the statement that these pharmaceutical preparations for dermal use have/would have improved penetration and/or bioavailability than that of creams and gels with conventional excipients. * Annual tonnage of D5 and D6 expected to be used in these pharmaceutical products. * Confirmation whether for D6 what is described is a direct use of the substance or whether D6 is only present as an impurity through a use of silicone polymers.   As the Dossier Submitter, we are unable to support your request for a derogation as insufficient evidence to justify it was supplied in your request. Further information can be submitted in the 60 day consultation on the SEAC draft opinion, which SEAC will consider before adopting their opinion. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment on the use of D5 and D6 in topical pharmaceutical products. We agree with the Dossier Submitter, there is need for more information and better justification of your request for derogation. |
| **SEAC Rapporteurs comments:**  The SEAC Rapporteurs note that a new pharmaceutical is being developed at relatively high concentrations of D5 (up to 10%) and D6 (less than 5%). These concentrations are considerably higher than in other medical devices. The organisation claims that the medicines to be developed will have improved penetration and/or bioavailability than that of creams and gels with conventional excipients, and also that stability problems that may occur during the storage of the gels/creams may be avoided. Additional information was submitted on request. The SEAC Rapporteurs support the Dossier Submitter’s conclusion that the additional information provided was not enough to support a derogation. Further information can be submitted in the 60 day consultation on the SEAC draft opinion, which SEAC will consider before adopting their opinion. |
| **2130** | **Date:** 2019/05/20 14:02  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** MedTech Europe  **Org. country:** Belgium | **Comment:**  MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.  MedTech Europe supports the exemptions for medical devices for the treatment of scars and wounds (3b) as well as for medical devices for the care of stoma (3c).  At the same time, we would like to point out that the proposed restriction does not exempt similar medical devices for the prevention of wounds (skin cleaning and protection). We are of the opinion that these medical devices should also be exempted from the restriction. It would in our opinion not be justified to exempt from the planned restriction products for the treatment of wounds but not for the prevention of skin damage. To ensure that products for skin cleaning and protection remain available for healthcare providers, we ask that an exemption is added for medical devices for wound care prevention.  Further information is provided in our reply to specific information request 4. |
| **Answer to specific info request 4:**  Medical devices for the prevention of wounds may contain cyclosiloxanes (D4, D5 or D6) in concentrations above 0.1% as impurities/residual from siloxane based polymers or siloxane based substances used as raw materials and purchased from silicone suppliers. We estimate that in most or even all of these products, the concentration of D4/D5/D6 is below 0.2% weight by weight.  Medical device skin cleaners and protectants are used e.g. to avoid that patients develop open, difficult healing, often chronic and painful wounds as a side effect of urinary and/or faecal incontinence causing disruptions of the skin barrier function and leading to superﬁcial skin damage. Macerated skin and superﬁcial skin changes are associated with infections, incontinence-associated dermatitis (IAD), pressure ulcer development and open wounds. Complications due to chronic wounds can cause general deterioration of health and even premature death. Preventing instead of treating such wounds relates to a very favourable risk-benefit ratio and saves costs in healthcare systems.  Medical device skin cleaners are intended to remove excrement, urine and other irritants that could contribute to the development of skin injury.  Medical device skin protectants are intended to provide a barrier that helps to prevent skin damage and injury from exposure to moisture and/or irritants such as urine or stool.  Given that only limited volumes of these products are sold and their low concentration of D4/D5/D6 (<0,2%), MedTech Europe estimates that the total amount of D4/D5/D6 in wound prevention (skin cleaning and protection) products is below 1 tonne/year. One manufacturer estimated that their products contain approximately 0.15-0.3 tonnes of D4/D5/D6 per year. |
| **Dossier Submitter response:**  Thank you for the information on the specific uses of silicone polymers where a concentration limit of 0.1 % w/w would mean that these uses would be inadvertently affected by the restriction.  We have reviewed and taken into consideration the justifications and information provided in this consultation, and we have updated the Background Document accordingly. The committees will evaluate the information provided. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment. We appreciate the Dossier Submitter’s effort to incorporate the information provided into the Background Document. |
| **SEAC Rapporteurs comments:**  The respondent indicated the limited scope of the restriction proposal for medical applications and ask that an exemption is added for medical devices for wound care prevention. They estimate that in most or even all of these products, the concentration of D4, D5 and D6 is below 0.2% weight by weight, which is comparable to other submissions in the consultation. One manufacturer estimated that their products contain approximately 0.15-0.3 tonnes of D4, D5, D6 per year. SEAC rapporteurs can support the proposal by the Dossier Submitter. |
| **2134** | **Date:** 2019/05/20 14:35  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** France  **Company name confidential:** Yes | **Comment:**  Our products are used in adults, children including infants as an adjunctive treatment for skin dryness during certain types of dermatosis such as atopic dermatitis, ichthyosis or psoriasis and for superficial burns affecting a small area of skin. More than 175 million patients have been used our products to treat themselves since its first launch in 1998. Efficacy and safety have been evaluated in many clinical trials in atopic dermatitis and ichthyosis, both diseases presenting the most severe xerosis of the approved indication. Substitution could be possible but hard to find a proper one to fulfill our specifications as Decamethylcyclopentasiloxane (D5) and/or Dodecamethylcyclohexasiloxane (D6)) gives to the finished product good spreading properties.  It also contributes to the treatment observance and efficacy, in particular for skin disorders (damaged skins, hyper-sensitivity) and when large skin area has to be treated on the same level as Scar, wound or stoma treatment. This is why we would like to extend the possible derogation to all skin treatment and not only Wound/stoma and scar treatment. |
| **Dossier Submitter response:**  Thank you for your comment requesting a derogation for mixtures with topical application. After reviewing the information provided we have concluded that there is insufficient justification for the derogation that you have requested. We note that further information was requested from you as a follow-up to your comment. We note also that despite our request, no further information on these questions was received:   * Use and technical function of D4, D5 and D6 * Type of skin treatment products * Legal status of the skin treatment products (MD, medicines, OTC, cosmetics) * Tonnage and concentration information * Possible substitution and alternatives * Socio-economic impact of a potential restriction   Further information can be submitted in the 60 day consultation on the SEAC draft opinion, which SEAC will consider before adopting their opinion. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment on the use of D5 and D6 in topical skin care products. We agree with the Dossier Submitter, there is a need for more information and better justification of your request for derogation. |
| **SEAC Rapporteurs comments:**  The company requested an extension of the proposed derogation for wound/stoma and scar treatment to all skin treatments. The company remarked that substitution could be possible but problematic. Although further information was requested, it was not provided. The SEAC Rapporteurs support the Dossier Submitter’s conclusion and request that further information to substantiate a derogation is provided in the 60 day consultation on the SEAC draft opinion. |
| **2141** | **Date:** 2019/05/20 15:06  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Description of analytical methods  **Type:** Individual  **Country:**  Canada  **Attachment:** | **Comment:**  The European Chemicals Agency (ECHA, 2019) has recently published proposals to restrict the use of three cyclic volatile methylsiloxanes: i.e., D4, D5 and D6. These actions are based on the designation of these substances as very persistent (vP) and very bioaccumulative (vB). The documentation employs ‘Mackay-type’ multi-media mass balance models, specifically SimpleBox 4. I thus have a distant ‘parental’ interest in evaluating if the models are being used effectively and correctly for the purposes that they were designed to accomplish. Regretfully, I conclude that in my opinion they are not being employed properly. |
| **Dossier Submitter response:**  Thank you for your comments. We have grouped the comments received into three broad categories and will respond to them as such: (i) Assessing risks of PBT/vPvB substances, (ii) Stock modelling and (iii) Typographic errors in the Annex XV restriction report.   1. Assessing risks of PBT/vPvB substances in a REACH regulatory context:   Comments relating to the quantitative risk assessment of PBT/vPvB substances were received from several respondents. The following response is relevant to all related comments and refers to the general principles applied to the risk assessment of PBT/vPvB substances under the REACH regulation.  With regard to comments citing an absence of risk and toxicity, we note that D4 has been classified as Aquatic Chronic 1 (https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180d84c7b) confirming that T properties according to REACH Annex XIII are based on both environmental and human health hazards (Repr. 2, H361f, Aquatic Chronic 1, M-factor of 10).  With regard to the reversibility of the effects, REACH Guidance R.11 emphasises the possibility for a substance with PBT/vPvB properties to move between different environmental compartments. Such properties render the effects of accumulation, especially in the presence of continuous ongoing emissions, unpredictable in the long-term, even with a cessation of emissions. Exposure from the sediment compartment to sediment-dwelling organisms is possible as is the partitioning from sediment back to water. Additionally, over time, chemical accumulation may lead to an increase in the internal concentration of a substance in an organism that may cause toxic effects after long-term exposure even when external concentrations are low. Such effects are very difficult to be estimated, even with the use of higher-tier, dynamic models that are difficult to validate and introduce numerous additional uncertainties (i.e. in the parameters used, the extent and rate of emission cessation, model validation, etc.).  Referring to the choice of compartment, REACH Annex XIII refers to “data obtained under relevant conditions” that must be used in the assessment of PBT/vPvB properties of substances. ECHA Guidance R.11 specifies that if a conclusion “P” or “vP” is reached for one compartment, no further testing or assessment of persistence of other environmental compartments is normally necessary, acknowledging in this way the fact that a conclusion for one compartment has broader environmental implications. Generally, rapid dissipation to air does not mean that the substances do not have PBT or vPvB properties (in sediment, in soil, in water, depending on the case).  Incorporating the atmospheric compartment in the assessment of fate and behaviour of releases of D4, D5 and D6 was considered to be relevant due to (i) the continuous releases of these substances to this compartment in relatively large quantities and (ii) the potential for fate processes to result in the accumulation of D4, D5 and D6 in surface media, including aquatic sediments, via the atmosphere. The Dossier Submitter notes that the chemical safety assessment of these substance in REACH registration dossiers includes fate and behaviour modelling incorporating the atmospheric compartment.  ECHA Guidance R.11 continues by stating that these specific concerns occur particularly with substances that can be shown both to persist for long periods and to bioaccumulate in biota and which can give rise to toxic effects after a longer time and over a greater spatial scale than substances without these properties. These effects may be difficult to detect because of long-term exposures at low concentrations and the long life-cycles of species at the top of food chains. In the case of vPvB substances, there is concern that even if no toxicity is demonstrated in laboratory testing, long-term effects might be possible since high but unpredictable levels may be reached in humans or the environment over extended time periods.  *The properties of the PBT/vPvB substances lead to an increased uncertainty in the estimation of risk to human health and the environment when applying “conventional” quantitative risk assessment methodologies* *e.g. by derivation of risk characterisation ratios. For PBT and vPvB substances a “safe” concentration in the environment cannot be established using the methods currently available with sufficient reliability for an acceptable risk to be determined in a quantitative way.*  Emissions and subsequent exposure, in the case of a PBT/vPvB substance, are therefore considered as a proxy for risk.  Finally, with regard to the hazard and risk assessment, the identification of D4, D5 and D6 as substances of very high concern due to their PBT/vPvB properties are decided by the ECHA Member State Committee (MSC) and is not under consideration during the opinion-making process for this restriction proposal. PBT/vPvB substances under REACH are non-threshold substances where releases to all compartments shall be minimised.   1. Stock modelling:   Thank you for the comments provided on the SimpleBox modelling, and for acknowledging the appropriateness of the modelling tool to explore the fate, exposure and presence of D4, D5 and D6 in the modelled environment.  As stated in the Annex XV restriction report, multi-media fate modelling was conducted after consultation with the ECHA PBT Expert Group. The approach also recognises recently published research on socio-economic analysis for PBT/vPvB substances in the REACH Authorisation and Restriction contexts. This research, undertaken for the European Commission, reported that a ‘stock pollution approach’ could provide additional useful information within a socio-economic analysis compared to simply considering releases to environmental compartments.  The model was not used in a deterministic or predictive capacity but to provide insight into the chemical fate and partitioning of D4, D5 and D6 between different environmental compartments at steady state after different modes of entry into the environment. Level III (Mackay-type) models, such as the SimpleBox model, are routinely used for this purpose. As reported in the Annex XV restriction report, “the model was not parameterised to predict environmental concentrations but rather provide an indicative assessment of the proportion of D4, D5 and D6 that would remain ‘unreacted’ in the environment after release”. The results of the modelling provide order-of-magnitude estimates that are primarily used to support the socio-economic impact assessment outlined in the Annex XV report. Thus, the Dossier Submitter does not agree with the conclusion that the model was not employed properly.  With regard to ‘Good Modelling Practices’ and transparency, the Dossier Submitter notes that a publically available version of a widely used and established multimedia fate model (SimpleBox, version 4.01 – spreadsheet version) was used for the modelling reported in the Annex XV restriction proposal. This was done precisely to increase the transparency and reproducibility of the performed simulations; degradation rates were used in units of s-1 instead of half-lives, as a required by SimpleBox.  Serving the same key principles of transparency and reproducibility, Tables 2 and 3 (in the Appendix to the Annex XV restriction report) recorded the most sensitive input parameters, namely compartmental emissions (total and percentile contributions), key physical-chemical parameters and degradation rates in air.  The key input parameters mainly originated from the published SVHC identification dossiers and have been referenced accordingly. We acknowledge that several values for the required input parameters have been reported in the literature. However, we do not consider that a discussion on which is the ‘best’ value to use in this particular case is appropriate or, indeed, necessary in the context of the objectives of the modelling reported as this was not intended to predict precise concentrations in the environment.  With regard to atmospheric half-lives, the model used does not require degradation half-lives as a direct model input, rather degradation rate values in cm3 molecules-1 s-1, with an OH radical concentration of 5E+05 molecules. Due to comments by the commentator but also others on a potential disproportionate use of atmospheric degradation reaction rates, these rates have been revisited and, indeed, revised by almost an order of magnitude, using the rates proposed in comment #2196. The computations (including a sensitivity analysis) have been adjusted accordingly, with only a minor impact to the atmospheric chemical presence and, thus, unreacted mass. In fact, a similar exercise performed by another respondent (#2196) indicates that the computations performed by the Dossier Submitter may have well underestimated the importance of the atmospheric compartment for D4, D5 and D6, possibly due to the overestimation of the influence of advection (see also Annex B in comment #2177).  Regarding the inclusion of water and sediment degradation rates, the Annex XV restriction report has been amended accordingly. However, we note that their absence from the Annex XV report did not hinder other stakeholders from commenting and/or providing further data. Ín fact, a respondent was able to accurately reproduce the entire range of computations using the EUSES model, with remarkable similarity in the predictions (#2196).  The Dossier Submitter concludes that these considerations support the appropriateness, transparency and reproducibility of the modelling exercise reported in the Annex XV report.   1. Typographic errors:   Thank you for reporting some typographic errors in the Annex XV Restriction report. These have been corrected:   1. Stock unit |
| **RAC Rapporteurs comments:**  Thank you very much for your comment. We agree with the Dossier Submitter that the identification of D4, D5 and D6 as substances of very high concern due to their PBT/vPvB properties is decided by the ECHA Member State Committee (MSC) and is not under consideration during the opinion-making process for this restriction proposal.  For clarification D4 has indeed been classified as Aquatic Chronic 1, M-factor of 10, (<https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-dislist/details/0b0236e180d84c7b>) confirming that the T properties according to REACH Annex XIII are based on both environmental and human health hazards (Repr. 2, H361f, Aquatic Chronic 1, M-factor of 10).  We also agree with the Dossier Submitter that the properties of the PBT/vPvB substances lead to an increased uncertainty in the estimation of risk to human health and the environment when applying “conventional” quantitative risk assessment methodologies e.g. by derivation of risk characterisation ratios. For PBT and vPvB substances a “safe” concentration in the environment cannot be established using the methods currently available with sufficient reliability for an acceptable risk to be determined in a quantitative way. Emissions and subsequent exposure, in the case of a PBT/vPvB substance, are therefore considered as a proxy for risk.  We also appreciate the fact, that used modelling is useful for assessment of fate of cyclic siloxanes in the environment. The ‘stock pollution approach’ could provide additional useful information compared to simply considering releases to environmental compartments.  We also acknowledge the correction of stock units.  It should be noted that the model was not parameterised to predict environmental concentrations but rather provide an indicative assessment of the proportion of D4, D5 and D6 that would remain ‘unreacted’ in the environment after release. The model results provide order-of-magnitude computations that support the restriction proposal. Thus, we support the Dossier Submitte’s conclusion that the model was employed properly. |
| **SEAC Rapporteurs comments:**  As it concerns the PBT and vPvB judgement no comments from the SEAC Rapporteurs. |
| **2145** | **Date :** 2019/05/20 15 :26  **Content :**  Information on alternatives ;  Information on costs;  Other socio economic analysis (SEA) issues;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** The Polish Union of Cosmetics Industry  **Org. country:** Poland  **Attachment:** | **Comment:**  The cyclic methyl siloxanes Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6) are key ingredients in many categories of cosmetic products. In certain products silicones are present in concentrations up to 100%. These substances are used as emollient ingredients (skin conditioning), hair conditioning, cleaning and as solvents.  It should be noted that cyclic silicones are characterized by specific polarity, which affects their unique  physico-chemical properties. Silicones D5 and D6 have a unique effect on the sensory properties of the product. Due to these properties, there is a fear that products formulated without silicones will not have the same properties as the silicones product and thus will perform differently during consumer use.  According to our knowledge, there are some known alternatives, proposed by the raw materials suppliers in the market. It is currently impossible to fully assess replaceability of D5 and D6, however, efforts are made by the cosmetics industry. On the basis of current knowledge replacement of D5 and D6 in leave-on cosmetic products will be a complex and lengthy process.  Therefore, transitional period (5 years) proposed by ECHA raises our concerns and doubts. Based on these complexities, we assume that potential reformulation efforts could take longer than 5 years in case of certain products of product categories.  All necessary steps will require considerable amount of human work and costs that cosmetic products producers will have to bear.  It is important for the cosmetics industry while replacing D5 and D6 in leave-on cosmetic products – to keep and ensure the high quality of products expected by the consumers. The reformulation process should not limit the consumers’ choice and acceptance of products, especially make-up and hair products, as those categories are expected to the the most challenging in reformulation process.  If producers do not have insufficient time to carry out reformulation process and final placed products do not correspond with consumers preferences, this may lead to develop of a “grey area”. Consumers could start to acquire products containing D5 and D6 from outside the EU on a massive basis through online purchase.  Please see the detailed position attached. |
| **Answer to specific info request 1:**  According to our knowledge, there are some known alternatives, proposed by the raw materials suppliers in the market. Currently, replacements such as: Dimethicone, Isodecyl Neopentanoate, Dicaprylyl Carbonate, available for not more than one year, are tested by the cosmetics manufacturers as D5 and D6 alternatives in leave-on and rinse-off cosmetic products. It is currently impossible to fully assess replaceability of D5 and D6, however, efforts are made by the cosmetics industry. On the basis of current knowledge replacement of D5 and D6 in leave-on cosmetic products will be a complex and lengthy process. There is no one-to-one substitution strategy that will comprehensively address all of the key performance benefits that are derived from these key ingredients. Each product must be reformulated separately as alternatives to particular cyclosiloxanes are different in various finished products.  Therefore, transitional period (5 years) proposed by ECHA raises our concerns and doubts. Based on these complexities, we assume that potential reformulation efforts could take longer than 5 years in case of certain products of product categories.  It is important for the cosmetics industry while replacing D5 and D6 in leave-on cosmetic products – to keep and ensure the high quality of products expected by the consumers. The reformulation process should not limit the consumers’ choice and acceptance of products, especially make-up and hair products, as those categories are expected to the most challenging in reformulation process.  D5 and D6 silicones provide the unique sensorial properties of products. Among others, they give a “silky touch” effect on the skin / hair, which is particularly appreciated by consumers and could be difficult to replaced by other ingredients. Due to their volatility, these substances evaporate quickly from the surface of the skin and hair without causing any fat effect.  Please see the detailed position attached. |
| **Dossier Submitter response:**  Thank you for the additional information provided on potential alternatives to the use of D5 and D6 in cosmetic products and their availability, the types of cosmetic products that would be most challenging to reformulate and the time that it would take to reformulate products.  The information on potential alternatives has been taken into account in our analysis of alternatives, and has been reflected in the Background Document.  We note that as a follow-up to the submission of your comment, we requested further information from you on the following:   * Concentration of siloxanes in products * Existence of other potential alternatives * Products / product categories which would require more than 5 years for reformulation * Results of initial tests on alternatives * Research to identify alternatives * Reasons why make-up and hair products are the most challenging to reformulate * Whether you agree with the DS conclusion that the presence of products without D4, D5 and D6 in each product group indicates that they can be replaced.   You provided some replies to these questions in #2672.  Regarding the transitional period, we have reviewed the varied evidence presented in responses to this consultation, both in confidential and non-confidential submissions. We have received information on the difficulties of reformulation, particularly for some products, as well as the potential timelines for the process. We have also received information supporting the possibility of reformulation taking place more quickly in some cases.  We have considered this additional information when proposing transitional periods. The justification for the transitional periods proposed has been updated and is described in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you very much for your information on potential alternatives to D4, D5 and D6. We also appreciate the incorporation of these data in the Background Document by the Dossier Submitter.  We appreciate that the Dossier Submitter has reviewed and taken into consideration the justifications and information provided in this consultation, and updated the Background Document accordingly. |
| **SEAC Rapporteurs comments:**  Consolidated in the response to the later submission by the same respondent: see #2672. |
| **2170** | **Date:** 2019/05/20 17:46  **Content:**  Hazard or exposure  **Type:** Individual  **Country:**  United Kingdom  **Attachment:** | **Comment:**  Please see attachment |
| **Dossier Submitter response:**  Thank you for the comments provided on the multi-media fate modelling described in the Annex XV report and its Annexes.  Regarding degradation rate constants, we have updated the analysis in the Background Document along the lines of your comment, and similar comments from other respondents. Please see responses to comments #2141 and #2196.  Regarding Table 8, the Annex XV restriction report already stated that the (limited) monitoring data are extracted from the D4 Registration dossier (CSR). It is confirmed that the comparison with monitoring data from rural locations only served as a means to check the selection of model input parameters and emission estimates and not as a quantitative one-to-one comparison of the model results with, the limited available, monitoring data.  On other issues, we wanted to thank you for reporting some typographical errors in the Annex XV Restriction report. These have been corrected:   1. Stock unit 2. Sanchis et al. (2015) is referring to the wrong pole (Appendix - Figure 11) 3. Unreacted stock: the term ‘unreacted’ has been revised |
| **RAC Rapporteurs comments:**  Thank you very much for your comments. We agree with your proposal for changing the degradation rate constants and appreciate that the Dossier Submitter has updated the Background Document.  Also your information on stock units, Sanchís et al. (2015) and “unreacted stock” is appreciated. |
| **SEAC Rapporteurs comments:**  As it concerns the SimpleBox estimations no comments from the SEAC Rapporteurs. |
| **2177** | **Date:** 2019/05/20 18:11  **Content:**  Scope or restriction option analysis;  Environmental emissions;  Information on costs;  Information on benefits;  Other socio economic analysis (SEA) issues;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Cefic - CES Silicones Europe  **Org. country:** Belgium  **Attachment:**    <redacted>  **Privacy comment:** The EU restriction monitoring project is currently in the initial phase. A publication will be made when the study is completed. | **Comment:**  Please refer to attached documents. |
| **Answer to specific info request 4:**  Please refer to attached documents. |
| **Dossier Submitter response:**  Thank you for the comments provided on the following topics: (i) Assessing risks of PBT/vPvB substances, (ii) Stock modelling and (iii) Typographic errors in the Annex XV restriction proposal. **Please refer to the responses to comments #2141 and #2170** in relation to these topics.  In addition, the Dossier Submitter does not dispute the characteristics of siloxanes described in the comment. However, D4, D5 and D6 were identified as SVHCs because they meet the criteria for PBT and vPvB substances under Annex XIII of REACH. Annex XIII does not provide particular considerations for the identification of PBT or vPvB substances that exhibit specific characteristics, such as those with a moderate ability to accept hydrogen bonds (e.g. D4, D5 and D6) or those with low adsorption potential, high solubility and low reactivity (e.g., perfluorooctanoic acid (PFOA)). The Dossier Submitter notes that other substances having specific characteristics (e.g., volatility, surface activity) have previously been identified as SVHC based on their PBT/vPvB properties. These include, for example, musk xylene and henicosafluoroundecanoic acid.  With regard to your additional comments related to the risk assessment of PBT/vPvB substances, we note that quantitative risk assessment methodology, as described in the submitted documentation ‘Annex B-D4\_5\_6\_Risk Assessment\_FiNAL’, is not applicable to PBT/vPvB substances under REACH.  REACH sets out that quantitative risk assessment cannot be carried out with sufficient reliability for PBT/vPvB substances and, therefore, the calculation of a Risk Characterisation Ratio (RCR) is not appropriate. Instead, a separate PBT/vPvB assessment is required and releases of PBT/vPvB substances shall be minimised.  We also note your disagreement with the ECHA Member State decision on the SVHC identification of D4, D5 and D6.  With regard to the hazard and risk assessment comment in general, we remind you that that the identification of D4, D5 and D6 as substances of very high concern due to their PBT/vPvB properties was decided by the ECHA Member State Committee (MSC) and is not under consideration during the opinion-making process for this restriction proposal. PBT/vPvB substances under REACH are non-threshold substances where releases to all compartments shall be minimised  You also provided the following additional comments, on the stock modelling, and more specifically that releases to sludge were not incorporated into the modelling work. We acknowledge that emissions via sludge were not explicitly incorporated in the modelling work (releases to the environment via sludge were rather assumed to contribute directly to atmospheric releases). However, as described in the Annex XV report, we note that the scope of the modelling was not to specifically quantify the role of the sediment compartment as a repository for these substances. Rather it was to investigate the role and significance of emissions to the atmosphere when considering a steady-state environmental stock of D4, D5 and D6. These data were used to inform the socio-economic analysis presented in the Annex XV report, specifically the cost-effectiveness estimates.  You also submitted comments on the following topics: (iv) Feedback on WWTP mass modelling, (v) D6 Kow value and (vi) Silicone polymers (socio-economic information)   1. Feedback on WWTP mass modelling (D4 and D5)   Thank you for confirming that the sampling and measurement of D4 and D5 in municipal WWTP influents are feasible to monitor the effectiveness of the existing restriction on D4 and D5 in wash-off products (Annex A1-Initial report-Executive Summary v3.0). The study was realised in six different locations.  The study gives information on the estimated mass loading in municipal WWTP influent. We note that the estimated mass loading in WWTP influent based on monitoring data are in the same order of magnitude as those estimated in the Annex XV report and, with the exception of the lower estimate for D4, are within the upper and lower estimates provided:   |  |  |  | | --- | --- | --- | |  | WWTP influent –  AXV estimates\* | WWTP influent –  Study extrapolation\*  (source: Annex A1-Initial report-Executive Summary v3.0) | | D4 | 19 – 37 tpa (28 tpa) | 6.5 – 30.6 tpa (13 tpa) | | D5 | 135 – 484 tpa (310 tpa) | 231 – 349 tpa (280 tpa) |   *\*: ‘Considering only the releases from professional and consumer uses + impurity in silicone polymers from cosmetics uses. Excluding the releases from formulation (industrial use) and the releases from impurities in silicone polymers because this releases might not enter domestic STP’*  We note that extrapolating the results from six sampling locations to the EU scale has limitations with regards to representativeness.  It should also be noted that the releases to surface water indicated in the summary note (2019-05-20\_CES\_input\_to\_Annex XV-Consultation.pdf) do not take into account the fact that not all households in EU are connected to a municipal WWTP (currently 90% connection rate in Europe).  Despite these limitations, these data suggest that the cosmetics sector appears to be close to completely phasing out the use of D4 and D5 in wash-off cosmetic products (confirmed by #2191 and #2549 and the market studies reported by the Dossier Submitter in the Annex XV restriction report). We consider that these data support the estimates of releases of D4 and D5 to wastewater reported in the Annex XV report, providing additional evidence that further risk management is needed. In addition, this study supports the effectiveness and monitorability of the existing restriction of D4 and D5 in wash-off products.   1. D6 Kow value (log10) and solubility unit   The D6 log Kow value, and solubility units indicated in the Annex XV Restriction proposal (Table 2 – Annex XV report) are were publicly available and disseminated on the ECHA website (i.e. information submitted by the lead registrant) at the time of the Annex XV Restriction preparation.  The D6 registration dossier would therefore need to be updated to correct this information if it is considered to be erroneous.  Nevertheless, the Dossier Submitter takes note of the updated value, and unit provided, and has updated the Annex XV restriction proposal accordingly.  It should be noted that this value has no impact on the calculation of WWTP efficiency (made using SimpleTreat v4), nor on the stock modelling (made using SimpleBox) as the models used calculated Koc values (as outlined in the paragraph below).  As indicated in section B.4.1.2 and B.9.2.5 of the restriction proposal, although log Kow is an important surrogate property for environmental fate assessment, measured data for key end points (e.g. bioaccumulation) are available and therefore preferred.  The overall removal efficiency in WWTP has been calculated for D6 (but also D4, and D5) based on the values of the Vp, and mean Koc, and noting that the substances are not readily biodegradable (i.e. log Kow was not used). As far as the stock modelling using SimpleBox is concerned, the same approach was taken, namely experimentally-derived carbon-water partition coefficient (Koc) values were used to derive octanol-water partition coefficients (Kow), by use of the Karickhoff equation (Mackay, D, 2001).   1. Silicone polymers   Thank you for confirming that silicone polymer manufacturers are already responding customer demands to lower the level of impurities in silicone polymers.  The Dossier Submitter confirms that uses of silicone polymers are intended to be outside of the scope of the proposal– this has been made clear in the proposed wording of the restriction scope and in the requests for additional information to ensure that appropriate derogations are proposed where these would be needed.  However, derogations specifying different (higher) concentration limits for particular uses of silicone polymers will still be necessary to allow enforcement authorities to distinguish between uses of D4, D5 and D6 that are intended to be restricted and uses of silicone polymers with high residual concentrations of D4, D5 and D6 that are not intended to be restricted.  Regarding the comments provided in Annex C:   * The Dossier Submitter acknowledges that the costs associated with the uses of silicone polymers are not detailed. This is because uses of silicone polymers are out of scope of the restriction, and the possible derogations for uses of silicone polymers where the concentration of D4, D5 and/or D6 is above 0.1% w/w are intended to ensure they are not inadvertently affected. * Regarding the proportion of the tonnage of silicone polymers used in cosmetic products, the Dossier Submitter has relied on the information provided by Cosmetics Europe. * The Dossier Submitter acknowledges the uncertainty over the use of D4, D5 and D6 in rigid polyurethane. The original Annex XV report included that data due to it being included in a registration dossier. Since then, further information has been provided by PU Europe as well (see comment #2344) confirming no use of D4, D5 and D6. This will be updated in the Background Document * The data provided in the 2013 Reconsile SEA on uses of silicone polymers and the concentration of D4, D5 and/or D6 in them covered the silicone polymers themselves, not the final products, where the concentration could be significantly lower. The Dossier Submitter therefore opted to use the information provided by the sectors about the final products. Further information about concentrations in final products has been provided in this consultation, and the Dossier Submitter will propose derogations to ensure they are not inadvertently affected by the restriction. * The assumption of co-ordination with baseline reformulations was included also in the restriction proposal on D4 and D5 in wash-off cosmetic products. It was scrutinised by the SEAC at the time and considered to be credible. * The Dossier Submitter acknowledges that there is little cost information (for the non-cosmetic product uses) in the Annex XV report, as insufficient data was available to provide a fuller analysis. The report explains why an alternative approach was taken for these uses. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment. We agree with the Dossier Submitter that the identification of D4, D5 and D6 as substances of very high concern due to their PBT/vPvB properties was decided by the ECHA Member State Committee (MSC) and is not under consideration during the opinion-making process for this restriction proposal.  We agree with the Dossier Submitter that the quantitative risk assessment methodology, as described in the submitted documentation ‘Annex B-D4\_5\_6\_Risk Assessment\_FiNAL’, is not applicable to PBT/vPvB substances under REACH. REACH sets out that quantitative risk assessment cannot be carried out with sufficient reliability for PBT/vPvB substances and, therefore, the calculation of a Risk Characterisation Ratio (RCR) is not appropriate. Instead, a separate PBT/vPvB assessment is required and releases of PBT/vPvB substances shall be minimised.  Your comments, on the stock modelling, and more specifically that emission to sludge were not incorporated into the modelling work was noted. We agree with the Dossier Submitte’s explanation (releases to the environment via sludge were rather assumed to contribute directly to atmospheric releases) and also support the fact that the scope of the modelling was not to specifically quantify the role of the sediment compartment as a repository for these substances. Rather it was to investigate the role and significance of emissions to the atmosphere when considering a steady-state environmental stock of D4, D5 and D6.  We also appreciate the provided data on estimated mass loading in municipal WWTP influent confirming that the sampling and measurement of D4 and D5 (and D6, see  #2469) in municipal WWTP influents are feasible to monitor the effectiveness of the existing restriction on D4, D5 and D6 in wash-off products. We also agree with the Dossier Submitter that there are some limitations to extrapolate the results from six sampling points to the EU scale.  Thank you very much for the correction of the D6 Kow value. It should be noted that this value has no impact on the calculation of WWTP efficiency (made using SimpleTreat v4), nor on the stock modelling (made using SimpleBox) as the models used calculated Koc values.  We also very appreciate the effort of industry to lower the residual impurities of D4/D5 and D6 in silicone polymers, although the uses are out of scope of the proposed restriction. |
| **SEAC Rapporteurs comments:**  Silicones Europe provided a letter with several annexes. Of these mainly annex C on costs is relevant to the SEAC Rapporteurs. The SEAC Rapporteurs can support the argumentation provided by the Dossier Submitter, e.g. on the presence in polyurethane and the cost information of the non-cosmetic uses. Limited information on these costs was submitted during the consultation. Further comments are provided in response to #2469. |
| **2185** | **Date:** 2019/05/20 18:46  **Type:** MemberState  **Country:**  Sweden  **Attachment:** | **Comment:**  - |
| **Dossier Submitter response:**  Thank you for your comment. Regarding the transitional period, we have reviewed the varied evidence presented in responses to this consultation, both in confidential and non-confidential responses. We have received information on the difficulties of reformulation, particularly for some products, as well as the potential timelines for the process. We have also received information supporting the possibility of reformulation taking place more quickly in some cases. We have considered all the information submitted in the consultation when proposing the transitional period for this restriction. The justification for the transitions periods is reflected in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment, noted.  We appreciate that the Dossier Submitter has reviewed and taken into consideration the justifications and information provided in this consultation when proposing the transitional period for this restriction and reflected that in revisions to the Background Document. |
| **SEAC Rapporteurs comments:**  The Swedish CA proposes that the implementation period is reduced to 2 years for three cosmetic product categories and indicates that this should be considered proportional. The  the cost per reduction of release to water would still be lower than in the existing restriction of D4 and D5 in wash-off products.  The costs of the restriction cannot be directly compared to that of the D4 and D5 in wash-off cosmetics as in this current restriction proposal both emissions to water and air were taken into account in the cost-effectivness estimates. Furthermore, comment #2145 indicate that make-up and hair products are mentioned as categories that are expected to be the most challenging in the reformulation process. |
| **2191** | **Date:** 2019/05/20 19:12  **Content:**  Environmental emissions  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Cosmetics Europe  **Org. country:** Belgium  **Attachment:** | **Comment:**  Dear Sir/Madam,  Cosmetics Europe is submitting cosmetic specific comments to the ECHA consultation concerning a possible new REACH Annex XV Restriction on D4 and D5 in leave-on products and other consumer/professional products as follows:  • The cosmetics Industry would like to reiterate the significant decline of emissions to the aquatic environment following the introduction of the D4 & D5 wash off REACH restriction in January 2018 (2018/35/EC). This is supported by environmental monitoring data submitted to ECHA by CES and Unilever. The downward trend is expected to continue following the deadline of the wash-off Restriction (Jan 2020). As a result, the Cosmetic Industry believes that this significant reduction should be taken into account to assess the actual impact of the regulatory action before implementing any additional Restriction. Since the implementation of the regulation ends on 31st January 2020, the Cosmetics Industry requests that ECHA review the aquatic emissions of D4 and D5 by 2025 to further establish whether additional risk management requirements are necessary for cosmetic leave on products.  • The restriction report provides details and an analysis of the cosmetic Industry use of D4 & D5 from an “app” called CosmEthics in preference to the data which Industry submitted in Memos A and F. The CosmEthics App is a consumer app and has not been developed for the purposes of data collection for regulatory purposes and as such it is inappropriate to use these unvalidated data in preference to those submitted by Cosmetics Europe.  • The Cosmetics Industry is also aware of the ECHA report; “Potential overlap between proposed restrictions on D4, D5, D6 and microplastics” (20 March 2019), which suggests that the reformulation costs of D4 & D5 containing products can be combined with reformulation costs for other ingredients such as Microplastics. As noted in Memos B, C, D & E, the reformulation of products using D5 alone is complex and using the analysis of the CosmEthics App to determine the percentage overlap is inappropriate for the reasons provided above. To completely redesign the chassis of a product because of multiple ingredient changes involves greater amount of time and cost. Identification of a replacement for D5/D4 to deliver unique properties is a separate exercise to identification of a replacement for another ingredient in the formulation. Therefore, multiple ingredient changes can be considered as cumulative costs not “double counting” as suggested in the report.  • In addition, Cosmetics Europe would like to provide new information that will allow to refine the preliminary RAC assessment of the fraction of D5 that might be released to waste-water following application of leave-on personal care products (PCPs). Cosmetics Europe is finalizing an assessment that integrates all available data from the literature as well as the consumer habits and practices data in the most comprehensive probabilistic exposure assessment available to date. The outcome confirms that leave-on PCPs do not contribute significantly to the release of D5 to surface waters, and therefore suggests that the proposed additional REACH Restriction on leave-on PCPs is disproportionate. The outcome of this assessment is supported by the intermediate report on the monitoring program being undertaken on D5 in wastewater and submitted to ECHA separately by the European Council of Silicones (CES).  The details of the assessment can be found in the attached draft report by Crème-Cosmetics Europe. In brief, 11700 tons of D5 were used in leave-on PCPs in 2018. In order to assess the fraction of D5 that is released to wastewater following product application, the following parameters were considered.  1. Amounts of D5 in leave-on PCPs used by the European population,  2. Duration between product application and following washing event  3. Kinetics of D5 evaporation from a skin/hair following product application.  The results of the assessment are as follows:  Wash-off PCPs Leave-on PCPs  Fraction of D5 released to wastewater following application of PCPs 701.1 t/y (RAC opinion) 43 t/y (Crème-Cosmetics Europe assessment)  Corresponding D5 concentration in influent of wastewater treatment plants 38 µg D5/L (Crème-Cosmetics Europe assessment) 2.3 µg D5/L (Crème-Cosmetics Europe assessment)  The results demonstrate that the emission from leave-on products into wastewater is significantly lower than from wash-off products, due to evaporation of D5 from products during the period they remain applied on the skin/hair.  Cosmetics Europe is looking into possibilities to further refine this assessment and will submit respective information later during the public consultation, if available.  In compliance with the 2018 REACH restriction on the use of D5 in wash-off PCPs, D5 may not be placed on the market in wash-off PCPs in a concentration greater than or equal to 0.1% by weight after January 2020. The goal of the proposed restriction is to reduce emissions of D5 from wash-off PCPs by 97%. The restriction is expected to substantially reduce the EU’s concern for aquatic environments receiving discharges from wastewater treatment plants, focusing on the uses that do pose a concern. The calculated D5 influent concentrations reported above are in line with the actual influent concentrations measured in the influent of European wastewater treatment plants (<1 to 29 µg D5/L) (CES report).  It is therefore recommended to maintain the current REACH Restriction on wash off PCPS until the monitoring program is finalized and the consequence of the 2018 REACH Restriction on the environmental releases becomes fully apparent and characterized.  Cosmetics Europe would like to take this opportunity to thank ECHA for the willingness to take into consideration our comments on this important topic.  Cosmetics Europe stands ready to answer any questions you may have. |
| **Dossier Submitter response:**  Thank you for the comments provided and for confirming the decline of D4 and D5 emissions from wash-off cosmetics following the adoption of the restriction on D4 and D5 in wash-off cosmetics products. This information has already been taken into account in the Annex XV restriction report by setting to zero the D4 and D5 tonnage in the wash-off cosmetics (we consider that when the restriction proposal will enter into force, D4 and D5 would have been phased on from wash-off cosmetics). Only tonnages for D6 have therefore been taken into account in the Annex XV restriction report.  Thank you for submitting an update of the Crème Global study (Cosmetics EuropeCE\_D5 report 20\_05\_2019\_Final.pdf), that was previously submitted in the call for evidence for the preparation of the Annex XV report. We acknowledge the probabilistic assessment that has been made in this report. However, we consider that some of the assumptions reported in the report are questionable. For example, the time interval between application and washing is surprisingly long in some cases: e.g. a median value for the washing off of hand cream of 11 hours after application, etc. In addition, whilst the Gouin *et al*. (2013) study and that of Montemayor *et al*. (2013), were used as starting point in the Crème Global statistical modelling, and tend to support each other, we think that there are a number of uncertainties in both studies that limit their usefulness (as noted in the RAC opinion on the restriction proposal for D4 and D5 in wash-off cosmetic products) and, therefore, they should be used with caution.  The results from the Crème global study are interesting in terms of central tendency; nevertheless, it is difficult to assess the reliability of the results, in particular the estimated release factor to waste water. Indeed, the difference between the mean and the median estimated values is important (an order of magnitude; indicating highly skewed data distributions), and no other statistical descriptors of the underlying distributions (e.g. min/max, interquartile range) of the events has been provided in the study.  Nevertheless, with regards to the release factor of D5 in waste water from leave-on products, we agree that this factor is lower than the one that was applied for wash-off products in the UK restriction proposal on D4 and D5. This is why, in the Annex XV restriction report, we have also taken into account various factors such as (i) the cosmetics types (e.g. leave-on vs wash-off), (ii) the different cosmetics categories (e.g. lipstick, eye make-up, body cream etc…), (iii) consumer habits in term of cosmetics removal (shower vs wipe/cotton removal). These various parameters have been reflected in the release factors applied to leave-on products.  We also note that the release factor indicated in the Crème Global study is within the range of the release factor used by the Dossier Submitter to estimate the release to waste water for leave-on cosmetics: mean release factor of 0.37% (and median of 0.03%) for D5 in various type of leave-on cosmetic). Indeed the release factors to waste water used in the Annex XV restriction report are 0.1 – 2.6% if the leave-on cosmetics is washed off, and 0.1% if the leave-on cosmetics is first remove with a pad/cotton disposed in a bin.  With respect to the use of data from the CosmEthics database, we would like to highlight that this database was only one of the sources used. Data was corroborated with two additional databases from national consumer associations: QueChoisir (France) and Forbrugerrådet Tænk in Denmark (Danish Consumer Council THINK Chemicals, 2018), and with the results of a market survey commissioned by ECHA from COWI in 2018. For formulations belonging to large companies, the data provided by Cosmetics Europe was used. However, for formulations belonging to SME the Dossier Submitter considered that the data provided by Cosmetics Europe had methodological problems, and the data from the other sources (which were consistent with each other) provided a more reliable estimate. In any case, the data provided by Cosmetics Europe was consistent with the ranges that was used for number of formulations affected.  Regarding the potential overlap between the restrictions on D4, D5 and D6 and the one on intentionally added microplastics, we note that the cost calculations undertaken in each of the restriction proposals were done without account of any potential cost-savings resulting from the overlap. We will take note of the evidence provided on the potential impact of the overlap on costs in the report mentioned. |
| **RAC Rapporteurs comments:**  Thank you very much for the comments provided and for confirming the decline of D4 and D5 emissions from wash-off cosmetics following the adoption of the restriction on D4 and D5 in wash-off cosmetics products. The Dossier Submitter has already taken this information into account in the Annex XV restriction report by setting to zero the D4 and D5 tonnage in the wash-off cosmetics.  We also appreciate the submitting an update of the Crème Global study (Cosmetics EuropeCE\_D5 report 20\_05\_2019\_Final.pdf). We agree with the Dossier Submitter that some of the assumptions reported in the report are questionable (e.g. the time interval between application and washing-off is surprisingly long in some cases: hand-cream washed off 11 hours after application (reported as a median value). In addition, whilst the Gouin *et al*. (2013) study and that of Montemayor *et al*. (2013), were used as starting point in the Crème Global statistical modelling, and tend to support each other, we think that there are a number of uncertainties in both studies that limit their usefulness (as noted in the RAC opinion on the restriction proposal for D4 and D5 in wash-off cosmetic products) and, therefore, they should be used with caution. It should be also noted that the release factor indicated in the Crème Global study is within the range of the release factor used by the Dossier Submitter. |
| **SEAC Rapporteurs comments:**  Cosmetics Europe submitted comments and information on the emissions due to various product groups and provided comments on various other topics. The SEAC Rapporteurs took note of the answer of the Dossier Submitter that they did their cost estimations for D4, D5 and D6 and microplastics independently.  The SEAC Rapporteurs do not see a problem in taking aboard information from the CosmEthics, among other sources, as such information may be valuable providing insight in the current use of the siloxanes. We note that the release from the leave-on cosmetics mentioned in the Cosmetics Europe response is not negligible compared to the wash-off cosmetics (43 versus 701 tonnes); furthermore, cost-effectiveness of the measure is in the range of that of other restrictions, as indicated in the Background Document. |
| **2196** | **Date:** 2019/05/20 19:29  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** PFA-Brussels sprl  **Org. country:** Belgium  **Attachment:** | **Comment:**  - |
| **Dossier Submitter response:**  Thank you for the comments provided.  The comment comprises a modelling exercise to critique the multi-media fate modelling reported by the Dossier Submitter. The confirmatory modelling was undertaken using EUSES (incorporating SimpleBox as its fate module) and used the same key parameters as those used by the Dossier Submitter (most importantly emissions and key physical-chemical and partitioning data). The comment confirmed that the computations presented in the Annex XV restriction report are consistent with:   1. The key physical-chemical properties and assumptions on environmental processes for D4-D6 used in REACH registration CSRs; 2. REACH CSR computations relating to regional and continental D4-D6 emissions; 3. EUSES computations relating to regional air and freshwater stocks for D4-D6; 4. EUSES computations relating to continental scale air, freshwater and the total continent stocks for D4-D6, including compartmental distributions; 5. EUSES computations relating to mass percentages present in environmental compartments and the total amount emitted for D4-D6; 6. EUSES computations and the CSRs relating to PECs for both D4 and D6. This was despite the fact that PECs reported in the Annex XV report were based on regional emissions only, while the PECs generated by EUSES are based on regional and continental emissions;   The Dossier Submitter notes that much higher air distributions and, thus, stocks were predicted by the use of EUSES, possibly due to higher advection from the regional SimpleBox environment compared to the Annex XV restriction report computations. In addition, the Dossier Submitter notes that the modelling reported in the Annex XV report may have overestimated the sediment chemical stock compared to EUSES due to the absence of the sludge module present in EUSES.  These results indicate that the multi-media fate modelling in the Annex XV report and annexes were reported in sufficient detail to be reproducible.  Nevertheless, the degradation rates in air used by the Dossier Submitter were revised based on the comment and all simulations have been updated in the Background Document.  Thank you also for reporting the typographical errors on the stock unit in the Annex XV restriction proposal. This has been corrected. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment confirming the reproducibility of the computations presented in the restriction proposal.  We also appreciate that the Dossier Submitter has incorporated all changes to the modelling and all simulations were transparently given in the Annex XV restriction report.  Comment on stock unit noted. |
| **SEAC Rapporteurs comments:**  Comments concern SimpleBox modelling, no comments by the SEAC Rapporteurs. |
| **2213** | **Date:** 2019/05/20 22:39  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Information on costs;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United Kingdom  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** The confidential document in the attachment includes confidential company sales and volume information and confidential product composition information. In order to protect our company's commercial interests and intellectual property, this information must not be placed in the public domain. It can only be used by ECHA and the relevant member state competent authorities for the purposes of this restriction assessment. | **Comment:**  Our company comments are provided in the attached CONFIDENTIAL document. |
| **Answer to specific info request 4:**  Our company comments are provided in the attached CONFIDENTIAL document. |
| **Dossier Submitter response:**  Thanks for your (confidential) comment. |
| **RAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **SEAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **2229** | **Date:** 2019/05/21 10:55  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** European Semiconductor Industry Association  **Org. country:** Belgium | **Comment:**  ESIA would like to comment of the restriction proposal on D4, D5 and D6 in leave on personal care products and consumer and professional products. ESIA agrees that ECHA’s restriction proposal is targeted and proportionate to the risk identified. ESIA comments relate to D4.    ESIA would like to reiterate that the semiconductor industry is using silicon polymers in critical innovative applications in the cleanroom for semiconductor manufacturing. For the manufacture of these silicon polymers (that occurs within our industry’s supply chain), D4 is an indispensable building block (99% volume used as intermediate) as identified in the dossier. D4 is a critical precursor material used in low quantities for a key step in the semiconductor manufacturing process: deposition of dielectric layers in formation of transistors in advanced semiconductor technologies. D4 itself does not remain in the product (the silicon microchip).  D4 is essential to a key European enabling industry sector like semiconductor manufacturing where appropriate measures are in place controlling the potential exposure.  ESIA believes that restriction proposal regulatory option chosen for D4 is proportionate to the specific risks identified to be managed and the European Commission’s request for uses of D4 and D5 in leave on cosmetics and in other consumer and professional products in 2016.The industrial use of D4 for semiconductor industry is beyond the restriction scope. In comparison to other regulatory approaches (RMOs) including potential authorisation this regulatory option provides the most targeted and appropriate approach to the risk and ensures that the risk reduction capacity is significant. |
| **Dossier Submitter response:**  Thank you for your response to the consultation. We note your points about the use of silicone polymers in the semiconductor industry, and that you do not expect the restriction to affect your industrial applications. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment regarding the use of silicone polymers in the semiconductor industry. |
| **SEAC Rapporteurs comments:**  The Industry or trade association is in support of the choosen RMO. The SEAC Rapporteurs are in support of this RMO as well. |
| **2248** | **Date:** 2019/05/27 10:32  **Content:**  Baseline;  Information on benefits;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Bayer AG  **Org. country:** Germany | **Comment:**  Our company uses D4 and D5 based silicone polymers for production of long term intrauterine medicinal products (IUS (Intra Uterine Systems)) and implants.  As stated in the ECHA restriction report, it is not technically possible to produce silicone polymers with “zero content of D4, D5 and D6” using conventional production techniques.  Manufacturing of our medicinal products and the silicone polymers are performed at industrial sites and no emission of the elastomers and their respective monomers to the environment takes place. For IUS and implants there are no instructions for disposal in the package insert. But the insertion and removal is always done by health care professionals in hospitals or in doctor’s surgery. Depending on local waste requirements, the removed IUS or implants for example might need to be handled as biohazards. Due to the residual content of hormone in the IUS or implant the product might pose a risk to the environment and should be disposed of according to the local waste disposal requirements. Proper waste disposal is therefore already triggered by the remaining API (active pharmaceutical ingredient) in the products. The risk to the environment is negligible and no release of all above mentioned products takes place under reasonably foreseeable conditions of use.  We herewith would like to point out that there are medicinal products on the EU market with D4 and D5 based silicon polymers. ECHA’s assumption that there is no use of D4 in pharmaceutical products (p.67, Annex XV dossier) therefore is not correct.  Despite our products containing < 0.1 % of D4 (Octamethylcyclotetracioxane) and/ or D5 (Decamethylcyclopentasiloxane) residual amounts, a restriction of these (D4, D5, D6) could lead to disruption of supply and thus a disruption in the production of our products, which are used globally for both reproductive and women’s health.  The impact of using D4, D5 and D6 within the health care industry is < 5% of total amount of D4, D5 and D6 (Figure 3 Annex XV dossier). According to the Annex XV dossier table 7 even in case of a high release scenario, the release from pharmaceutical industry (pharmaceutical products and medical devices) in total would be 305 t/y compared to a total environmental release of all uses of ca. 18 000 t/y means a share of ca. 1.7% for pharmaceutical industry.  We assume that our manufacturing together with our supply chain of medicinal products containing D4 and D5 based silicon polymers with rest monomeric contents of <0.1% are exempted from restriction according to 1 b). Nevertheless, as no environmental exposure takes place during manufacturing and use of IUS and implants we request an exemption for the use of silicone polymers in medicinal products. |
| **Answer to specific info request 3:**  Our company uses D4 and D5 based silicone polymers for production of long term intrauterine medicinal products (IUS (Intra Uterine Systems)) and implants.  As stated in the ECHA restriction report, it is not technically possible to produce silicone polymers with “zero content of D4, D5 and D6” using conventional production techniques.  Manufacturing of our medicinal products and the silicone polymers are performed at industrial sites and no emission of the elastomers and their respective monomers to the environment takes place. For IUS and implants there are no instructions for disposal in the package insert. But the insertion and removal is always done by health care professionals in hospitals or in doctor’s surgery. Depending on local waste requirements, the removed IUS or implants for example might need to be handled as biohazards. Due to the residual content of hormone in the IUS or implant the product might pose a risk to the environment and should be disposed of according to the local waste disposal requirements. Proper waste disposal is therefore already triggered by the remaining API (active pharmaceutical ingredient) in the products. The risk to the environment is negligible and no release of all above mentioned products takes place under reasonably foreseeable conditions of use.  We herewith would like to point out that there are medicinal products on the EU market with D4 and D5 based silicon polymers. ECHA’s assumption that there is no use of D4 in pharmaceutical products (p.67, Annex XV dossier) therefore is not correct.  Despite our products containing < 0.1 % of D4 (Octamethylcyclotetracioxane) and/ or D5 (Decamethylcyclopentasiloxane) residual amounts, a restriction of these (D4, D5, D6) could lead to disruption of supply and thus a disruption in the production of our products, which are used globally for both reproductive and women’s health.  The impact of using D4, D5 and D6 within the health care industry is < 5% of total amount of D4, D5 and D6 (Figure 3 Annex XV dossier). According to the Annex XV dossier table 7 even in case of a high release scenario, the release from pharmaceutical industry (pharmaceutical products and medical devices) in total would be 305 t/y compared to a total environmental release of all uses of ca. 18 000 t/y means a share of ca. 1.7% for pharmaceutical industry.  We assume that our manufacturing together with our supply chain of medicinal products containing D4 and D5 based silicon polymers with rest monomeric contents of <0.1% are exempted from restriction according to 1 b). Nevertheless, as no environmental exposure takes place during manufacturing and use of IUS and implants we request an exemption for the use of silicone polymers in medicinal products. |
| **Dossier Submitter response:**  Thank you for your response to the consultation. We note your points about the use of silicone polymers in your industry. Uses of silicone polymers are outside the scope of this restriction. However, we are seeking information about the concentration of D4, D5 and D6 as impurities in uses of silicone polymers so that we can consider a derogation to make sure those uses remain out of scope. In any case, from the information you provide, it seems clear that your products contain D4, D5 and D6 in concentrations below 0.1% w/w, so they would not be affected by the restriction. |
| **RAC Rapporteurs comments:**  Thank you very much for your information regarding the use of D4 in pharmaceutical products. The other comments noted. |
| **SEAC Rapporteurs comments:**  No further comments from the SEAC Rapporteurs. |
| **2260** | **Date:** 2019/05/29 16:38  **Content:**  Information on alternatives;  Information on benefits;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United Kingdom  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** Protection of commercial interests in information supplied | **Comment:**  - |
| **Dossier Submitter response:**  Thanks for your (confidential) comment. |
| **RAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **SEAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **2270** | **Date:** 2019/06/06 09:42  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** C.T.S. Srl  **Org. country:** Italy | **Comment:**  Cyclometicone D5 is used in conservation field as a temporary barrier for water cleaning or for the application of water-based material (mortars, consolidants....) on water-sensible materials. Restorers use it as professionists, in safe conditions and in a very limited quantity. Without this solvent some operations will involve noxious materials (Chlorinated solvents) or will became impossible. |
| **Dossier Submitter response:**  Thank you for the information provided on the use of D5 in the cleaning of art and antiques, and on the alternatives for the use of this substance. We note that the information you submit confirms the analysis in the restriction dossier. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment on use of D5 for restoration and also possible alternatives. |
| **SEAC Rapporteurs comments:**  This concerns the use of D5 in the cleaning of art and antiques. An exemption is already incorporated in the restriction proposal, which is supported by the SEAC Rapporteurs. No clear details are provided in the comment. Thus the SEAC Rapporteurs are not able to further scrutinise the comments. |
| **2342** | **Date:** 2019/07/02 14:43  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Bostik GmbH  **Org. country:** Germany  **Attachment:** | **Comment:**  - |
| **Answer to specific info request 4:**  Silicone polymers are essential and indispensable raw materials for production of silicone sealants and can be used up to 90% content in the final silicone sealant.  D4/D5/D6 have no known technical function in the silicone sealants and are not intentionally added by sealant producers.  D4/D5/D6 are impurities in the silicone polymers used as raw material for silicone sealants. So concentration of these impurities in the final silicone sealant solely depends on the concentration of D4/D5/D6 in the silicone polymers used.  Sealant producers are not able to reduce content of D4/D5/D6 impurities in the silicone polymers. Therefore sealant producers are not in the position to indicate potential maximum concentrations of D4/D5/D6 in the final silicone sealants.  Nevertheless sealant producers have to meet the requirement for maximum concentrations of SVHCs of <0,1% which are indispensable criteria for some environmental labels (e.g. Nordic Swan, Blue Angel, Emicode, LEED, DGNB, Basta, …). Therefore sealant producers expect to receive silicone polymers with concentration of D4/D5/D6 below 0,1% as soon as possible.  Silicone sealants represent a significant share of the European sealant market because of their specific properties (e.g. durability, weathering resistance, chemical resistance,…). They can not likely be replaced by other sealants due to these specific properties. Therefore to avoid market interruption a reasonable transition period is needed which allows producers of silicone polymers to meet reduction targets for contents of D4/D5/D6 in silicone polymers. |
| **Dossier Submitter response:**  Thank you for your response to the consultation. We note your points about the use of silicone polymers in your industry and that you do not expect the restriction to affect the placing on the market of silicone sealants. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment, noted. |
| **SEAC Rapporteurs comments:**  Sealant producers expect to receive silicone polymers with concentration of D4, D5 and D6 below 0.1% as soon as possible. The company, a producer of silicone sealants, indicates that to avoid market interruption a reasonable transition period is needed which allows producers of silicone polymers to meet reduction targets for contents of D4, D5 and D6 in silicone polymers. No data on concentrations and amounts are provided in the comment. Thus, the SEAC Rapporteurs are unable to further scrutinise the data. |
| **2344** | **Date:** 2019/07/05 15:33  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** PU Europe  **Org. country:** Belgium | **Comment:**  PU Europe (European polyurethane insulation industry) representing insulation producers, raw material suppliers and component manufacturers, would like to show our agreement with the fact that industrial uses are excluded from the scope of the proposal for the restriction of D4, D5 and D6.  In addition to this, we have recently learnt that Reconsile REACH Consortium will remove the D5 PU rigid foams application exposure scenario from the CSR. Therefor we would like to refer to our input on this, as reflected in the restriction dossier, and insist that there is no evidence of the presence of D5 in members’ supplies, and that D5 is not deemed to be a building block of the type of silicone polymers used in the industry. We hope that this will be taken into account in an appropriate way and that the Annex VX restriction dossier will be amended accordingly. |
| **Dossier Submitter response:**  Thank you for your response to the consultation. We note your points about the use of silicone polymers in your industry and that you do not expect the restriction to affect the placing on the market of rigid PU foam.  The Annex XV restriction report has been updated: Rigid PU foam has been removed from the list of uses (for D5). |
| **RAC Rapporteurs comments:**  Thank you very much for your clarification that D5 is not deemed to be a building block of the type of silicone polymers used in the industry in the PU rigid foams. |
| **SEAC Rapporteurs comments:**  The Industry or trade association indicate that there is no evidence of the presence of D5 in members’ supplies, and that D5 is not considered to be a building block in the silicone polymers used in the polyurethane insulation industry. The Dossier Submitter has removed the use of D5 from the uses mentioned in the Background Document, which is supported by the SEAC Rapporteurs. |
| **2355** | **Date:** 2019/07/18 16:05  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Baseline  **Type:** MemberState  **Country:**  United Kingdom  **Attachment:** | **Comment:**  Please see attached file |
| **Dossier Submitter response:**  Thank you for your response to the consultation, and your support for the proposed restriction of D6 in wash-off products.  Since the UK restriction proposal on D4 and D5 in wash-off products, D4, D5 and D6 have been identified as PBT/vPvB substances (decision made by the ECHA Member State Committee).  No predicted concentrations in environmental compartments have been calculated, as this information is not strictly relevant for the risk assessment of PBT/vPvB substances under REACH (as outlined in Annex I). PBT/vPvB substances are subject to a PBT assessment and releases to all compartments shall be minimised. Nevertheless, the specific fate properties of D4, D5 and D6 were taken into account as an element of the socio-economic analysis, specifically the estimates of cost-effectiveness that have been calculated both on the basis of ‘releases’ and also on the basis of ‘releases that will remain in the environment, which recognises that a large proportion of releases to the atmosphere will degrade within this compartment and will not contribute to a long-term environmental stock.  Thank you also for the comments and remarks made on the following topics: (i) enforceability of Registrants' obligation to recommend appropriate RMMs, (ii) risk of alternatives for the cosmetic product uses, (iii) dry-cleaning, (iv) devolatilisation costs and (v) consider the info available from the current industry WWTP monitoring. We have taken note of these comments.  On the risk of the alternatives for the cosmetic product uses, this has been taken into account and a more detailed analysis of potential alternatives has been added to the Background Document.  Regarding the impacts of devolatilisation, we agree with your comment, and will mention this as a possibility in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment. We appreciate your support for proposed restriction. Also other information on alternatives, dry-cleaning, industry WWTP monitoring were noted.  Regarding the Sanchís et al. (2015) study RAC confirms that further research on the deposition of D4, D5, and D6 is needed since, because of the large quantities released to the atmospheric compartment, only low rates of deposition could be significant. |
| **SEAC Rapporteurs comments:**  Comments mainly relate to emissions and deposition of D4, D5 and D6. Thus, it is not a specific topic of the SEAC Rapporteurs. |
| **2385** | **Date:** 2019/08/06 22:43  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United States  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** We believe that disclosing some of the information submitted would undermine our intellectual property position. | **Comment:**  See Specific Information Request #2 Below. |
| **Answer to specific info request 2:**  See attachment. |
| **Dossier Submitter response:**  Thank you for your (confidential) comment. |
| **RAC Rapporteurs comments:**  Thank you for your (confidential) comment. |
| **SEAC Rapporteurs comments:**  Thank you for your (confidential) comment. |
| **2387** | **Date:** 2019/08/08 10:09  **Content:**  Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** Reason of confidentiality: Protection of commercial interests of a natural or legal person, includingintellectual property. Protection of CBI on uses and sales volumes. | **Comment:**  - |
| **Dossier Submitter response:**  Thank you for your (confidential) comment. |
| **RAC Rapporteurs comments:**  Thank you for your (confidential) comment. |
| **SEAC Rapporteurs comments:**  Thank you for your (confidential) comment. |
| **2469** | **Date:** 2019/09/02 17:00  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Baseline;  Description of analytical methods;  Information on benefits;  Other socio economic analysis (SEA) issues;  Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Cefic CES - Silicones Europe  **Org. country:** Belgium  **Attachment:**    <redacted>  **Privacy comment:** Contains provisional monitoring and SEA information. Please do not upload on ECHA website. | **Comment:**  Please refer to attached files in the submission |
| **Answer to specific info request 3:**  Please refer to attached files in the submission |
| **Answer to specific info request 4:**  Please refer to attached files in the submission |
| **Dossier Submitter response:(on non-confidential attachment only)**  Thank you for the comments provided on the following topics: (i) assessing risks of PBT/vPvB substances, (ii) stock modelling and (iii) phys-chem properties of the substance and (iv) municipal WWTP mass modelling for D4 and D5. These comments are visible in the document called ‘CES second input’.  The responses to these comments are available in the following consultation responses:  Assessing risks of PBT/vPvB substances: #2141 and #2177  Stock modelling: #2141, #2170 and #2177  Phys-chem properties: #2177  Municipal WWTP mass modelling for D4 and D5: #2177  In addition, you provided also additional comments on the following topics: (v) Additional comments on hazard, risk assessment and modelling tool, (vi) safety of D4 and D5 for human health (vii) municipal WWTP mass modelling for D6, (viii) impact of the proposed restriction, and (iv) enforceability.  (v) Additional comments on hazard, risk assessment and modelling tool:  We note your disagreement with the ECHA Member State decision on the SVHC identification of D4, D5 and D6.  The Dossier Submitter does not dispute the potentially low deposition fluxes from the atmosphere, especially in a modelling environment.  We acknowledge the findings of other models on long atmospheric transport distances driven by relative volatility and limited potential for surface deposition. We do not dispute these findings, rather the opposite. In fact, the model results in the Annex XV report confirm the relative small magnitude of air-to-surface deposition processes. The scope, as described also in previous responses, was to investigate the impact of continuous, long-term, emissions to air that are orders of magnitude greater than in the aquatic compartment. Furthermore, the RAC opinion on the UK restriction proposal for “wash-off” products clearly stated that “although the RAC opinion on the UK restriction proposal considered that the Sanchis et al. (2015a) study was insufficient to prove that deposition was occurring, its opinion noted that on the basis of the large tonnages of these substances released to the atmospheric compartment only low rates of deposition would be necessary to result in a concern.”  The use of more sophisticated modelling tools was not considered to be appropriate for the purposes of the modelling in the Annex XV report. Indeed the aim of the modelling was to provide an indicative, order of magnitude, assessment of the quantity of D4, D5 and D6 that would remain ‘unreacted’ in the environment after releases. The purpose was not to use the model to predict precise concentrations in specific environmental compartments. Instead, a simple, established (for regulatory purposes) and widely used model was utilised. The reproducibility of the modelling was confirmed by the exercise documented in comments #2196 and #2724.  Regarding the comparison of the model results with monitoring data, please refer to the response to comment #2170. In any case comparison with measurement data is hindered by the presence, location, type, quality, uncertainty and representativeness of any such monitoring data. We note the detection of these substance in remote biota and lakes.  We acknowledge that sludge was not specifically incorporated in the modelling, you can find a detailed response to this issue in #2177.  (vi) Safety of D4 and D5 for human health:  Publications on the safety of D4 and D5 for human health are provided (Annex C and Annex D). Please note that REACH does not provide a legal basis to look at the risk to human health for cosmetic products. Only the existing harmonised classification (according to CLP Annex VI) has been considered when assessing the use of D4 by professionals.   1. WWTP mass modelling (D6):   You will find our responses to your comment on the D4 and D5 WWTP mass modelling in #2177. The response below is only about the D6 WWTP mass modelling.  Thank you for confirming that the sampling and measurement of D6 in municipal WWTP influents are feasible to monitor the effectiveness of the proposed restriction on D6. (Annex B1-D6 mass loading estimate v3.0\_ExSumm). The study was realised in six different locations.  The study gives information on the estimated mass loading in municipal WWTP influent. The estimated mass loading in WWTP influent based on the monitoring data is somewhat lower than that reported in the Annex XV report. This might be related to the information on the tonnages of D6 used in the Annex XV report. Indeed, while D4 and D5 have been under regulatory scrutiny for several years, during which the quality of use and tonnage information available has progressively improved, this is not the case for D6, which has only relatively recently been under enhanced regulatory scrutiny. Nevertheless the estimates reported in the Annex XV report are within an order of magnitude of those from (limited) monitoring data:   |  |  |  | | --- | --- | --- | |  | WWTP influent –  AXV estimates\* | WWTP influent –  Study extrapolation\*  (Source: ANNEX B1 - D6 Mass Loading Estimate v3.0\_Ex Summ) | | D6 | 135 – 268 tpa (201 tpa) | 34 – 73 tpa (49 tpa) |   *\*: ‘Considering only the releases from professional and consumer uses + impurity in silicone polymers from cosmetics uses. Excluding the releases from formulation (industrial use) and the releases from impurities in silicone polymers because this releases might not enter domestic STP’*  We note that there are limitations to extrapolate the results from six sampling points to the EU scale.  It should also be noted that the releases to surface water indicated in the summary note (2019-09-02 CES second-input to Consultation Final.pdf) do not take into account the fact that not all households in EU are connected to a municipal WWTP (90% connection rate).  Despite the potential limitations of extrapolating data from six measurements to the EU-wide situation, this study nevertheless confirms that D6 is released in waste water (from wash-off cosmetic products and other uses), and that further regulatory action is necessary. The measurements also confirm that the proposed restriction would be monitorable.  (viii) Impact of the proposed restriction:  We confirm that uses of silicone polymers are out of scope of the restriction proposal, and that information was sought during the consultation regarding which uses of silicone polymers had concentrations above 0.1% w/w, in order to ensure they were not inadvertently affected by the restriction. The information provided for dental impression and reproduction materials and sealants and adhesives is noted, and will be used to propose a concentration limit for those uses that will ensure they are not affected.  The costs quoted in your response were considered in our original analysis of uses of silicone polymers.  Thank you also for the information regarding small volume uses of silicone polymers that would be affected by a 0.1% w/w concentration limit. In order to ensure these uses are not affected, we would require information about the concentration of D4, D5 and D6 in the final products.  Regarding the transitional period, we have reviewed the varied evidence presented in responses to this consultation, both in confidential and non-confidential submissions. We have received information on the difficulties of reformulation, particularly for some products, as well as the potential timelines for the process. We have also received information supporting the possibility of reformulation taking place more quickly in some cases. We have considered all the information available to us when proposing the transitional period for this restriction and reflected that in the revised Background Document.  (iv) Enforceability:  We note your comments on enforceability. The risk of contamination of samples by laboratory staff is not specific to D4, D5 and D6. The implementation of GLP (Good Laboratory Practice), and standard operating procedures should be applied to avoid contamination by laboratory staff. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment.  Please also refer to the following responses: #2141, #2170 and #2177.  We agree with the Dossier Submitter that the model results in the Annex XV report confirm the relative small magnitude of air-to-surface deposition processes. The scope was exactly to investigate the impact of continuous, decadal-long and ongoing emissions to air that are orders of magnitude higher than the respective in the aquatic compartment.  Furthermore, the RAC opinion on the UK restriction proposal for “wash-off” products clearly stated that “although the RAC opinion on the UK restriction proposal considered that the Sanchis et al. (2015a) study was insufficient to prove that deposition was occurring, its opinion noted that on the basis of the large tonnages of these substances released to the atmospheric compartment only low rates of deposition would be necessary to result in a concern.  We appreciate the information on the estimated mass loading of D6 in municipal WWTP influent. Although there are potential limitations on extrapolating data from six measurements to the EU-wide situation; this study nevertheless confirms that D6 are released in the waste water (from wash-off and other uses), and that further actions are needed. The measurements also confirm that the proposed restriction would be monitorable.  RAC appreciate that the Dossier Submitter has considered all the information available to them when proposed the transitional period for this restriction and reflected that in the revised Background Document.  The comment on enforceability was noted. We agree with the Dossier Submitter that contamination of samples by the laboratory staff is not specific to D4, D5 and D6. The implementation of GLP (Good Laboratory Practices) and standard operating procedures have to be applied to avoid contamination of all possible samples by the lab staff. |
| **SEAC Rapporteurs comments:**  The SEAC Rapporteurs took note of the submitted information on possible effects of the concentration limits for silicone polymers. More information on that topic was also submitted by others during the consultation and the Dossier Submitter has used that information to further specify the concentration limits in the scope of the restriction as already anticipated when requesting the information. |
| **2481** | **Date:** 2019/09/04 23:17  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** Yes  **Attachment:**  <redacted>    **Privacy comment:** This document contains confidential business information related to our company and our downstream customers. These data should not be shared to allow the protection of our interests. | **Comment:**  Please see the attached document |
| **Answer to specific info request 3:**  please see the attached document |
| **Answer to specific info request 4:**  please see the attached document |
| **Dossier Submitter response:**  Thanks for your (confidential) comment. |
| **RAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **SEAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **2484** | **Date:** 2019/09/05 16:15  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** EFCC (European Federation for Construction Chemicals  **Org. country:** Belgium  **Attachment:** | **Comment:**  Please refer to the attached document |
| **Answer to specific info request 4:**  Please refer to the attached document |
| **Dossier Submitter response:**  Thank you for your response to the consultation. We note your points about the use of silicone polymers in the construction chemicals industry and that you do not expect the restriction to affect the placing on the market of silicone polymers for the construction chemicals industry.  You also provided comments on the wording of the conditions of the restriction. Uses of silicone polymers are intended to be outside the scope of this restriction, as well as industrial uses. We are nevertheless seeking information about the concentration of D4, D5 and D6 as impurities in uses of silicone polymers so that we can consider a derogation to make sure those uses remain out of scope, and are not inadvertently captured by enforcement. Note that the current wording aims at expressing the intention of the Dossier Submitter, and that the European Commission will ultimately decide the final legal wording.  Finally, we would like to highlight that the restriction proposal has been prepared at the request of the Commission based on the intrinsic properties and hazards of the substances, and that the monitoring information you are referring to aims only at monitoring the efficiency of the D4 and D5 restriction in wash-off cosmetics. This monitoring does not include D6. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment on silicon polymers and restriction proposal. We also appreciate the information that there is no intentional use or addition of D4, D5 and D6 in the construction chemicals industry, which acts as downstream user of silicone polymers. |
| **SEAC Rapporteurs comments:**  No further comments from the SEAC Rapporteurs. |
| **2519** | **Date:** 2019/09/12 19:12  **Content:**  Environmental emissions  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Unilever R&D Vlaardingen B.V.  **Org. country:** Netherlands | **Comment:**  Unilever would like to make ECHA aware of recent publication relating to:  Estimation of the contribution made to down‐the‐drain emissions of D5 by personal care product categories in the European Union  Abstract  Aquatic risk assessment of personal care chemicals requires quantifying the contribution of all product types containing the ingredient to down‐the‐drain emissions. We developed a probabilistic model framework embracing stochastic variability associated with individual consumers and their behaviours in the EU, as well as other sources of uncertainty related to losses following applications (e.g. volatilisation). The model was applied to decamethylcyclopentasoloxane (D5), an emollient used in wash‐off (WO) and leave‐on (LO) products. Quantifying contributions from each product category containing D5 to down‐the‐drain emissions is necessary to inform optimal risk management options.  Simulation results for the baseline scenario (2012) supports the argument that leave‐on products make up a minor contribution (7.1%) to the down‐the‐drain emissions of D5 with only 0.20% of the D5 used in LO products being released to wastewater. The most influential model parameters are the release factor from WO products and the time between application and use for various LO product types, stressing the importance of embracing stochastic variability across individuals’ behaviour when assessing contributions of various product types to environmental emissions.  The downward trend in WO use from 2010 to 2016 is reflected in declining concentrations in wastewater influent over the same period. Uncertainty remains about future levels of D5, once phasing out from WO products is complete.  The probabilistic model in conjunction with high tier consumer habits data is a promising high tier tool for the characterisation of complex emission scenarios of personal care ingredients.  Links to full article:  https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4208  https://doi.org/10.1002/ieam.4208 |
| **Dossier Submitter response:**  Thank you for your comment.  Research efforts, undertaken by industry, in the field of environmental emissions characterisation are welcomed. We understand also that this research is not yet concluded for all different categories of leave-on cosmetics.  In the Annex XV restriction report, the Dossier Submitter has also taken into account various factors such as (i) the cosmetics types (e.g. leave-on vs wash-off), (ii) different cosmetics categories (e.g. lipstick, eye make-up, body cream etc.), (iii) and consumer habits in terms of cosmetics removal (shower vs wipe/cotton removal).  These various parameters have been reflected in the release factors applied for the different types of cosmetic products.  We note also that the release factor indicated in the SETAC publication (release factor of 0.2% for D5 in one type of leave-on cosmetic) is within the range of the release factor used by the Dossier Submitter to estimate the release to the environment for this type of cosmetics (release factor range: 0.1 – 2.6%). |
| **RAC Rapporteurs comments:**  Thank you very much for your comment, and we also agree with the Dossier Submitter that release factor indicated in the SETAC publication (release factor of 0.2% for D5 in one type of leave-on cosmetic) is within the range of the release factor given in the Background Document. |
| **SEAC Rapporteurs comments:**  Comments regarding downward trend of the emissions. No comments from the SEAC Rapporteurs. |
| **2549** | **Date:** 2019/09/17 12:23  **Type:** MemberState  **Country:**  Denmark | **Comment:**  - |
| **Answer to specific info request 1:**  The Danish EPA considers substitution/ phasing out D4, D5 and D6 in all cosmetic products likely to be achievable within a shorter transition time than the proposed 5 years and at a lower cost.  Importantly, D4 has recently been listed on ANNEX II in the cosmetic regulation covering substances prohibited in cosmetic products ((EU) 2019/831). Since there is already a ban of using D4 as an ingredient in cosmetic products, the inclusion of D4 in the calculation of the costs of reformulation as a direct consequence of the present restriction proposal may result in serious overestimation.  The Danish EPA has observed that reformulation and substitution of various products covering different product categories are already taking place. A random sample of historical data going back to 2015 collected in the database of The Danish Consumer Council’s app “Kemiluppen” shows that out of 27 products declared to contain D4, D5, D6 and/or cyclomethicone, the composition of cyclic siloxanes has been changed in 26% (7 products) products and 19 % are now completely cyclometicone free. These products represent diverse product types of both Leave On and Rinse Of products (foundation, hair conditioner, sunscreen and deodorant).  We have not performed extensive comparison analyses of the historical and present declaration lists. However, dimethicone seems to be at least a part of the substitution solution, which is in line with the observation of others.  Cyclomethicone is very often the central ingredient in hair oil claimed to possess anti frizzl properties. Although we did not identify any reformulated products within this category in our relatively small sample size, we are aware of several products in this product category on the marked, which are cyclomethicone free. These products seem to contain dimethicone as the main substance.  The identified reformulated products are both Wash Of and Leave On products. In the restriction of D4 and D5 in Rinse Of products, a transition period of 2 years was agreed. Based on the observation that reformulation of various products is already taken place, the fact that cyclomethicone free products - representing all categories of cosmetic products - are available on the marked, and since D4 is already prohibited ((EU) 2019/831), we recommend a better justification for the longer transition period of 5 years to avoid unnecessary extended exposure of the environment. |
| **Dossier Submitter response:**  Thank you for your comments.  Indeed, we are aware that there is already a ban of using D4 as an ingredient in cosmetic products, and the costs of reformulation that were calculated reflect this.  The information from your database regarding the evolution of content of D4, D5 and D6 in cosmetic products, and which proportions have already been reformulated since 2015 is very valuable, and will be reflected in the Background Document as supporting information.  Regarding the transitional period, we have reviewed the varied evidence presented in responses to this consultation, both in confidential and non-confidential submissions. We have received information on the difficulties of reformulation, particularly for some products, as well as the potential timelines for the process. We have also received information supporting the possibility of reformulation taking place more quickly in some cases. We have considered all the information available to us when proposing the transitional period for this restriction and reflected that in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  Indeed, we are aware that there is already a ban of using D4 as an ingredient in cosmetic products, and the costs of reformulation that were calculated reflect this.  The information from your database regarding the evolution of content of D4, D5 and D6 in cosmetic products, and which proportions have already been reformulated since 2015 is very valuable, and we acknowledge that the Dosser Submitter will reflect this in the Background Document as supporting information. |
| **SEAC Rapporteurs comments:**  As indicated the Background Document currently contains a more elaborate justification of the transitional period reflecting the various comments made in the consultation. The SEAC Rapporteurs can agree with the transitional period and the justification provided by the Dossier Submitter. |
| **2560** | **Date:** 2019/09/17 20:33  **Content:**  Hazard or exposure;  Environmental emissions  **Type:** Individual  **Country:**  United Kingdom  **Attachment:** | **Comment:**  See Attachment |
| **Dossier Submitter response:**  Thank you for your follow-up question.  The responses to the comments received during the consultation are only published after the SEAC opinion publication (i.e. end of 2019 in this case).  In a similar manner, and in accordance with the restriction procedure, the Dossier Submitter is waiting for the end of the consultation period in order to update the Background Document.  You will find a response to your comments in #2170, as well as #2196. |
| **RAC Rapporteurs comments:**  Thank you very much for your question, noted. |
| **SEAC Rapporteurs comments:**  No comments from the SEAC Rapporteurs. |
| **2589** | **Date:** 2019/09/19 11:15  **Content:**  Scope or restriction option analysis;  Baseline;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Sanofi group  **Org. country:** France  **Attachment:** | **Comment:**  Dear Sirs, please find our comments in the attachment. |
| **Dossier Submitter response:**  Thank you for the information that the concentration of D4, D5 and D6 in siliconised pen- needles is significantly below 0.1% w/w and that siliconised plungers contain only trace amounts of the substance(s). These uses of silicone polymers would therefore not be affected by the restriction.  Regarding your request for clarification that prescription medication/pharmaceutical products and medical devices for prescription medicine should not be regarded as ‘consumer products’, we will amend the Background Document and make our intentions clearer. |
| **RAC Rapporteurs comments:**  Thank you very much for your information on concentration of cyclic siloxanes in siliconised pen- needles and siliconised plungers.  RAC also appreciates the changes made by the Dossier Submitter to the Background Document to make the proposed restriction clearer. |
| **SEAC Rapporteurs comments:**  No further comments from the SEAC Rapporteurs. |
| **2636** | **Date:** 2019/09/20 00:56  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Personal Care Products Council  **Org. country:** United States  **Attachment:** | **Comment:**  - |
| **Dossier Submitter response:**  Thank you for your comments.  Regarding the potential overlap between the restrictions on D4, D5 and D6 and the one on intentionally added microplastics, we note that the cost calculations undertaken in each of the restriction proposals were done without account of any potential cost-savings resulting from the overlap. We will take note of the evidence provided on the potential impact of the overlap on costs in the report mentioned.  Regarding the transitional period, we have reviewed the varied evidence presented in responses to this consultation, both in confidential and non-confidential responses. We have received information on the difficulties of reformulation, particularly for some products, as well as the potential timelines for the process. We have also received information supporting the possibility of reformulation taking place more quickly in some cases. We have considered all the information available to us when proposing the transitional period for this restriction and reflected that in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you very much for your information on potential overlap between this restriction and the one on microplastics and also for comment on transitional period.  RAC appreciates that the Dossier Submitter has considered all the information available to them when proposed the transitional period for this restriction and reflected that in the Background Document. |
| **SEAC Rapporteurs comments:**  The SEAC Rapporteurs took note of the fact that product development may take 8-10 years. However, there have also been comments that reformulation may take considerably shorter time. As indicated, the Dossier Submitter have incorporated their considerations in the Background Document. |
| **2638** | **Date:** 2019/09/20 07:04  **Content:**  Hazard or exposure;  Environmental emissions;  Information on alternatives;  Information on benefits;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Japan Cosmetic Industry Association  **Org. country:** Japan  **Attachment:** | **Comment:**  - |
| **Answer to specific info request 1:**  Roles of volatile cyclic silicones in personal care products.  In recent development of cosmetic products, cosmetic industry has been invested considerably to utilize efficacies of Cyclosiloxanes for a variety of cosmetic products as follows,    \*Highly volatile  \*Colorless, transparent and odorless  \*Water-repellent and oil-repellent  \*Highly oxygen-permeable  \*Highly safe as a cosmetic ingredient with low irritancy potential  \*Wide solubility of silicone resins or oily ingredients  \*Gives silky smooth touch to cosmetic products when applied on skin  In the next following section, examples of excellent properties of Cyclosiloxanes are described with respect to functions in cosmetic products. These properties are essential features of Cyclosiloxanes in cosmetic products in order to meet wide variety of expectations of consumers[1,2,3,4].  【Hair care products】  For hair care products, there are needs such as to improve hair texture after application to keep hair style. Leave-on hair care products, e.g. hair treatment, should be easy to comb with smooth texture and leave moisture and radiance to hair. In order to achieve these functions, silicone polymers or silicone emulsions dissolved in Cyclosiloxanes have essential roles. Especially, Cyclosiloxanes dissolves highly polymerized dimethyl silicones, frequently used in hair treatment products, to result in a thin film evenly covering the surface of hair.  【Foundation / Mekeup products】  Foundations should have a function of concealing fine wrinkles, skin pores and pigment spots and provide a unified, natural skin finish. Also, makeup products add colors effectively on a face for makeup effects. Silicone resins dissolved in Cyclosiloxanes give a strong film on a skin after evaporation to provide long lasting effect for foundations or makeup products. This film gives appropriate moisturizing effect together with a protective barrier allowing skin to breathe at the same time.  High skin compatibility of Cyclosiloxanes make foundations or makeup products applicable to sensitive face or mucous membrane as well.  【Sunscreen product】  Sunscreen product also requires comfortable texture with long lasting and water resistance in order to provide effective UV protection for both daily life and leisure use. Choice of silicone resins in Cyclosiloxanes is essential for long lasting effect and high water resistance in terms of appropriate film formation with easy applicability and non-greasy texture.  Safety is also important for sunscreen products since they are applied on a large part of the whole body. Thus, safeness of Cyclosiloxanes contributes to application of sunscreen product to whole body.  As mentioned above, Cyclosiloxanes (D4, D5 and D6) are widely used in a variety of formulations as irreplaceable solvent to dissolve various silicone polymers of necessary functions.  We have great difficulties in finding alternative ingredients not due to cost or time for development but due to unique physicochemical properties of them. We believe the opinion of ECHA is not realistic on replaceability of Cyclosiloxanes (D4, D5 and D6) with respect to their functions in cosmetic products.    1. Teruki Ikeda, et.al., (2009) Application of silicone to cosmetics, Fragrance Journal,37(2),19-26  2. Tetsuya Kawai, et.al., (2009) Application of silicone in hair care products, Fragrance Journal,37(2),33-37  3. Seiko Oota, et.al.,(2009) The development of new silicone dispersing agent and the application to the sunscreen, Fragrance Journal ,37(2),38-43  4. Venkataramana A.P.,et.al.,(2016) Research Journal of Pharmaceautical,Biological and Chemical Sciences ,RJPBCS,7(6),2516-2521 |
| **Dossier Submitter response:**  Thank you for your comments on the uses and functions of D4, D5 and D6 in cosmetic products.  We also note your statement regarding the decline of D4 and D5 in waste water. This information is confirmed by other comments, and by the market study we performed for the preparation of this Annex XV restriction report.  You inform us as well on the results of the Crème global study. You can find responses related to this topic in #2191. We note that the release factor indicated in your comment refers to the median value from the study and that the reported mean value (from this study) is 0.3%.  We also note your disagreement with the ECHA Member State decision on the SVHC identification of D4, D5 and D6, as well as on the Risk Assessment methodology applied to PBT/vPvB substances. Please refer to the comment #2177, #2469 and  #2724 for a response.  Regarding your comments about the availability of alternatives, this issue has been evaluated by the Dossier Submitter, considering the evidence provided by all respondents from industry and Member States, and also on the availability of alternative products on the market. This analysis is described in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment. Please also refer to the comment #2177, #2191, #2469 and #2724 for a response. |
| **SEAC Rapporteurs comments:**  As the submission deals for a large part with PBT issues no comments by the SEAC Rapporteurs. |
| **2643** | **Date:** 2019/09/20 10:59  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** <redacted>  **Org. country:** France  **Company name confidential:** Yes  **Privacy comment:** pas de commentaires | **Comment:**  Il est important pour le patient que ces dispositifs médicaux contenant D4/D5 ou D6 à destination topique soient exemptés de cette restriction. A noter que ces produits sont également agréés par un organisme notifié avant sa commercialisation et contrôlés par l'autorité compétente nationale (Ansm) dans ses missions du contrôle après commercialisation des produits sur son territoire. |
| **Answer to specific info request 1:**  pas de commentaires |
| **Answer to specific info request 2:**  pas de commentaires |
| **Answer to specific info request 3:**  1.les matières premières contenant D4/D5 ou D6 dans des produits finis sont-ils utilisés pour des dispositifs médicaux, cosmétiques ou produits pharmaceutiques conformes à la réglementation ?  Oui, les dispositifs médicaux, les produits cosmétiques ou pharmaceutiques sont conformes à la réglementation.Les dispositifs médicaux sont validés par un organisme notifié, les médicaments par l'Agence nationale (Ansm) et les cosmétiques par la surveillance de commercialisation (Ansm)  2.Pour chacune de ces matières premières utilisées dans votre (vos) formulation(s), quel est le pourcentage moyen de la matière première utilisée ?  Suite une consultation d'adhérent, le pourcentage se situe entre 0,5 à 5%.  3.Dans quel type d'applications topiques finales utilisez-vous ces différentes matières premières ?  le traitement des signes et des symptômes de la peau sèche (xérose) notamment dans le cadre de certaines maladies dermatologiques (dermatite atopique, ichtyose,...) ou du pied diabétique  4.Si différentes applications couvertes, dans quel rapport ?  - Traitement des cicatrices  - Traitement des plaies  - Traitement des stomies  - Traitement de la peau lésée  -  5. Quelle est la valeur ajoutée liée à l'utilisation de ces matières premières qui serait perdue ?  Émollients, Propriétés sensorielles.  6. Quel effet aurait pour conséquence sur les patients si ces produits disparaissaient du marché ?  Nos produits sont utilisés chez l'adulte, l'enfant et le nourrisson comme traitement d'appoint pour le dessèchement de la peau lors de certains types de dermatoses comme la dermatite atopique, l'ichtyose ou le psoriasis et pour les brûlures superficielles touchant une petite surface de peau. Plus de 175 millions de patients ont utilisé ces produits pour se soigner à partir du premier lancement en 1998 (année application de la directive 93/32 des dispositifs médicaux). L'efficacité et l'innocuité ont été évaluées dans de nombreux essais cliniques sur la dermatite atopique et l'ichtyose, deux maladies présentant la xérose la plus grave des indications approuvées.  7. Une substitution serait-elle possible dans vos formulations ?  Oui, c'est possible, mais il est difficile d'en trouver une qui réponde aux spécifications car le décaméthylcyclopentasiloxane (D5) et/ou le dodécaméthylcyclohexasiloxane (D6) donne au produit fini de bonnes propriétés de dispersion.  Elle contribue également au respect et à l'efficacité du traitement, en particulier pour les affections cutanées (peaux abîmées, hypersensibilité) et lorsque de grandes surfaces cutanées doivent être traitées au même niveau que le traitement des cicatrices, plaies ou stomies. |
| **Answer to specific info request 4:**  pas de commentaires |
| **Dossier Submitter response:**  Thanks for your comment. The information provided is not robust enough to justify a derogation for **all** ‘substance based’ medical devices with topical application.  For the moment based on the information provided via the call for evidence and this consultation, only specific derogations for ‘substance based’ medical devices, as defined in Regulation 2017/745, are proposed by the Dossier Submitter. Please see the updated Background Document for additional details.  *Courtesy translation:*  *Merci pour votre commentaire. Les informations fournies ne sont malheureusement pas suffisantes pour justifier d’une dérogation pour* ***tous*** *les dispositifs médicaux à usage cutané.*  *Pour le moment, sur la base des informations fournies lors des précédents “appels à preuves” et lors de la présente consultation publique, seules des dérogations spécifiques pour certains types de dispositifs médicaux à usage cutané ont été proposées (exemple: traitements de cicatrices). Vous trouverez dans le ‘background document’ plus de détails sur les dérogations proposées.* |
| **RAC Rapporteurs comments:**  Thank you very much for your comment, noted. |
| **SEAC Rapporteurs comments:**  No further comments by the SEAC Rapporteurs. |
| **2654** | **Date:** 2019/09/20 11:52  **Content:**  Scope or restriction option analysis;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Denmark  **Company name confidential:** Yes | **Comment:**  Comments to 'Scope or restriction option analysis':  The Annex XV dossier on D4, D5 and D6 (cyclosiloxanes) states (page 67 - 68, pt. 2.6.4) that:  • ‘No use of D4 has been reported for medical device or pharmaceutical products’  • ‘Use of D5 and D6 has only been reported in a limited number of applications, essentially for topical uses’ [Table 20: Head Lice treatments, scar/wound treatments, stoma care products]  However, the Annex XV report has not identified additional uses of cyclosiloxanes as constituents in silicones applied to pharmaceutical products/medical device such as:  • Pen-needles for injectable pharmaceutical products.  Needles are shaped in such a way as to reduce the force required to pierce and penetrate the skin. A thin layer of silicone coating on the tip of the needle lubricates the needle and reduces the friction of the metal surface of the needle considerably both during the puncture of the skin and when the needle is dragged back. This is essential for pain relief and for prevention of skin damage when using the needles.  The lubricant contains small amounts of cyclosiloxanes (D4 and D6). The concentration of the cyclosiloxanes in the lubricated needles is significantly below 0.1 % (and thus not in scope the proposed restriction)  • Plungers for injectable systems for injectable pharmaceutical products.  Siliconisation is needed to reduce the friction in the injectable system and thus facilitate the injection of the pharmaceutical product while maintaining drug product purity and function to deliver precise doses.  The siliconised injection systems contain trace amounts of the cyclosiloxanes (D6).  Users of injectable pharmaceutical products and medical device products for injection are usually seen as patients meaning ‘any natural person who seeks to receive or receives healthcare provided by health professionals in a Member State’. Such pharmaceutical products will usually be available by prescription only and should not be regarded as consumer products.  Proposed clarification to be added  We suggest that the restriction makes it clear that prescription medication/pharmaceutical products and medical device for prescription medicine, should not be regarded as ‘consumer products, meaning substances or mixtures or articles that can be purchased from a retail outlet by members of the general public’ (pg. 8 of the Annex XV report).  Please make clear in the restriction proposal that medical device with an intended use for pharmaceutical applications on prescription are out of scope.  This proposal will make the restriction clearer. As the concentration of D4/D5/D6 is significantly below 0.1 % in the uses mentioned above these uses will be exempt with the current wordings but the mix up of consumer products with medical devices and pharmaceutical products may cause confusion. |
| **Answer to specific info request 1:**  No comments |
| **Answer to specific info request 2:**  no comments |
| **Answer to specific info request 3:**  Please see comments above (general comments) |
| **Answer to specific info request 4:**  Please see comments above (general comments) |
| **Dossier Submitter response:**  Thank you for your participation to the consultation.  You will find the response to your comment in #2589. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment, noted. |
| **SEAC Rapporteurs comments:**  Additional medical applications comparable to that of Sanofi Group (#2589), No further comments from the SEAC Rapporteurs. |
| **2659** | **Date:** 2019/09/20 12:59  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** Yes  **Attachment:**  <redacted> | **Comment:**  - |
| **Dossier Submitter response:**  Thanks for your (confidential) comment. |
| **RAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **SEAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **2666** | **Date:** 2019/09/20 14:26  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** MedTech Europe  **Org. country:** Belgium | **Comment:**  This is to correct a typo in MedTech Europe's previous submission of 20 May 2019 with reference no. 2130. The requested exemption is for medical devices for 'wound prevention'and not 'wound care prevention'. The word 'care' should be deleted, as the point was to distinguish wound prevention products (for which currently no derogation is foreseen) from wound care products (for which a derogation is included in the restriction proposal). |
| **Answer to specific info request 4:**  See our previous submission |
| **Dossier Submitter response:**  Thank you for the information. The Background Document has been updated accordingly. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment, noted. |
| **SEAC Rapporteurs comments:**  No further comments by the SEAC Rapporteurs. |
| **2672** | **Date:** 2019/09/20 15:04  **Content:**  Information on costs;Other socio economic analysis (SEA) issues;  Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** The Polish Union of Cosmetics Industry  **Org. country:** Poland  **Attachment:** | **Comment:**  This document is a complemented position, contained additional information posaed by the Committee for Socio-Economic Analysis (SEAC) during first step of consultation carried out in May 2019. |
| **Answer to specific info request 1:**  According to our knowledge, there are some known alternatives, proposed by the raw materials suppliers in the market. Currently, replacements such as: Dimethicone, Isodecyl Neopentanoate, Dicaprylyl Carbonate, Undecane, Tridecane, Dicaprylyl Ether, Propylheptyl Caprylate, Caprylyl Caprylate/Caprate, Hydrogenated Farnesene and Coco-Caprylate are available for some time. They are tested by the cosmetics manufacturers as D5 and D6 alternatives in leave-on and rinse-off cosmetic products. There are also available alternatives are alkanes (C13-15, C15-19) but they are subject to excise tax procedures, so the purchase of such raw materials cause administrative burden. Moreover the alkanes are not suitable for some applications, e.g. cause unacceptable weigh hair down and greasiness when used in hair and skin products. It is currently impossible to fully assess replaceability of D5 and D6, however, efforts are made by the cosmetics industry. On the basis of current knowledge replacement of D5 and D6 in leave-on cosmetic products will be a complex and lengthy process. There is no one-to-one substitution strategy that will comprehensively address all of the key performance benefits that are derived from these key ingredients. Each product must be reformulated separately as alternatives to particular cyclosiloxane are different in various finished products. The Union cannot agree with the conclusion made by ECHA that the presence on the market of products with and without D5 and D6 indicates that they can be replaced in all product categories. As mentioned, it can't be easily done in at least some categories, in particular makeup products and hair products. Alternative raw materials cause weigh hair down, improper spreading of make-up products − smearing, slipping. The test results are unsatisfactory. Appropriate product rheology cannot be achieved with the replacement to only one alternative and mixtures of various alternatives are necessary. Moreover, replacement requires product by product approach. It is cause that products cause stinging eyes (replacements show higher rate of migration than silicones that stay on the skin and then evaporate). |
| **Dossier Submitter response:**  Thank you for your response to the follow-up questions regarding your initial submission to this consultation.  The information on potential alternatives and the practicalities of substitution has been taken into account in our analysis of alternatives, and has been reflected in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment, noted. RAC also appreciates that the Dossier Submitter has incorporated new information on potential alternatives to the Background Document. |
| **SEAC Rapporteurs comments:**  Consolidated version of #2145  The Polish Union of Cosmetics Industry describe the unique characteristics of the products and the consumer appreciation. They also mention a number of alternative substances, which have been taken aboard in the list of alternatives by the Dossier Submitter. Various information on substitution and the time needed for that has been submitted and has been considered in further preparing the draft opinion. It was useful that certain product groups were specifically mentioned in the comments. |
| **2683** | **Date:** 2019/09/20 15:54  **Content:**  Baseline  **Type:** Individual  **Country:**  France | **Comment:**  Regarding the wording of the derogation,could you please clarify the following sentence :  By way of derogation, paragraph 1 shall not apply to:  a) Placing on the market for use at industrial sites (except for dry cleaning industrial sites), and use as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of the REACH Regulation are met  in :  By way of derogation, paragraph 1 shall not apply to:  a) Placing on the market for use at industrial sites (except for dry cleaning industrial sites)  b) Placing on the market for use as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of the REACH Regulation are met  In order to make it very clear that use at industrial sites is allowed by this restriction.  Thank you very much for taking this comment into account. |
| **Dossier Submitter response:**  Thank you for your comment on the wording of the proposed restriction.  Note that the current wording aims at expressing the intention of the Dossier Submitter and that the European Commission will ultimately decide the final legal wording, should a restriction be agreed. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment on the wording of the proposed restriction, noted. |
| **SEAC Rapporteurs comments:**  No further comments by the SEAC Rapporteurs. |
| **2705** | **Date:** 2019/09/20 17:26  **Content:**  Environmental emissions  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Dow  **Org. country:** United Kingdom  **Attachment:** | **Comment:**  Dow would like to express our full support for the comments submitted to this consultation by Silicones Europe (CES).  In the attached paper, we also want to underline a number of specific concerns with the sections of ECHA's restriction proposal covering emissions to air, potential re-deposition to surface media, and the use of modelling to support restricting such emissions.  Thus we would urge in this case that in order to come to any meaningful conclusions on concerns resulting from emissions to air and potential re-deposition to surface media, an in-depth assessment of the current state of the science should be completed and fully taken into account by the RAC. We would note that such an opportunity has not been provided to date by the Annex XV dossier. |
| **Dossier Submitter response:**  Thank you for the comments provided on the environmental fate modelling.  We would like to answer to the following statements, and refer you to the responses already provided in the following comments #2141, #2170, #2177 and #2469:   1. “The only study suggesting that cyclic siloxanes may deposit to surface media (Sanchis et al, 2015)”: This is not accurate, several other references are provided in the response to comment #2469 that highlight the presence of these substances in remote environments, presumably also due to atmospheric deposition; 2. “Modelling approach is not designed to accurately address re-deposition”: There is wide consensus, also between commenting parties during the current consultation, that SimpleBox is an appropriate tool for estimating the fate and partitioning of chemicals, including cyclic siloxanes. As addressed in other responses (e.g. comment #2469), the aim of the multi-media fate modelling was not to precisely calculate deposition fluxes or estimate compartment-specific concentrations; 3. “Modelling is not carried out in accordance with GMP”: Issue addressed in comment #2141; 4. “It is not possible to reproduce results”: Issue addressed in comments #2141, 2196 and 2716; 5. “Not indicated if the Koc has been manually modified in each line as required in this version of Simple box”: All of the necessary manual modifications were performed to the best our understanding. The results of the modelling were closely reproduced by another respondent to the consultation (#2196). 6. “There is a lack of clear documentation”: Issue addressed in comments #2141 and #2196; 7. “it is unclear how critical parameters were inputted into the SimpleBox model”: Issue addressed in comment #2177 and the Background Document; 8. “There is no emission to sludge and overestimation of the concentrations to sediment”: See response to #2469;   Potential for re-deposition and arctic contamination (additional references provided): See response to comment #2469. |
| **RAC Rapporteurs comments:**  Thank you very much for your comments. The Sanchíz et al (2015) study is not the only study suggesting that cyclic siloxanes may re-deposit to surface media. The study by Krogseth et al. (2013) (Occurrence and seasonality of cyclic volatile methyl siloxanes in Arctic air. Environ. Sci. Technol., 47 (2013), pp. 502-509) showed the presence of D4 and D5 in the remote arctic region with seasonal changes (higher amount of D4 and D5 during the winter season).  Please also refer to the responses to the following comments #2141, #2170, #2177, #2196, #2469 and #2716. |
| **SEAC Rapporteurs comments:**  Mainly deals with fate modelling through Simplebox and the characteristics of the substances. No further comments by the SEAC Rapporteurs. |
| **2716** | **Date:** 2019/09/20 18:25  **Content:**  Environmental emissions  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** PFA-Brussels SPRL  **Org. country:** Belgium  **Attachment:** | **Comment:**  - |
| **Dossier Submitter response:**  The Dossier Submitter notes that an earlier response to the consultation from this respondent (comment #2196, dated 20th May 2019) reported the results of a series of confirmatory modelling simulations that successfully reproduced the modelling described in the Annex XV report. On this basis, we do not agree with the statement that “there is a lack of transparency in this modelling which does not allow a proper scrutiny of the environmental fate”.  The comment notes that the modelling presented by ECHA “may be appropriate for the stated purpose of estimating the proportion of the substance released that remains ‘unreacted’ in the environment. However, it does not address the question of whether releases to air result in significant concentrations in water/sediment”  The Dossier Submitter notes, as acknowledged by the respondent, that the precise quantification of the concentrations arising in different environmental compartments (i.e. water/sediment) was not the objective of the modelling exercise, as also presented in the responses to comment #2705.  The modelling was primarily conducted to support the socio-economic analysis, specifically to provide a complimentary estimate of cost-effectiveness based on ‘releases that remain in the environment’ rather than on releases alone.  In relation to the comments that releases to air only result in an insignificant increase in surface media concentrations and that, consequently, a restriction on uses that result in releases to air are unnecessary, the Dossier Submitter notes that it is not aware of any uses of D4, D5 and D6 that would only result in releases to air. Although in some uses the majority of releases occur to the atmosphere there remains a potential for releases to the aquatic compartment. The Dossier Submitter notes that the recycling of leave-on cosmetic product packaging is likely to result in significant releases to the aquatic compartment (through the shredding and washing of packaging containing residual D4, D5 and D6) despite the intended use of these products mainly resulting in atmospheric releases. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment. We agree with the Dossier Submitter that the simulations successfully reproduced the modelling described in the Annex XV report and confirmed that key input parameters had been appropriately selected. RAC acknowledges that the modelling was sufficiently reported.  We also agree with the Dossier Submitter that the precise quantification of concentrations arising in different environmental compartments (i.e. water/sediment) was not the objective of the modelling reported in the Annex XV report. |
| **SEAC Rapporteurs comments:**  See also #2196. As comments mainly deal on estimations with SimpleBox on stock no further comments by the SEAC Rapporteurs. |
| **2722** | **Date:** 2019/09/20 19:20  **Content:**  Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** France  **Company name confidential:** Yes  **Attachment:**  <redacted>    **Privacy comment:** protection of our commercial interests would be undermined | **Comment:**  See confidential comments attached |
| **Dossier Submitter response:**  Thanks for your (confidential) comment. |
| **RAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **SEAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **2724** | **Date:** 2019/09/20 19:31  **Content:**  Hazard or exposure;  Environmental emissions  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Cefic CES - Silicones Europe  **Org. country:** Belgium  **Attachment:** | **Comment:** |
| **Dossier Submitter response:**  Thank you for the comments and insights on the following topics (i) assessing risks, (ii) Stock modelling and (iii) Enforcement.  (i) Assessing risks of PBT/vPvB substances  The Dossier Submitter cannot comment on the relevance of the tests to determine the bioaccumulation status of D4, D5 and D6. These comments have already been addressed to and considered by the ECHA Member State Committee. The ECHA Member State Committee (MSC) has indeed decided to identify D4, D5 and D6 as substances of very high concern due to their PBT/vPvB properties and this is not under consideration during the opinion-making process for this restriction proposal. PBT/vPvB substances under REACH are non-threshold substances where releases to all compartments shall be minimised  (ii) and (iii) Stock modelling and enforcement  All comments have already been addressed in the previous responses to CES comments. We therefore invite you to refer to responses to #2177 and #2469 as well as the associated responses provided to other stakeholders: #2170 and #2705. |
| **RAC Rapporteurs comments:**  Thank you very much for your comment. We support the Dossier Submitter; the identification of D4, D5 and D6 as substances of very high concern due to their PBT/vPvB properties is indeed decided by the ECHA Member State Committee (MSC) and is not under consideration during the opinion-making process for this restriction proposal, as well the emission of non-threshold substances should be minimised to all compartments.  Please also refer to responses to comments #2177 and #2469. |
| **SEAC Rapporteurs comments:**  See also #2705 and #2469. #2724 Mainly concerns PBT/vPvB characteristics and stock modelling, no further comments by the SEAC Rapporteurs. |
| **2736** | **Date:** 2019/09/20 21:37  **Content:**  Scope or restriction option analysis;  Information on costs;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United Kingdom  **Company name confidential:** Yes  **Attachment:**  <redacted>  **Privacy comment:** The attached confidential document contains proprietary business information regarding sales volumes and values, residual D4, D5 and D6 levels in sealant polymers and products, as well as a description of current process capability and technical challenges pertaining to further reduction of residues. This information must be treated by ECHA in the strictest confidence to ensure protection of <redacted>'s commercial interests and its intellectual property. | **Comment:**  ECHA have requested additional information regarding the use of silicone polymers in sealants in order to assess the need for a specific derogation. <redacted> has provided such information in the attached confidential document. |
| **Answer to specific info request 4:**  The attached confidential document contains information regarding sales volumes and values, residual D4, D5 and D6 levels in sealant polymers and products, as well as a description of current process capability and technical challenges pertaining to further reduction of residues. |
| **Dossier Submitter response:**  Thanks for your (confidential) comment. |
| **RAC Rapporteurs comments:**  Thanks for your (confidential) comment. |
| **SEAC Rapporteurs comments:**  Thanks for your (confidential) comment. |