

UK proposes restriction on octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in personal care products that are washed off in normal use¹

Summary

The United Kingdom is proposing a restriction for personal care products, that are washed off in normal use, if they contain more than or equal to 0.1% by weight of octylmethylcyclotetrasiloxane (D4) or decamethylcyclopentasiloxane (D5).

The public consultation on this proposed restriction will start on 18 June 2015 and end on 18 December 2015. However, the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome early comments by 1 September 2015 to assist them in their initial discussions.

GENERAL REMARKS

An Annex XV restriction report, prepared by the United Kingdom (Dossier Submitter), has been received by ECHA. A public consultation on the proposed restriction is open for six months² to allow stakeholders³ to submit comments or relevant additional information (such as monitoring data or information on alternatives) for consideration by ECHA's committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC). The public consultation includes a series of questions on elements of the proposal that would benefit from additional information (see a subsequent section of this information note). Responses to the public consultation are invited from stakeholders located within or outside the EU.

An additional, 60 day, public consultation on the draft SEAC opinion will be held at a later stage of the opinion making process.

The opinions of RAC and SEAC on the restriction proposal will take into account the comments and information received during the public consultation. ECHA will periodically (once a month) publish the non-confidential comments and information that it has received on its website. At the end of the opinion making process ECHA will publish responses to the non-confidential comments and information received.

More information on the [restrictions process](#) can be found on the ECHA website.

Potential respondents to the public consultation should be aware that:

- The vPvB properties of D4 and D5 were recently the subject of an [opinion of the ECHA Member State Committee](#). Discussions on these properties are outside of the scope of the RAC and SEAC opinion on this restriction proposal.
- The [approach of SEAC to evaluate restriction proposals and applications for authorisation for PBT and vPvB substances](#) is available on the ECHA website.

¹ The information note has been prepared based on the Annex XV report prepared by the United Kingdom.

² The duration of the public consultation is six months according to Article 69(6) of REACH.

³ Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities.

PUBLIC CONSULTATION

- Where no or limited information on the costs to industry, or certain sectors of industry, of the proposed restriction are submitted during the public consultation, SEAC will understand that the proposed restriction could be considered proportionate or have little impact on the relevant sector.
- Where derogations to the restriction have been recommended by the Dossier Submitter they are considered to be within the scope of the restriction proposal and will be assessed by RAC and SEAC. As such, these derogations could potentially be removed during the committee opinion making process if they are not considered to be sufficiently justified. Therefore, stakeholders affected by derogations are advised to respond to the public consultation to either support or contest them.
- Additional, new, derogations may be added to the scope of the proposed restriction during opinion making based on comments or information received during the public consultation. However, such derogations need to be fully justified on the basis of either risk (i.e. emissions potential for vPvB / PBT substances) or socio-economic considerations.
- To support either an existing derogation or inform us of the need for an additional derogation, please provide:
 - o Information on the use/application, including tonnage/volume of D4 or D5 used per year.
 - o Relevant operating conditions, risk management measures and emissions to environmental compartments from the use on an EU-wide basis.
 - o Technical and/or economic information describing why the use of alternative substances is not considered feasible, including costs of alternatives and reformulation.

Suggested restriction (SCOPE)

D4 and D5 shall not be placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products that are washed off in normal use conditions.

Personal care products shall be taken to mean any substance or mixture intended to be placed in contact with various external parts of the human body (epidermis, hair, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.

Normal use may be determined by packaging instructions, indicating the purpose of the product and how it shall be used.

There are no uses that are proposed to be derogated (excluded) from the scope of the restriction.

Reasons for action

ECHA's Member State Committee (MSC) recently concluded that D4 and D5 have vPvB properties. D4 also has properties that are consistent with the criteria for a PBT substance. Both substances are siloxanes (a group of silicon containing organic chemicals) and have a range of generally similar uses. A particular concern is the release of these substances into freshwater and their subsequent persistence and build-up in aquatic sediments, followed by bioaccumulation through the food chain. One use that results in significant emissions of these substances into water is via their presence in personal care products that are washed off in normal use conditions. A restriction of this use would make a significant contribution to reducing their presence in water and aquatic sediments. A targeted approach to risk management through a REACH restriction is considered by the Dossier Submitter to be more appropriate than alternative regulatory approaches that would also affect other uses of D4 or D5 that are currently considered to be of lesser concern.

Consequences of the action

The intention of the restriction is to minimise emissions of D4 and D5 to the aquatic environment from their use in personal care products that are washed off under normal use (e.g. shampoos, shower-gels, make-up removing products). The restriction is proposed to enter into force at least two years after the date of its publication in the Official Journal of the European Union. There are no proposed derogations from the restriction.

Personal care products that are washed off under normal use conditions that contain D4 or D5 would need to be withdrawn from the market or reformulated so that they no longer contained D4 or D5 above 0.1% (by weight). No single "drop-in" alternative to the use of D4 or D5 in personal care products that are washed off under normal use has been identified. However, many personal care products that are washed off in normal use do not contain D4 or D5, particularly most new formulations, suggesting that substitution is technically and economically feasible.

The proposed restriction is likely to affect both production decisions for the producers of personal care products that are washed off in normal use and consumption decisions for consumers. Assuming that reformulation to remove D4 and D5 is completely successful the aggregate cost of reformulation ranges from €7.6-42 million and €23-61 million per year dependent on if either a five or two year compliance period is assumed. Costs are greater if reformulation is less successful. The aggregate environmental benefits of the proposed restriction are conservatively estimated to be around €0.65 billion. It is also clear that the proposed restriction would only have a minor impact on the affordability of personal care products to consumers.

SPECIFIC INFORMATION REQUESTED

Questions on specific elements of the proposal that would benefit from additional information have been identified below. Stakeholders are referred to the definitions of wash-off and leave-on personal care products (PCPs) used in the restriction proposal.

Question 1: Do you have information on the type/category (e.g. shower gel, hair care products, shaving products, moisturisers, sun protection products, baby wipes etc) and number of different personal care product (PCP) formulations containing D4 or D5, that

are currently sold by your company or placed on a market (differentiating between EU and non-EU markets where possible)? Which of these PCPs can be considered as leave-on or wash-off? Please identify PCP formulations that contain D4 or D5 as an intentional component and PCP formulations that contain D4 or D5 only as an impurity or constituent in another substance (including where D4 is present as an impurity/constituent of D5). In addition, please let us know which types/categories of leave-on PCPs are likely to be washed-off within 24 hours of application.

Question 2: Do you have information on the function of D4 or D5 in the PCP formulations described in Question 1 and the minimum concentration (expressed as % by weight) that is required in order for D4 or D5 to fulfil this intended function? If possible, please distinguish between PCP formulations that contain D4 or D5 as an intentional component and personal care product formulations that only contain D4 or D5 as an impurity or constituent in another substance (including where D4 is an impurity/constituent in D5).

Question 3: Do you have information on the typical concentration (% by weight) and overall tonnage of D4 or D5 sold by your company or placed on a market (differentiating between EU and non-EU markets where possible) in the PCP formulations described in Question 1? If possible, please distinguish between PCP formulations that contain D4 or D5 as an intentional component and PCP formulations that contain only D4 or D5 as an impurity or constituent in another substance (including where D4 is an impurity/constituent in D5).

Question 4: Do you have information on the size or rate of emissions to either the atmosphere (via evaporation) or to wastewater of D4 or D5 from PCPs under normal use conditions, principally wash-off and leave-on PCPs. For example, do you have information on typical application rates of products and the length of time required for D4 or D5 to completely evaporate from the various external parts of the human body (i.e. epidermis, hair, nails, lips and external genital organs) under normal use conditions or the effectiveness of washing to remove any residual D4 or D5?

Question 5: Do you have information on the transfer of D4 or D5 in different types of PCPs from the various external parts of the human body into clothes or on the subsequent emissions of D4 or D5 to wastewater from washing clothes?

Question 6: Do you have monitoring data on D4 or D5 concentrations in the environment, biota or in humans, other than that which is already presented in the Annex XV report?

Question 7: According to the Annex XV report, there is no single “drop-in or one-for-one” alternative substance that could be used to replace D4 or D5 in PCPs that are washed off in normal use. However, as many PCPs within this category do not contain either D4 or D5 please tell us the identity and specific applications of alternatives to D4 and D5.

Question 8: Based on your response to Question 7, please tell us if there are any human health or environmental issues concerning the use of alternatives to D4 and D5 in PCPs that are washed off in normal use?

Question 9: Based on your response to Question 7, please tell us if there are any relevant technical considerations that should be considered by ECHA’s scientific

committees when assessing the proposed restriction (e.g. in relation to the performance of alternative substances)?

Question 10: Please tell us if there are any relevant economic considerations that should be considered by ECHA's scientific committees when assessing the proposed restriction (e.g. Do you have information about the normal frequency and costs connected to both minor and major reformulations of PCPs containing D4 or D5 that are washed-off in normal use and are these specific to different categories of PCPs)?

Question 11: Do you have information about potential testing and related costs that would have to be undertaken to ensure compliance with the proposed restriction?

Comments preferably by 1 September 2015

The opinion making process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 18 June 2015. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 18 December 2015 RAC and SEAC would appreciate receiving comments by 1 September 2015 to assist them in their preliminary discussions on the restriction proposal.

The final opinions of both Committees are scheduled to be available by 10 June 2016. ECHA will send these two opinions to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.

Please note: Information received after the closing date of the public consultation and information not submitted through the relevant web form (e.g. via email) will not be taken into account by RAC and SEAC in their opinion making.