5 March 2020

Draft background document for decamethylcyclopentasiloxane (D5)

Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during the consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the consultation on the inclusion of decamethylcyclopentasiloxane (D5) on the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 5 June 2020) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

Name: Decamethylcyclopentasiloxane (D5)
EC Number: 208-764-9
CAS Number: 541-02-6

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[2]. Results of the prioritisation of all substances included in the Candidate List by July 2019 and not yet recommended or included in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/13640/prior_results_cl_subst_march_2020_en.pdf.

2.1. Intrinsic properties

Decamethylcyclopentasiloxane (D5) was identified as a Substance of Very High Concern (SVHC) according to Article 57(d) and (e) as it meets the criteria of a PBT and vPvB substance and was therefore included in the Candidate List for authorisation on 27 June 2018, following ECHA's decision ED/61/2018.

2.2. Volume used in the scope of authorisation

The total volume of D5 manufactured and/or imported into the EU is according to registration data (ECHA, 2019a) in the range of 10,000 - 100,000 t/y.

Some uses appear not to be in the scope of authorisation, such as - to the extent they fall under the generic exemptions from authorisation requirement - uses as laboratory reagent and uses as intermediate, e.g. in the manufacture of silicone polymers.

Taking into account the volume corresponding to those uses, the volume in the scope of authorisation is estimated to be above 10,000 t/y.

More detailed information on the main uses and the relative share of the total tonnage is provided in Annex I.

2.3. Wide-dispersiveness of uses

Registered uses of D5 in the scope of authorisation include uses at industrial sites (e.g. formulation of mixtures, production of electronic articles, use of household care products in industrial settings), uses by professional workers (e.g. washing and cleaning, polishes and waxes, or dry cleaning) and consumers (e.g. leave-on personal care products, polishes and waxes, washing and cleaning products).

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[2] Document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf

Furthermore, according to registrations the substance is present in articles in volumes above 10 t/y (e.g. electronic articles).

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

Restrictions

The placing on the market of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in wash-off cosmetic products in a concentration equal to or above 0.1 % is restricted (entry 70 of Annex XVII to REACH[3]). Those uses are not considered for the prioritisation.

Furthermore, ECHA at the request of the Commission submitted in January 2019 a proposal to restrict octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) in consumer and professional products. It is foreseen to restrict the placing on the market of D4, D5, and D6 as substances, constituents of other substances (except polymers) or as constituents in mixtures in a concentration equal to or above 0.1 %[4]. Currently known uses at industrial sites (e.g. formulation, production of articles, use in non-metal surface treatment) and some minor professional uses are proposed not to be covered by the possible future restriction. The scope as currently defined and further information of the proposed restriction can be found in the draft background document to the final RAC and draft SEAC opinion (ECHA, 2019b).

If the proposed restriction on D4, D5 and D6 was adopted with its current scope the prioritisation is assumed to change as follows (see also Table 2 in Section 2.5):

Some uses of D5 in the scope of authorisation would be covered by the restriction. The remaining uses in the scope of authorisation would be formulation for export and use in the production of electronic articles at industrial sites. According to information that ECHA collected in the context of the restriction process, the volume corresponding to those uses is estimated to be in the range of 1,000 to <10,000 t/y. Furthermore, the substance would still be present in articles in volumes above 10 t/y (e.g. electronic articles). Therefore, the proposed future restriction could reduce the scores for volume (from 15 to 12) and wide-dispersiveness of uses (from 15 to 7).

ECHA will take into account the developments under the restriction process when finalising its recommendation.

Grouping

Decamethylcyclopentasiloxane (D5) is considered together with octamethylcyclotetrasiloxane (D4) and dodecamethylcyclohexasiloxane (D6) as a group for the purpose of their inclusion in Annex XIV. The three Candidate List substances are structurally similar and could potentially replace each other in some of their uses.

[3] Entry 70 of Annex XVII to REACH (Substances restricted under REACH) at https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e182463cd3

[4] The status of this restriction proposal can be followed at https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade

2.5. Conclusion

Table 1: Prioritisation results based on current situation

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Decamethylcyclo-pentasiloxane (D5) is identified as PBT and vPvB meeting the criteria of Article 57 (d) and (e) Score: 15	The amount of decamethylcyclo-pentasiloxane (D5) used in the scope of authorisation is >10,000 t/y Score: 15	Decamethylcyclo-pentasiloxane (D5) is used at industrial sites, by professional workers and by consumers Initial score: 15 Furthermore, the substance is used in articles in volumes >10 t/y Refined score: 15 (maximum score to be assigned)	45	Grouping with octamethylcyclo-tetrasiloxane (D4) and dodecamethylcyclo-hexasiloxane (D6)

Table 2: Prioritisation results in case the proposed restriction was adopted with its current scope

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Decamethylcyclo-pentasiloxane (D5) is identified as PBT and vPvB meeting the criteria of Article 57 (d) and (e) Score: 15	The amount of decamethylcyclo-pentasiloxane (D5) used in the scope of authorisation would be 1,000 to <10,000 t/y Score: 12	Decamethylcyclo-pentasiloxane (D5) would be used at industrial sites Initial score: 5 Furthermore, the substance would be used in articles in volumes > 10 t/y Refined score: 7	34	Grouping with octamethylcyclo-tetrasiloxane (D4) and dodecamethylcyclo-hexasiloxane (D6)

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, decamethylcyclopentasiloxane (D5) receives priority among the substances on the Candidate List (see link to the prioritisation results above).

Although the priority score for D5 is assumed to be lower in case the proposed restriction was adopted with its current scope (ECHA, 2019b), the substance would still receive priority based on prioritisation criteria and grouping considerations.

Therefore, it is proposed to prioritise decamethylcyclopentasiloxane (D5) for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the consultation. ECHA will apply the Annex XIV entries approach[5] and the criteria described in the implementation document[6]. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

A summary of the information currently available is provided in Annex I.

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 10th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

ECHA will allocate to the same slot substances considered as a group (see Section 2.4), i.e. decamethylcyclopentasiloxane (D5) will be allocated to the same slot as octamethylcyclotetrasiloxane (D4) and dodecamethylcyclohexasiloxane (D6).

[5] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf

[6] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for decamethylcyclopentasiloxane (D5).

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to recommend exemptions for uses of decamethylcyclopentasiloxane (D5) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;
- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;
- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account

ECHA's previous responses to Art. 58(2) exemption requests[7]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[8], there is no need to propose an additional specific exemption.

3.3.2 Exemption of product and process oriented research and development (PPORD)

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of decamethylcyclopentasiloxane (D5) for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for decamethylcyclopentasiloxane (D5)[9].

[7] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/13640/8th_recom_respdoc_methylpyrrolidone_en.pdf, or in section C.2 in https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_lead_stabilisers_en.pdf including references given therein

[8] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/13640/generic_exempt_auth_2020_en.pdf

[9] As of 15 September 2019

4. References

Annex XV SVHC report (2018): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH article 57. Decamethylcyclopentasiloxane (D5). Submitted by Germany, March 2018.

https://echa.europa.eu/documents/10162/2ad6bb2e-3eca-dd87-e705-db5c71ac4ffe

ECHA (2019a): Decamethylcyclopentasiloxane (D5). ECHA's dissemination website on registered substances. Accessed on 15 September 2019.

https://echa.europa.eu/search-for-chemicals

ECHA (2019b): Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) Background Document to the Opinion on the Annex XV dossier proposing restrictions on octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6). Draft from December 2019.

https://echa.europa.eu/documents/10162/831f49e1-3ddb-56ff-eaff-fd5daa9e40d5

RCOM (2018): "*Responses to comments*" document. Document compiled by Germany from the commenting period 08/03/2018 - 23/04/2018 on the proposal to identify decamethylcyclopentasiloxane (D5) as a Substance of Very High Concern.

https://echa.europa.eu/documents/10162/6cd63239-fdf6-bb3b-1bfb-fdfd39a23fad

Annex I: Further information on uses

1. Further details on main (sector of) uses and relative share of the total tonnage

1.1. Current situation

The restriction draft background document (ECHA, 2019b) estimates a total volume of D5 manufactured and/or imported into the EU of about 50,000 t/y, which is in line with registration data (ECHA, 2019a). More than 20,000 t/y of D5 are used in uses within the scope of authorisation, including uses by professionals and consumers in a variety of products (ECHA, 2019b). These products include personal care products, cosmetics, household care products, dry cleaning, washing and cleaning products, polishes and waxes as well as coatings (ECHA, 2019a).

Furthermore, the industrial use in the production of electronic articles is reported in registrations. Based on available information D5 seems to be used as processing aid in the semiconductor industry. Volumes for this use are not provided but seem to be low.

1.2. Situation if the proposed restriction was adopted with its current scope

Most consumer and professional uses of D5 reported in registration dossiers fall under the scope of the proposed restriction. Nevertheless, some uses in the scope of authorisation would remain and based on the available information, the volume in these uses is above 1,000 t/y.

The formulation and/or (re)packaging of mixtures for export is proposed not to be covered by the possible restriction. It is assumed that mainly formulated cosmetics will be exported outside the EU (ECHA, 2019b) and to a lesser extend other formulations (e.g. household care products, washing and cleaning products). The volume currently formulated for export is estimated to be around 5,000 t/y for both, D5 and D6. The majority of this amount seems to correspond to D5 (ECHA, 2019b). Applying a realistic worst-case scenario, it is assumed that the volume of D5 formulated for export will remain above 1,000 t/y.

The use in the manufacture of electronics seems not to fall under the proposed restriction, as the industrial production of articles is not covered. It is expected to continue at low volumes.

The proposed restriction includes derogations for some minor professional uses, e.g. the use of D5 and D6 as certain medical devices, or the use of D5 in strictly controlled closed dry cleaning systems (ECHA, 2019b). These uses, whether they will continue or not, will have no impact on the overall priority of the substance.

2. Structure and complexity of supply chains

The following assumptions are made based on currently available information and will be used, together with any relevant information from consultation, to allocate the substance group to a specific LAD slot in the final recommendation.

D5 is manufactured and/or imported by a high number of registrants (ECHA, 2019a). No precise and up-to-date information is available on the number of industrial sites where the substance is currently used. However, from the type of uses (e.g. number of applications in cosmetics, washing and cleaning products, medical devices), it could be assumed that these take place at

more than 100 sites within the EU. This is confirmed by information from the restriction draft background document (ECHA, 2019b), stating that D5 is formulated into a very high number of cosmetics products and household products, which is in many cases done by SMEs.

The supply chain can be characterised[10] by the following actors: formulators, users at industrial sites, professional workers, consumers, article producers and article assemblers (multi-layer assembling chain), (relevant life cycle stages: F, IS, PW, C, SLs).

D5 seems to be used in the following product categories: Cosmetics, personal care products, washing and cleaning products, semiconductors, coatings and paints, pharmaceuticals, polishes and wax blends, (relevant product categories: PC9a, PC 29, PC 31, PC33, PC 35, PC 39).

A number of sectors is relying on the substance in some of their uses including household care products, washing and (dry) cleaning sector, manufacturers of computer, electronic and optical products, electrical equipment or health care services (relevant sector of use categories: SU16, SU20, SU0).

Uses of D5 in the scope of authorisation seem to be relevant for the production of article types such as machinery, mechanical appliances, electrical/electronic articles and vehicles (relevant article categories: AC1, AC2).

Some of the categories mentioned are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers, the Annex XV SVHC report (2018) and/or the draft background document of the ongoing restriction (ECHA, 2019b).

[10] Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf