14 April 2021

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) in the Authorisation List or in the registration dossiers[1] as well as the MSC opinion[2] were taken into consideration when finalising the recommendation and are reflected in the present document.

Contents

[1] As of the last day of the consultation, i.e. 5 June 2020
[2] Opinion of the Member State Committee on the draft tenth recommendation of the priority substances to be included in Annex XIV, adopted on 10 February 2021

1. Identity of the substance

Identity of the substance as provided in the Candidate List[3]:

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

Decamethylcyclopentasiloxane (D5) meets the criteria of Article 57 (d) of Regulation (EC) 1907/2006 (REACH) as a substance which is persistent, bioaccumulative and toxic when it contains ≥ 0.1 % w/w octamethylcyclotetrasiloxane (D4) (EC No: 209-136-7).

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[4]. 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 are available at https://echa.europa.eu/documents/10162/13640/prior_results_cl_subst_march_2020_en.pdf.

The prioritisation results of the substances included in the draft 10th recommendation have been updated as necessary after the consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft10threc_substances_april2021_en.pdf.

As stated above, registration information as available on the last day of consultation (5 June 2020) was considered. Therefore, the impact of the UK withdrawal from the EU (for which the transition period ended 31 December 2020) was not taken into account.

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, 2020a) 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.

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

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 or use of household care products at industrial sites), uses by professional workers (e.g. washing and cleaning, sealants, coatings, polishes and waxes or dry cleaning) and consumers (e.g. leave-on personal care products, polishes and waxes or washing and cleaning products).

Furthermore, there are indications that the substance might be present in articles in volumes below 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 ≥ 0.1 % is restricted (entry 70 of Annex XVII to REACH[5]). 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 ≥ 0.1 %[6]. Currently known uses at industrial sites (e.g. formulation, production of articles, use in non-metal surface treatment) are proposed not to be covered by the upcoming restriction. Certain professional uses are proposed to be derogated. The scope as currently defined and further information of the upcoming restriction[7] can be found in the background document to the final RAC and draft SEAC opinion (ECHA, 2020b).

If the upcoming 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 the use in the production of electronic articles at industrial sites as well as certain professional uses derogated from the restriction.

- Currently, the volume used for the formulation for export is estimated to be between 1,000-10,000 t/y (ECHA, 2020b). However, this might drop considerably once the restriction is in place (potentially to below 1,000 t/y).

[5] Entry 70 of Annex XVII to REACH (Substances restricted under REACH) at https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e182463cd3
[6] The status of this restriction proposal can be followed at https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade.
[7] In the present document the term "upcoming restriction" is used when referring to the restriction proposal submitted by ECHA (on the request of the Commission) in 2019. The final RAC/SEAC opinion was adopted on 12 March 2020 and sent to the European Commission for final decision in June 2020.

- The volume used in the production of electronic articles seem to take place at lower volumes but cannot be quantified.
- According to ECHA (2020b), professional uses derogated from the restriction (e.g. dry cleaning in closed systems, certain uses as medical devices) are assumed to take place at 10-100 t/y. Professional uses might also include uses in mixtures of silicone polymers for e.g. coating and sealing where D5 is added intentionally; however, the volumes for those uses cannot be quantified based on the available data.

Furthermore, there are indications that the substance might be present in articles in volumes <10 t/y (e.g. electronic articles).

In conclusion, based on the information available and related uncertainties, if the upcoming restriction was adopted with its current scope the volume of D5 in the scope of authorisation is estimated to be in the range of 100 - 10,000 t/y. The substance is used at industrial sites and by professional workers and might be present in articles below 10 t/y. Therefore, the upcoming restriction could reduce the scores for volume from currently 15 to 9-12 (range given to reflect uncertainties) and wide-dispersiveness of uses from 15 to 11, resulting in a reduction of the total score from 45 to 35-38 (middle value 37).

Grouping

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

2.5. Conclusion

In order to adequately take into account the impact of the upcoming restriction (not yet adopted), ECHA made two assessments when assessing the priority of the substance: The first assessment (Table 1) reflects the current situation, while the second assessment (Table 2) reflects the situation if the upcoming restriction was adopted with its current scope.

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)		
Decamethylcyclopentasiloxane (D5) is identified as PBT and vPvB meeting the criteria of Article 57 (d) and (e) Score: 15	The amount of decamethylcyclopentasiloxane (D5) used in the scope of authorisation is >10,000 t/y Score: 15	Decamethylcyclopentasiloxane (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 octamethylcyclotetrasiloxane (D4) and dodecamethylcyclohexasiloxane (D6)

Table 2: Prioritisation results in case the upcoming restriction was adopted with its current scope (see ECHA, 2020b)

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Decamethylcyclopentasiloxane (D5) is identified as PBT and vPvB meeting the criteria of Article 57 (d) and (e) Score: 15	The amount of decamethylcyclopentasiloxane (D5) used in the scope of authorisation would be 100 to <10,000 t/y Score: 9-12	Decamethylcyclopentasiloxane (D5) would be used at industrial sites and by professionals Initial score: 10 Furthermore, the substance would be used in articles in volumes < 10 t/y Refined score: 11	35-38 (37)	Grouping with octamethylcyclotetrasiloxane (D4) and dodecamethylcyclohexasiloxane (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 upcoming restriction was adopted with its current scope (ECHA, 2020b), the substance would still receive priority based on prioritisation criteria and grouping considerations.

Therefore, **decamethylcyclopentasiloxane (D5) is recommended for inclusion in Annex XIV**.

3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[8] and as further specified in the practical implementation document[9]. The draft Annex XIV entries for all the substances that underwent consultation are available at https://echa.europa.eu/documents/10162/13640/10th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at https://echa.europa.eu/documents/10162/13640/10th_axiv_recommendation_april2021_en.pdf.

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for decamethylcyclopentasiloxane (D5):

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

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain. Groups of substances are considered together.

During the consultation, comments were received arguing for longer timelines due to high complexity of the supply chains for the siloxanes D4, D5 and D6. The long shelf-life of some medical devices was also brought forward as argument for later LADs. It was also requested to align the transitional arrangements with the transition periods outlined in the upcoming restriction on the siloxanes.

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

[9] 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

ECHA has seen no reason to diverge from its proposal for latest application dates and sunset date based on the comments received (see detailed response in RCOM, 2021). The MSC is of the opinion that the LAD allocation proposed by ECHA is appropriate[2].

ECHA made the final LAD allocation using all available relevant information including that received in the consultation.

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

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

3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for decamethylcyclopentasiloxane (D5).

During the consultation ECHA did not receive comments requesting upfront review period for specific uses.

ECHA therefore **does not recommend to include in Annex XIV any review periods** for uses of decamethylcyclopentasiloxane (D5).

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for (categories of) uses of decamethylcyclopentasiloxane (D5) on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the consultation ECHA received some requests for exemptions referring to different derogations from the upcoming restriction. Existing Community legislation was not referred to in those requests.

In its opinion MSC expresses the view that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses at this stage, as the upcoming restriction cannot be taken into account until it is adopted. It further expressed that MSC would like ECHA to invite the European Commission to review the possibility for an exemption under Article 58(2) at the stage of drafting of, and discussions amongst REACH Committee experts on, the Annex XIV entry for the siloxane substances D4, D5 and D6, as the final scope of the restriction will be known at that stage.

ECHA has carefully assessed all the requests made (see detailed assessment in Section C, in particular C.2, of the response document (RCOM, 2021)). ECHA concluded that there is currently no sufficient basis to propose Article 58(2) exemptions for a use or a category of uses of decamethylcyclopentasiloxane (D5).

ECHA therefore **does not 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.

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

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of decamethylcyclopentasiloxane (D5) for PPORD.

During the consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications had been submitted by the end of the consultation[10].

ECHA therefore **does not recommend exempting any use of decamethylcyclopentasiloxane (D5) for PPORD** from authorisation.

[10] As of 05 June 2020

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

ComRef (2021): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 05/03/2020 – 05/06/2020 on ECHA's proposal to include decamethylcyclopentasiloxane (D5) in its 10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/10th_recom_comref_d5_en.rtf

ECHA (2020a): Decamethylcyclopentasiloxane (D5). ECHA's dissemination website on registered substances. Accessed on 5 June 2020.

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

ECHA (2020b): 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). March 2020.

https://echa.europa.eu/documents/10162/f148d6f2-4284-a3c1-fd08-8cdaddf73978

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

RCOM (2019): "Response to comments document (RCOM)". Document compiled by ECHA from the commenting on the Annex XV dossier proposing restriction on Siloxanes D4/D5/D6, commenting period 20/03/2019 - 20/09/2019.

https://echa.europa.eu/documents/10162/cbadf070-fe4c-3440-9ebd-84396cdfed44

RCOM (2021): "Responses to comments" document. Document compiling the responses to comments from commenting period 05/03/2020 – 05/06/2020 on ECHA's proposal to include octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) in its 10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/10th_recom_respdoc_d4_d5_d6_en.pdf

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 background document (ECHA, 2020b) estimates a total volume of D5 manufactured and/or imported into the EU to be about 50,000 t/y which is in line with registration data (ECHA, 2020a).

A major use of D5 is for the manufacture of silicone polymers, which is considered to be an intermediate use (RCOM, 2021). It is recognised that D5 can remain in silicone polymers as unreacted monomer in concentrations above 0.1 %. Where D5 can be considered an impurity or constituent of the silicone polymer, such uses would not require authorisation (RCOM, 2021).

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, 2020b). The majority are uses of personal care products, cosmetics, household care products, dry cleaning, washing and cleaning products, polishes and waxes as well as coatings (ECHA, 2020a).

Furthermore, uses in the production of electronic articles at industrial sites are reported in registrations. Some of those actually seem to be uses of silicone polymers which are not identified as SVHCs and therefore do not fall under the authorisation requirement (ComRef, 2021). Several others are considered to be in the scope of authorisation, e.g. the use as processing aid, in-situ coatings or as potting agent (RCOM, 2021; ECHA, 2020a). Volume per use data are not provided in any of the registrations, however the number of registrations reporting those uses decreased with the latest updates and remaining volumes seem to be low. Though there are uncertainties, it is assumed that the substance is present in electronic articles in volumes below 10 t/y for which releases cannot be excluded.

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

As described in Section 2.4, consumer and most professional uses of D5 reported in registration dossiers fall under the scope of the upcoming restriction. However, uses not covered by the restriction (because they are not in the scope of the upcoming restriction, or have been proposed to be derogated) and falling in the scope of authorisation are considered for the prioritisation in this scenario (RCOM, 2021). These uses include for example uses in electronic articles and the formulation and/or (re)packaging of mixtures at industrial sites.

It is assumed that mainly formulated cosmetics will be exported outside the EU (ECHA, 2020b) and - to a lesser extend – also 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, 2020b). Therefore, it is assumed that the volume of D5 formulated for export is currently above 1,000 t/y. However, based on information provided during consultation (ComRef, 2021), this amount could drop considerably once the upcoming restriction will be in place. Those exported products could be replaced by products reformulated for the European market where D5 and D6 would have been substituted (ComRef, 2021) but it is unclear if and to what extend this substitution would take place for exported products.

According to the current scope of the upcoming restriction, the use of D5 and D6 as certain medical devices is derogated (see ECHA, 2020b). Based on information available to ECHA (2020b), it can be assumed that the amount of D5 used in that use is between 10-100 t/y.

In addition, D5 is derogated from the restriction for the professional uses in the cleaning or restoration of art and antiques, as well as the use in strictly controlled closed dry cleaning systems for textile, leather and fur where the cleaning solvent is recycled or incinerated. According to ECHA (2020b), the use in the cleaning or restoration of arts and antiques takes place at low quantities (around 0.3 t/y), though it is assumed that the complete volume would be released to the environment. The volume for the use in dry cleaning is estimated to be 50 t/y. The upcoming restriction foresees to give a longer transitional period to allow users to comply with the strictly controlled conditions of the derogation. Therefore, it is assumed that most of the currently used volume for dry cleaning would still remain once the upcoming restriction is in place.

In conclusion, based on realistic worst-case assumptions and considering the remaining uncertainties, it is estimated that a volume of 100 - 10,000 t/y would correspond to uses of D5 in the scope of authorisation if the upcoming restriction was adopted with its current scope (ECHA, 2020a and ECHA, 2020b).

2. Structure and complexity of supply chains

The following assumptions were made to allocate the substances D4, D5 and D6 as a group to a specific LAD slot. For the purpose of LAD assignment groups of substances are considered together. The information for the group is summarised below.

Some of the categories mentioned below are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers (ECHA, 2020a), the Annex XV SVHC report (2018), the background document of the upcoming restriction (ECHA, 2020b) and/or comments received during consultation (ComRef, 2021).

2.1 Current situation

D4, D5 and D6 are manufactured and/or imported by more than 50 registrants (ECHA, 2020a). Information provided in registrations and available to ECHA (2020b) indicates that the substances are used at well above 100 industrial sites within the EU.

The supply chain can be characterised[11] 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, SL (multi-layer)).

D4, D5 and D6 seem to be used in the following product categories: Adhesives, sealants, air care products, coatings, paints, fillers, putties, non-metal-surface treatment products, heat transfer fluids, hydraulic fluids, leather treatment products, pharmaceuticals, polishes, wax blends, polymer preparations and compounds, semiconductors, washing and cleaning products, cosmetics and personal care products (relevant product categories: PC 1, PC3, PC9a, PC9b, PC15, PC16, PC17, PC23, PC29, PC31, PC32, PC33, PC35, PC39).

A number of sectors is relying on the substances in some of their uses including manufacturers of fine chemicals, rubber products, plastics products, computers, electronic and optical products, electrical equipment, general manufacturing, e.g. machinery, equipment, vehicles, other transport equipment, building and construction work and health services (relevant sector of use categories: SU 9, SU11, SU12, SU16, SU17, SU 19, SU20).

[11] 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

Uses of D4, D5 and D6 in the scope of authorisation seem to be relevant for the production of article types such as vehicles, machinery, mechanical appliances, electrical/electronic articles, rubber and plastic articles (relevant article categories: AC1, AC2, AC10, AC13).

2.2 Situation if the upcoming restriction was adopted with its current scope

If the upcoming restriction on D4, D5 and D6 was adopted with its current scope, the assumptions made for the LAD assignment could change as follows:

Though it is likely that the number of industrial sites where the substances are used will drop the information available (ECHA, 2020a; ECHA, 2020b, ComRef, 2021) still indicates that the substances would be used at more than 100 industrial sites within the EU.

Once the upcoming restriction is in place, D4, D5 and D6 are likely still to be used in the following product types: Adhesives, sealants, coatings, fillers, putties, non-metal-surface treatment products, heat transfer fluids, hydraulic fluids, pharmaceuticals, polymer preparations and compounds, semiconductors, washing and cleaning products (relevant product categories: PC 1, PC9a, PC9b, PC15, PC16, PC17, PC29, PC32, PC33, PC35).

A number of sectors will still be relying on the substances in some of their uses including manufacturers of fine chemicals, rubber products, plastics products, computer, electronic and optical products, electrical equipment, general manufacturing, e.g. machinery, equipment, vehicles, other transport equipment and health services (relevant sector of use categories: SU 9, SU11, SU12, SU16, SU17, SU20).

Uses of D4, D5 and D6 in the scope of authorisation seem still to be relevant for the production of a number of article types such as vehicles, machinery, mechanical appliances, electrical/electronic articles, rubber and plastic articles (relevant article categories: AC1, AC2, AC10, AC13).