14 April 2021

Background document for dodecamethylcyclohexasiloxane (D6)

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 dodecamethylcyclohexasiloxane (D6) 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.

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[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: Dodecamethylcyclohexasiloxane (D6)
EC Number: 208-762-8
CAS Number: 540-97-6

Dodecamethylcyclohexasiloxane (D6) 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). In addition to its intrinsic properties, it also meets the criteria of Article 57 (e) of Regulation (EC) 1907/2006 (REACH) as a substance which is very persistent and very bioaccumulative (vPvB) when it contains ≥ 0.1 % w/w decamethylcyclopentasiloxane (D5) (EC No. 208-764-9) or ≥ 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

Dodecamethylcyclohexasiloxane (D6) 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 D6 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. the manufacture of silicone polymers.

[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

Taking into account the volume corresponding to those uses, the volume in the scope of authorisation is estimated to be in the range of 1,000 - 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 D6 in the scope of authorisation include uses at industrial sites (e.g. formulation of mixtures and the use of household care products at industrial sites), uses by professional workers (e.g. personal care products or household care products) and consumers (e.g. end-use of cosmetics, polishes and waxes or washing and cleaning products).

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

Restriction

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 %[5]. 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[6] 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):

Most uses of D6 currently falling within the scope of authorisation would be restricted. The only remaining major use in the scope of authorisation would be the use in formulation for export. Currently, the volume used for the formulation for export is estimated to be between 100-1,000 t/y. However, this might drop considerably once the restriction is in place (potentially to below 100 t/y). Additionally, a minor professional use (likely below 10 t/y) as certain medical devices is derogated from the restriction and would consequently fall within the scope of authorisation.

In conclusion, based on the information available and related uncertainties, if the upcoming restriction was adopted with its current scope the volume of D6 in the scope of authorisation is estimated to be in the range of 10 - 1,000 t/y (based on ECHA, 2020b and ComRef, 2021). Therefore, the upcoming restriction could reduce the scores for volume from currently 12 to 6-9 (range given to reflect uncertainties) and wide-dispersiveness of uses from 15 to 7, resulting in a reduction of the total score from 42 to 28-31 (middle value 30).

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

[6] 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.

It is noted that D6 is not falling under the restriction on wash-off cosmetic products (entry 70 of Annex XVII to REACH[7]) which covers only D4 and D5.

Grouping

Dodecamethylcyclohexasiloxane (D6) is considered together with octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) 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 concluding on the priority of the substance. The first assessment (Table 1) reflects the current situation, while the second assessment (Table 2) reflects the situation in case 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)		
Dodecamethylcyclohexasiloxane (D6) is identified as PBT and vPvB meeting the criteria of Article 57 (d) and (e) Score: 15	The amount of dodecamethylcyclohexasiloxane (D6) used in the scope of authorisation is 1,000 t/y to <10,000 t/y Score: 12	Dodecamethylcyclohexasiloxane (D6) is used at industrial sites, by professional workers and by consumers Score: 15	42	Grouping with octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5)

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

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)		
Dodecamethylcyclohexasiloxane (D6) is identified as PBT and vPvB meeting the criteria of Article 57 (d) and (e) Score: 15	The amount of dodecamethylcyclohexasiloxane (D6) used in the scope of authorisation would be 10 to <1,000 t/y Score: 6-9	Dodecamethylcyclohexasiloxane (D6) would still be used at industrial sites and one minor professional use (< 10 t/y). Score: 7	28-31 (30)	Grouping with octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5)

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, dodecamethylcyclohexasiloxane (D6) receives priority among the substances on the Candidate List (see link to the prioritisation results above).

Although the priority score for D6 is assumed to be lower in case the upcoming restriction was adopted with its current scope, the substance would still receive priority based on prioritisation criteria and grouping considerations.

Therefore, **dodecamethylcyclohexasiloxane (D6) 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.

[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

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for dodecamethylcyclohexasiloxane (D6):

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.

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. dodecamethylcyclohexasiloxane (D6) was allocated to the same slot as octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5).

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 dodecamethylcyclohexasiloxane (D6).

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 dodecamethylcyclohexasiloxane (D6).

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 dodecamethylcyclohexasiloxane (D6) 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 dodecamethylcyclohexasiloxane (D6).

ECHA therefore **does not recommend exemptions** for uses of dodecamethylcyclohexasiloxane (D6) 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 dodecamethylcyclohexasiloxane (D6) 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 dodecamethylcyclohexasiloxane (D6) 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. Dodecamethylcyclohexasiloxane (D6). Submitted by Germany, March 2018.

https://echa.europa.eu/documents/10162/8f9dc1d3-1ea4-f270-711e-7b099535915e

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 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_comref_d6_en.rtf

ECHA (2020a): Dodecamethylcyclohexasiloxane (D6). 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 dodecamethylcyclohexasiloxane (D6) as a Substance of Very High Concern.

https://echa.europa.eu/documents/10162/50402243-546c-5d76-3961-f7836b9427c8

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

A major use of D6 is for the manufacture of silicone polymers, which are not identified as SVHCs and therefore do not fall under the authorisation requirement (ComRef, 2021). It is recognised that D6 can remain in silicone polymers as unreacted monomer in concentrations > 0.1 %. Where D6 can be considered an impurity or constituent of the silicone polymer, such uses would not require authorisation (RCOM, 2021).

Information collected in the context of the restriction complemented the registration information with further details. The restriction background document (ECHA 2020b) estimates that more than 1,000 t/y of D6 are used in uses within the scope of authorisation, most of it by professionals and consumers in a variety of products. These products include personal care products, cosmetics, household care products, washing and cleaning products, polishes and waxes (ECHA, 2020a).

As D6 is not covered by the restriction on wash-off cosmetic products (entry 70 of Annex XVII to REACH[7]), the registered use of D6 in wash-off cosmetics (ECHA, 2020a) is taken into account for prioritisation.

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

As described in Section 2.4, most consumer and professional uses of D6 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 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. Only a minor part of this volume seems to correspond to formulation of D6. Therefore, it is assumed that the volume of D6 formulated for export is currently between 100 and 1,000 t/y. However, based on information provided during consultation (ComRef, 2021), this amount could drop considerably once the upcoming restriction was in place. Those exported products could be replaced by products reformulated for the European market where D4, D5 and D6 would have been substituted. But it is unclear 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 D6 used in that use is below 10 t/y.

In conclusion, based on realistic worst-case assumptions and considering the remaining uncertainties, it is estimated that a volume of 10 - 1,000 t/y of D6 would correspond to uses of D6 within 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).

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).

[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

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).