

5 March 2020

Draft background document for octamethylcyclotetrasiloxane (D4)

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 octamethylcyclotetrasiloxane (D4) 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.

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1. Identity of the substance

Identity of the substance as provided in the Candidate List¹:

Name: Octamethylcyclotetrasiloxane (D4)
EC Number: 209-136-7
CAS Number: 556-67-2

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 authorisation². 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.

2.1. Intrinsic properties

Octamethylcyclotetrasiloxane (D4) 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 D4 manufactured and/or imported into the EU is according to registration data (ECHA, 2019a) in the range of 100,000 - 1,000,000 t/y. Part of the tonnage reported in registrations relates to the monomer imported as part of polymers and is therefore not considered for priority assessment.

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 in e.g. 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 in the range of 1,000 t/y - <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 D4 in the scope of authorisation include uses at industrial sites (e.g. formulation, use in non-metal surface treatment and production of electronic articles).

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

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

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 REACH³). 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, no uses of D4 would fall under that restriction. Therefore, no impact on the volume or the wide-dispersiveness of uses for D4 is expected.

ECHA will take into account any further developments under the restriction process before finalising its recommendation.

Grouping

Octamethylcyclotetrasiloxane (D4) is considered together with decamethylcyclopentasiloxane (D5) 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 and all related documents can be found 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)		
Octamethylcyclotetrasiloxane (D4) is identified as PBT and vPvB meeting the criteria of Article 57 (d) and (e) Score: 15	The amount of octamethylcyclotetrasiloxane (D4) used in the scope of authorisation is 1,000 t/y to <10,000 t/y Score: 12	Octamethylcyclotetrasiloxane (D4) is used at industrial sites Initial score: 5 Furthermore, the substance is used in articles in volumes >10 t/y Refined score: 7	34	Grouping with decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (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)		
Octamethylcyclotetrasiloxane (D4) is identified as PBT and vPvB meeting the criteria of Article 57 (d) and (e) Score: 15	No impact Score: 12	No impact Score: 7	34	Grouping with decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6)

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, octamethylcyclotetrasiloxane (D4) receives priority among the substances on the Candidate List (see link to the prioritisation results above).

The priority score for D4 is assumed not to be impacted by the proposed restriction if adopted with its current scope (ECHA, 2019b), i.e. the substance would still receive priority based on prioritisation criteria and grouping considerations.

Therefore, it is proposed to prioritise octamethylcyclotetrasiloxane (D4) 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 approach⁵ and the criteria described in the implementation document⁶. 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. octamethylcyclotetrasiloxane (D4) will be allocated to the same slot as decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6).

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for octamethylcyclotetrasiloxane (D4).

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

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

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 octamethylcyclotetrasiloxane (D4) 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 requests⁷. It is noted that any Art. 58(2) request is assessed case-by-case.

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

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation⁸, 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 octamethylcyclotetrasiloxane (D4) 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 octamethylcyclotetrasiloxane (D4)⁹.

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

ECHA (2016): Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC) Background Document to the Opinion on the Annex XV dossier proposing restrictions on Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5). Final from June 2016.

<https://echa.europa.eu/documents/10162/feaa3a2-ffc0-4b74-4ec8-3c869d4adae7>

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. Octamethylcyclotetrasiloxane; D4. Submitted by Germany, March 2018.

<https://echa.europa.eu/documents/10162/50488161-546d-2048-828a-b6d9ef29f310>

ECHA (2019a): Octamethylcyclotetrasiloxane (D4). 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 octamethylcyclotetrasiloxane (D4) as a Substance of Very High Concern.

<https://echa.europa.eu/documents/10162/47ac46b8-b4ee-dcff-4c55-d21b0b83772d>

Annex I: Further information on uses

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

The total volume of D4 manufactured and/or imported into the EU is according to registration data (ECHA, 2019a) above 100,000 t/y.

The use of the substance in the production of electronic articles is reported in registrations. Based on available information D4 seems to be used as processing aid in the semiconductor industry. Volumes per use are not provided in registrations. However, based on realistic worst case assumptions it is estimated that 1,000 - <10,000 t/y of D4 are used for the production of electronics (ECHA, 2019a and ECHA, 2019b).

According to registration information D4 is used in non-metal surface treatment in volumes between 100 - <1,000 t/y. The use appears to be for the production of surface treated silica (ECHA, 2016).

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.

D4 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.

The supply chain can be characterised¹⁰ by the following actors: formulators, users at industrial sites, articles producers and articles assemblers (multi-layer assembling chain), (relevant life cycle stages: F, IS, SLs).

D4 seems to be used in the following product categories: Non-metal-surface treatment products and Semiconductors (relevant product categories: PC15, PC33).

A number of sectors is relying on the substance in some of their uses including manufacture of computer, electronic and optical products, electrical equipment, manufacture of rubber products, manufacture of plastics products, manufacture of other non-metallic mineral products, e.g. plasters, cement, (relevant sector of use categories: SU 11, SU 12, SU 13, SU16).

Uses of D4 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 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