Recommendation of the European Chemicals Agency of 14 April 2021 for the inclusion of substances in Annex XIV to REACH (List of Substances subject to Authorisation)

The European Chemicals Agency,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), establishing a European Chemicals Agency (ECHA), amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 58 thereof,

Having regard to the version of the Candidate List of Substances of Very High Concern for authorisation as last amended by Decision ED/71/2019 on 16 July 2019[2],

Having regard to the opinion of ECHA's Member State Committee of 10 February 2021[3],

Whereas:

(1) This Recommendation aims to assist the Commission in taking its decision under Article 58(1) of the REACH Regulation to include substances referred to in Article 57 in Annex XIV to the REACH Regulation.

(2) Article 58(3) of the REACH Regulation requires ECHA to make further recommendations of priority substances at least every second year with a view to including further substances in Annex XIV.

(3) Using the approach developed to support the prioritisation of substances for inclusion in Annex XIV under Article 58(3) of the REACH Regulation[4], ECHA prioritised the following seven substances from the Candidate List for its draft Recommendation of substances to be included in Annex XIV[5]:

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1 OJ L 396, 30.12.2006, p 1

2 https://www.echa.europa.eu/candidate-list-table
Note that this is a link that also includes amendments made to the Candidate List after 16 July 2019. These amendments have not been considered in this recommendation.

3 https://echa.europa.eu/documents/10162/13576/msc_opinion_10th_draft_rec_adopted_10022021_en.pdf/dee677cc-4c9d-de87-3397-dfa0c2703e65

4 https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf

5 https://echa.europa.eu/documents/10162/13640/prior_results_cl_subst_march_2020_en.pdf
as published on ECHA's website on 5 March 2020

Draft recommendation		
#	*Substance name*	*EC*
1	*Octamethylcyclotetrasiloxane (D4)*	*209-136-7*
2	*Decamethylcyclopentasiloxane (D5)*	*208-764-9*
3	*Dodecamethylcyclohexasiloxane (D6)*	*208-762-8*
4	*Terphenyl, hydrogenated*	*262-967-7*
5	*Dicyclohexyl phthalate (DCHP)*	*201-545-9*
6	*Disodium octaborate*	*234-541-0*
7	*Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)*	*209-008-0*

(4) Under Article 58(4) of the REACH Regulation ECHA published on its website on 5 March 2020 the draft Recommendation and invited all interested parties to submit comments by 5 June 2020. ECHA has analysed and prepared responses to comments received and they are provided to the Commission as part of the recommendation documents. Public versions are made available on ECHA's website[6].

(5) Article 58(3) of the REACH Regulation provides that the number of substances included in Annex XIV shall take account of the Agency's capacity to handle applications in the time provided for.

(6) ECHA has taken into account information received during the consultation and in updated registrations and updated the priority assessment of the substances by applying the prioritisation approach[4].

(7) ECHA recommends the following seven substances for inclusion in Annex XIV:

Recommendation		
#	**Substance name**	**EC**
1	Octamethylcyclotetrasiloxane (D4)	209-136-7
2	Decamethylcyclopentasiloxane (D5)	208-764-9
3	Dodecamethylcyclohexasiloxane (D6)	208-762-8
4	Terphenyl, hydrogenated	262-967-7
5	Dicyclohexyl phthalate (DCHP)	201-545-9
6	Disodium octaborate	234-541-0
7	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)	209-008-0

(8) ECHA is required under Articles 58(1) and (3) of the REACH Regulation to recommend for each priority substance an Annex XIV entry specifying: its identity; its intrinsic properties referred to in Article 57; the date(s) referred to in Article 58(1)(c)(ii) of the REACH Regulation by which an application should be received if the applicant wishes to continue to use the substance or place the substance on the market ("latest application date", LAD); the date referred to in Article 58(1)(c)(i) of the REACH Regulation from which the placing on the market and use of a substance is prohibited unless an authorisation is granted ("sunset date"); the

[6] See comments and responses given under "Details" of all substances at the link: https://www.echa.europa.eu/previous-recommendations

review periods for certain uses, if appropriate; and uses or categories of uses to be exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

(9) Using the approach developed to support determining the Annex XIV entries of prioritised substances[7], ECHA has determined the specific Annex XIV entries for each of the above listed substances.

(10) In order to identify the substances under Article 58(1)(a) of the REACH Regulation ECHA provides the names of the substances and, where applicable, their EC numbers and CAS numbers.

(11) For the transitional arrangements referred to in Article 58(1)(c) of the REACH Regulation, ECHA has applied for each substance a standard time period of 18 months between the suggested latest application date and the sunset date because neither the available information for the recommended substances nor the comments received during consultation provide information that would support the recommendation of longer periods.

(12) The latest application dates have been set having regard to ECHA's capacity to handle applications in the time provided for, under Article 58(3) of the REACH Regulation, over a period of 6 months (18, 21, or 24 months from entry into force) to distribute the workload in the authorisation application and decision phase more evenly.

(13) The information available for the recommended substances, including the comments received during the consultation, does not provide information that would justify for the upfront definition of review periods for any uses of the substances under Article 58(1)(d) of the REACH Regulation.

(14) Article 58(1)(e) in conjunction with Article 58(2) of Regulation (EC) 1907/2006 provides for the possibility of exemptions of uses or categories of uses in cases where there is specific EU legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of the risks.

(15) ECHA has received during the consultation comments requesting exemptions of some uses. Based on its assessment of these exemption requests[6], ECHA does not recommend any exemptions from the authorisation requirement under Article 58(1)(e) and Article 58(2) of the REACH Regulation.

(16) Article 56(3) of the REACH Regulation requires Annex XIV to specify if it applies to product and process orientated research and development (PPORD). The information available for the recommended substances, including the comments received during consultation, does not provide grounds to recommend exemptions from the authorisation requirement for PPORD under Article 56(3) of the REACH Regulation.

[7] https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf; https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

HEREBY RECOMMENDS that for the reasons set out in the respective substance-specific background documents linked in Annex I to this recommendation, the following entries are included in Annex XIV to the REACH Regulation (List of Substances subject to Authorisation)

Draft Annex XIV entries									
#	**Substance**	**EC number**	**CAS number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii)****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
1	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)	209-008-0	552-30-7	Respiratory sensitising properties (Article 57f – human health)	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None
2	Dicyclohexyl phthalate (DCHP)	201-545-9	84-61-7	Toxic for reproduction (Article 57c), Endocrine disrupting properties (Article 57f – human health)	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None
3	Terphenyl, hydrogenated	262-967-7	61788-32-7	vPvB (Article 57e)	Date of inclusion in Annex XIV plus 21 months	Latest application date plus 18 months	None	None	None
4	Octamethylcyclo tetrasiloxane (D4)	209-136-7	556-67-2	PBT (Article 57d), vPvB (Article 57e)	Date of inclusion in Annex XIV plus 24 months	Latest application date plus 18 months	None	None	None
5	Decamethylcyclo pentasiloxane (D5)	208-764-9	541-02-6	PBT (Article 57d), [1)] vPvB (Article 57e)	Date of inclusion in Annex XIV plus 24 months	Latest application date plus 18 months	None	None	None
6	Dodecamethylcyclo hexasiloxane (D6)	208-762-8	540-97-6	PBT (Article 57d), vPvB (Article 57e) [2)]	Date of inclusion in Annex XIV plus 24 months	Latest application date plus 18 months	None	None	None
7	Disodium octaborate	234-541-0	12008-41-2	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 24 months	Latest application date plus 18 months	None	None	None

Notes to the Draft Annex XIV entries table

* Reference is made to the identified SVHC properties in accordance with Article 57 of the REACH Regulation and to the corresponding classification in accordance with Annex VI, Table 3.1 (*List of harmonised classification and labelling of hazardous substances)* of REGULATION (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

** The LADs were determined on the basis of the General approach for the preparation of draft Annex XIV entries for substances to be included in Annex XIV[7] and as further specified in the practical implementation document[7]. The proposed assignment of the substances aims at supporting an even workload for all parties during the opinion forming and decision making on the authorisation applications. The assignment to the different slots reflects ECHA's current assumptions taking into account the information available about the complexity of the substances' supply chains in a particular recommendation round and how they compare with each other.

1) 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) 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).

Done at Helsinki, 14 April 2021
For the European Chemicals Agency,

(e-signed)[8]

Jack de Bruijn

Director of Prioritisation and Integration

[8] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision approval process.

Annex I - Reasons for the recommendation to include the prioritised substances in Annex XIV

This Annex provides links to all documents relevant for this recommendation.

Table 1 below lists all substances recommended. It provides for each substance the links to the specific:

- **Background document**
  The background document provides information on the proposed Annex XIV entries, in particular on latest application and sunset dates, on review periods for certain uses and on uses or categories of uses exempted from authorisation. It also reflects how ECHA has taken account of the comments received in the consultation as well as the MSC opinion. In addition, the reasons for prioritising the substance are specified.

- **Comments and references to responses document (ComRef)**
  The ComRef document consists of the compilation of the comments submitted during the consultation for a substance. For each comment the reference(s) to ECHA's response(s) in the response document is given.

- **Response document**
  The response document is the compilation of ECHA's responses to the comments submitted during the consultation. Response documents are developed per substance or group of substances.

The additional documents relevant for the recommendation are listed below and can be found on ECHA's website under "Details" of all substances at the link: https://www.echa.europa.eu/previous-recommendations

- General Approach for Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) (10 February 2014, editorially updated 5 March 2020);

- General Approach for the preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV (18 November 2015, editorially updated 5 March 2020);

- Setting LADs - Practical implementation of the Annex XIV entries approach (2 March 2017, editorially updated 5 March 2020);

- Priority assessment results of the Candidate List substances included in the Candidate List by July 2019 (5 March 2020);

- Draft 10th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation (5 March 2020);

- Updated priority assessment results of the substances included in ECHA's 10th draft recommendation (14 April 2021);

- Opinion of the Member State Committee on the 10th draft recommendation of the priority substances and Annex XIV entries (Adopted on 10 February 2021).

Table 1: List of substances recommended and links to the relevant documents.

#	Substance name (EC number)	Background document	Comments and references to responses document (ComRef)	Response document
1	Octamethylcyclotetrasiloxane **(D4)** (209-136-7)	https://echa.europa.eu/documents/10162/13640/10th_recom_final_backgdoc_d4_en.pdf	https://echa.europa.eu/documents/10162/13640/10th_recom_comref_d4_en.rtf	https://echa.europa.eu/documents/10162/13640/10th_recom_respdoc_d4_d5_d6_en.pdf
2	Decamethylcyclopentasiloxane **(D5)** (208-764-9)	https://echa.europa.eu/documents/10162/13640/10th_recom_final_backgdoc_d5_en.pdf	https://echa.europa.eu/documents/10162/13640/10th_recom_comref_d5_en.rtf	*[see D4]*
3	Dodecamethylcyclohexasiloxane **(D6)** (208-762-8)	https://echa.europa.eu/documents/10162/13640/10th_recom_final_backgdoc_d6_en.pdf	https://echa.europa.eu/documents/10162/13640/10th_recom_comref_d6_en.rtf	*[see D4]*
4	Terphenyl, hydrogenated (262-967-7)	https://echa.europa.eu/documents/10162/13640/10th_recom_final_backgdoc_terphenyl_hydrogenated_en.pdf	https://echa.europa.eu/documents/10162/13640/10th_recom_comref_terphenyl_hydrogenated_en.rtf	https://echa.europa.eu/documents/10162/13640/10th_recom_respdoc_terphenyl_hydrogenated_en.pdf
5	Dicyclohexyl phthalate **(DCHP)** (201-545-9)	https://echa.europa.eu/documents/10162/13640/10th_recom_final_backgdoc_dchp_en.pdf	https://echa.europa.eu/documents/10162/13640/10th_recom_comref_dchp_en.rtf	https://echa.europa.eu/documents/10162/13640/10th_recom_respdoc_dchp_en.pdf
6	Disodium octaborate (234-541-0)	https://echa.europa.eu/documents/10162/13640/10th_recom_final_backgdoc_disodium_octaborate_en.pdf	https://echa.europa.eu/documents/10162/13640/10th_recom_comref_disodium_octaborate_en.rtf	https://echa.europa.eu/documents/10162/13640/10th_recom_respdoc_disodium_octaborate_en.pdf
7	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride **(trimellitic anhydride; TMA)** (209-008-0)	https://echa.europa.eu/documents/10162/13640/10th_recom_final_backgdoc_tma_en.pdf	https://echa.europa.eu/documents/10162/13640/10th_recom_comref_tma_en.rtf	https://echa.europa.eu/documents/10162/13640/10th_recom_respdoc_tma_en.pdf