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Updated priority assessment results of the substances included in the draft 10th recommendation for inclusion in Annex XIV

This table includes the updated prioritisation results of the substances included in the draft 10th Annex XIV recommendation. The prioritisation results have been updated based on the comments received in the consultation and registration updates submitted by 5 June 2020. The prioritisation results of all substances assessed in the 10th recommendation round can be found in the prioritisation results document which was published at the start of the consultation on 5 March 2020 (available at: https://echa.europa.eu/documents/10162/13640/prior_results_cl_subst_march_2020_en.pdf).

ECHA has applied the generic prioritisation approach as described in the document "General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation" (available at: https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf).

The substances D4, D5 and D6 are considered as a group.

Substance	EC no.	CAS no.	Registration status YES/INT/NO (INT=only intermediate registrations)	Scores			Verbal description			Total score (range)	Total score (middle value)	Further considerations (grouping, other)	Conclusion
				Inherent properties	Volumes	Wide-dispersive use	Inherent properties	Volumes	Wide-dispersive use				
Decamethylcyclopentasiloxane (D5)	208-764-9	541-02-6	YES	15	15 *(9-12)*	15 *(11)*	PBT (Article 57d); vPvB (Article 57e)	The total volume of D5 manufactured and/or imported into the EU is according to registration data 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 >10,000 t/y. [score 15] *If the upcoming restriction was adopted with its current scope (see further considerations), 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. However, this might drop considerably once the restriction is in place (potentially to below 1,000 t/y). Uses in the production of electronic articles and derogated professional uses seem to take place at volumes <100 t/y. Therefore, based on the information available and related uncertainties, the volume of D5 in the scope of authorisation is estimated to be in the range of 100 - <10,000 t/y (if the upcoming restriction was adopted with its current scope).* *[score 9-12]*	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 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, washing and cleaning products). Furthermore, there are indications that the substance might be present in articles in volumes <10 t/y (e.g. electronic articles). [score 15] *If the upcoming restriction was adopted with its current scope (see further considerations), 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 (e.g. dry cleaning in closed systems, certain uses as medical devices). Furthermore, there are indications that the substance might be present in articles in volumes <10 t/y (e.g. electronic articles).* *[score 11]*	45 *(35-38)*	45 *(37)*	Grouping with D4 and D6 <u>Restriction (REACH):</u> The placing on the market of D4 and D5 in wash-off cosmetic products in a concentration ≥ 0.1 % is restricted (entry 70 of Annex XVII to REACH). Those uses are not considered for the prioritisation. Furthermore, ECHA at the request of the Commission submitted in January 2019 a proposal to restrict D4, D5 and 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 %. 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. *<u>Note:</u> The impact of this upcoming (not yet adopted) restriction on the priority is given in blue italics.*	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, decamethylcyclopentasiloxane (D5) gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, decamethylcyclopentasiloxane (D5) <u>is recommended</u> for inclusion in Annex XIV.**
Dodecamethylcyclohexasiloxane (D6)	208-762-8	540-97-6	YES	15	12 *(6-9)*	15 *(7)*	PBT (Article 57d); vPvB (Article 57e)	The total volume of D6 manufactured and/or imported into the EU is according to registration data 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. 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. [score 12] *If the upcoming restriction was adopted with its current scope (see further considerations), 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 is derogated from the restriction and would consequently fall within the scope of authorisation. In conclusion, based on the information available and related uncertainties, the volume of D6 in the scope of authorisation is estimated to be in the range of 10 - <1,000 t/y (if the upcoming restriction was adopted with its current scope).* *[score 6-9]*	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). [score 15] *If the upcoming restriction was adopted with its current scope (see further considerations), the only remaining uses in the scope of authorisation would be the use in formulation for export and a minor professional use (likely < 10 t/y) as certain medical devices derogated from the restriction.* *[score 7]*	42 *(28-31)*	42 *(30)*	Grouping with D4 and D5 <u>Restriction (REACH):</u> ECHA at the request of the Commission submitted in January 2019 a proposal to restrict D4, D5 and 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 %. 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. *<u>Note:</u> The impact of this upcoming (not yet adopted) restriction on the priority is given in blue italics.*	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, dodecamethylcyclohexasiloxane (D6) gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, dodecamethylcyclohexasiloxane (D6) <u>is recommended</u> for inclusion in Annex XIV.**
Terphenyl, hydrogenated	262-967-7	61788-32-7	YES	13	12	12	vPvB (Article 57e)	The amount of terphenyl, hydrogenated manufactured and/or imported into the EU is according to registration data in the range of >10,000 t/y. Part of this tonnage is exported outside the EU based on registration information. All the uses appear to fall within the scope of authorisation, except some uses in scientific research and development, to the extent they fall under the generic exemptions from authorisation requirement. Taking into account the information available on 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.	Registered uses of terphenyl, hydrogenated in the scope of authorisation include uses at industrial sites (use in heat transfer fluids, use as solvent/process medium, formulation and use of adhesives and sealants, paints, coatings, inks, formulation and use of additives in plastics, formulation of construction products) and uses by professional workers (heat transfer fluids, uses of adhesives and sealants, coatings/inks and paints). [initial score 10] Furthermore, according to registrations the substance is used in articles in volumes >10 t/y (e.g. plastic articles, coated articles). [refined score 12]	37	37		On the basis of Art. 58(3) prioritisation criteria terphenyl, hydrogenated gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, terphenyl, hydrogenated <u>is recommended</u> for inclusion in Annex XIV.**

Octamethylcyclotetrasiloxane (D4)	209-136-7	556-67-2	YES	15	9-12 *(9-12)*	7 *(7)*	PBT (Article 57d); vPvB (Article 57e)	The total volume of D4 manufactured and/or imported into the EU is according to registration data 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 (based on registrations and information provided during consultation), the volume in the scope of authorisation is estimated to be in the range of 100 - <10,000 t/y. [score 9-12] *If the proposed restriction was adopted with its current scope (see further considerations), no uses of D4 would fall under that restriction. Therefore, no impact on the volume is expected.* *[score 9-12]*	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). [initial score 5] Furthermore, based on registrations and information from consultation, the substance is present in articles in volumes >10 t/y (e.g. electronic articles) for which releases cannot be excluded. [refined score 7] *If the upcoming restriction was adopted with its current scope (see further considerations), no uses of D4 would fall under that restriction. Therefore, no impact on the wide-dispersiveness of uses is expected.* *[score 7]*	31-34 *(31-34)*	33 *(33)*	Grouping with D5 and D6 <u>Restriction (REACH):</u> The placing on the market of D4 and D5 in wash-off cosmetic products in a concentration ≥ 0.1 % is restricted (entry 70 of Annex XVII to REACH). Those uses are not considered for the prioritisation. Furthermore, ECHA at the request of the Commission submitted in January 2019 a proposal to restrict D4, D5 and 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 %. 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. *<u>Note:</u> The impact of this upcoming (not yet adopted) restriction on the priority is given in blue italics.*	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, octamethylcyclotetrasiloxane (D4) gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, octamethylcyclotetrasiloxane (D4) <u>is recommended</u> for inclusion in Annex XIV.**
Dicyclohexyl phthalate (DCHP)	201-545-9	84-61-7	YES	7	9	12	Toxic for reproduction (Article 57c); Endocrine disrupting properties (Article 57(f) - human health)	The amount of dicyclohexyl phthalate (DCHP) manufactured and/or imported into the EU is according to registration data in the range of 100 - 1,000 t/y. All tonnage appears to be in the scope of authorisation.	Registered uses of DCHP in the scope of authorisation include uses at industrial sites (e.g. formulation and use of organic peroxides with DCHP as phlegmatizer and dispersion agent, use of adhesives, formulation and use of plastisol used as sealant or in textile printing, formulation and use as co-plasticiser in PVC, rubber and plastic compounds) and by professional workers (e.g. use of organic peroxide formulations containing DCHP, use of plastisol). [initial score 10] The use of organic peroxide formulations and plastisol are also registered for consumer uses. However, these uses fall under the restriction on substances that are toxic for reproduction (REACH Annex XVII, entry 30) used in concentrations ≥0.3%. However, DCHP is also identified as SVHC under Art. 57(f) due to endocrine disrupting properties. Therefore, uses of the substance in mixtures at concentrations ≥0.1% require authorisation (Art. 56(6)(a)). There is uncertainty whether any consumer uses in the concentration range between 0.1% and 0.3% are taking place (which would be in the scope of authorisation). For the purpose of prioritisation consumer uses of DCHP have not been considered. Furthermore, according to registration data, a substance in article notification and a comment received during consultation, the substance is used in articles (e.g. machinery, electrical/electronic articles or vehicles, to which adhesives have been applied, as well as plastic, rubber and textile articles) in volumes >10 t/y. [refined score 12]	28	28	Grouping with other phthalates already recommended for or included in Annex XIV.	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, dicyclohexyl phthalate (DCHP) gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, dicyclohexyl phthalate (DCHP) <u>is recommended</u> for inclusion in Annex XIV.**
Disodium octaborate	234-541-0	12008-41-2	YES	1	12	12	Toxic for reproduction (Article 57c)	The amount of disodium octaborate manufactured and/or imported into the EU is according to registration data in the range of 1,000 – 10,000 t/y. Some uses appear not to be in the scope of authorisation, such as the use as active substance in biocidal products. However, as tonnage per use information is not provided in registrations, realistic worst-case assumptions are applied and all tonnage is considered in the scope of authorisation. Therefore, it is estimated that the volume in the scope of authorisation is 1,000 – 10,000 t/y.	Registered uses of disodium octaborate in the scope of authorisation include various uses at industrial sites (e.g. formulation of mixtures, use in paints and coatings, cement, cellulose insulation, construction materials, adhesives) and by professional workers (e.g. use in paints and coatings, cellulose insulation, construction materials, as micronutrient in fertilisers). The consumer uses of micronutrient fertilizers and of construction materials are also registered. However, as there is a generic restriction on CMR substances (Annex XVII, entry 30) to be used as substances or in mixtures sold to the general public public above the concentration limit, consumer uses of the substance should not take place and are not considered for the priority assessment. [initital score 10] Furthermore, the substance is used in articles in volumes > 10 t/y (e.g. cellulose insulation, construction materials or painted articles). [refined score 12]	25	25	Grouping with other borates recommended in the 6th Annex XIV recommendation	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, disodium octaborate gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, disodium octaborate <u>is recommended</u> for inclusion in Annex XIV.**
Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)	209-008-0	552-30-7	YES	1	0	0	Respiratory sensitising properties (Article 57(f) - human health)	The amount of benzene-1,2,4-tricarboxylic acid 1,2-anhydride (TMA) manufactured and/or imported into the EU is according to registration data in the range of 10,000 - 100,000 t/y. Based on registration information it appears that the substance is only used for uses falling outside the scope of authorisation (i.e. use as intermediate in manufacturing of esters, use as monomer in the manufacturing of polymers and, to the extent the conditions for the generic exemption for the use in Scientific Research and Development are met, laboratory use). Therefore, in conclusion, it is estimated that there is no volume in the scope of authorisation.	There appears to be no registered uses of benzene-1,2,4-tricarboxylic acid 1,2-anhydride (TMA) falling in the scope of authorisation. [score 0]	1	1	Grouping with HHPA and MHHPA recommended in the 9th Annex XIV recommendation	Although other substances on the Candidate List assessed in this recommendation round get higher priority based on Art. 58(3) prioritisation criteria, **benzene-1,2,4-tricarboxylic acid 1,2-anhydride (TMA) <u>is recommended</u> for inclusion in Annex XIV** on the basis of grouping considerations.