

Updated priority assessment results of the substances included in the draft 9th recommendation for inclusion in Annex XIV

1 October 2019

This table includes the updated prioritisation results of the substances included in the draft 9th Annex XIV recommendation. The prioritisation results have been updated based on the comments received in the public consultation and registration updates submitted by 5 December 2018. The prioritisation results of all substances assessed in the 9th recommendation round can be found in the prioritisation results document which was published at the start of the public consultation on 5 September 2018 (available at: https://www.echa.europa.eu/documents/10162/13640/prioritisation_results_of_substances_sept_2018_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", version 10 February 2014.

Substances considered as one group are highlighted by the same colour.

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
4,4'-isopropylidenediphenol (bisphenol A)	201-245-8	80-05-7	YES	7	12	10	Toxic for reproduction (Article 57 c); Endocrine disrupting properties for human health and the environment (Article 57f)	The amount of 4,4'-isopropylidenediphenol (bisphenol A) manufactured and/or imported into the EU is according to registration data above 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 uses as intermediate (in e.g. the manufacture of polycarbonate, epoxy resins, coating materials, substances or polymers) and to the extent it falls under the generic exemptions from authorisation requirement uses as laboratory reagent. Based on the registration information on volumes provided for most of these 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 4,4'-isopropylidenediphenol (bisphenol A) in the scope of authorisation include uses at industrial sites (formulation and use of epoxy resin hardeners) and uses by professional workers (e.g. use of epoxy resin hardeners). [score 10] The substance is reported for use in the production of various types of articles, however this seems not to be relevant for the WDU assessment: For thermal paper, the use will be limited to concentrations <0.02% by 2020 due to a restriction (entry no. 66 of REACH Annex XVII). In epoxy resin articles cured with bisphenol A containing hardeners the substance seems to react and releases are considered unlikely. It is noted that some uses are reported by members of the joint registration, which are not (any more) covered by the joint CSR of the lead registrant (e.g. industrial and professional use as anti-oxidant for processing PVC, production and recycling of thermal paper). Therefore, these uses were not considered for priority assessment.	29	29	Restriction (REACH): The placing on the market of thermal paper containing BPA in concentration of ≥0.02% by weight is restricted after January 2020. Regulation on plastic and food contact materials BPA is permitted for use in food contact materials in the EU under Regulation (EU) 10/2011 (amended by Regulation (EU) 2018/213) relating to plastic materials and articles intending to come into contact with foodstuff. However, there are prohibitions on the use of BPA in certain food contact materials e.g. for the manufacture of polycarbonate baby bottles and infant 'sippy' cups. EFSA is currently re-evaluating the risks to public health related to the presence of BPA in foodstuffs.	On the basis of Art. 58(3) prioritisation criteria 4,4'-isopropylidenediphenol (bisphenol A) gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, 4,4'-isopropylidenediphenol (bisphenol A) is recommended for inclusion in Annex XIV.
1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1.6,9,02,13.05.1,10]octadeca-7,15-diene ("Dechlorane Plus™")	-	-	YES	13	9	7	vPvB (Article 57e)	The amount of "Dechlorane Plus" manufactured and/or imported into the EU is according to registration data in the tonnage band of 100 to 1,000 t/y. All tonnage appears to be in the scope of authorisation. Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 100 - 1000 t/y.	According to the registration information, "Dechlorane Plus" is used at industrial sites as a flame retardant in adhesives/sealants and polymers. [initial score 5] Furthermore, the substance is used in articles in volumes > 10 t/y (e.g. computers, electronics, vehicle textiles, automobiles, aerospace and defence engines). [refined score 7]	29	29	According to the information in the Annex XV SVHC report, Dechlorane Plus is a potential substitute for DecaBDE (EC 214-604-9) which is restricted (entry no. 67 of REACH Annex XVII) and listed as POP under the Stockholm Convention. Recently Norway has submitted a proposal to include Dechlorane Plus as POP under the Stockholm Convention. The decision to include Dechlorane Plus into Annex XIV may be impacted depending on the further developments.	On the basis of Art. 58(3) prioritisation criteria 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1.6,9,02,13.05.1,10]octadeca-7,15-diene ("Dechlorane Plus™") gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1.6,9,02,13.05.1,10]octadeca-7,15-diene ("Dechlorane Plus™") is recommended for inclusion in Annex XIV.
Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) with ≥0.1% w/w 4-heptylphenol, branched and linear (4-HPb)	-	-	YES	7	6	15	Endocrine disrupting properties (Article 57(f) - environment)	The amount of reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) manufactured and/or imported into the EU is according to registration data in the range of 10-100 t/y. All tonnage appears to be in the scope of authorisation.	Registered uses of RP-HP in the scope of authorisation include uses at industrial sites (e.g. formulation of lubricant additives, lubricants and greases, and in lubricants and greases in vehicles and machinery), uses by professional workers (e.g. in lubricants and greases in vehicles and machinery) and uses by consumers (e.g. in lubricants and greases in vehicles and machinery). [score 15]	28	28		On the basis of Art. 58(3) prioritisation criteria Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) with ≥0.1% w/w 4-heptylphenol, branched and linear (4-HPb) get priority for inclusion in Annex XIV among the Candidate List substances. Therefore, Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) with ≥0.1% w/w 4-heptylphenol, branched and linear (4-HPb) are recommended for inclusion in Annex XIV.
Dioxobis(stearato)trilead	235-702-8	12578-12-0	YES	1	9	5	Toxic for reproduction (Article 57 c)	The amount of dioxobis(stearato)trilead manufactured and/or imported into the EU is according to registration data in the range 1,000 – 10,000 t/y. Part of that tonnage is directly exported after manufacture. Therefore, the volume for use in the EU is estimated to be in the range 100 - 1,000 t/y. The total tonnage of dioxobis(stearato)trilead manufactured and/or imported appears to have significantly decreased over the last years. However, recent registration updates (from 2018) confirm manufacture/import in the range 100- 1,000 t/y. Based on registration information, it cannot be excluded that part of the tonnage reported relates to the use as stabiliser in PVC that will be covered by the upcoming restriction. However, this use is still reported, also in recently updated dossiers and despite the assumed phase-out by industry, ECHA cannot exclude that the tonnage reported relates to the use that is not covered by the voluntary commitment and/or the upcoming restriction (formulation of lead stabilisers for export). This use falls under the scope of authorisation. Therefore, in conclusion the tonnage for use in the scope of authorisation is estimated to be in the range of 100- 1,000 t/y.	Registered uses of dioxobis(stearato)trilead in the scope of authorisation include uses at industrial sites (formulation of lead stabilisers). [Score 5] Further registered uses of dioxobis(stearato)trilead include industrial use of stabilisers; PVC processing; uses of lead-stabilised plastic articles. These uses are not considered for priority setting as they should not happen anymore when the foreseen restriction will apply.	15	15	Grouping with other lead substances that can be used as stabilisers in PVC. Other further consideration: The stabiliser sector had a voluntary commitment to replace lead-based stabilisers in all their formulations sold in the EU market by the end of 2015. According to Vinylplus progress reports 2016 and 2017, ESPA members (European Stabilisers Producers Association representing most of the registrants of lead compounds used as stabilisers) completed the replacement. The use as stabiliser is however still reported in registration dossiers. Furthermore ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016. The restriction proposal was presented for first discussion at REACH Committee in February 2019 and is expected to be adopted in the course of 2019. The scope of the restriction is specific in that it will cover the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds. The uses in the scope of the restriction and related tonnage are not considered for priority setting (i.e. scoring) as they should not happen anymore when the currently foreseen restriction will apply. The restriction (and the voluntary commitment) do not cover however the formulation of lead stabilisers for export.	On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, dioxobis(stearato)trilead gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, dioxobis(stearato)trilead is recommended for inclusion in Annex XIV.

Fatty acids, C16-18, lead salts	292-966-7	91031-62-8	YES	1	12	5	Toxic for reproduction (Article 57 c)	<p>The amount of Fatty acids, C16-18, lead salts manufactured and/or imported into the EU is according to registration data in the range of 1,000 - 10,000 t/y. Part of the tonnage manufactured is directly exported outside EU. Therefore, the volume for use in the EU is estimated to be in the range of 1,000 - 10,000 t/y.</p> <p>The total tonnage of Fatty acids, C16-18, lead salts manufactured and/or imported appears to have significantly decreased over the last years. However, recent registration updates (from 2018) confirm manufacture/import over 1,000 t/y.</p> <p>Based on registration information, it cannot be excluded that part of the tonnage reported relates to the use as stabiliser in PVC that will be covered by the upcoming restriction. However, this use is still reported, also in recently updated dossiers and despite the assumed phase-out by industry. ECHA cannot exclude that the tonnage reported relates to the use that is not covered by the voluntary commitment and/or the upcoming restriction (formulation of lead stabilisers for export). This use falls under the scope of authorisation.</p> <p>Therefore, in conclusion the tonnage for use in the scope of authorisation is estimated to be in the range of 1,000- 10,000 t/y.</p>	<p>Registered uses of fatty acids, C16-18, lead salts in the scope of authorisation include uses at industrial sites (formulation of lead stabilisers). [Score 5]</p> <p>Further registered uses of fatty acids, C16-18, lead salts include industrial use of stabilisers; PVC processing; uses of lead-stabilised plastic articles. These uses are not considered for priority setting as they should not happen anymore when the foreseen restriction will apply.</p>	18	18	<p>Grouping with other lead substances that can be used as stabilisers in PVC.</p> <p><u>Other further consideration:</u></p> <p>The stabiliser sector had a voluntary commitment to replace lead-based stabilisers in all their formulations sold in the EU market by the end of 2015. According to Vinylplus progress reports 2016 and 2017, ESPA members (European Stabilisers Producers Association representing most of the registrants of lead compounds used as stabilisers) completed the replacement. The uses as stabiliser are however still reported in registration dossiers.</p> <p>Furthermore ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016. The restriction proposal was presented for first discussion at REACH Committee in February 2019 and is expected to be adopted in the course of 2019. The scope of the restriction is specific in that it will cover the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds.</p> <p>The uses in the scope of the restriction and related tonnage are not considered for priority setting (i.e. scoring) as they should not happen anymore when the currently foreseen restriction will apply.</p> <p>The restriction (and the voluntary commitment) do not cover however the formulation of lead stabilisers for export.</p>	<p>On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, fatty acids, C16-18, lead salts gets priority for inclusion in Annex XIV among the Candidate List substances.</p> <p>Therefore, fatty acids, C16-18, lead salts are recommended for inclusion in Annex XIV.</p>
Trilead dioxide phosphonate	235-252-2	12141-20-7	YES	1	12	7	Toxic for reproduction (Article 57 c)	<p>The amount of trilead dioxide phosphonate manufactured and/or imported into the EU is according to registration data in the range of 1,000 - 10,000 t/y. Part of the tonnage is directly exported after manufacture. Therefore, the volume of trilead dioxide phosphonate for use in the EU is estimated to be in the range 1,000 - 10,000 t/y.</p> <p>The total tonnage of trilead dioxide phosphonate manufactured and/or imported appears to have significantly decreased over the last years. However, recent registration updates (from 2018) confirm manufacture/import over 1,000 t/y.</p> <p>Based on registration information, it cannot be excluded that part of the tonnage reported relates to the use as stabiliser in PVC that will be covered by the upcoming restriction. However, this use is still reported, also in recently updated dossiers, and despite the assumed phase-out by industry. ECHA cannot exclude that the tonnage reported relates to uses that are not covered by the voluntary commitment and/or the upcoming restriction (formulation of stabilisers for export; use in rubber; use in mirror coating). These uses fall under the scope of authorisation. It is noted that no information has been provided in registrations on the tonnage for the different uses.</p> <p>Therefore, in conclusion the tonnage for uses in the scope of authorisation is estimated to be in the range of 1,000- 10,000 t/y.</p>	<p>Registered uses of trilead dioxide phosphonate in the scope of authorisation include uses at industrial sites (e.g. formulation, use in rubber production, use in the production of coatings and application of coatings for mirror backing). In addition, comments received during the SVHC and the Annex XIV public consultations indicate a use in greases (anti-friction coating), assumed to be limited to industrial use. [Initial score 5]</p> <p>Furthermore, based on registration data, the substance appears to be used in articles (e.g. rubber articles, coatings). [refined score 7]</p> <p>Further registered uses of trilead dioxide phosphonate include industrial use of stabilisers; PVC processing; uses of lead-stabilised plastic articles. These uses are not considered for priority setting as they should not happen anymore when the foreseen restriction will apply.</p>	20	20	<p>Grouping with other lead substances that can be used as stabilisers in PVC.</p> <p><u>Other further consideration:</u></p> <p>The stabiliser sector had a voluntary commitment to replace lead-based stabilisers in all their formulations sold in the EU market by the end of 2015. According to Vinylplus progress reports 2016 and 2017, ESPA members (European Stabilisers Producers Association representing most of the registrants of lead compounds used as stabilisers) completed the replacement. The uses as stabiliser are however still reported in registration dossiers.</p> <p>Furthermore ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016. The restriction proposal was presented for first discussion at REACH Committee in February 2019 and is expected to be adopted in the course of 2019. The scope of the restriction is specific in that it will cover the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds.</p> <p>The uses in the scope of the restriction and related tonnage are not considered for priority setting (i.e. scoring) as they should not happen anymore when the currently foreseen restriction will apply.</p> <p>The restriction (and the voluntary commitment) do not cover however the formulation of lead stabilisers for export.</p>	<p>On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, trilead dioxide phosphonate gets priority for inclusion in Annex XIV among the Candidate List substances.</p> <p>Therefore, trilead dioxide phosphonate is recommended for inclusion in Annex XIV.</p>
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethylthio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)			YES (under the mono-constituent substances DOTE and MOTE respectively)	1	12	7	Toxic for reproduction (Article 57 c)	<p>The amount of reaction mass of DOTE and MOTE manufactured and/or imported into the EU is, according to registration data, estimated to be > 1,000 t/y. Some registrants have made use of the option allowing the registration of individual constituents for multi-constituent substances and have submitted registration dossiers for DOTE and MOTE as individual substances.</p> <p>The European Tin Stabilisers Association (ETNSA) representing most of the registrants of DOTE and MOTE provided information to the authorities in 2013 indicating that DOTE and MOTE are used as multi-constituent substances in almost all of their applications (Annex XV SVHC report).</p> <p>All uses appear to be in the scope of authorisation, apart from the use in food packaging. Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 1,000 - 10,000 t/y. This estimation is consistent with information received in the public consultation on the draft recommendation regarding tonnage used in food packaging (max 400-500 t/y).</p>	<p>Registered uses of reaction mass of DOTE and MOTE in the scope of authorisation include uses at industrial sites (production of dry-blend of DOTE); production of dry-blend of MOTE; processing of polymers containing DOTE as a stabiliser through calendaring, extrusion, injection and low energy manipulation of plastic articles; processing of polymers containing MOTE as a stabiliser through calendaring, extrusion, injection and low energy manipulation of plastic articles). [Initial score 5]</p> <p>Furthermore according to some registrations the substance is used in articles (plastic articles) in volumes > 10 t/y. The extent to which the substance 'reaction mass of DOTE and MOTE' as such is present in the articles remains unclear as contradictory information was provided by industry regarding the extent to which the substance transforms during PVC processing. Based on available information it cannot be excluded that part of the reaction mass remains unreacted in the matrix. [refined score 7]</p>	20	20	<p>Grouping with DOTE</p> <p><u>Other further consideration:</u></p> <p>In October 2017 Germany submitted a CLH dossier for DOTE, proposing to revise the current harmonised classification in Annex VI of the CLP Regulation. The substance was discussed at ECHA's Risk Assessment Committee (RAC) in November 2018. RAC adopted by consensus the opinion to retain the current classification for DOTE as Repr. 1B.</p>	<p>On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, reaction mass of DOTE and MOTE gets priority for inclusion in Annex XIV among the Candidate List substances.</p> <p>Therefore, reaction mass of DOTE and MOTE is recommended for inclusion in Annex XIV.</p>
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-stannatetradecanoate (DOTE)	239-622-4	15571-58-1	YES	1	3-12	5-7	Toxic for reproduction (Article 57 c)	<p>The amount of DOTE manufactured and/or imported into the EU is estimated to be > 1,000 t/y based on registration information. Registrants have made use of the provision allowing the registration of individual constituents for multi-constituent substances and have submitted registration dossiers for DOTE and MOTE as individual substances.</p> <p>The European Tin Stabilisers Association (ETNSA) representing most of the registrants of DOTE provided information to the authorities in 2013 indicating that DOTE is not manufactured, imported or marketed as mono-constituent (Annex XV SVHC report) but only in reaction mass with MOTE. This could not be confirmed based on registration information.</p> <p>In 2018 the Organotin REACH consortium indicated that DOTE is used as pure substance in low volume.</p> <p>All uses appear to be in the scope of authorisation, apart from the possible use in food packaging (uncertain use, uncertain tonnage but maximum 400-500 t/y based on information from the public consultation on the draft recommendation). Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 1 - 10,000 t/y.</p>	<p>Registered uses of DOTE in the scope of authorisation include uses at industrial sites (e.g. production of dry-blend of DOTE); processing of polymers containing DOTE as a stabiliser through calendaring, extrusion, injection and low energy manipulation of plastic articles; reactive catalyst) [Initial score 5]</p> <p>In previous registrations and other sources of information the substance was reported to be used in articles (plastic articles). All registrations have been updated in 2016 and the references to the use in articles have been removed, however, the information provided does not allow to reliably conclude that there is no use in articles anymore. The extent to which the substance DOTE is present in the articles remains unclear as contradictory information has been provided by industry regarding the extent to which the substance transforms during PVC processing. Based on available information it cannot be excluded that part of the substance remains unreacted in the matrix.</p> <p>The volume used in articles is unknown but might be < 10 t/y. [refined score 5-7]</p>	9-20	15	<p>Grouping with reaction mass of DOTE and MOTE</p> <p><u>Other further consideration:</u></p> <p>In October 2017 Germany submitted a CLH dossier for DOTE, proposing to revise the current harmonised classification in Annex VI of the CLP Regulation. The substance was discussed at ECHA's Risk Assessment Committee (RAC) in November 2018. RAC adopted by consensus the opinion to retain the current classification for DOTE as Repr. 1B.</p>	<p>On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, DOTE gets priority for inclusion in Annex XIV among the Candidate List substances.</p> <p>Therefore, DOTE is recommended for inclusion in Annex XIV.</p>
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	209-218-2	561-41-1	YES	1	6	12	Carcinogenic (Article 57a)	<p>The amount of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with Michler's Ketone (MK) or Michler's Base (MB) ≥0.1% manufactured and/or imported into the EU is according to registration data in the range of 10-100 t/y.</p> <p>All tonnage appears to be in the scope of authorisation.</p>	<p>Registered uses of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with MK or MB ≥0.1% in the scope of authorisation include uses at industrial sites (formulation and end use of printing inks) and by professional workers (use of printing inks). [Initial score 10]</p> <p>Article service life was removed from registrations, however given the use in printing inks, the substance is expected to end up in articles, e.g. printed articles. [refined score 12]</p>	19	19		<p>On the basis of Art. 58(3) prioritisation criteria 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] gets priority for inclusion in Annex XIV among the Candidate List substances.</p> <p>Therefore, 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] is recommended for inclusion in Annex XIV.</p>

2-Methoxyethanol	203-713-7	109-86-4	YES	1	12	5	Toxic for reproduction (Article 57c)	The amount of 2-methoxyethanol 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 use as intermediate in the manufacture of chemicals and use as laboratory chemical in scientific research and development. Based on the registration information on volumes corresponding to different uses of the substance, the volume in the scope of authorisation is estimated to be in the range of 1,000 - 10,000 t/y.	Registered uses of 2-methoxyethanol in the scope of authorisation include uses at industrial sites (formulation of mixtures, use as solvent, processing aid and extraction agent). [score 5]	18	18	Grouping with 2-ethoxyethanol	On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, 2-methoxyethanol gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, 2-methoxyethanol is recommended for inclusion in Annex XIV.
Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis and trans-isomers [1] are covered by this entry] (HHPA)	201-604-9, 236-086-3, 238-009-9	85-42-7, 13149-00-3, 14166-21-3	YES	1	12	5	Respiratory sensitising properties (Article 57(f) - human health)	Some uses appear not to be in the scope of authorisation, such as use as intermediate including use as monomer in the manufacture of thermoplastics. Based on information from registrations, this volume corresponds to around 35 % of the total volume whereas that volume is claimed to be around 65 % according to information provided during public consultation. In any case, the total volume of HHPA in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.	Registered uses of HHPA in the scope of authorisation include uses at industrial sites (formulation of mixtures; hardener for epoxy resins; process regulator for polymer processes; production of switchgears; production of high voltage rotating machines). [score 5]	18	18	Grouping with MHPHA	On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, HHPA gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, HHPA is recommended for inclusion in Annex XIV.
Hexahydro-methylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans-stereoisomeric forms) and all possible combinations of the isomers [1] are covered by this entry] (MHHPA)	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9	YES	1	12	5	Respiratory sensitising properties (Article 57(f) - human health)	The amount of MHHPA manufactured and/or imported into the EU according to registration data is in the range of 1,000 - <10,000 t/y. Some uses appear not to be in the scope of authorisation, such as use as intermediate including use as monomer in the manufacture of thermoplastics. Based on information from registrations, this volume corresponds to around 30 % of the total volume whereas that volume is claimed to be around 65 % according to information provided during public consultation. In any case, the total volume of MHHPA in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.	Registered uses of MHHPA in the scope of authorisation include uses at industrial sites (e.g. formulation of mixtures; hardener for epoxy resins; process regulator for polymer processes; production of switchgears; production of high voltage rotating machines). [score 5]	18	18	Grouping with HHPA	On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, MHHPA gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, MHHPA is recommended for inclusion in Annex XIV.
Tetraethyllead	201-075-4	78-00-2	YES	1	12	5	Toxic for reproduction (Article 57 c)	The amount of tetraethyllead manufactured and/or imported into the EU is according to registration data in the range of 1,000 - <10,000 t/y. The substance is used in aviation fuels. All tonnage is formulated into fuel additive within the EU. Therefore, the volume in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.	Registered uses of tetraethyllead in the scope of authorisation include uses at industrial sites (formulation of fuel additives and of fuels with additives). [score 5] The use of the additised fuel by industrial and professional workers as well as consumers is registered specifying the tetraethyllead content to be below the specific concentration limit of 0.1%. Therefore, use of the additised fuel appears to be outside the scope of authorisation. The use of the substance or the fuel additive by professional workers or consumers are advised against.	18	18		On the basis of Art. 58(3) prioritisation criteria tetraethyllead gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, tetraethyllead is recommended for inclusion in Annex XIV.
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	YES	1	-	-	Toxic for reproduction (Article 57 c)					Grouping with other lead substances that can be used as stabilisers in PVC. Other further consideration: ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016. The restriction proposal was presented for first discussion at REACH Committee in February 2019 and is expected to be adopted in the course of 2019. The scope of the restriction is specific in that it will cover the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds. Even though the restriction may cover the use of sulfurous acid, lead salt, dibasic as stabiliser, this has no impact on the score as there is no active registration for this substance.	Although other substances on the Candidate List assessed in this recommendation round get higher priority based on Art. 58(3) prioritisation criteria, sulfurous acid, lead salt, dibasic is recommended for inclusion in Annex XIV on the basis of grouping considerations.
2-Ethoxyethanol	203-804-1	110-80-5	YES	1	6-9	7	Toxic for reproduction (Article 57c)	The amount of 2-ethoxyethanol manufactured and/or imported into the EU is according to registration data in the range 100 - 1,000 t/y. Most of the tonnage seems to be used as intermediate. The use as intermediate and the use as laboratory chemical in scientific research and development appear to be outside the scope of authorisation. Taking into account the volume corresponding to the above uses as reflected in registrations and the Annex XV SVHC report, the volume in the scope of authorisation is estimated to be in the range of 10 - 1,000 t/y.	Registered uses of 2-ethoxyethanol in the scope of authorisation include uses at industrial sites (e.g. formulation of mixtures, use as a solvent in manufacture of chemicals). [initial score 5] Furthermore, according to registration information the substance is used by professional workers (use as solvent) in volumes <10t/y. [refined score 7]	14-17	16	Grouping with 2-methoxyethanol	On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, 2-ethoxyethanol gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, 2-ethoxyethanol is recommended for inclusion in Annex XIV.
[Phthalato(2-)]dioxotrilead	273-688-5	69011-06-9	YES	1	-	-	Toxic for reproduction (Article 57 c)					Grouping with other lead substances that can be used as stabilisers in PVC. Other further consideration: ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016. The restriction proposal was presented for first discussion at REACH Committee in February 2019 and is expected to be adopted in the course of 2019. The scope of the restriction is specific in that it will cover the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds. Even though the restriction may cover the use of [phthalato(2-)]dioxotrilead as stabiliser, this has no impact on the score as there is no active registration for this substance.	Although other substances on the Candidate List assessed in this recommendation round get higher priority based on Art. 58(3) prioritisation criteria, [Phthalato(2-)]dioxotrilead is recommended for inclusion in Annex XIV on the basis of grouping considerations.

Trilead bis(carbonate) dihydroxide	215-290-6	1319-46-6	YES	1	3	5	Toxic for reproduction (Article 57 c)	<p>The amount of trilead bis(carbonate)dihydroxide manufactured and/or imported into the EU is, according to registration data, in the range of 10-100 t/y. All tonnage registered is used in the preparation of PTC (positive temperature coefficient) ceramic materials. This use appears to be an intermediate use and therefore not to be in the scope of authorisation. However, information from other sources indicates that there may be some minor uses in the scope of authorisation.</p> <p>Therefore, in conclusion, the volume in the scope of authorisation is estimated to be <10 t/y.</p>	<p>There is no registered use of trilead bis(carbonate)dihydroxide appearing to be in the scope of authorisation. (initial score 0)</p> <p>However, information arising from the SVHC public consultation indicates that the substance may be used as lead stabiliser in PVC and in the manufacture of primary explosives. In addition, further information provided by industry indicates that this substance was used in artists' paints. This use is derogated from the generic restriction on CMR substances used as substances or in mixtures sold to the general public. However, there is a specific entry on lead carbonates where intended for use as paint (entry no. 16 of REACH Annex XVI). Member States may permit on their territory the use of this substance in paints (for use in restoration and maintenance of works of art and historic buildings and their interiors) but given the nature of the restriction it is likely that this would be for professional use only. (refined score 5)</p>	9	9	<p>Grouping with other lead substances that can be used as stabilisers in PVC.</p> <p><u>Other further consideration:</u> ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016. The restriction proposal was presented for first discussion at REACH Committee in February 2019 and is expected to be adopted in the course of 2019. The scope of the restriction is specific in that it will cover the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds.</p> <p>Even though the restriction may cover the use of trilead bis(carbonate)dihydroxide as stabiliser, this should have no impact on the score as the substance has not been registered for that use.</p>	<p>On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, trilead bis(carbonate) dihydroxide gets priority for inclusion in Annex XIV among the Candidate List substances.</p> <p>Therefore, trilead bis(carbonate) dihydroxide is recommended for inclusion in Annex XIV.</p>
Lead oxide sulfate	234-853-7	12036-76-9	YES	1	0-3	0-5	Toxic for reproduction (Article 57 c)	<p>Lead oxide sulfate is according to registration data currently not manufactured and/or imported into the EU. However, the registration status of the substance is still active, and uses in the scope of authorisation are still in the registration dossier. During the public consultation on the draft recommendation industry commented that the registered uses are taking place in small volumes.</p> <p>In conclusion, the volume in the scope of authorisation is estimated to be in the range of 0 - <10 t/y.</p>	<p>Uses of the substance at industrial sites in the scope of authorisation (in the production of coatings and inks and application of coatings and inks for mirror backing) are still registered. Industry stated in the public consultation that these uses are taking place. (score 0- 5)</p> <p>Furthermore, according to registration data the substance is used in articles (mirror coatings). However, it appears that the release of the substance from these articles might be negligible.</p>	1-9	5	<p>Grouping with other lead substances that can be used as stabilisers in PVC.</p> <p><u>Other further consideration:</u> ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016. The restriction proposal was presented for first discussion at REACH Committee in February 2019 and is expected to be adopted in the course of 2019. The scope of the restriction is specific in that it will cover the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds.</p> <p>Even though the restriction may cover the use of lead oxide sulfate as stabiliser, this should have no impact on the score as the substance has not been registered for that use.</p>	<p>On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, lead oxide sulfate gets priority for inclusion in Annex XIV among the Candidate List substances.</p> <p>Therefore, lead oxide sulfate is recommended for inclusion in Annex XIV.</p>