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Updated priority assessment results of the substances included in the draft 11th recommendation for inclusion in Annex XIV

This table includes the updated prioritisation results of the substances included in the draft 11th Annex XIV recommendation. The prioritisation results have been updated based on the comments received in the consultation and registration updates submitted by 2 May 2022. The prioritisation results of all substances assessed in the 11th recommendation round can be found in the prioritisation results document which was published at the start of the consultation on 2 February 2022.

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".

The substances 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one and 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone are considered as a group.

All relevant documents are available at https://echa.europa.eu/recommendations-for-inclusion-in-the-authorisation-list

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				
2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers	-	-	YES	1	12-15	15	Toxic for reproduction (Article 57 c)	The amount of 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers manufactured and/or imported into the EU is according to registration data above 10,000 t/y. Uses by consumers are falling under the generic restriction of CMR substances sold to the general public (since 1 March 2022). Volumes corresponding to those uses are mostly unknown. Furthermore, some uses appear not to be in the scope of authorisation, such as the use as intermediate in the production of biocidal active substances and the use in cosmetics. Based on information from registration dossiers on the volume corresponding to those uses, the volume in the scope of authorisation is estimated to be between 1,000 - >10,000 t/y.	Registered uses of 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers in the scope of authorisation include uses at industrial sites (as fragrance in cleaning products, such as industrial spraying and treatment of articles) and uses by professional workers (e.g. washing and cleaning products, polishes and waxes). Consumer uses e.g. in cleaning and air care products are also registered. However, the recent classification of the substance as Repr. 1B is legally binding since March 2022. The substance is included in Appendix 6 to REACH, relevant for the entry 30 of REACH Annex XVII, thus it falls under the generic restriction on Reprotoxic substances used as substance or in mixtures sold to the general public. Consumer uses of the substance above the specific concentration limit should not take place anymore and are therefore not considered for the priority assessment. [initial score 10] Furthermore, according to registrations the substance is used in scented articles, from which release is intended. [refined score 15]	28-31	30		On the basis of Art. 58(3) prioritisation criteria 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers <u>is recommended</u> for inclusion in Annex XIV.**
Lead	231-100-4	7439-92-1	YES	1	15	12	Toxic for reproduction (Article 57c)	The amount of lead manufactured and/or imported into the EU is according to registration data above 1,000,000 t/y. Part of this tonnage is exported outside the EU. Some uses appear not to be in the scope of authorisation such as the use as intermediate (e.g. in the manufacture of lead oxide for stabiliser manufacturing), in medical devices and, to the extent the conditions for the generic exemption for the use in Scientific Research and Development are met, the uses as laboratory agent and in chemical analysis. Based on use and tonnage information provided by the Lead REACH Consortium during the consultation on ECHA's draft recommendation, it is estimated that more than 90% of the total amount of lead metal manufactured and/or imported into the EU is used for uses falling in the scope of authorisation. Therefore, in conclusion, the volume in the scope of authorisation is estimated to be >>10,000 t/y.	Registered uses of lead in the scope of authorisation include uses at industrial sites (such as in the production of lead batteries, lead articles or alloys, in the production and use of solder, in galvanisation, as heat transfer fluid or in formulation and use of lubricant) and uses by professional workers (e.g. use of lead solder, use of materials to be in contact with drinking water, use as construction material, use for building or maintenance of art artefacts or musical instruments). The consumer use of solder reported in a high number of registration dossiers has been advised against by the lead registrant and falls under a generic restriction on CMR substances used as substances or in mixtures sold to the general public above the concentration limit (REACH Annex XVII, entry 30). Therefore, consumer uses of the substance above the limit should not take place and are not considered for the priority assessment. [initial score 10] Furthermore, according to registrations, substance in article notifications and comments submitted during consultation, the substance is used in a wide variety of articles, e.g. machinery, vehicles, construction, electronic or sanitary applications (such as batteries, cast, rolled or extruded articles, screws, nuts, bolts, valves, bearings, faucets or cable sheathing). For some articles releases of the substance cannot be excluded (e.g. lead sheets in the building sector). The volume used in those articles is >10 t/y. [refined score 12]	28	28	<u>Restrictions proposed or completed but not yet in force</u> -Lead in projectiles (for firearms and airguns), and in fishing sinkers and lures for outdoor activities; -Use of lead shots over wetlands; -Use of lead compounds to stabilise PVC and on the placing on the market of PVC articles stabilised with lead compounds. ECHA did assess the impact of the proposed or completed-but not yet in force restrictions and concludes based on the information available that the priority of lead remains high even if for the purposes of prioritisation, it is considered that there are currently no remaining uses of lead in shot and ammunition and that lead in PVC is banned. <u>Other considerations</u> The European Commission in its amendment of Annex XIV (Commission Regulation (EU) 2020/171) postponed the decision on the inclusion of four lead compounds in the authorisation list, which are as well used in battery production. Reference was made to the Chemical Agents and Industrial Emissions Directives covering lead and its compounds and to the revision of the binding occupational and biological limit values. Recommending lead brings it to the same regulatory stage as the other lead compounds with similar uses already recommended.	On the basis of Art. 58(3) prioritisation criteria lead gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, lead <u>is recommended</u> for inclusion in Annex XIV.**
Ethylenediamine	203-468-6	107-15-3	YES	1	12	12	Respiratory sensitising properties (Article 57(f) - human health)	The amount of ethylenediamine manufactured and/or imported into the EU is according to registration data above 10,000 t/y. Part of the registered tonnage is related to monomer imported as part of polymers and is therefore not considered for priority assessment. Part of the tonnage is reported as directly exported outside the EU. Some uses appear not to be in the scope of authorisation, such as uses as intermediate (including use as monomer at industrial sites) and, to the extent the conditions for the generic exemption are met, uses in scientific research and development. Taking into account the information on the volume corresponding to those uses provided in registrations, the volume in the scope of authorisation is estimated to be 1, 000 10,000 t/y.	Registered uses of ethylenediamine in the scope of authorisation include uses at industrial sites (e.g. use as processing aid / scavenging agent in refinery streams / corrosion inhibitors; use as process additive) and uses by professional workers (e.g. use as process additive or corrosion inhibitor, use in control of odour emission). [Initial score 10] According to registrations the substance is used in plastic and wood articles. Furthermore, the substance has been reported for use in consumer mixtures in the Nordic Product Registers (SPIN database) every year for more than 15 years (last year disseminated: 2019). The use in consumer mixtures is not confirmed in registration dossiers. [refined score 12]	25	25		On the basis of Art. 58(3) prioritisation criteria ethylenediamine gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, ethylenediamine <u>is recommended</u> for inclusion in Annex XIV.**

Glutaral	203-856-5	111-30-8	YES	1	12	10-12	Respiratory sensitising properties (Article 57(f) - human health)	The amount of glutaral manufactured and/or imported into the EU is according to registration data in the range of 1,000 - <10,000 t/y. Part of this tonnage is exported outside the EU. Some uses appear not to be in the scope of authorisation, such as uses as intermediate, and, to the extent they meet the conditions for the generic exemptions, uses as laboratory reagent in scientific research and development, use in medical devices and formulation of biocidal products. Based on information from registration dossiers on the volume corresponding to those uses, the volume in the scope of authorisation is estimated to be 1,000 - <10,000 t/y.	Registered uses of glutaral in the scope of authorisation include uses at industrial sites (e.g. uses in leather tanning, as hardener in X-ray film developers, corrosion inhibitor, crosslinker and auxiliary for polymerisation reactions) and uses by professional workers (e.g. leather tanning, X-ray film developer and corrosion inhibitor). [Initial score 10] There is uncertainty on the presence of the substance in articles. There are indications that glutaral could remain in leather articles as a result of leather tanning. Those residual amounts would, however, be limited to concentrations below 0.1% if a proposed restriction on sensitisers in textiles will be adopted (see further considerations). Presence in articles may potentially result from other registered uses e.g use as crosslinker, use as auxiliary for polymerisation reactions and use in X-Ray film developer. The substance is expected to mainly react during the use, however there is uncertainty on potential residual unreacted amount. [refined score 10-12]	23-25	24	Restriction FR and SE submitted in June 2019 a restriction proposal on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances. The final opinion of RAC and SEAC was sent to COM for decision making in September 2020. Glutaral has a harmonised classification as skin sens. 1A. Therefore, leather articles containing glutaral are within the scope of this proposed restriction. For current status, see https://echa.europa.eu/registry-of-restriction-intentions	On the basis of Art. 58(3) prioritisation criteria glutaral gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, glutaral is recommended for inclusion in Annex XIV.**
2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	YES	1	12	10	Toxic for reproduction (Article 57 c)	The amount of 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one manufactured and/or imported into the EU is according to registration data in the range of 1,000 - 10,000 t/y. All tonnage used in the EU 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 1,000 - <10,000 t/y.	Registered uses of 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one in the scope of authorisation include uses at industrial sites (such as formulation of inks and coatings, use as photoinitiator in UV-curable inks, coatings and adhesives) and uses by professional workers (use as photoinitiator in UV-curable inks, coatings and adhesives). [score 10]	23	23	Grouping with 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one is recommended for inclusion in Annex XIV.**
2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	YES	1	9	10	Toxic for reproduction (Article 57 c)	The amount of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone manufactured and/or imported into the EU is according to registration data in the range of 100 - 1,000 t/y. All tonnage used in the EU 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 - <1,000 t/y.	Registered uses of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone in the scope of authorisation include uses at industrial sites (such as formulation of coatings and inks, use as photoinitiator in UV-curable coatings, inks and adhesives) and uses by professional workers (use as photoinitiator in UV-curable coatings, inks and adhesive). [score 10]	20	20	Grouping with 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone is recommended for inclusion in Annex XIV.**
Orthoboric acid, sodium salt	237-560-2	13840-56-7	NO	1	-	-	Toxic for reproduction (Article 57 c)			-	-	Grouping with other borates recommended in the 6th and 10th Annex XIV recommendations.	Although other substances on the Candidate List assessed in this recommendation round get higher priority based on Art. 58(3) prioritisation criteria, **orthoboric acid, sodium salt is recommended for inclusion in Annex XIV** on the basis of grouping considerations.
Diisohexyl phthalate	276-090-2	71850-09-4	NO	1	-	-	Toxic for reproduction (Article 57 c)			-	-	Grouping with other phthalates already recommended for or included in Annex XIV.	Although other substances on the Candidate List assessed in this recommendation round get higher priority based on Art. 58(3) prioritisation criteria, **diisohexyl phthalate is recommended for inclusion in Annex XIV** on the basis of grouping considerations.