

Updated priority assessment results of the substances included in the draft 8th recommendation for inclusion in Annex XIV

5 February 2018

This table includes the updated prioritisation results of the substances included in the draft 8th Annex XIV recommendation. The prioritisation results have been updated based on the comments received in the public consultation and registration updates submitted by 2 June 2017. The prioritisation results of all substances assessed in the 8th recommendation round can be found in the prioritisation results document which was published at the start of the public consultation on 2 March 2017 (available at: https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_march_2017_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.

The blue colour used in the table indicates the phenolic benzotriazoles substance group (UV-320, UV-327, UV-328 and UV-350).

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-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	25973-55-1	YES	15	9	15	PBT (Article 57 d); vPvB (Article 57 e)	The amount of 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) 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. 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 UV-328 in the scope of authorisation include uses at industrial sites (e.g. formulation and use of preparations containing additives, formulation and use of masterbatches and compounds in the manufacture of plastics products, formulation and use of adhesives and sealants), uses by professional workers (e.g. use of additive resulting in inclusion into a matrix, including application in coatings, adhesives and plastics, use of polyurethane, use of adhesives or sealants) and uses by consumers (e.g. use of additive resulting in inclusion into a matrix, including application in coatings, adhesives and printing inks, use of polyurethane, use of adhesives or sealants). [score 15] Furthermore, based on information from registrations and substance in article notifications the substance is used in articles (e.g. plastic articles).	39	39	Grouping with other phenolic benzotriazoles (UV-320, UV-327, UV-350).	On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) is recommended for inclusion in Annex XIV.
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)	-	-	YES	13	>3	15	vPvB (Article 57 e)	One substance of this group entry had been notified under Directive 67/548/EEC (NONS). A further substance covered by the group entry is pre-registered with an envisaged registration deadline of May 2018. This substance was also commented on by a further company during the public consultation indicating a volume used of < 10 t/y. Based on the available information, the volume in the scope of authorisation is assumed to be > 1 t/y.	This group of substances covers for example, the product with the trade name "karanal". Based on public information sources the main use of karanal in the scope of authorisation is as a fragrance ingredient in applications such as fine fragrances, soaps and detergents. It is assumed that these uses cover the use types IND, PROF and CONS. [score 15]	>31	>31		On the basis of Art. 58(3) prioritisation criteria, 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, the karanal group is recommended for inclusion in Annex XIV.
1-Methyl-2-pyrrolidone (NMP)	212-828-1	872-50-4	YES	1	15	10-12	Toxic for reproduction (Article 57c)	The amount of 1-Methyl-2-pyrrolidone (NMP) 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 in plant protection products and pharmaceuticals. Based on an OECD study on the world market from 2007, the volume corresponding to those uses would be ~30 % which is also assumed for the European market. Further minor uses in laboratories are also expected not to be in the scope of authorisation. In the absence of further information, the volume in the scope of authorisation is estimated to be in the range of 10,000 - 100,000 t/y.	Registered uses of 1-Methyl-2-pyrrolidone (NMP) in the scope of authorisation include uses at industrial sites (formulation & (re)packing of substances and mixtures, in coatings, cleaning agents, oil field drilling and production operations, as binders and release agents, as functional fluids, polymer processing, water treatment), and uses by professional workers (e.g. in coatings, as functional fluids) [initial score: 10]. There is uncertainty regarding the use of NMP in articles. Although the use in plastic articles above 10 t/y has been notified (hoses of PVC) and according to registrations the substance may be present in coated articles, no article service life has been registered for NMP. Furthermore, a number of comments were received claiming that NMP is not (or only in concentrations <0.1%) present in the final articles. As the presence of NMP in articles and its potential release cannot be further clarified, a range of 0-2 is assigned for the article service life to express this uncertainty. [refined score: 10-12] The consumer use in ink is registered. As CMRs are banned for supply to the general public, that use should be limited to concentrations below the concentration limit, and therefore outside the scope of authorisation.	26-28	27	Other concluded regulatory actions: CLH The Annex VI entry of NMP was revised in the 9th ATP to CLP, removing the Specific Concentration Limit (SCL) of 5% for Repr. 1B (H360D) so that the Generic Concentration Limit (GCL) of 0.3% applies. The 9th ATP entered into force 8 August 2016 and shall apply from 1 March 2018. The potential impact on uses of NMP and its priority needs to be seen. Restriction In August 2013, the Netherlands submitted a proposal to restrict the manufacture and use of NMP unless specified exposure limit values are met. In the REACH Committee in October 2017 the Member States voted positively on the draft Annex XVII amendment prepared by the Commission. After scrutiny by the European Parliament and Council, the restriction is foreseen to be adopted in the first half of 2018. The suggested restriction sets exposure limit values for workers. Therefore, it may influence the level of control at industrial sites and professional settings. It remains to be seen, however, whether and to which extend the new limit values would have an impact on the volume in the scope of authorisation or the wide-dispersiveness of uses – factors which are taken into account in prioritisation. Grouping: NMP is a polar aprotic solvent that can be used (to some extent) in same applications as DMF and DMAC both of which have been already recommended for inclusion in Annex XIV, therefore also grouping considerations apply.	On the basis of Art. 58(3) prioritisation criteria, 1-Methyl-2-pyrrolidone (NMP) gets priority for inclusion in Annex XIV among the Candidate List substances. Moreover, the substance is considered for grouping with other substances already recommended. Therefore, 1-Methyl-2-pyrrolidone (NMP) is recommended for inclusion in Annex XIV.

2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	223-383-8	3864-99-1	NO	13	3-6	7	vPvB (Article 57 e)	According to one substance in article notification 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327) is used in the scope of authorisation in tonnages between >0 and <100 t/y.	The substance is used at industrial sites. [initial score 5] Furthermore, the substance is used in plastic articles. [refined score 7]	23-26	25	Grouping with other phenolic benzotriazoles (UV-320, UV-328, UV-350).	On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327) gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327) is recommended for inclusion in Annex XIV.
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	271-094-0, 272-013-1	68515-51-5, 68648-93-1	YES	1	9	12-15	Toxic for reproduction (Article 57 c)	The amount of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) manufactured and/or imported in 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 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) include uses at industrial sites (e.g. polymer processing - production of PVC compounds, formulation and use in coatings) and uses by professional workers (e.g. use in adhesives, use in artist supply). [initial score 10] The substance is also registered for consumer uses, e.g. lubricants and adhesives, building materials, artist supply. However, the uses of CMR substances by the general public is restricted pursuant to entries 28-30 of REACH Annex XVII, except for the use in artists' paint or the uses in mixtures in concentration lower than 0.3%. Restriction for this substance applies from 1 January 2015. Therefore consumer uses in the EU, if still existing, should be limited to those uses. Uses below the 0.3% concentration limit are exempted from authorisation. It could be assumed that the use in artists' paint in concentrations higher than 0.3% represents only a relatively low tonnage (<10t/y) but this has not been confirmed. Furthermore, according to registration data the substance is used in articles (e.g. rubber and plastic articles, coated articles). [refined score 12-15]	22-25	24	Grouping with other phthalates already recommended for/included in Annex XIV	On the basis of Art. 58(3) prioritisation criteria further strengthened by grouping considerations, 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) gets priority for inclusion in Annex XIV among the Candidate List substances. Therefore, 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) is recommended for inclusion in Annex XIV.
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	253-037-1	36437-37-3	NO	13	-	-	vPvB (Article 57 e)			-	-	Grouping with other phenolic benzotriazoles (UV-320, UV-327, UV-328).	Although other substances on the Candidate List assessed in this recommendation round get higher priority based on Art. 58(3) prioritisation criteria, 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) is recommended for inclusion in Annex XIV on the basis of grouping considerations.
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7	NO	15	-	-	PBT (Article 57 d); vPvB (Article 57 e)			-	-	Grouping with other phenolic benzotriazoles (UV-327, UV-328, UV-350).	Although other substances on the Candidate List assessed in this recommendation round get higher priority based on Art. 58(3) prioritisation criteria, 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) is recommended for inclusion in Annex XIV on the basis of grouping considerations.